Lavandula Angustifolia and Melissa Officinalis for agitation management in older adults: A mixed method study

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DEDICATION

For my mother Kay Churchill
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Statement of Authentication

The work presented in this thesis is, to the best of my knowledge and belief, original except as acknowledged in the text. I hereby declare that I have not submitted this material either in full or in part, for a degree at this or any other institution.

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(Signature)
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<tr>
<td>AD</td>
<td>Alzheimer's Disease</td>
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<tr>
<td>BPSD</td>
<td>Behavioural and Psychological Symptoms of dementia</td>
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<td>CMAI</td>
<td>Cohen Mansfield Agitation Inventory</td>
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<td>CNS</td>
<td>Central Nervous System</td>
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<td>EMA</td>
<td>European Medicines Agency</td>
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<td>FTD</td>
<td>Frontotemporal dementia</td>
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<tr>
<td>GABA</td>
<td>Gamma aminobutyric acid</td>
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<td>GP</td>
<td>General Practitioner</td>
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<td>HBM</td>
<td>Health Belief Model</td>
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<td>IPA</td>
<td>International Psychogeriatric Association</td>
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<td>ITT</td>
<td>Intention To Treat</td>
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<td>MMSE</td>
<td>Mini Mental State Examination</td>
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<td>NIH</td>
<td>National Institute of Health</td>
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<td>NPI</td>
<td>Neuropsychiatric Inventory</td>
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<tr>
<td>NSWNMA</td>
<td>Nursing and Midwifery Association of New South Wales</td>
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<tr>
<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
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<tr>
<td>PLST</td>
<td>Progressively Lowered Stress Threshold</td>
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<td>PP</td>
<td>Per Protocol</td>
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<tr>
<td>QoL</td>
<td>Quality of Life</td>
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<tr>
<td>QoL-AD</td>
<td>Quality of Life Alzheimer's Disease</td>
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<tr>
<td>RACF</td>
<td>Residential Aged Care Facility</td>
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<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<tr>
<td>TGA</td>
<td>Therapeutic Goods Association</td>
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<tr>
<td>VaD</td>
<td>Vascular dementia</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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Abstract

Lavandula Angustifolia and Melissa Officinalis for agitation management in older adults: A mixed method study

Purpose: This study was completed to provide evidence of effect for Lavender Angustifolia (Lavender) and Melissa Officinalis (Lemon Balm) essential oils as agitation managements for older people with and without a dementia diagnosis living in Residential Aged Care Facilities (RACFs). This research further sought to explore nurse understanding of agitation management and the viability for nurse administered essential oils for behaviour management in residents living in RACFs.

Method: The research was a three-phase sequential design consisting of two phases of semi-structured nurse interviews and a single blind randomised controlled trial [RCT]. Phase I involved semi-structured interviews conducted with 11 nurse participants, focusing on their understanding of agitation management, including the use of essential oils, and their understanding of and attitudes toward the conduct of research in the RACF environment. Findings influenced pre-trial nurse education, timing of intervention and data collection procedures of the Phase II RCT to best support the nurse and the success of the research. Phase II consisted of a 2x3 factorial design single blind RCT that investigated 49 residents with a history of agitation. Participants were allocated to group 1 residents with a dementia diagnosis or group 2 residents without dementia, as determined by their MMSE score or dementia diagnosis. Each resident was randomised within the group to a treatment sequence of Lavender, Lemon Balm or placebo Sunflower oil using a computerised random number generator. All residents received all treatments and as such acted as their own control. The trial was conducted over a 10-week period with residents receiving two drops of the assigned treatment oil daily for two weeks followed by a two-week washout period before commencing the consecutive treatment. Post trial, Phase III, involved semi structured interviews conducted with 10 nurses to identify perceived changes in agitation identified on their ward and influencing factors that effecting the conduct of this research conducted in the RACF. Behavioural and quality of life data were collected using the Neuropsychiatric Inventory (NPI) and Cohen-Mansfield Agitation Inventory (CMAI) and the Quality of Life-Alzheimer’s Disease (QoL-AD) (Finkel et al. 1992; Smart, Hermann, & Lanctot, 2011; Thorgrimsen et al., 2014a). Content analysis used word and phrase frequency to organise qualitative data into key concepts and themes in Phases I and III. While SPSS statistical software version
Results: This research identified differences in essential oils effect on agitation in residents with dementia and without dementia. Further this study provided evidence for the factors that influence nurse compliance to research as well as the practicality for nurse administration of essential oils as agitation managements for residents in the RACF environment.

Phase I: Nurse's identified various approaches to managing agitation in RACFs, the most frequently identified interventions being distraction (91%), providing space (64%) and medication (45%). More than two-thirds of nurses acknowledged agitation was managed differently in residents with and without a dementia diagnosis due to impaired communication (55%) or comprehension (55%). Nurses (50%) were supportive of research with barriers to compliance identified as demanding workload (50%), fear of reprisal (30%) and insufficient education on the research (20%). The provision of pre-trial nurse education (70%) was considered to facilitate compliance to research.

Phase II: Despite reductions in agitation behaviours, Lavender or Lemon Balm did not significantly reduce agitation when compared independently to placebo. However, clinically significant difference was shown when Lavender and Lemon Balm treatments were compared in the effect difference between the with and without dementia groups on the NPI P=0.04, DF47 F(1, 4.39) Fc=4.05 and CMAI P=0.05 DF46.72 F(1,4.19) Fc=4.05. This significantly opposing difference is supported in the CMAI domain of physical aggressive behaviours P=0.02 DF47 F(1, 5.46) Fc=4.05 and NPI irritability P=0.02 DF37.56 F(1,5.65) Fc=4.11. A post hoc analyses demonstrates Lemon Balm to reduce NPI total agitation score P=0.02 DF35 T(1,5.61) Tc=2.03 and physical non-aggressive behaviours P=0.02 DF27 F(1,5.84) Tc=2.05 in residents without dementia when compared to Lavender and placebo. Lavender reduced physical non-aggressive behaviour in residents with dementia when compared to Lavender and placebo on post hoc analysis P=0.4 DF114 F(1,5.84) Tc=2.05. Lemon Balm was significantly less effective in reducing irritability in residents with dementia when compared to Lavender and placebo on post hoc analysis P=0.01 DF113 (1,7.75) Tc=1.98. Further a clinically significant reduction of physical non aggressive behaviour on the CMAI was demonstrated when the Lavender and Lemon Balm scores were combined in comparison to the placebo P=0.02 DF47 F(1,6.38) Fc=4.5. A clinically significant lower
quality of life was reported in residents without dementia when compared to those with dementia independent of essential oil treatment QoL-AD P=0.03 DF34.23 F(1, 5.07) Fc=4.13.

**Phase III:** The majority of nurses (90%) perceived essential oils had been effective in reducing agitation in the residents despite results of the single blind RCT revealing no significant effect. Half the nurses (50%) reported the oils were effective for some residents. This phase of the study also asked nurses to reflect on the process used to conduct this research project. The majority considered research process to be unobtrusive (60%), routinely timed (60%) with effective communication (40%) between researcher and nurses as positively support the research process in RACFs.

**Conclusion:** These findings support a clinically significant opposing effect of the essential oils Lavender when compared to Lemon Balm in residents with dementia and without dementia. These results indicate that Lemon Balm may be effective in reducing agitation in residents without dementia and less effective in reducing irritability in residents with dementia. Further Lavender may be effective in reducing physical non-aggressive behaviours. Despite a reduction in the resident behaviour with treatment there was no clinically significant decline in agitation when Lavender or Lemon Balm was independently compared to placebo. Nurses maintained strong belief throughout the trial in the ability of the essential oils to reduce agitation in some residents. Facilitators of nurse compliance to research were identified as projects that provided research education were unobtrusive in the RACF environment, routinely timed with effective communication between researchers and nurses.

**Key words:** agitation, aged care, antipsychotic medication, dementia, essential oil, Lavender, Lemon Balm, mixed methods, nurse research compliance, randomised controlled trial.
Chapter 1 Introduction

1.1 Overview
Agitation is a frightening and debilitating symptom of many diseases and disorders common to older people, which manifests in observable, non-purposeful, physical or verbal behaviour. Nurses are frequently challenged to manage agitation in residential aged care facilities [RACF] with available interventions often proving ineffective or hazardous to the residents (Dombeck, 2015; Cohen-Mansfield, Libin and Marx, 2007; NSW DoH, 2014). This three-phase, sequential design, mixed method study explored the effectiveness and practicality of Lavender and Lemon Balm essential oils as a nurse initiated agitation management for older adults living in RACFs. A 2x3 factorial design, single blind, randomised controlled trial [RCT] included 49 residents with and without dementia. Semi-structured interviews with nursing staff prior to and following the single blind RCT informed the researcher of the practicalities for conducting essential oil research for agitation management in the RACF setting.

This introductory chapter presents the significance, aims, and research questions that drove this research. Finally, the structure of the thesis is presented outlining the content of the eight chapters deemed necessary to answer the research questions.

1.2 Agitation in Residential Aged Care Facilities
Agitation is recognised by aged care literature as the most common behavioural problem in RACFs (AIHW, 2012; DoHA, 2012). The Australian Institute of Health and Welfare (2015a) reports that over two-thirds of older people living in RACFs require high-level nursing care for their behaviour alone. Agitation is indicated by observable non-purposeful physical or verbal behaviours that are widely considered to have origins of internal turmoil (Grose & Schub, 2013; Kovach & Noonan, 2005; Pritchard & Brighty, 2015). While best practice management promotes the identification of causative factors through detailed assessment and the resolving of these factors to reduce resident
distress, agitation is not well managed in RACFs (NSW DoH, 2014). Older people living in RACFs are susceptible to agitation due to complex medical diagnoses, cognitive decline, mental illness or reliance on multiple medications (Pritchard & Brighty, 2015), although agitation is most frequently reported in residents with dementia. Australian statistics report 81.8% of residents with dementia and 45.6% of residents who do not have dementia require high-level nursing care for their behaviours (AIHW, 2015b).

The literature acknowledges agitation as the most intractable behavioural and psychological symptom of dementia [BPSD] (Ballard & Corbett, 2010) that is observed in up to 90% of presentations (Agronin, 2014; DeYoung, Just, & Harrison, 2002; Drouillard, Mithani, & Chan, 2013). Agitated behaviours commonly related to dementia include wandering, resistance to care and verbal disruption. The complication of a dementia diagnosis often impairs a resident’s communication or insight making identification of causative factors difficult. Agitation in dementia is often recurrent and the causative factors are unresolved. Agitation is common in the dementia disease trajectory however it is also noticed in the conditions of anxiety or depression (Drageset, Eide, & Ranhoff, 2013; Pritchard & Brighty, 2015).

Anxiety and depression are considered to be the most common mental health conditions for older people living in Australian RACFs, and in 2011, 78% of residents were considered to have a mental health condition (ABS, 2013). Anxiety or depression are associated with the agitated behaviours such as hand-wringing, restlessness, pacing, irritability and sleep disturbances (Beyond Blue, 2015; Drageset, Espehaug & Kirkevold, 2012). Despite the high reported prevalence of anxiety and depression, the conditions are underreported in RACFs (AIHW, 2013). The high frequency of agitation in facilities coupled with increased frailty of residents and the complexity of care needs, in addition to disproportionately low nurse to resident ratio can prove challenging for the aged care nurse (NSW NMA, 2016).
Nurses in RACFs are frequently required to manage residents with agitation while prioritising competing demands of an already ambitious workload. Agitation is unpredictable, distressing for the person exhibiting the behaviour and disruptive for those within the vicinity of the behaviour (NSW DoH, 2014; NSW NMA, 2016). An agitated person can feel intense fear, is often disorientated and may not fully comprehend their immediate surrounds. Safety is a concern, requiring an immediate response from the nurse to manage the situation (King, 2012). Pressing care priorities are often postponed as the nurse attempts to calm the residents and identify causes for the behaviour. Where agitation is managed effectively in the RACF environment, the nurse can subdue the situation expediently and return to their routine tasks. However, agitation is not well managed generally in the RACF environment, with a lack of effective or safe management available to the nurse (DoHA, 2012; NSW DoH, 2014).

Nurses in RACFs use a variety of strategies to manage agitation when causative factors are not forthcoming. Distraction or restraint are frequently used to manage behaviours in RACFs, and there is developing interest in the use of complementary therapies to manage agitation (Abermain, Vander, Van Bortel & Elseviers, 2014). Distraction is achieved by diverting the resident’s attention to another activity or topic. This strategy is considered to shift the resident’s attention from the distressing subject to a more agreeable topic or activity resulting in modifying behaviour. However, distraction is a short term remedy and once the diversion ceases the agitation often returns (NSW DoH, 2014). Time poor work schedules and reoccurring agitation in a resident can leave nurses frustrated at their inability to resolve the situation, a frustration that often results in the use of chemical or physical restraint to manage behaviour (Edberg et al., 2008; Hofmann & Hahn, 2014; Lesser & Hughes, 2006; Poole & Mott, 2003).

Nurses use restraints to contain agitation for an interim period, however restraints are often humiliating and carry detrimental side effects for the resident. Restraints are the
intentional restriction of a person’s movement through device or force, or intentional use of medication for the sole purpose of controlling a person’s behaviour (NSW DoH, 2014). Research reports that using restraint is demoralising for an older person and is often interpreted as punishment, increasing the agitation (DoHA, 2012). Restraints increase the risk of physical injuries including falls and negatively impact an older person’s quality of life. Further, restraints carry side effects that contribute to increased cognitive decline, morbidity and mortality (Cohen-Mansfield, Libin, & Marx, 2007; DoHA, 2014; NSW DoH, 2014). Effective agitation management techniques are required for residents living in RACFs with some research promoting the use of essential oils Lavender or Lemon Balm as a possible solution.

1.3 Lavender and Lemon Balm

Lavender and Lemon Balm essential oils can have calmative benefits with minimal side effects or interactions with concurrent medications (Kayne, 2009). Further essential oils delivered by aromatherapy are often enjoyable for residents and come at a low cost to the facility. Essential oils are procured from plants and administered by aromatherapy through inhalation, ingestion or absorption (Thorgrimsen et al., 2014b). Essential oils when inhaled are believed to act upon the limbic system, principally the amygdala and hippocampus to elicit a response representative of the oils therapeutic benefit (Cavanagh & Wilkinson, 2002; Elisabetsky, Marschner, & Souza, 1995; Huang et al., 2008), however the mechanism of action is largely uncertain.

Lavender and Lemon Balm’s chemical profile is similar to pharmaceutical medications used to minimise agitation in older adults (Burns et al., 2011). Both essential oils mediate serotonin in the body by inhibiting the main neuronal transmitter in the central nervous system to reduce neuronal excitability and regulate muscle tone (Abdou et al., 2006). Lemon Balm is classified as a GABA transaminase inhibitor with broad-spectrum activity in addition to potency for 5-hydroxy-tryptamine and y-aminobutyric acid receptors.
(Burns et al., 2011), as such it was considered to be potentially more effective in reducing agitation than Lavender. A change in agitation management to include essential oils requires nurses to understand the detrimental effects of agitation and the ability of essential oils to assist in managing the behaviour.

1.4 Theoretical Framework – Health Belief Model [HBM]

The Health Belief Model [HBM] originally developed by the social psychologists Hochbaum, Rosenstock and Kegels is the theoretical framework used in this study, as it predicts and explains health behaviours that lead to the adoption of new health management practice (Hochbaum, Kegels & Rosenstock, 1952). The HBM assumes that people are rational in their thinking and actions, that they will take appropriate steps to accept practices that best support health improvement under the right circumstances (Hayden, 2014; Mikhail, 1981). The HBM explains an individual's actions or lack of actions relating to their personal health, often observed in the practices they adopt or dismiss to support their health. The HBM applies concepts of individual perception, modifying factors in addition to the likelihood of change (Cheung et al., 2015) to demonstrate how health behaviour influences the adoption of new health practices.

The HBM was developed in the 1950s by researchers at the US Public Health Service to understand better why people use preventative screening programs (Rosenstock, 1974a; Katasky, 1977). In an era where Tuberculosis and Polio were common conditions, researchers were challenged to explain why people were not attending the low-cost screening and vaccination programs to avoid disease. Early investigations of population attitudes towards preventative health technology and screening identified six constructs that are thought to influence health behaviour. They include 1) perceived susceptibility, how likely an individual believed they were to contract the condition 2) perceived seriousness being the level of difficulty contracting the condition would create to their life 3) Perceived benefits of taking action, will the action reduce the risk of susceptibility or seriousness of the condition 4) Perceived barriers to taking action, negative aspects
or action such as inconvenience, expense or pain can result in avoidance 5) Readiness to
act, is achieved when barriers are weak and the benefits to action strong and finally 6)
cue to action, is a trigger to appropriate action such as a health crisis that can change
trigger the decision-making process (Rosenstock 1974b; Rosenstock, Stretcher &
Becker, 1988).

The HBM has its origin in Lewinian's theory that contends behaviour to be guided by two
variables; the first, “the value of the outcome to the individual and the second, the
estimated probability that the action will result in their expected outcome” (Maiman &
Becker 1977, p336). The HBM adopts a phemonomological approach that contends the
individual alone is responsible for decision making with the environment having little
influence on this choice (Rosenstock, 1974). The HBM model today acknowledges
societal influences on decision making process to explain psychosocial choices in the
context of health. This model has been employed to assist in changing behaviours for
patients with coronary artery bypass grafts, osteoporosis, smoking addiction, breast
examination, asthma, sexual health and obesity issues among others (King, Kaighobadi
Abedeyazdan, Moshgdar & Golshiri, 2017; Quaranta & Spencer, 2015).

The HBM is used to explain why a person selects a health practice to support or maintain
their own health (Rosenstock, 1974). The six constructs of the HBM are applied in this
study to understand what influences a nurses management of agitation in RACFs.

Agitation is widespread in Australian RACFs (Australian Institute of Health, 2015c) with
legislation preventing older people from self-administering medications that can
alleviate symptoms (Australian Government, 2012). Nurses are therefore well
positioned to select managements that influence agitation outcomes for older people.
Nurses must be able to identify which older persons are susceptible to having an agitated
episode and understand the seriousness that this behavioural episode poses to the older
person, their families, staff and all those within the vicinity of the behaviour. Nurses need to be aware of the benefits to managing agitation well and knowledgeable of the barriers that need to be overcome in providing effective agitation management in the RACF setting. Also, RACF nurses need to feel confident in their ability to manage and minimise the risk of recurrent agitative episode in an older person. A nurses knowledge of agitation and their attitudes towards agitation can influence their perceptions of susceptibility, seriousness, benefits and barriers that contribute to their choice in agitation management strategy.

This HBM has been successfully employed by other researchers to explain a healthcare professionals behaviour in managing other person conditions. Quaranta and Spencer (2015) used the HBM to understand school nurse management of student asthma. Their results found that nurses who believed asthma management was important illustrating perceived susceptibility and seriousness of students with asthma. Also, nurses with higher self-efficacy or confidence in their ability to manage the asthma were more likely to perform the behaviour. Smith et al. (2011) investigated reasons why parents delay or refuse to vaccinate their 24-month children using the HBM. Their results show that parents that delayed immunisation are less likely to believe their child is susceptible, less likely to believe vaccinations are an important health initiative, less likely to believe that vaccinating can reduce the threat of disease, more likely to be concerned with vaccination efficacy and safety. Brinsley, Sinkowitz-Cochran and Cardo (2005) investigated low levels of compliance to the guidelines that prevent antimicrobial resistance for patients. Their findings indicated that medical officers did not perceive patients to be highly susceptible to antimicrobial resistance perceiving other hospital problems to be a more serious issues.

This thesis adapts the HBM as a theoretical framework to explain the actions or lack of actions by the nurse in adopting new health practices, such as essential oils to manage
the agitation of the older people in their care. The study applied the six constructs of the HBM to nurses to understand better the management strategies employed to support an older person with agitation in an RACF. Semi structured interviews with nurses informed researchers of their understanding and attitude towards agitation, agitation management, essential oils and the research that was conducted in their facility. Interview questions were designed to understand susceptibility focused on a nurses ability to understand agitation to identify the agitative needs of the people they care for and to nurse susceptibility to the effects of agitation on the environment in which they work. Nurse perception of how serious a problem they considered the agitation to be was explored concerning the resident, staff and all those within the environment. The benefits and barriers of different agitation management strategies for people with and without dementia were examined encouraging deliberation.

A randomised controlled trial was conducted to establish a scientific evidence of effect for essential oils in the management of older person agitation for nurse reference. The trial was conducted in the facility to identify any potential barriers that may contend with nurse initiated administration of essential oils in the RACF setting. Nurse self-efficacy level for the potential administration of nurse initiated essential oils for agitation management was explored in staff attitude and knowledge of essential oils. The researchers anticipated that nurses speaking of their knowledge and attitudes toward agitation and its management would increase awareness and deliberation among nurses resulting in a 'readiness to act'. In the understanding that a 'readiness to act' would occur if the benefits to adopting an agitation management were greater than the practical barriers to the strategies implementation. The researchers presence and focus on agitation management was also considered a encourage a 'cue to action', or trigger, among staff to take action to mindfully select the most appropriate, effective and safe agitation management to older people in their care.
1.4.1 Individual perception

The HBM concept of individual perception indicates that the nurse’s belief about agitation, as well as their belief in the management strategies that are available to reduce the behaviour, will influence their choice in the management method they employ. Among the four constructs of individual perception are included two categories being perceived susceptibility and seriousness that can be applied to a nurse’s experience of managing agitation in the workplace. The remaining two categories of perceived barriers and benefits can be applied to a nurse’s selection of management strategy to address resident agitation in the RACF environment. A more detailed discussion of the concepts and their related constructs follows.
1.4.1.1 Perceived susceptibility

The construct of perceived susceptibility refers to the individual’s belief in the level of personal risk they bear in contracting or being indirectly affected by a health condition (Rosenstock, 1974). Nurses are directly responsible for the care and provisions of health regimes to residents within RACFs. While the nurse is not directly susceptible to contracting agitation, the prevalence of agitation on the ward renders them acutely aware of the susceptibility of the residents and makes them indirectly susceptible to the behaviour. Nurses are often subjected to constant repetitive verbal responses, verbal abuse or physical violence while also responsible for the safety of numerous vulnerable older adults. Many nurses find the agitation of others distressing and the restraint management barbaric and ineffective. Nurses understand that the older adults in their care deserve better management methods than those currently provided in many RACFs (Cheung et al., 2015; Gray & Rutledge, 2013).

Perceived susceptibility is subjective and when an individual perceives they are at increased risk of being indirectly affected by agitation, they are often motivated to seek health regimes to prevent or reduce this risk (Rosenstock, 1974). However the HBM model postulates that susceptibility to a condition alone does not always lead to the adoption of new health practices to mitigate risk (Gray & Rutledge, 2013). When perceived susceptibility combines with the seriousness, it results in a perceived threat to a person’s health status and current lifestyle (Cheung et al., 2015). For example, an individual may perceive themselves susceptible to agitation, however if this condition does not seriously affect their current lifestyle, the individual is less likely to take preventative action.

1.4.1.2 Perceived seriousness

The HBM states the construct of perceived seriousness is informed by an individual’s knowledge of the health condition and the degree of difficulty they perceive the health
status would create to their current lifestyle (Rosenstock, 1974). Detrimental effects of agitation such as physical, psychological, and communicative impairments on an older person's lifestyle are well documented; however, perceived seriousness remains subjective. When a nurse cannot manage agitation in one resident, this can adversely affect their work and create a stressful environment for other residents, family and staff on the ward. Similarly, nurses who are frustrated by the intractable nature of agitation and its time-consuming management that interferes with the routine tasks required to care for others, are more likely to deem agitation as seriously affecting their daily routine. In contrast, a RACF nurse who considers agitation to be a natural part of the ageing process will be less likely to feel the situation can be changed or to view the condition as serious.

A high perceived seriousness combined with susceptibility to a health condition is enough to be recognised as a health threat for many individuals, however it may or may not be sufficient to action the adoption of new health practices (Gray & Rutledge, 2013). An individual must be able to see definite benefits associated with health behaviour change to incorporate the new practice into their lives.

1.4.1.3 Perceived benefits

The HBM construct of perceived benefits refers to the degree to which the person believes that adopting the new practice will cure, prevent or manage the symptoms of the health condition (Rosenstock, 1974). Health promotion research suggests the availability of a health practice correlates strongly with benefits, as people are more likely to adopt and comply with a new health practice if it is readily available, and they believe the recommended action is effective in preventing or reducing the threat of a health condition (Mikhail, 1981). A new health practice can only be adopted if the individual believes that the benefits of the practice outweigh the barriers (Gray & Rutledge, 2013; Wu et al., 2012).
1.4.1.4 Perceived Barriers

Research shows that perceived barriers are the most important construct in determining whether a person will take on a new health practice. Perceived barriers are the physical and psychological difficulties a person believes they will encounter when adopting the proposed health action (Rosenstock, 1974). Physical barriers include lack of access due to cost or availability (Sharifirad, Pirzadeh, & Azadbakht, 2011; Wu et al., 2012). Psychological barriers may include disbelief that the treatment will be effective in preventing or reducing the condition. The complexity of adopting a new health practice contains both physical and psychological characteristics. Difficulties associated with starting a new health regime are developing a habit of compliance, fear of noncompliance to health regime, the inconvenience of having to give up current lifestyle choices and the embarrassment created by the change (Rosenstock, 1974; Hayden, 2014).

Cheung’s (2007) findings show that a major barrier to complementary and alternative medicine use is the limited evidence of effect and education surrounding the use of therapies. Clearly a person is more likely to adopt a new health practice if they believe the recommended action to be effective in preventing or reducing the complication of a health problem. Further research of Lavender or Lemon Balm effect as an agitation management, with strict adherence to research methodological procedure is needed to provide the scientific community with the evidence they require and the consumer confidence in the efficacy of the health practitioners with the evidence to take the required action (Gray & Rutledge, 2013).

1.4.2 Modifying factors

The second HBM concept, modifying factors suggests health behaviours are amended and enabled by variables such as demographics, personality, attitudes towards the health procedure, advice and social pressures, level of education, motivations as well as past experiences and skills (Rosenstock, 1974). A person’s age, genetic history and
personality can influence their perception of susceptibility to a health condition or how serious the health condition could potentially impact on their lifestyle (Hayden, 2014). In addition, the structural variable of knowledge and past experiences can influence a person's health management preferences. A nurse who has been unsuccessful in resolving agitation in the past and has tried essential oils with some success, is more likely to use essential oil management for agitation. In contrast, a nurse who has found complementary therapies to be ineffective as a management previously is less likely to adopt the practice. Cues to action are also considered a construct of modifying factors; they include any stimuli that trigger a person's decision to change behaviour (Rosenstock 1974; Hayden, 2014).

1.4.2.1 Cues to action

Cues to action are internal or external motivators that trigger a person to change their health behaviour positively through the adoption of healthier practices (Rosenstock, 1974). A cue to action can be a consequence of the concern created by personal analysis of perceived susceptibility and seriousness of contracting a particular health condition that in turn elicits a positive health change. External motivators are often the outcome of recommendations from health professionals or as a result of media exposure (Gray & Rutledge, 2013; Mikhail, 1981). Cues to action motivate people to take control of their health condition by prompting them to accept advice and comply with the adopted health practice. Nurses continue to comply with the adopted practices of chemical restraint to reduce older person agitation in the knowledge that the medications are often ineffective and expose residents to side effects that can create a worse problem than the initial agitation (Jeste & Maglione, 2013). Often this knowledge is enough to warrant a cue to action to adopt less invasive and efficient methods to manage agitation (Chaudrue, 2013). However some nurses continue to ask for chemical restraints for their residents, this resistance to adopting safer, less invasive management may be attributed to low levels of self-efficacy, or belief that administering the intervention will elicit
positive change. A lack of evidence of effect and practicality of essential oil use in the clinical environment often influences the likelihood of change in health management.

1.4.3 Likelihood of action

Self-efficacy or the belief that the health practice will have a beneficial effect and that the practice is accessible and achievable is necessary for a person to take action in adopting a new health practice (Rosenstock, 1974; Cheung et al., 2015). This state deemed as a readiness to action is achieved through personal analysis of perceived susceptibility and seriousness of the health condition, coupled with a weighing up of perceived benefits against barriers to adopting the health practice. Individuals with low levels of readiness often require a strong stimuli cue to action for health practice to be adopted. In contrast, a person with a high degree of readiness may only require a small stimulus cue to action for the same practice to be adopted (Franckowiak & Glick, 2015; Hayden, 2014).

1.4.3.1 Self-efficacy

The adoption of a new health practice is dependent on an individual’s self-efficacy or belief in their own ability to take control and manage their health by incorporating the new practice into their lifestyle (Rosenstock, 1974; Franckowiak & Glick, 2015; Hayden, 2014). If the person believes they cannot implement the health practice, or that it may be difficult to assimilate into their current lifestyle, they may not take action even if they believe the health practice has benefits (Rosenstock, 1974). Many older adults in the RACF environment are reliant on nursing staff to provide health interventions; therefore this research in this is primarily aimed at creating self-efficacy in nurses. Identifying perceived barriers to the implementation of positive health practices and providing support for education and encouragement may foster self-efficacy.

Finally, in the HBM for a new health practice to be adopted, the individual must conduct a personal risk analysis of the threat to health and an evaluation of remedies, particularly, the benefits and ease implementation to lifestyle. As with risk management
the probability of a useful outcome and likelihood of the risk occurring play an essential role in a person's decision making. A beneficial result must, therefore, be weighed against the individual's objection to implementing the health practice (Rosenstock, 1974; Hayden, 2014). As such the nurse may consider their susceptibility and the seriousness of agitation in their workplace. Modifying factors of age, personality, education, experience and health literacy will affect their perception of susceptibility and seriousness as well as their perception of benefits and barriers to adopting essential oils for management (Chaudrue, 2013; Gray & Rutledge, 2013).

In line with the HBM, this study examined the nurse perception with the objective of identifying perceived susceptibility and seriousness of agitation as well as their perception of the benefits and barriers to implementing essential oils as an agitation management in the RACF setting. Further, the single blind RCT was conducted to provide evidence of essential oil efficacy as management for agitation to overcome existing barriers. Research assistants supported the essential oil intervention in the RACF to ensure compliance and foster self-efficacy in nurses. A final interview with nursing staff was conducted to monitor changes in attitudes that had occurred over the essential oil trial.

Nurses in RACFs acknowledge agitation to be distressing for the person experiencing the agitation and all those in the vicinity of the behaviour, including the staff (NSW NMA, 2016; Hofmann & Hahn, 2014). Agitation management requires the urgent attention of the nurse, is time-consuming, and the intractable nature of the behaviour often leaves the nurse frustrated. There is evidence that agitation management commonly used in RACFs is ineffective or unjustifiable (Burns et al. 2011); however nurses continue to comply with these management methods while remaining non-compliant to research that investigates alternate management (Burns et al. 2011). The HBM has been used in health promotion to influence people towards healthier choices or management of
health conditions (Quaranta & Spencer, 2015). The Health Belief model provides an understanding of the barriers, facilitators and practicalities as well as the potentiality for use of nurse administration of essential oils in the management of older adult agitation in RACFs.

The HBM postulates that for the nurse to adopt a new health practice such as essential oils, the change is reliant on two factors. The first factor is dependent on the value that the nurse attributes to the reduction or elimination of agitation in the RACF environment. The second factor is the belief held by the nurse that the essential oils or new health management could reduce or eliminate agitation on the ward (Rosenstock, 1974).

1.5 Gaps in the literature
This research sought to give evidence to Lavender or Lemon Balm's effect as agitation management by addressing limitations in the literature and expanding on current knowledge. Pertinent areas of methodological limitation, inclusion of residents without dementia, nurse understanding of agitation management and nurse compliance to research were identified as areas for further investigation. Specific areas for investigation are discussed in further detail.

1.5.1.1 Managing agitation for residents without dementia
Previous studies investigating the use of Lavender or Lemon Balm essential oils for agitation management in RACFs have largely focused on residents diagnosed with dementia (Burns et al., 2011; Fu et al., 2013; Fujii et al., 2008; Lin, Chan, Ng, & Lam, 2007). One study (Sakamoto et al., 2012) that did include people who do not have dementia, primarily investigated the effect of Lavender essential oils influence on older adult falls, over a 12-month period. The inclusion of residents without dementia who exhibit unresolved agitation in essential oil studies can create a more inclusive policy for management of agitation in RACFs. In addition, essential oils may have a differing effect
on agitation for people with and without dementia that requires investigation. Finally, essential oil therapy when administered by the nurse is often enjoyable and well tolerated by older people, potentially improving quality of life for the resident without dementia.

1.5.1.2 Nurse understanding of agitation management

The literature reports that nurses consider complementary therapies to be effective in reducing agitation, however they continue to use restraint to mitigate behaviour (Azermai et al., 2014). Restraints contribute to physical and psychological decline while placing the resident at increased risk of serious injury and mortality (NSW NMA, 2016). Further, Ballad and Corbett’s (2010) systematic review of efficacy and safety for chemical restraints commonly used in RACFs found a threefold increased risk of cardiovascular event to outweigh the temporary reduction of agitation experienced by the older person at 12 weeks. Coon et al., (2014) research found chemical restraints continued to be prescribed to older adults regardless of educational initiatives to reduce prescribing. Other research suggests restraints may be popular as they serve to lessen the nurse’s workload, provide ease in resident surveillance, short-term agitation management (Hofmann & Hahn, 2014; Jeste & Maglione, 2013) and minimise disruption to other residents (Abermain et al, 2014). The reasons why nurses do not adopt gentler strategies such as complementary therapies for agitation management in favour of continued restraint use is an important area for research.
1.5.1.3 Nurse compliance to research

Nurse compliance to essential oil research protocol was recognised as a limitation in two studies (Burns et al., 2011; Fu et al., 2013). Burns et al (2011) study found essential oil bottle weight at research conclusion to indicate that the nurses had only administered 50% of the intervention to the older person. Nurses compliance to research protocol is necessary to provide the evidence of the intervention effect that nursing management requires for a basis of clinical practice. The research speculates that nurse participation in research may be influenced by competing workload demands, level of research knowledge or challenges to research implementation in the RACF environment (Akerjordet, Lode, & Severinsson, 2012; Roll et al., 2013; Vedelø & Lomborg, 2011). Alternatively nurses may lack belief in the benefits of the essential oil intervention to reduce agitation or its practicality in the RACF setting (Gray & Rutledge, 2013; Hayden, 2014). Further investigation of nurse perceptions and barriers to the administration of essential oils is necessary to ensure practicality of the potential agitation management in Australian RACFs. Several areas for further investigation have been identified from the literature that supported the significance of this study.

1.6 Significance of study

This study is significant as it adds knowledge to the current body of evidence surrounding the use of essential oil to manage agitation in older adults living in RACFs. Specifically, knowledge has been added in the three areas of (1) agitation management for older people with and without dementia living in RACFs, (2) the efficacy of Lavender compared to Lemon Balm for the management of agitation in this population and (3) nurse compliance to research in the RACF setting.

This study is the first to compare agitation, agitation management and essential oil effect for agitation for older people with and without dementia in a single study. Baseline agitation comparisons between older people with dementia living in RACFs raises
awareness of the frequency and commonalities of behaviours exhibited in the different cognitive groups. Nursing strategies used to manage agitation in older people were compared for differences and similarity in approach.

The study is also the first to compare Lavender and Lemon Balm essential oils for effect as agitation management of residents in RACFs. Lavender and Lemon Balm essential oils have demonstrated some evidence of effect in reducing agitation in older people with dementia and without dementia living in RACFs (Ballard et al., 2002; Lin et al., 2007; Fujii et al., 2008; Sakamoto et al., 2013). This study compares the effect of Lavender and Lemon Balm essential oils between residents with and without dementia.

This study overcomes some methodological limitations identified in previous studies such as blinding methods and counterbalancing, and therefore adds to the body of evidence for the effect of Lavender and Lemon Balm as agitation management for residents in RACFs.

This study is further significant as it examined the RACF environment for influencing factors that can improve nurse compliance to research. This study investigated nurse knowledge of agitation management to establish their understanding of the research problem. Nurse perceptions were further investigated to identify preconceived beliefs in essential oils effect and the practicalities of implementing essential oil research in the RACF environment. Finally, this research provides direct nurse responses for non-compliance to research and influencing factors that can support future research in the RACF environment.

1.7 Purpose

The purpose of the study was to evaluate the effectiveness of Lavender and Lemon Balm essential oils as agitation management for residents with and without dementia, in RACFs. This study also sought to explore nurses understanding of agitation management
for residents in RACFs and to improve nurse research compliance by identifying influencing factors that support research in the RACF environment.

1.8 Research objectives and questions

Phase I

The objectives of Phase I were to:

1. Explore nurse understanding of agitation and its influence on the management of resident behaviour in RACFs?
2. Explore nurse perception of essential oils and their use to manage agitation.
3. Explore nurse attitudes towards research in RACFs and identify barriers to research in that setting.

Phase II

The research questions for Phase II were:

1. What is the effectiveness of Lavender compared to Lemon Balm and a placebo for the management of agitation in residents of RACFs with and without a dementia diagnosis?
2. What are the differences between Lavender compared to Lemon Balm and a placebo for the management of agitation in residents of RACFs with and without a dementia diagnosis?

Phase III

The objectives of Phase III were to:

1. Determine if nurse's perception of the use of Lavender and Lemon Balm to manage agitation has changed by participation in Phase II.
2. Determine factors that can facilitate nurse participation in research conducted in the RACF setting.
1.9 Organisation of thesis

This thesis consists of eight chapters and reports three Phases undertaken in a sequential mixed-methods design. A summary of each chapter is provided below.

**Chapter 1** provides background to the research topic and describes elements of the Health Belief Model [HBM] that provides the theoretical framework for this research. This chapter also provides the study significance, purpose, objectives, research questions and thesis organisation.

**Chapter 2** presents the context in which this research is situated and is organised into three major sections: the problem of agitation in RACFs, nurse management of agitation and the use of essential oils to manage agitation.

**Chapter 3** describes the properties of Lavender and Lemon Balm essential oils and presents a review of the published literature relating to the use of Lavender or Lemon Balm essential oils to manage agitation.

**Chapter 4** presents the methodology for a three phase, sequential, mixed methods study design that examines the effectiveness and practicality of Lavender and Lemon Balm as agitation management in the RACF setting.

**Chapter 5** presents the Phase I finding of 11 semi-structured nurse interviews exploring nurses understanding of agitation, its management and research in the RACF setting.

**Chapter 6** reports the findings from Phase II, 2x3 factorial design single blind RCT investigating the effectiveness of Lavender and Lemon Balm on agitation in residents.
Chapter 7 presents the Phase III findings of 10 semi-structured interviews describing nurses' perceptions of agitation management, essential oils and the conduct of research post the implementation of the RCT in Phase II.

Chapter 8 presents a discussion of the main findings and recommendations of the thesis.
Chapter 2 Research Context

2.1 Overview

This chapter examines the context in which this research is situated and is organised into three major sections. The first section examines the ageing population, the high prevalence of agitation in this population and the problem this presents for care in the RACF environment. The second section explores definitions of agitation including a list of associated behaviours. Further, this section explores causative factors that can contribute to agitation in older people. National guidelines for the assessment of agitation in RACFs that guide nurse responses to agitated behaviour are also presented. The final section examines the current nurse initiated interventions to reduce agitation in residents in RACF.

2.2 Ageing, agitation and RACF care

People in developed countries are, in general living longer than in previous generations due to advances in the standard of living, education, healthcare provision and nutrition. (AIHW, 2015b). Currently people aged 60 years and over account for 12.5% of the global population and this figure is predicted to rise to almost 22% in 2050 (Guzaman, Pawliczko, Beales, Till, & Voelcker, 2012). In Australia, the older adult population has increased by 300% in the last five decades. The most dramatic increase has been in 85 year and over population, that has increased by 153% in the last two decades in comparison with a total growth in population of 32%. The older adult population in Australia is predicted to continue to rise with the over 85 years age group increasing four fold by 2060 (AIHW, 2015b).

As older adults are living longer, frailty and the complexity of age related disorders and comorbidities have increased. Chronic health conditions of dementia, diabetes, musculoskeletal disorders and sensory impairment are prevalent in this population (AIHW, 2015b). The need to provide care for the aged population will be complicated by
a progressive decline in the contingent workforce and the necessity for family members to work to support household need. This poses the question of how the community will support the care needs of older adults in years to come (Valenzuela, 2015). A greater demand will be placed on RACFs to accommodate older adults with increased frailty and higher complexity of care needs who can no longer live in the community. Residential aged care facilities operate on a minimal nurse to resident ratio, therefore services and facilities will require efficient and effective management if nurses are to meet the care needs of residents (Willis et al., 2016).

2.2.1 Australian RACFs and their vulnerable population

Residential aged care facilities provide accommodation and supported living for people who can no longer live at home, frequently due to infirmity or diminished cognitive capacity. In 2014, RACFs were home to 273,559 Australians over the age of 65 (AIHW, 2015b). The majority of people that live in aged care are over the age of 80 years (77%), the mean age for women 85.8 and men 81.6 years. Ninety-six percent of RACF residents are now over the age of 65 years and one in three residents are over the age of 90 years (AIHW, 2015b; DSS, 2015).

Australian RACFs are home to people from diverse cultural and socioeconomic backgrounds. Many of these residents are first generation migrants to Australia who seek to retain their heritage after they move to the facility (ABS, 2013). The population over the age of 65 years born outside Australia is reportedly growing rapidly with multicultural representation in RACF increasing (ABS, 2013; AIHW, 2015b; DSS, 2015).

Older adults are entering aged care with increasing levels of frailty and complexity with the majority of service providers now making available a mixed level of high and low care in each facility (AIHW, 2012; AIHW 2015a). The health conditions common to older people in RACFs include disorders of the nervous, endocrine, cardiovascular or musculoskeletal systems or cancer (AIHW, 2015c). Infirmity and increased dependence
on care staff can escalate challenging behaviour in residents (DoHA, 2014; Pritchard & Brighty, 2015).

The Australian Institute of Health and Welfare (2015c) reported in the residential aged care census 2013-2014, that behavioural problems were prevalent among residents in RACFs, with over two-thirds (67%) of residents requiring high-level care to manage behaviours. Further, it was noted that 52% of people living in RACFs have a recorded dementia diagnosis, of these residents 81.1% required high-level care for behaviours. It was also noted that 45.6% of residents who did not have a dementia diagnosis also required high-level care for behaviours (AIHW, 2015b). Management of behaviour is a priority in RACFs to provide a safe, conducive living environment for all residents.

2.2.2 Agitation in the RACF environment

Agitation is common in the RACF environment and nurses are frequently challenged to manage unpredictable, disruptive, abusive or physically violent behaviour among residents (Cohen-Mansfield et al., 2007; NSW NMA, 2016). Agitation requires the immediate attention by staff to resolve the situation, protect the agitated person and regain environmental equilibrium (Zwijsen et al., 2014), which imposes a significant burden on nurses as it diverts attention from the care of other residents (King, 2012). The time necessary to assess, manage or continually monitor a resident with agitation is highly demanding of the nurse’s time and some manifestations of agitated behaviour are seemingly intractable (Poole & Mott, 2003).

Time restrictive schedules and reoccurring agitation can leave nurses discouraged at their inability to manage the situation effectively (Edberg et al., 2008; Poole & Mott, 2003). This often results in the use of chemical or physical restraint to control the behaviour (Hofmann & Hahn, 2014; Lesser & Hughes, 2006) as a strategy to enable nurses the convenience to resume care duties with the knowledge that the resident’s behaviour is contained, with nurses monitoring their response to being restrained (Kong
& Evans 2016). However, restraints are a short-term management for behaviour and are often ineffective while posing significant risk to the older adults physical and emotional wellbeing (NSW NMA, 2016; Poole & Mott, 2003).

Agitation affects an older person’s social circumstance, as behaviours are not well understood by others, leading to misunderstandings and quarrels. People with agitation are more likely to become victims of social discrimination that can result in isolation (King, 2012). Family members often feel distressed and helpless at the behaviour they witness (Kyomen & Whitfield, 2008) and this can result in fewer visits or a request for chemical restraint in the hope that their relative will settle (Hofmann & Hahn, 2014).

The costs to the facility in staffing and training as a result of agitation are high. Increased sick leave, worker’s compensation and staff turnover attributed to carer strain are expensive. The recruitment of new employees or the reliance on agency staff is both expensive and compromises continuity of care (Edberg et al., 2008; Zwijsen et al., 2014). Ongoing training in agitation assessment and safety is often mandatory for staff, proving expensive to the organisation. Due to the high frequency of agitation in RACFs, staff training is pivotal to provision of resident and staff safety (Burn et al. 2011; O’Conner et al., 2013).

### 2.3 Defining agitation

There is a lack of consensus in determining a concise definition for agitation; rather there is agreement that agitation pertains to a specific set of observable physical and verbal behaviours widely accepted to have an origin of inner turmoil (Grose & Schub, 2013; Kovach & Noonan, 2005; Pritchard & Brighty, 2015). New South Wales Health (2014) defines agitation as a phenomenon that is multi-dimensional and complex associated with a person’s psychosomatic condition. Pritchard and Brighty (2015) postulated that agitation is a subjective experience of inner tension observable to others in the person’s

While some consensus has been reached, a lack of clarity in defining the limitation of agitation has created some confusion in the literature. Dewing (2010) noted that agitation is often used interchangeably with aggression (Ballard, Corbett, Chitramohan, & Aarsland, 2009a), similarly anxiety and agitation often share the same representation in the literature (Alzhiemers Association, 2015). Poole and Motte's (2003) attempt to clarify a definition led to the identification of 47 behaviours considered agitation. Garriga et al. (2016) combines previous thought on agitation to propose a definition of non-productive and "repetitious activity that consists of behaviours such as pacing, fidgeting, wringing of the hands, pulling of clothes and inability to sit still (p 87)". This ambiguity has led to the reliance on measurement tools that assess agitation to clarify meaning, in particular the widely accepted Cohen-Mansfield Agitation Inventory (CMAI) and Neuropsychiatric Inventory (NPI). Measurement tools of the CMAI and NPI, while currently relied on by researchers to inform characteristics of agitation, are designed to measure behaviours in the clinical setting rather than provide clarification and meaning. Dewing (2010) postulated that greater clarity is needed in defining agitation and associated behaviours.

In 2015 the International Psychogeriatric Association formed an Agitation Definition Workgroup to develop a provisional consensus definition of agitation that can be applied in clinical and research settings. An interim definition by Cummings et al. (2015) defined agitation to be a symptom common to neuropsychiatric disorders that can contribute to institutionalisation, disability and diminished quality of life for the older person and the caregiver. The research community waits with anticipation for the IPA revised definition of agitation.
In the absence of a definition of agitation this study uses the three behavioural constructs determined by Cohen-Mansfield and Billing (1986) of physical aggressive, physical non-aggressive, and verbal behaviour that was aggressive or non-aggressive, to clarify the behavioural characteristic of agitation. Table 1 lists presents Cohen-Mansfield behaviour categories with characteristic and examples provided.

<table>
<thead>
<tr>
<th>Category</th>
<th>Characteristic</th>
<th>Behaviour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical aggressive agitation</td>
<td>Motor activity hostility</td>
<td>Biting, falling intentionally, grabbing, hitting, hurting oneself or others, falling intentionally, kicking, pushing, scratching, sexual advances, spitting, tearing things or throwing.</td>
</tr>
<tr>
<td>Physical non aggressive agitation</td>
<td>Motor activity in the absence of hostility</td>
<td>Exit-seeking behaviour, handling things, hiding things, hoarding, inappropriate dressing or disrobing, inappropriate eating or drinking, night awakening, pacing, repetitive mannerisms and restlessness.</td>
</tr>
<tr>
<td>Verbal agitation</td>
<td>Vocal activity</td>
<td>Aggressive - cursing, insults, making strange noises, shouting, screaming and verbal sexual advances. Non aggressive - attention seeking, complaining, negativism, repetitive sentences or questions.</td>
</tr>
</tbody>
</table>

Table 1 Cohen-Mansfield (1986) behaviour categories

2.3.1 Causes of agitation

Causative factors of agitation provide differing perspectives on the origin of the agitated behaviour. Cohen-Mansfield summarised four models that explain causes of agitation including the biological; unmet need; behavioural, and environmental models (Cohen-Mansfield, 2000). The literature considers all causes of agitation to have beginnings in the unmet need model with each model containing some overlap (Bidewell & Chang, 2010). Despite overlap, models have independent schools of thought and disciplinary perspectives that explain the cause of agitation. Each model is discussed separately in this section.
2.3.1.1 Biological model

The biological model attributes agitation to underlying pathology. Agitation from biological causes is considered common in older adults precipitated by acute or chronic illness in the presence of degeneration associated with ageing or infirmity. Agitation from acute biological disturbances can often be resolved with careful assessment to identify cause and treatment. Agitation resulting from chronic biological causes can prove more difficult to resolve, often requiring ongoing monitoring and attention to management plans (DoHA, 2014). Biological conditions common to older people that result in agitation include delirium, sensory deficit, chronic or unresolved pain, anxiety, depression and dementia (Pritchard & Brighty, 2015).

Delirium is agitation that results from acute biological conditions. Common older adult conditions associated with delirium are infection, particularly urinary tract, dehydration, polypharmacy, and chemical or electrolyte imbalances (Kyomen & Whitfield, 2008; Pritchard & Brighty, 2015). Older adults are predisposed to delirium due to increased frailty; any condition that affects the neuronal processes can precipitate delirium in a vulnerable adult (Fick, Kolanowski, Beattie, & McCrow, 2009; Fong, Tulebaev, & Inouye, 2009). Delirium accounts for 30-40% of hospital presentations by older adults, with symptoms that include sudden onset of acute confusion often accompanied by hyperactivity or hypoactivity (El-Alfy, Abourashed, & Matsumoto, 2012; NSW DoH, 2014). Delirium in the presence of chronic conditions or sensory impairment can further compound the person's agitation.

Sensory deficits such as impaired hearing or eyesight can make communication difficult, increasing the likelihood of a situation to be misinterpreted (Alzheimers Australia, 2012; Ballard & Corbett, 2010) which may result in resident’s needs being misconstrued by staff. This can prove frustrating for the older adult and time consuming for the carer in their attempt to determine an older adult's requirements. Agitation can result from the
older adult becoming anxious or irritable, concerned that their needs may not be met (Pritchard & Brighty, 2015). Visual and hearing aids may mitigate this situation correcting the agitation.

Pain is not well managed in RACFs with estimates that 85% of residents experience pain at least once a week (Conway & Higgins, 2011) often presenting as agitation. Older adults can contribute to pain being unresolved due to attitudes of stoicism, fear of addiction to pain medication and belief that pain is a natural part of ageing, these beliefs are more prevalent in people aged over 65 years (Savvas & Gibson, 2015). Pain that is unresolved or chronic can contribute to agitated behaviours of restlessness, irritability, anxiety and depression (Ballard & Corbett, 2010).

The role of anxiety (Twelftree & Qazi, 2006) or depression (Volicer, Frijters, & Van der Steen, 2012) and their relationship to agitation is well documented in the literature (Drageset et al., 2013). Conditions of anxiety or depression can be attributed to situational circumstance or imbalances in the central nervous system (CNS). Major mediators for anxiety appear to be related to increases in norepinephrine, serotonin, dopamine, and gamma-aminobutyric acid (GABA) neurotransmitters with the sympathetic nervous system providing many of the symptoms (Alexander, Sahib, Michael, & Jason, 2013). Major mediators for depression in the CNS appear to be the depletion of neurotransmitters serotonin, norepinephrine or dopamine (McCrae & Khan, 2014). The conditions of anxiety and depression are reported to be high among older people living in the residential aged care environment (Royal Australian and New Zealand College of Psychiatrists, 2010).

Australian Bureau of Statistics (2013) reported that in 2011 78% of residents exhibited a mental illness with 26% of these residents not having a diagnosis of dementia. The most prevalent mental health conditions for older people without dementia are anxiety and depression. A 2010 review of anxiety and depression in Australian RACFs revealed
34.7% of residents held a diagnosis of one or both of these conditions (RANZCP, 2010). In light of these figures, the literature still attests that anxiety and depression are under-reported in RACFs with anxiety being the more prevalent of the two conditions (AIHW, 2013). Drageset et al., (2013) claimed that due to increased aged related health loss, powerlessness, and dependency many people living in RACFs feel vulnerable, regardless of existing diagnosis and previous mental health background. These older adults are more likely to become anxious or depressed and experience agitation.

The AIHW (2013) reported that residents with depression were more likely to exhibit verbal or physical agitation in the trajectory of their health condition. Residents without dementia who have depression experienced verbal agitation (34%) or physical agitation (25%) twice as often as people without dementia who do not have depression. Drageset et al., (2012) and Beyond Blue (2015) specify the agitated behaviours of anxiety and depression commonly include the wringing of hands, pacing, restlessness, anxious physical or verbal reactions, irritability, aggressiveness, anger, and sleep disturbances. Anxiety or depression is further complicated for people with dementia as these agitated behaviours may be overlooked and attributed to the dementia trajectory.

Agitation is claimed to be the most frequently observed and intractable Behavioural and Psychological Symptoms of Dementia [BPSD] (Akhondzadeh, Noroozian, & Mohammadi, 2003; Ballard & Corbett, 2010). BPSD is common in people with dementia with 90% of this population experiencing one or more symptoms in their trajectory (DeYoung et al., 2002; Raetz, 2013). Agitated behaviour in dementia can include aggressiveness, delusions, hoarding, irritability, resistance to care, restlessness, sleep problems, wandering and yelling (Raetz, 2013). The symptom of aggression is most concerning, often triggered during interactions when assisting the older person with their care needs. Aggression affects the quality of the person’s relationship with their carer and is
rated among the most common reason why people present to permanent RACF residency (AIHW, 2012.).

Agitation is commonly associated with dementia, which is an umbrella term for a variety of progressive brain diseases that are characterised by loss of core abilities in addition to abnormalities of mood and behaviour (Holmes, 2012). The four common types of dementia presentations are Alzheimer's Disease, Vascular Dementia, Dementia with Lewy Bodies and Frontotemporal Dementia (Hughes, 2011).

Alzheimer's Disease (AD) is characterised by progressive insidious loss of core function, changes in mood and behaviour as the brain becomes increasingly atrophied. The brain is lighter with increased silver inter-neuronal tangles and extra-neuronal plaques with amyloid deposits (Hughes, 2011). The risk of AD increases with age and genetic predisposition (Holmes, 2012).

Vascular Dementia (VaD) is a common form of dementia that results from the loss of neurons and axioms resulting from impaired supply of blood to the brain that often occurs during cerebral infarcts or stroke (Holmes, 2012). VaD is characterised by sudden onset of symptoms and changes in a person's function; the mix of a person's retained and lost function are dependent on the area of the brain affected by the impaired blood supply (Hughes, 2011).

Lewy Bodies Dementia contains extracellular structures called Lewy's bodies that are also located in the cerebral cortex of people with Parkinson's disease. Amyloid plaque is present, however there is no neocortical pathology as in AD. Lewy Bodies Dementia presents as altered consciousness, vivid visual illusions, and hallucinations. People with Lewy Bodies Dementia often have difficulty in maintaining attention and spatial awareness, and therefore falls are not uncommon (Holmes, 2012; Hughes, 2011).
Frontotemporal Dementia (FTD) is characterised by atrophy of the cerebral hemispheres and presents with changes in personality and communication difficulties in the form of altered speech. Communication is often complicated by progressive aphasia, repetition or mutism (Holmes, 2012; Hughes, 2009).

Residents with dementia often present with impaired communication and progressive aphasia which can prove frustrating for the resident when attempting to communicate needs or requirements to care staff in RACFs.

2.3.1.2 Unmet need theory

The literature considers all agitated behaviour to have an origin in unmet need (King, 2012) with agitation being a response to incongruence in physical, social or environment circumstance (Dewing, 2010). The Macquarie Dictionary defines need as a "case or instance in which some necessity or want exists; that is, a requirement." (Macquarie Dictionary, 2013 p.1140). Needs can be common to an age group or an individual preference of that person. Older adults have common needs associated with their age, declining health and protection of their human rights. Individual needs are often formed from preferences created over a lifetime of routine and habit. These individual preferences are often intractable in an older person's personality, form their identity and the way in which they perceive themselves. However, individual preferences may be difficult to accommodate in the institutionalised environment of the RACF, which can lead to resident distress. The unmet need theory recognises that the RACF environment often fails to meet the individual physical, emotional and spiritual requirements of the older person. If needs are not met, frustration or anxiety often ensues, culminating in agitation (DoHA, 2014).

In 1991 the UN declared their principles for the older person with the aim to bring awareness to the contributions made by older people to society and “add life to the years of life added” (United Nations, 1991). The Declaration contains 18 principles under
categories of independence, participation, care, self-fulfilment and dignity and these principles are designed to underpin the minimum standards of older adult care provision in RACFs (United Nations, 1991). Brownie and Horstmanshof (2012) acknowledge the principles to be embedded in Australian RACF care standards and often promoted to older Australians as achievable when entering into a RACF. A promise made by providers that often proves challenging to deliver in the RACF environment.

Further, the UN principles recognise the needs of older adults to include but not be limited to; access to effective timely pain relief, exercise, mentally stimulating activities, hobbies, maintaining habitual routines, socialisation and the need to practice spirituality in an accepting and accommodating environment (Ball & Haight, 2005; Cohen-Mansfield, Thein, Marx, Dakheel-Ali, & Freedman, 2012; Turner, 2005). Yet despite increases in government funding, RACFs often have difficulty meeting the individual preferences and care demands for older adults. Cognitively intact older people have associated entry into RACFs with a loss of autonomy and independence, loneliness and containment in the facilities, stating feeling "trapped, stuck, confined, isolated and discouraged" (Brownie & Hortmanshoff, 2012, p. 778) and of institutionalised conformity "We are told when to eat when to shower, everything and no one says a0 word" (Brownie and Hortmanshoff, 2012, p. 781). These unmet needs and unrealised expectations contribute to increased anxiety, loneliness and frustration, often observed as agitation.

Older adults frequently have social and emotional unmet needs with many encountering life changes and challenges previously unconsidered when entering a RACF. Adapting to the new environment can prove challenging for older adults as many lifetime habits require changing to conform to facility life and the loss of privacy can be confronting. Older adults experience significant losses that are often not considered earlier in life; many residents are contemplating the loss of independence, activities of daily living (ADLs) and home (Drageset et al., 2012). Progressive loss of health is common as 80%
of older people have one or more chronic conditions (AIHW, 2010). Furthermore, older people can also experience loss of family or friends through relocation or death, leading to isolation and loneliness (Drageset et al., 2012).

Making new friends can also be difficult due to failing health and high incidents of cognitive decline in facilities (Routasalo, Savikko, Tilvis, Strandberg, & Pitkala, 2006). In addition, Erikson’s theory (1959) of psychosocial development consisting of eight distinct lifestyle phases, considers many individuals contemplate their accomplishments in the later stage of life. An older person who perceives they conducted their life with integrity is more likely to look back with satisfaction. While an individual who perceives their life to have been unproductive is more likely to experience despair and possible depression (McLeod, 2013).

It is hardly surprising that a higher prevalence of depression and anxiety is reported for older adults living in RACFs when compared with similar populations in the community (Brownie & Horstmanshof, 2012; Dragaset et al., 2013). These incongruences for older people in the RACF environment serve to increase stress in many individuals.

### 2.3.1.3 **Behavioural Model**

The Behavioural model implies that the agitated behaviour is learned and persists as the older person receives a reward for this behaviour in the environment, with the nurse’s attention being the reward (Pavlov, 1927; Watson & Raynor, 1920). The behavioural model suggests that the unmet need for attention or companionship stemming from loneliness or to alleviate boredom can be the driver for some resident’s agitated behaviour (Bidewell & Chang, 2010). The nurse is required to manage agitation in an equitable and consistent manner. When nurses believe that a residents’ behaviour is a result of attention seeking they can become frustrated with the time spent managing the agitation that takes priority over competing care demands. In time, the resident’s
behaviour may be overlooked or trivialised re-enforcing the unmet need for attention in the environment (Reader & Gillespie, 2013).

2.3.1.4 Environmental model

The Environmental model links agitation to external factors that cause the older person stress, as it postulates that a person is more content when the environment aligns with their needs. Increased vulnerability to environmental stresses is common in older people due to a dementia diagnosis or the lowering of a person’s stress threshold with age (Chrabaszcz, 2014). Environmental stresses may include, but are not limited to unmet care needs, noise, sensory impairment or difficulties in completing everyday tasks such as eating or grooming. The Progressively Lowered Stress Threshold (PLST) theory considers each individual to have a stress threshold that is set during adulthood that can be temporarily altered during times of illness, or permanently altered during episodes of brain damage as in the case of dementia. When this threshold is breached the person has limited coping mechanisms to deal with stress and may begin to exhibit agitated behaviours such as aggression, wandering, shouting, irritability or compulsive, repetitive physical or verbal behaviour (Tyrrell, 2014).

Older adults with dementia or infirmity can be susceptible to environmental stressors. Stressors in the environment can render a person anxious, often resulting in anger or irritability if they perceive to have lost personal freedom or control over the situation (Anderson, 2011). This response is a reaction to perceived loss of autonomy, independence and value. According to Chrabaszcz (2014), common stressors in older adults include fatigue, changes in routine, noise, as well as demands that the resident places on themselves or others that are unachievable. Physical conditions of pain, acute illness or depression were also found to increase agitation in older adults influencing a persons stress threshold (Alzheimers Australia, 2012).
Agitation in RACFs impacts on the person and all those within the vicinity of the behaviour. A careful initial assessment of the resident’s circumstances and their response can identify triggers or underlying causes that may contribute to the agitation (Raetz, 2013). Identifying causes of agitation can enable staff to correctly and appropriately manage the situation to reduce or eliminate agitated behaviour (NSW DoH, 2014).

2.3.2 Assessment of agitation

In Australia, there are set guidelines and protocols for the management of older adult agitation in RACFs. The New South Wales Department of Health guidelines (2014), recommend a careful assessment of the older person’s physical, mental and psychosocial status as well as environmental circumstances to identify causes of agitation (NSW DoH, 2014). Within 28 days of entering an aged care facility residents are assessed for the Aged Care Funding Instrument [ACFI] as well as social background and preferences are documented in the first 28 days of residency (Australian Government, 2016). These assessments, which are regularly updated, determine Government subsidy and also assist staff to provide personalised care and activities to the resident. This detailed account of the resident can alert staff to incongruences in the resident’s usual health status or environment that can trigger agitation. Nurses use information from these assessments of the older persons usual health status, their preferences and routine behaviours when assessing and managing agitation (Australian Government, 2017).

The New South Wales Department of Health (2014) recommends a six-step process for nurses when responding to older people with agitation in RACFs. The first step recommends nurses remain calm when approaching a person with agitation. Further, to be respectful of the person’s feelings and to reassure all within the vicinity of the behaviour. Secondly, to identify details of the behaviour and event for later documentation. Thirdly, the nurse must assess the older person’s physical, mental and psychosocial status, and environmental situation. The fourth step requires the nurse to
identify causative factors from the assessment that may have triggered the agitation. A fifth step requires the nurse to choose and implement a management strategy that can reduce the trigger of the agitation. Evaluation of the resident’s response to the management strategies is the final step in the process. If the behaviour is not resolved by the final step, the nurse is required to begin the process again (NSW DoH, 2014).

Identification of causative factors for agitation with the implementation of strategies to minimise their impact is considered the most effective way to reduce agitation in an older person (DoHA, 2014). However when causative factors are not forthcoming this process can prove frustrating and time-consuming for the nurse. The assessment process requires one-on-one interaction with the resident to identify causes. The time taken to assess and manage agitation is often increased if the older person’s communication or comprehension is impaired (Ballard & Corbett, 2010). When causative factors are not identified by assessment, nurses employ a variety of management strategies to reduce agitation with varying degrees of effect and safety.

### 2.4 Management of agitation in RACFs

This section discusses how nurses manage agitation in the RACF environment, described under the headings: distraction; physical restraint; chemical restraint, and complementary therapies.

#### 2.4.1 Distraction

Nurses frequently use distraction as a management strategy to de-escalate agitation in older people (Duxbury, Pulsford, Hadi & Sykes, 2013). Using distraction techniques to divert the older person’s attention to another topic or activity and reduce the focus of the causative faction, an older person is often consumed by frightening, strong emotions that lead the individual to feel out of control with their environment (King, 2012). Distraction strategies can allow the emotions time to decrease in intensity to be more easily managed by the older person. Older people may be more susceptible to distraction
techniques for behaviour management. Weeks and Hashner (2014) report that older people are more likely to process distractions in their environment than younger people. Further, they suggest distraction can reduce an older person's memory of the original topic of concentration.

Nurses are frequently challenged to initiate appropriate person-centred distraction interventions for older people experiencing agitation in their care (Duxbury et al., 2013). A person's level of engagement in a distraction topic may be directly related to their interest in the new scenario presented (Dombeck, 2015). Nurses are guided by their knowledge of the older person's preferences when implementing distractions including conversational topics, activities or complementary therapies. For example, a nurse may instigate a song for a resident with an appreciation for singing or a conversation about the arrival of a new great-grandchild for another. Distraction is, however, a temporary strategy and when the activity finishes or the nurse is no longer available to instigate distraction agitation often reoccurs for the older person (Dombeck, 2015). Reoccurring agitation can leave the nurse frustrated with their inability to manage the behaviour which can result in the use of restraint to manage behaviour (Hofmann & Hahn, 2014).

2.4.2 Physical restraint

One form of management of agitation is the use of physical restraint. Physical restraint is the intentional restriction of a person's movement through device or force (NSW DoH, 2014; Garriga et al., 2016). The use of restraints in RACFs is supported in circumstances where there is a serious threat to the resident or another resident's safety. Methods of physical restraint in RACFs include lap belts, tablespots, bed rails and water chairs (Hughes, 2009; NSW DoH, 2014). Restraints are an attempt to provide a safe environment for the resident, however research indicates a lack of efficacy and increased risk to resident safety with the use of restraint (Royal College of Nursing, 2008). Research into use of restraints report confusion is escalated in the resident and
communication is impaired further compromising the ability to identify causative factors. These side effects also contribute to increased cognitive decline, risk of morbidity and mortality (Cohen-Mansfield et al., 2007; NSW DoH, 2014).

Further investigation into physical restraints report that residents maintain better physical health and mobility and are more able to participate in activities when they are not restrained (NSW DoH, 2014). The use of physical restraint is demoralizing for an older person and is often interpreted as punishment. Restraints impair a resident’s self-reliance, detrimentally affecting their self-confidence that can contribute to physical and psychological decline (NSW NMA, 2016). Some suggest that physical restraints are more likely to contribute to increased risk of serious injury from inappropriate use or resident’s resistance (NSW DoH, 2014; Tilly & Reed, 2006).

Awareness of the detrimental effect of physical restraint on older adults has resulted in new procedural monitoring in facilities, consisting of an hourly assessment of the resident’s emotional and physical wellbeing as well as the continued justification for restraint requirement (Burns, Jayasinha, & Brodaty, 2014). Restraints for older people in RACFs are not limited to physical restriction of movement and often include chemical restraint.

2.4.3 Chemical restraints
Chemical restraint is the intentional use of medication for the sole purpose of controlling a person’s behaviour (NSW DoH, 2014). Medications prescribed for chemical restraint in older adults usually influence gamma-Aminobutyric [GABA] processes, acetylcholine, and serotonin or dopamine neurotransmitters to lower agitation. Atypical antipsychotics are the most commonly prescribed chemical restraints to manage agitation in older adults. The Australian Commission on Safety and Quality in Healthcare (2015) reported that 919,026 Pharmaceutical Benefits Scheme [PBS] antipsychotic medication prescriptions were dispensed in 2013–2014 for people over the age of 65
years, representing more than 25% of this population. A total cost of antipsychotic medications use to the PBS was estimated in 2007 to be $334.4 million (Hollingworth, Siskind, Nissen, Robinson, & Hall, 2010). Medications used in agitation include predominantly atypical antipsychotics as well as alternate pharmacology’s of benzodiazepines, cholinesterase inhibitors, memantime, antidepressants and anticonvulsant medications. These medications are discussed in further detail in this section.

2.4.3.1 Atypical antipsychotics
Atypical antipsychotics are neuroleptic medications that act as major tranquilisers, originally used in schizophrenia. This medication is used to subdue agitation in some RACF residents. Atypical antipsychotics block the receptors of dopamine and serotonin to remove the negative symptoms of apathy, jumbled thoughts, concentration difficulties and difficulties in interacting (Chioca et al., 2013). Atypical antipsychotic medications include but are not limited to risperidone, olanzapine and quetiapine. Atypical antipsychotics have demonstrated an effect in reducing aggressive behaviour over a period of 12 weeks however, serious adverse effects overshadow evidence for efficacy (Livingston et al., 2014; Nguyen & Paton, 2008).

Ballard and Corbett’s (2010) systematic review investigated 18 placebo-controlled trials for efficacy and safety of atypical antipsychotics use in people with BPSD. The review found a significant benefit in aggression over 12 weeks, however the study reported a three fold increase in cerebrovascular events, a 1.5 to 1.7 fold increase in the risk of Parkinson’s, increased sedation and a 1.6 to 1.7 increased risk of mortality. Jeste and Maglione (2013) attempted to compare the long-term safety and effectiveness of atypical antipsychotics aripiprazole, olanzapine, quetiapine, and risperidone in 332 older adults with agitation. A participant withdrawal rate of 50% after six months revealed reasons for withdrawal to be adverse side effects (51.6%) and lack of effect (26%). A further
breakdown of these results revealed that 23% of the withdrawals had experienced a severe adverse event resulting in hospitalisation or death. The authors concluded, “Antipsychotic medications are neither safe or effective” (Jeste & Maglione, 2013, p.4).

Coon et al’s (2014) systematic review of data spanning 27 years investigated initiatives to reduce inappropriate antipsychotic prescribing in RACFs. They reported that educational programs, in-services, medication reviews and multicomponent interventions provided some short-term reduction in antipsychotic prescribing however little difference in the long-term prescribing. They concluded that for antipsychotic prescribing to be reduced, long-term change of culture, environment and availability of non-drug alternatives were required in the RACF setting. Abermain et al. (2014) investigated general practitioner [GP] and nurse barriers to reducing antipsychotic use in RACFs with three main barriers being identified. Firstly, GPs were concerned that ceasing atypical antipsychotic medications would negatively impact a resident’s quality of life. In contrast, two systematic reviews (Akhondzadeh et al., 2003; Banerjee, 2009) investigating atypical antipsychotics report a perceived lowered quality of life in older adults when taking antipsychotics. Further adverse effects related to the use of antipsychotics including increased falls, impaired communication and confusion appear to conflict with the GP opinion that the resident’s quality of life would deteriorate if the medication were ceased.

The second reason for atypical antipsychotic continuation was the fear of a reoccurrence of the initial behaviour and the third reason was that the behaviour would be a hindrance to others and risk of harm to the resident (Azermai et al., 2014). It has also been suggested that atypical antipsychotics reduce nurse workload by lessening the need for surveillance and repetitive agitation management (Jeste & Maglione, 2013). In the absence of evidence-based alternatives, it appears that atypical antipsychotics will continue to be prescribed regardless of side effects. Interestingly, Abermain et al., (2014)
reported that GPs perceive non-pharmacological agitation management to be ineffective, a belief that was in opposition to the nurses who believed these complementary therapy methods to be effective managements.

2.4.3.2 Alternate Pharmacology

There is limited pharmacological evidence for the effectiveness of alternative medications compared to current practice in the management of agitation. Alternate pharmacology investigated for agitation management for older adults in RACFs are cholinesterase inhibitors, memantine, antidepressants and anticonvulsant medications. There is some limited but promising evidence that cholinesterase may have some benefits in reducing anxiety or apathy. Memantine showed benefits over three to six months in irritability, lability, agitation-aggression and agitation or psychosis (Ballard et al., 2009; Ballard et al., 2009b). However, Livingstone et al.’s (2014) review reported memantine as ineffective on agitation behaviour.

Ballard and Corbett’s (2010) review of anticonvulsant medications for dementia revealed two small cross over RCTs and several case studies. The results reported that the use of Carbamazepine demonstrated a significant improvement in overall behaviours in one of two trials. The case studies for sodium valproate found low dosages to be ineffective while high doses were unable to be tolerated by participants.

The antidepressant citalopram demonstrated a significant effect in reducing agitation and aggression in older adults with severe Alzheimer’s Disease (AD) (Ballard & Corbett, 2010). Pollack et al.’s (2007) study reported citalopram to be comparable in effect to risperidone in the management of agitation symptoms in moderate to severe dementia. A further study demonstrated citalopram's effect in reducing irritability without sedation. Another antidepressant, Mirtazapine has also demonstrated reductions in agitation similar to that of citalopram. However, cardiac side effects and reduced
cognition in participants excludes Mirtazapine use in the older adult population (Livingston et al., 2014).

Chemical and physical restraints are crude expedients in the absence of better management methods. Ideally an intervention, which will either eliminate the cause or if possible, target symptoms in a way that maintains the dignity and welfare of the older person, is a more desirable approach. Some promote complementary therapies as an alternative agitation management strategy (Watson, Chang & Johnson, 2011; Turner, 2005).

2.4.4 Complementary therapies

Complementary therapies are based on traditional philosophies that aim to restore resident health while not interfering or interacting with concurrent healthcare regimes (Lindquist & Snyder, 2013; Kayne, 2009). Complementary therapies commonly used for agitation management in RACFs include aromatherapy, exercise, massage, heat packs and music therapy. A therapy's effectiveness is empirically determined by observing the cause and effect relationship between healing technique and the illness. When used as agitation management, complementary therapies can provide relaxation, distraction and social interaction for the resident (Kayne, 2009). Currently there is a lack of scientific evidence to support the efficacy of complementary therapies and little is known about the mechanism of action in reducing agitation in older people. This section discusses complementary therapies in concept, safety, observed effect and scientific evidence.

The concept of holistic health is fundamental to complementary therapies, it incorporates the health management of a person's physical, emotional and spiritual wellbeing concurrently. Complementary therapies are categorised under four domains of practice being biological, manipulation and body-based practices, mind-body therapies and energy-based therapies (WHO, 2002). Therapies known for their relaxing, low side effects are often enjoyable and applications are popular in the care management
of frail persons owing to their gentle nature (Halcon, 2013; WHO, 2002). When considering the controversy surrounding the efficacy and safety of restraints, it is understandable why complementary therapy management is promoted as a first-line management for agitation or used concurrently with medications (Azermai et al., 2014; NSW DoH, 2014).

Distraction is an accepted management method for biological pain and environmental boredom and may provide necessary stimuli without over stimulating. Relaxation can calm psychological distress and anxiety in an older person regardless of lucidity. Social interaction may provide the necessary attention certain older people may require to feel heard and acknowledged. Needs are met in a variety of ways through the application of complementary therapies leaving the older person in a more approachable state to identify and possibly communicate further unmet needs either verbally or non-verbally (Cohen-Mansfield, 2000).

Raetz's (2013) systematic review of the evidence for a non-pharmacological approach to BPSD included complementary therapies of aromatherapy, exercise, massage and music therapy. Based on the evidence reviewed, aromatherapy and massage received the highest level (level A) recommendation indicating evidence was patient orientated, of good quality and reported a reducing effect on agitation. Music therapy and exercise received a B level recommendation indicating that evidence for effect was inconsistent or limited. A review by Dewing (2010) also supports evidence of reduction in agitation with the use of aromatherapy and massage only. Essential oils may prove an effective management for older person agitation with low side effects and limited medication interactions that warrants further investigation.
2.5 Summary

This chapter has discussed the ageing population focusing on the growing number of older people that are presenting to RACFs with increased levels of frailty and complexity of care needs. The high prevalence of agitated behaviours among this age group living in RACFs has been identified as a major area of concern for the care of residents. The nurse challenges to agitation management, of time poor work schedules, frustration at the inability of staff to resolve behaviour and competing demands in the RACF environment were discussed. Agitation management has also been reported as costly to the facility in staff training or absences due to workplace stress.

The term agitation has been defined in this chapter as an umbrella term with behaviour categories of physical aggressive behaviour, physical non aggressive behaviour and verbal agitation. Each agitation category has been presented with corresponding behaviours listed. Causes of older person agitation have been explored under the biological, unmet need and environmental model’s. The current six-step process that guides nurse assessment of agitation in RACFs has been reviewed.

A review of current RACF nurse initiated interventions to manage agitation reported that distraction and restraint were identified as being short-term, ineffective or having detrimental side effects. A need for more available, safe and effective options for the management of agitation in residents in RACFs has been established. Finally, this chapter has presented preliminary evidence for the use of complementary therapy of essential oils as a potential solution for agitation management that is further explored in Chapter 3.
Chapter 3 Essential Oil Literature Review

3.1 Overview
This chapter consists of three major sections. The first section examines the origin of essential oils and their therapeutic benefits. This section also examines the constituents of essential oils, modes of actions to determine suitable oils with anti-agitation properties and methods of administration. The second section examines the properties and benefits of Lavender and Lemon Balm essential oils for reduction of agitation, investigating the potential effects on the nervous system and safety in administration. The final section appraises seven RCTs of Lavender or Lemon Balm essential oils for effect on agitation in residents in RACFs. Trials are examined for contrasting and consistent themes and methodological quality.

3.2 Essential oils for health and wellbeing
Aromatherapy is the use of essential oils derived from plant materials to manage health conditions; the oils are administered by ingestion, inhalation or absorption through the skin (Halcon, 2013; Mills & Bone, 2013).

Essential oils are formed in plants during photosynthesis by chloroplast cells. Chloroplast cells absorb energy from the sun and convert it into sugar bonds. These bonds form molecules to provide the plant with glucose necessary for growth, fatty acids for energy, proteins for plant repair as well as the hydrocarbons of terpenes and related terpenoids that are essential oils (Halcon, 2013). These essential oils are contained in the glands, sacs and veins of the plants that are located in the leaves, flower, fruit and woody stem. The essential oils strong aromatic fragrance is considered to protect the plant from parasites and herbivores while attracting bees for pollination and plant survival (Mills & Bone, 2013).

There is evidence of use of essential oils for medicinal purposes in the ancient Persian, Egyptian, Roman and Greek civilisations, and in Europe in the 10th century. Details of
distillation, application and oil selection for specific health conditions spans centuries through documentation or cultural practice. A Persian manuscript dated at 450BC describes balsamic aromatic substances as popular in religious ceremonies and for medical purposes. In addition, over 200 references are made to the anointing and the healing of the sick with essential oils in the Bible (Soni, Upadhyay, & Upadhyay, 2013). Hildegard of Bingen distilled and documented the medicinal purposes of Lavender in the 12th century and her writings incorporated many herbal and oil remedies that became popular in the following centuries (Bingen and Hozeski, 1997). The rise of the pharmaceutical industry in the 13th century encouraged distillation of many oils that were used to combat illness (Nussbaum, 2014), including the black death of the 14th century and was a major influence in the rise of alchemy in the 16th century (Weiyang, Vermaak, & Viljoen, 2013).

Essential oils were again used for medicinal purposes in a French hospital during World War I when a chemist Rene-Maurice Gattefosse applied Lavender oil to burn wounds of soldiers for its antibacterial and wound healing properties (Dunning, 2005). Interest in the healing properties of essential oils continues today and although there is sparse scientific evidence of effect, they remain popular due to their traditional benefit, low side effects and pleasant aroma. Essential oils are administered by dermal absorption, ingestion and inhalation. Routes of administration are explored in the following section.

3.2.1 Dermal absorption
Essential oils can be applied topically to the skin by massage, compress or Balm, with the oil penetrating the skin through the pores and hair follicles. As the skin is permeable to fat-soluble molecules, the oils travel the 0.5 to 4.00 mm thickness of the skin to reach the blood capillaries and enter the blood stream. Cal (2006) investigated skin penetration of essential oil terpenes linalool, linalyl acetate Terpinen-4-ol, citronellol and alpha-pinene. Terpenes of Linalool, Linalyl acetate and Citronellol, are major constituents of Lavender
and Lemon Balm essential oils. That study found no penetration of linalyl acetate or linalool, with Citronellol the only terpene to permeate the skin. These results contrast with Jager, Biuchbauer, Jirovetz and Fritzer's (1992) case study of one person that demonstrated linalool and linalyl acetate to be detected in the plasma 19 minutes after massage to the skin.

### 3.2.2 Inhalation

Absorption of essential oils by inhalation, or breathing in are probably absorbed through the upper and lower respiratory system (Halcon, 2013). Not all constituents are taken into the lungs; some will enter the brain through receptor cells of the upper respiratory system. Absorption by the respiratory system occurs when oil and oxygen are inhaled, the nose warms the air and the volatile and aromatic particles in the oil dissolve in the mucus that covers the olfactory epithelium at the top of the nasal cavity. Receptor cells link the roof of the nasal cavity to the olfactory bulb from where the cilia transmit signals to the central nervous system [CNS] (Halcon, 2013).

Once the cilia detect the aromatic molecules, a message is sent by the olfactory receptors to the olfactory bulb which transmits the information to the limbic system in the brain. The limbic system's amygdala governs the emotional response while the hippocampus is involved in retrieval of memories surrounding the scent. The limbic system interacts with the cerebral cortex to control heart rate, blood pressure, breathing, stress and hormone levels (Fontaine, 2014; Halcon, 2013; Kayne, 2009). It links aroma to sensations of pain or pleasure, emotions and memories. This explains how an aroma can recall memories and feelings of long ago (Soudry, Lemogne, Malinvaud, Consoli, & Bonsfils, 2011).

Anosmia, loss of scent, is believed to impair the benefits of essential oils in an individual, however a recent study by Chioca (2013) found that inhalation of Lavender essential oils
can induce anxiolytic effects through the CNS or stimulate the olfactory system in mice regardless of the absence of scent.

### 3.2.2.1 Patch inhalation

Scent has also been detected by the unconscious mind as identified in Lillehei, Halcon, Savik and Reis’s (2015) RCT that investigated the effects of inhaled Lavender from a patch on sleep quality of 79 college students who reported sleep difficulties. Participants were randomised to a placebo group of sleep hygiene only and a treatment group of sleep hygiene and Lavender inhalation patch. The study was conducted over five nights with the students wearing the inhalation patch on their chest. Sleep quality was recorded using a fitbit tracker on the Pittsburgh Sleep Quality Index (PSQI) and the United States National Institute of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS). Participants when receiving Lavender and sleep hygiene showed improved sleep quality at post intervention and at two-week post intervention.

However, scientific evidence requires essential oils to be tested for efficacy and safety with mechanism of effect explained in full before the practice can be evidence based. Further investigation is required into the selection of the most appropriate essential oils to maximise the clinical benefit of essential oils and produce quality evidenced research outcomes (Perry & Howes, 2011).

### 3.2.3 Therapeutic benefits of essential oils

Essential oils are comprised of chemical constituents that can be categorised into the following groups: terpenes, phenols, alcohols, oxides, esters, aldehydes, ketones, coumarins and furocoumarins. Individual constituent groups presented in table 2 claim therapeutic benefits, aroma and cautions. Essential oil that is high in a specified constituent is considered to produce the effects attributed to the constituent. Table 2 presents a summary of essential oil constituents including therapeutic benefit and safety.
The high content of aldehydes, terpenes and esters constituents that claim to produce anti-agitation like effects that are contained in Lavender and Lemon Balm essential oil warrants further investigation. A summary of Lavender and Lemon Balm composition and scientific evidence is reported in the following section.
<table>
<thead>
<tr>
<th>Constituent</th>
<th>Therapeutic Benefit</th>
<th>Plants rich in constituent</th>
<th>Caution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phenols</strong> (Carvacrol, eugenol, thymol, methyl chavicol)</td>
<td>Bacterial, antiseptic, stimulating for nervous system, circulation, liver and digestion, anti-infectious, fungicidal, immunostimulant, analgesic, antiviral, expectorant, sedative, spasmylic</td>
<td>Basil (sweet), Basil (Exotic), Fennel, Thyme, Clove</td>
<td>Can cause skin irritation</td>
</tr>
<tr>
<td><strong>Alcohols</strong> (Linalool, terpineol, borneol, citronella, geraniol)</td>
<td>Antiseptic, antiviral, stimulating, bacterial, anti-infectious, general tonic, germicidal, hormone regulator, fungicidal, parasitical</td>
<td>Bergamot, Geranium, <em>Lavender</em>, Sandalwood, Peppermint, Tea tree, Ylang-ylang</td>
<td>Non toxic</td>
</tr>
<tr>
<td><strong>Oxides</strong> (1,8 cineole, linalool oxide, bisabol)</td>
<td>Expectorant, Mucolytic 1,8 cineole – sedative, Linalool – analgesic, spasmylic</td>
<td>Eucalyptus, Marjoram, Rosemary</td>
<td>Skin irritant</td>
</tr>
<tr>
<td><strong>Esters</strong> (Linalyl acetate, geranyl acetate, bornyl acetate, lavendulyl acetate)</td>
<td>Fungicide, sedative, anti-inflammatory, balancing nervous system, analgesic, spasmylic.</td>
<td>Bergamot, Clary Sage, <em>Lavender</em>, Lemongrass, Sweet marjoram, Palmarosa, Rosemary</td>
<td>Gentle and generally safe to use</td>
</tr>
<tr>
<td><strong>Ketones</strong> (Thujone, pulegone, pinocarvone, menthone, jasmine, pinocamphone, fenchone)</td>
<td>Ease congestion, mucolytic, calming, cicatrisant, some are digestives, some analgesics and expectorant, antiviral, bactericidal, fungicidal, parasitical.</td>
<td>Toxic- Mugwort, Sage, Tansy, Wormwood, Pennyroyal, Buchu. Non-toxic – Roman Chamomile, Peppermint, Jasmine, Hyssop, Fennel</td>
<td>Warning some ketones are toxic and should only be used in low dilutions for short periods only</td>
</tr>
</tbody>
</table>

Table 2 Constituent groups benefits and cautions

Adapted from Tisserand & Young (2014) Essential oil Safety
3.3 Lavender and Lemon Balm for agitation management

Lavender and Lemon Balm contain high levels of terpenes, esters and aldehydes. These constituents claim therapeutic benefits of anxiolytic or sedative effect, however both can cause skin irritation or sensitivity when oils are in direct contact with the skin (Mills & Bone, 2013; Tisserand & Young, 2014). Lavender or Lemon Balm essential oils have been use for centuries in Europe for their calming effect to relieve feelings of distress, anxiety or insomnia (Mills & Bone, 2013). This section examines the chemical and therapeutic properties of Lavender and Lemon Balm essential oils, with reference to their potential use to reduce agitation for older people.

3.3.1 Lavender (Lavandula Angustifolia)

Lavender (Lavandula Angustifolia) is a perennial plant that grows 23cm to 90cm tall and is native to France. Lavender’s genus name lavare means ‘to wash’ as this plant was a favourite ingredient in herbal baths of both Greeks and Romans in 200BC. Lavender has a long history of medicinal use, possessing potent anxiolytic, sedative and calming properties (Cavanagh & Wilkinson, 2002).

The essential oil is contained in the flowers that yield a high volume of oil (Duda et al., 2015). Lavender has four chemotypes, being plants of the same botanical characteristics with distinctly different chemical compositions (Koulivand et al., 2013). Lavender chemotypes are Lavandula Angustifolia, Lavandula Stoechas, Lavandula Latifolia and Lavandula Intermedia. Lavandula Angustifolia is chiefly composed of 51linalyl acetate (3,7-dimethyl-1, 6-octadien-3yl acetate) and linalool (3,7- dimethylocta-1, 6-dien-3-ol) that account for approximately 90% of the essential oil. Other constituents include Lavandula, 1,8-cineole, lavandulyl acetate and camphor (Hritcu, Cioanca, & Hancianu, 2012; Woronuk, Demissie, Rheault, & Mahmoud, 2011). Lavender oils have antispasmodic, carminative, analgesic, sedative properties. They are also used traditionally as hypotensive, antiseptic, antimicrobial, antifungal, diuretic and general...
tonics.Externally, it can be used for wounds and superficial burns or oral hygiene (Duda et al., 2015; Koulivand et al., 2013). In China, Lavender is known as "cure-all" medicinal oil called White Flower Oil.

1.4.5.1 Mechanism of action on the nervous system
The high content of linalool or linalyl acetate is believed to be responsible for the observed anti-agitation effect (Linck et al., 2010; Takahashi et al., 2014; Tsang & Ho, 2010; Woronuk et al., 2011) however the mechanism of action is unclear. Linalool or linalyl acetate's action on the GABA processes, acetylcholine, and serotonin and dopamine neurotransmitters is still contentious (Takahashi et al., 2014; Woronuk et al., 2011).

GABAaa Neurotransmitter
The constituents of linalool or linalyl acetate found in Lavender may influence neurotransmitter GABA (Chioca et al., 2013) increasing the available GABAa in the brain to produce an anxiolytic effect similar to that of benzodiazepine (Koulivand et al., 2013). Hritcu, Cioanca and Hancianu (2012) investigated the effect of inhaled Lavender oil on anxiety-like and inhibited depression in Wisteria rats. The rats inhaled Lavender for 60 minutes daily for seven consecutive days before being subjected to behavioural testing designed to increase anxiety. The rats exposed to Lavender aroma participated in the behavioural testing for a longer period than the control rats. Bradley, Starkey, Brown and Lea (2007) compared effects of inhaled Lavender to diazepam, a GABA agonist, in Mongolian gerbils. The gerbils were exposed to Lavender continuously for 14 days or administered diazepam before being subjected to behavioural testing. The results found Lavender inhalation comparable in effect to diazepam in Mongolian rats. This indicating that Lavender was just as effective in producing an anxiolytic state as a benzodiazepine medication in the rats.
Dopamine or Serotonin

Chicoa et al. (2013) investigated whether the effect of the Lavender constituent of linalooll influenced an action on the GABAa similar to benzodiazepines or influenced dopamine or serotonin to create a similar effect to atypical antipsychotics in mice. Serotonergic mediation was studied by pretreating the mice with a serotonin 5-HT\textsubscript{1A} receptor antagonist before behavioural testing. Mice were exposed to either Lavender inhalation or neutral odor anxiolytic properties. This study attributed the effect of Lavender to a result from the constituent effect on serotonergic neurotransmission, which played a significant role in the anxiolytic effect and the participation of GABAa unlikely. Chicoa et al. (2013) reported that inhaled Lavender reduced serotonin syndrome when induced by fluoxetine plus 5-HTP indicative of effect along serotonin pathways. Further, mice were pretreated with a GABAa receptor antagonist at a dose blocking anxiolytic effect of diazepam; this did not interfere with Lavenders anxiolytic effect on the mice. This study however, does not exclude a synergistic effect that Lavender may have on both serotonin and GABA pathways, once the GABAa receptor antagonist block is removed.

Cholinergic System

Wang, Hu and Cheng (2011) postulated that Lavender’s anti-agitation effect may originate from influences in the cholinergic system to increase acetylcholine levels in the brain. Increases of acetylcholine in the brain have a similar effect to the parasympathetic nervous system to reduce anxiety and hyperactivity (Koulivand et al., 2013). The study investigating the mechanism of Lavender action in neuronal tissue indicated a weak cholinergic inhibition and the antioxidant effect that could contribute to neuroprotective factors (Wang et al., 2011).
3.3.2 Lemon Balm (Melissa Officinalis)

Lemon Balm (Melissa Officinalis) is a perennial plant that grows to 70-150cm tall and is native to Europe, North America, and Central Asia. The Genius name Melissa meant "bee" in Greek for the plants ability to attract bees and was first recorded in the Theophrastus’s Historia Plantarum in 300BC. The essential oil, which is contained in the leaves of the plant are terpenic aldehydes (32-42%) that comprise the constituents of citral, geranial and neral. Further constituents include the terpenic alcohols of geraniol, linalool, citronellol and octen-3-ol-1 (Duda et al., 2015). Lemon Balm can be ingested as a tea or used externally as an essential oil with the leaves used medicinally for their sedative, hypotensive and spasmolytic therapeutic properties (Ivanova, Gerova, Chervenkov & Yankova, 2005). The essential oil is often used for its sedative effect on neurological disorders or pain (Duda et al., 2015). The herb was valued in the eleventh century for treating depression and melancholy according to an old Arabian proverb “Balm makes the heart joyful and merry” (Fernie, 2013, p.39).

3.3.2.1 Effect on the nervous system

Lemon Balms action may influence the neurotransmitters gamma-aminobutyric acid (GABA) complex in the central nervous system (Chioca et al., 2013). An affinity for neurotransmitter GABAt, results in more available GABAa to the brain which produces an anxiolytic, sedative and muscle relaxant effect similar to that of benzodiazepine medication (Awad, Muhammad, Durst, Trudeau, & Arnason, 2009; Duda et al., 2015; Koulivand, Khaleghi, & Gorji, 2013). Abuhamdah et al., (2008) conducted an electrophysiological analysis using primary cultures of rat cortical neurons and reported that while Lemon Balm does exert a depressant effect on neural activity, this is not a reflection of its interaction with GABAa complex. In contrast Awad, Muhammad, Durst, Trudeau and Arnason’s (2009) study demonstrated the methanol extract of Lemon Balm to be a potent in-vitro inhibitor of rat brain GABA transaminase (GABAt), thereby increasing GABA in the brains.
A further trial by Ibarra, Feuillere, Roller, Lesburgere and Beracochea (2010) was conducted to determine the pathway of Lemon Balm’s anxiolytic effect on mice in the the gamma-aminobutyric acid (GABA), glutamate and cholinergic systems. Cyracos, a Lemon Balm tincture was administered to mice and investigated for effect in an anxiety-like reactivity. Lemon Balm significantly reduced the anxiety in the mice during elevated maze testing. In contrast to Abuhamdah et al’s (2008) findings Ibarra et al. (2010) concluded that anxiolytic effect was most likely attributed to GABAa processes rather than the glutamate or cholinergic system.

Cases et al’s (2011) pilot study of 20 people investigated the effect of Lemon Balm on mild to moderate anxiety disorder and insomnia. In this study 600mg of Cyracos Lemon Balm tincture was ingested by participants daily for 15 days, reducing agitation by 35% (1.30 ± 0.16 compared to 0.25 ± 0.10, p < 0.01) and lowering insomnia by 42% (p < 0.01). Ninety-five percent of subjects (19/20) responded to the treatment, of which 70% (14/20) achieved a full remission for anxiety, 85% (17/20) for insomnia and 70% (14/20) for both. The results suggest that Lemon Balm may be effective in reducing agitation via effect neurotransmitter gamma-aminobutyric acid (GABA).

### 3.3.3 Safety of Lavender and Lemon Balm

The Australian Therapeutic Goods Administration [TGA] regulates safety and ingredient quality of complementary medicine with a two-tiered system of both listed and registered complementary medicines. Essential oils such as Lavender and Lemon Balm can be purchased over the counter and are listed with the TGA and tested for safety and purity of oil. However, the oils are not tested for effectiveness in managing specific health complaints (TGA, 2015). Lavender (Lavandula Angustifolia) and Lemon Balm (Melissa Officinalis) hold assessment reports with the European Medicines Agency (EMA), the European union for the evaluation of medicinal products. The EMA assessments provide a comprehensive evaluation providing a description of the herb, a summary of non-
clinical and clinical data along with evaluation of clinical efficacy and safety (EMA, 2011). The EMA (2011) safety evaluation for Lavender essential oil concluded "no concern regarding human toxicity’ however ‘contact dermatitis may be possible in rare cases”. In addition the EMA (2012) safety evaluation reported no adverse effects with the use of Lemon Balm to have been reported in the literature or World Heath Organisation database of clinical trials.

Burn's et al's (2011) study of Lemon Balm essential oil reported adverse events in two participants when a 10% essential oil consistency was massaged twice daily. Further research is required to investigate safe doses of essential oil with some research considering a much lower potency of massage oil of 2.5% essential oil to be the optimal dosage for older people (Dunning, 2008). Most adverse side effects or medication interactions reported for essential oils result from use of high dosage essential oil above recommended levels or oil ingestion (Burns et al., 2011; EMA, 2012). The essential oils show potential to effectively manage agitation in older people however to be readily available to residents in RACFs the oils must be able to be administered by the nurse.

3.3.4 Nurse administered aromatherapy in RACFs

Aromatherapy in nursing practice is supported by the Complementary Therapies in Nursing and Midwifery Practice policy, which was re-endorsed at the 2009 ANF annual conference (ANF, 2011). Aromatherapy is well tolerated by the older people with minimal side effects or interactions with concurrent medications, therapies are relaxing and often enjoyed by older people (Fontaine, 2014; Halcon, 2013). Successful implementation of essential oils for agitation management into RACFs requires the support of not only the older adult with agitation but also the nurse administering the essential oil.

Although nurse initiated aromatherapy is endorsed by the Australian Nursing Federation, it is unfamiliar to many nurses in RACFs. Aromatherapy is not generally
included in undergraduate nursing courses, therefore nurses are responsible for acquiring their own knowledge of aromatherapy through accredited courses that build upon nursing practice (ANF, 2011). Many nurses have no knowledge about aromatherapy and when coupled with competing demands, may lead nurses to continue to rely on medications or restraints in an attempt to complete their workplace demands (King, 2012).

This being said, nurse initiated aromatherapy management is feasible as nurses are primary carers to older people in RACFs, they are knowledgeable of the resident’s health care requirements, and therefore able to quickly administer aromatherapy, monitor and assess physical and behavioural changes. This therapeutic relationship between nurse and resident may be extremely important in the administration of aromatherapy to elicit a positive healing response in agitation management in RACFs (Fontaine, 2014).

3.4 Lavender and Lemon Balm Research

This section reports the findings of a literature search of RCTs investigating Lavender or Lemon Balm essential oils to manage agitation for residents in RACFs. A search of electronic databases was conducted in July 2014 and again conducted in July 2016, alerts in each database set up to inform the researcher of newly published relevant literature that was accepted until August 2016. A computerised search using key terms of the databases Academic Search Complete (1978-current), CINAHL (1937 – current), Cochrane library (1800 – current), EMBASE (1947 – current), Joanna Briggs database (1998-current) MEDLINE (1826 - current), Mednar (1990-current), OVID (1946-current), ProQuest Social Science Journals (1971- current), PsycINFO (1987 – current), SCOPUS (1966 – current) was conducted. A copy of the search strategy is presented in Appendix A.

The search returned 107 potential studies of which 36 duplicates were removed from the Endnote file. A review of the 71 studies remaining found the title to be unrelated in
a further 37. The abstracts of the remaining 34 articles showed 25 more studies to be unrelated due to unrelated setting, population, administration methods outside a nurse’s scope of practice or used herbal extracts. The full text of the remaining nine potential studies justified the removal of a further two studies. The seven studies (Ballard, O’Brien, Reichelt, & Perry, 2002; Burns et al., 2011; Fu et al., 2013; Fujii et al., 2008; Lin et al., 2007; O’Connor et al., 2013; Sakamoto et al., 2012) remaining are discussed in this literature review. Lavender was investigated in five studies (Fu et al., 2013; Fujii et al., 2008; Lin et al., 2007; O’Connor et al., 2013; Sakamoto et al., 2012) with Lemon Balm investigated in two studies (Ballard et al., 2002; Burns et al., 2011) of the studies reviewed. The seven RCTs identified in this literature review are described further in this chapter. A summary of the studies can be found in Appendix B.

All seven studies included in this review are RCTs with a variety of comparisons. Study designs were complex with only one RCT (Fujii et al., 2008) using a single experimental group that was directly compared to a control group of usual care. Two RCTs (Ballard et al., 2002; Sakamoto et al., 2012) used a single experiment group that was compared to a placebo treatment. Another two RCTs (Burns et al., 2011; Fu et al., 2013) investigated two treatment groups that were compared with each other and to a third group of placebo treatment. The final two RCTs (Lin et al., 2007; O’Connor et al., 2013) adopted a crossover design that investigated the effect, both the treatment and placebo in each of the participants.

The time frames for the RCTs differed in the studies ranging from 360 days (Sakamoto et al., 2012), 12 weeks (Burns et al., 2011), eight weeks (Lin et al., 2007), six weeks (Fu et al., 2013), four weeks for two studies (Ballard et al., 2002; Fujii et al., 2008) to two weeks (O’Connor et al., 2013).

A total of 562 participants with an age range of 60-93 years were represented in the RCTs reviewed. Four trials (Fujii et al., 2008; Lin et al., 2007; O’Connor et al., 2013; Sakamoto
et al., 2012) included participants of 65 years and older with the remaining three studies (Ballard et al., 2002; Burns et al., 2011; Fu et al., 2013) including participants 60 years of age or older. All Seven RCTs (Ballard et al., 2002; Burns et al., 2011; Fu et al., 2013; Fujii et al., 2008; Lin et al., 2007; O’Conner et al., 2013; Sakamoto et al., 2012) reported information on participant gender and median age. Based on this information the combined median age of the participants were 80.8 years and the sample comprised of 56.5 % female population. Six trials (Ballard et al., 2002; Burns et al., 2011; Fu et al., 2013; Fujii et al., 2008; Lin et al., 2007; O’Conner et al., 2013) had reported a greater number of females in their sample. In contrast Sakamoto et al. (2012) investigated a predominantly male sample with 118 men and only 27 women initially recruited to the study.

All of the RCTs outlined above, were conducted in long-term care facilities, comparable to Australian RACFs. Participants were residents of special care or personal units within 23 RACFs. Six RCTs (Ballard et al., 2002; Burns et al., 2011; Fu et al., 2013; Lin et al., 2007; O’Conner et al., 2013; Sakamoto et al., 2012) were conducted in multicentre trials in Australia, Japan and the United Kingdom. Two studies (Fu et al., 2013; O’Conner et al., 2013) recruited participants from eight specialist psychogeriatric and three private nursing homes, and long-term care facilities in Australia. Another two studies (Ballard et al., 2002; Burns et al., 2011) used three clinical centres and two nursing homes in the UK. Further one study employed three nursing homes in Northern Japan (Sakamoto et al., 2012). Fujii et al. (2008) was the only study to conduct the entire trial in a single site setting that was located in Japan. Further Lin et al., (2007) study recruited participants living in aged care facilities in Hong Kong, however, did not specify how many facilities.

This review included RCTs from both Western (n=4) and Eastern (n=3) global communities. It is anticipated that these results will have resonance with Australia’s growing multicultural population residing in RACFs.
3.4.1 Lavender (Lavandula Angustifolia) studies

Scientific evidence for Lavender effect on agitation in older adults living in RACFs was also explored for similar and conflicting evidence. Five RCTs (Fu et al. 2013; Fujii et al. 2008; Lin et al. 2007; O’Conner et al. 2013; Sakamoto et al. 2012) identified in the literature search investigated the effectiveness of Lavender essential oil for reducing agitation in older adults. Studies used massage or inhalation to apply the Lavender oil to older adults who were assessed for changes in frequency and or severity of agitated behaviours. Outcomes in the studies were conflicting, the four studies (Fujii et al., 2008; Fu et al., 2013; Lin et al., 2007; Sakamoto et al., 2012) that used inhalation and scent application of Lavender demonstrating clinically significant reduction in agitation. Two RCTs, administered the essential oil by massage (Fu et al., 2014; O’Conner et al., 2011) Fu et al’s (2013) study used water spritz for inhalation and massage to administer essential oils. No significant decrease in agitation between treatment and placebo group was reported in two studies (Fu et al., 2013; O’Conner et al., 2011). Summaries of the five Lavender studies are reported separately in this section.

Lin et al’s (2007) single-blinded randomised controlled crossover trial of humidified Lavender essential oil reported a clinically significant reduction in the agitation of 70 older adults with moderate to severe dementia. All participants had a certified dementia diagnosis as specified by the inclusion criteria with measurement at Baseline on the Chinese CMAI and determined clinically significant agitation. In addition, Lin et al. (2007) used Cohen’s (1988) statistical table to project a required sample size of 70 participants to achieve a power of 0.8 with alpha at 0.05. Participants were then randomised to a treatment group by block randomisation, however further details of the randomisation process are not provided.

The interventions compared in Lin et al’s (2007) study included a Lavender essential oil treatment group and an odourless sunflower placebo group. Participants in this trial
received both treatment and placebo for effect on agitation. The treatment was two drops of 100% Lavender oil on each of two cotton swabs. Two humidifiers were placed either side of the resident’s head while they slept; one cotton swab was placed in each humidifier. The placebo treatment consisted of the essential oil treatment replaced with two drops of odourless sunflower oil administered in the same manner. Participants received one treatment for three weeks followed by a two-week washout period and then the alternate treatment for a following three weeks. Agitation was monitored on the Chinese CMAI and NPI during the study.

A clinically significant reduction in agitation was reported on the Chinese CMAI scores of 24.68 to 17.77 (t=10.79, Df69, p<0.001) and the Chinese NPI scores of 63.17 to 58.77 (t=14.59, Df69, p<0.001). Participants were asleep during the intervention and successfully blinded to treatment allocation, however, Lin et al. (2007) claimed difficulty in the ability to blind nurse's assessing behaviours to scent when they were also administering participant interventions.

Lin et al. (2007) was the only trial to report no participants withdrew, however a limitation was identified in the crossover trial. A second baseline data collection was not attended before the second treatment was administered and researchers acknowledged they considered the participants conditions to remain stable over the eight weeks trial duration. Further, assessors were not blinded to allocation group, potentially biasing reporting of outcomes. Lastly, medications were reported to have been monitored but not reported in this study. Lin et al’s (2007) outcomes of reducing agitation with inhaled Lavender was again demonstrated the following year in Fujii et al’s (2008) study.

Fujii et al. (2008) completed a double-blind, randomised controlled trial of Lavender inhalation and reported a significant reduction in agitation in 28 participants with mild to moderate dementia living in one long-term facility in Japan. A dementia diagnosis was made according to DSM-IV criteria however it is unclear whether staff, researcher or
physician made the diagnosis. Significant agitation was determined at baseline using the NPI, however, frequency or severity of minimal agitated behaviour for trials inclusion was not reported. A power calculation was completed to determine the number of participants required for generalisability of results for this study before recruitment. However, the study failed to meet the required sample size. Participants were randomised into two groups of Lavender oil and usual care. However, the randomisation process that was undertaken in this study is not reported. Fujii et al’s (2008) intervention included two drops of 100% Lavender oil that were applied directly to the participant’s collar three times daily after meals for a period of four weeks. The treatment group was then compared to a control group of usual care for changes in agitation. Agitation levels were monitored in both groups by nurses and reported on the NPI. Participant and staff blinding to allocation groups are unclear in the study, however, staff reported behaviours to an assessor trained in the NPI measurement tool and blinded to participant allocation.

A clinically significant improvement was demonstrated in agitation on the NPI (from 31 +/- 10 to 18 +/- 12, P < 0.01;) when compared to the control group (from 32 +/- 11 to 27 +/- 12). Clinically significant improvement is also demonstrated in the NPI subcategories of aberrant motor activity, agitation/aggression, hallucinations and irritability/lability, when compared to the control (Fujii et al., 2008).

Fujii et al’s (2008) outcomes support the Lin et al. (2007) study, however methodological flaws and lack of reporting detract from the overall results in this study. Limitations in Fujii et al. (2008) randomisation processes and lack of adequate blinding may have introduced bias into the study and a small sample size compromises the generalisability of results obtained. Further the medication monitoring process remains unclear and participant withdrawal is not reported. Sakamoto et al’s (2012), larger study of inhaled
Lavender supports Fujii et al's (2008) findings and overcomes many of the methodological flaws presented.

Sakamoto et al's (2012) randomised, placebo-controlled trial of Lavender Aromaseal™ patch demonstrated a clinically significant effect in reducing agitation of 145 participants with and without dementia. Sakamoto et al. (2012) did not report inclusion criteria for agitation, as participant agitation was a secondary measure to a primary measure of falls risk and investigated as a contributing factor to older adult falls. One hundred and forty-five older people with agitation from three aged care facilities in Japan were randomised into two groups to receive Lavender or placebo treatment patches. This study used randomised number generators or tables to allocate participants and used blocking to randomise participants by the facility. The person conducting the randomisation was independent of the study.

Sakamoto et al.'s, (2012) intervention involved Aromaseal™ Lavender scented 1x2cm aroma patches attached to the inside collar area of participant’s clothing worn for a 24-hour period and replaced by the nurse daily for 360 days. The patch was trialled against a placebo group of Aromaseal™ unscented patches. Sakomoto et al. (2012) reported details of comparable baseline data in both the placebo and treatment group.

Agitation significantly decreased on the $24.3 +/\ 5.4$ to $22.9 +/\ 2.3$ CMAI (P=. 04) in the Lavender group but not in the placebo group $24.5 +/\ 6.7$ to $24.0 +/\ 3.7$ (P=. 82). In addition, the Barthel index (Mahoney & Barthel, 1965) also found fewer falls in the Lavender group. Participants were not blinded to group allocation however dementia conditions may have obscured participants memory of patch. Care staff administered treatments and employed the services of a research assistant to assess behaviours independently. Care staff and the research assistant were blinded to group allocation and patch scent was mild enough that only the participant could detect the scent in the environment.
A power calculation was performed to determine the number of participants required for generalisability of results for this study before recruitment, however the study failed to meet this projected sample size at the trial’s conclusion, in part because of a 31% participant withdrawal rate that reduced the number of participants completing the trial (Sakamoto et al. 2012). The most common reasons for withdrawal included hospitalisation, transfer to another facility or death. A review of medication changes over the 12-month trial period was comparable to each group at baseline and the trials completion.

The limitations of the study include the omission of the concentration of Lavender Angustifolia oil used by the Aromaseal™ patch, that is not reported by the authors or recorded on the packaging of the commercial patch used in this study. Finally, the percentage of participants with dementia from the three facilities was not reported. Instead, the mean MMSE scores from the treatment 15.3 +/- 8.4 and placebo 14.6 +/- 8.1 group indicate cognitive decline was high among participants.

Despite methodological limitations, all Lavender inhalation studies gave positive outcomes for reduction of agitation in older people. Fu et al’s (2009) study investigated Lavender inhalation as a water spray against essential oil massage to determine greater effect in the mode of Lavender essential oil application.

Fu’s (2013) single blind randomised controlled trial of combination aromatherapy and massage, aromatherapy only or placebo of 61 older people with dementia, reported that despite a downward trend in behaviour, there was no clinically significant effect on agitation. Dementia was defined by cognitive functional impairment observed in people with dementia, MMSE score below 24 out of 30, in addition to feature of Alzheimer’s disease reported on the DMSV-TR. Fu et al’s (2013) study determined participants clinically significant agitation for inclusions by history of chemical and or physical restraint.
This trial was conducted in three RACFs in Australia and used the size of effect from Ballard et al's (2002) trial in a G*Power prior calculation to give a sample size of 45, 15 participants in each of the three groups at a power of 0.95 with an alpha of 0.5. Fu (2009) used a random number tables to allocate participants, used block allocation to randomise participants by the facility to one of three groups and reported the person conducting the randomisation was independent of the study.

Aromatherapy interventions were a 3% Lavender essential oil water solution which was sprayed as a mist at the participant’s chest area. The aromatherapy and hand massage treatment combined a five-minute hand massage with no essential oil with the aromatherapy intervention. The Placebo used the water solution spray without the essential oil. Treatments consisted of three sprays of mist at chest area twice daily for six weeks. Agitation levels were monitored in each group on the CMAI for the study duration.

No significant change in agitation was found between the groups, in fact increases in agitation were reported in the combination aromatherapy with the hand massage group. Fu (2009) acknowledged that participants were not blinded to treatment allocation. However, those administering interventions and assessors of behaviour were blinded to the allocation group. Fu (2009) employed an independent research assistant to administer interventions to the participants. This overcame assessor and allocation bias while ensuring compliance to treatment doses. The research assistant was blinding to intervention with the use of a nose clip and masking oil of rosemary essential oil smeared above the top lip.

Fu et al. (2009) reported that 48% of participants in the study had severe dementia postulating it is possible that massage may have been too invasive or oils too stimulating for this population. Withdrawals also led to a lower than anticipated sample size
compromising generalisability of results. The most common reasons for withdrawal in this study included participant refusal to participate or death.

A final study investigated Lavender massage for effect on reduction of agitation in older people with agitation living in RACFs. O’Conner et al’s (2013) single blind randomised controlled trial of Lavender massage in 77 participants with moderate to severe dementia reported no clinical significant change in agitation. Dementia was determined by a rating on the CDR scale of at least mild dementia by RACF staff. O’Conner et al. (2013) defined agitation for inclusion by a single agitated behaviour specific to a resident that occurred several times during the day and required staff intervention. An assessor monitored the specific agitated behaviour for changes in frequency from baseline during intervention sessions. This study used the Microsoft Excel software random number generators to allocate participants to groups without blocking, the person conducting the randomisation was independent of the study.

O’Conner et al. (2013) used an intervention of 30% Lavender lotion, of which 1ml was applied to each forearm of the participant and massaged for one minute. Three treatments were performed over a period of seven days with four days washout between treatments. The study investigated physical agitation only, the primary measure being the mean count of behaviours 30 minutes prior to interventions when compared to mean behaviours 60 minutes preceding intervention. A secondary measure of CMAI monitored agitation on a weekly basis informed by a regular carer. As residents are their own control in crossover trials, uniformity between placebo and treatment groups can be assured. However, outcomes may be attributed to disease progression if groups are not counterbalanced.

O’Conner et al. (2013) relied on the care staff to administer treatments and a research assistant assessed behaviours independently. Participants were not blinded to scent with researchers questioning the practicality of blinding participants to scent, therefore
the scent may trigger the essential oils therapeutic action in participants. Assessors however, were unaware of group allocation aided by the use of a nose clip and masking oil of rosemary essential oil smeared above the top lip when monitoring behaviour.

O’Conner et al. (2013) attempted to mitigate the risk of medication influences in their short trial by requesting staff not to change participant’s medication unless necessary, however changes were not reported. A power calculation was obtained to determine the number of participants required for generalisability of results before recruitment. However, the study failed to meet calculated sample size at the trials conclusion. The most common reasons for withdrawal included refusal to participate, breakthrough agitation or death

Six trials sought to investigate exclusively participants with dementia; however a diagnosis was obtained in only one study (Lin et al., 2007). The researcher or nurse through the use of a dementia or cognitive decline assessment tool often determined the dementia status of the participants. Five studies (Fu et al., 2013; Fujii et al., 2008; Lin et al., 2007; O’Conner et al., 2013; Sakamoto et al., 2012) used the Mini Mental State Examination [MMSE], four studies (Ballard et al., 2002; Burns et al., 2011; Fujii et al., 2008; O’Conner et al., 2013) used the Clinical Dementia Rating [CDR] scale, three studies (Fu et al., 2013; Fujii et al., 2008; Lin et al., 2007) used DSM-VI criteria or the NINCDS/ADRADA Alzheimer’s criteria (Ballard et al., 2002; Burns et al., 2011) to assess participant dementia. In the absence of a dementia diagnosis, two studies (Burns et al., 2011; O’Conner et al., 2013) referred to participants as having probable or possible dementia. A further study (Fu et al., 2013) referred to participants as having severe cognitive decline and possible dementia as indicated by scores on the MMSE, a scale that measures cognitive impairment.
3.4.2 Lemon Balm (Melissa Officinalis) studies

Two double-blind randomised controlled trials (Ballard et al., 2002; Burns et al., 2011) investigated Lemon Balm’s effect on agitation in older adults with dementia. Each study used an intervention of 10% Lemon Balm lotion administered with massage and conducted in RACFs in England; it is unclear if these facilities were the same in each trial. Results of the two trials are conflicting.

Ballard et al. (2002) investigated 72 participants with severe dementia and clinically significant agitation from eight National Health Care nursing homes in the United Kingdom. Consent for participants in this study was obtained from the next of kin as participants had severe dementia as confirmed by a Clinical Dementia Rating Scale (CDR) of three. Participants exhibited agitation at least daily with moderate to severe nurse management to be significant. Agitation was defined as a cluster of symptoms that lead to disturbed behaviours that could be measured on the CMAI and NPI measurement tools. Baseline behaviours on the NPI, CMAI and Dementia Care Mapping (DCM) were obtained for all participants.

The earlier study (Ballard et al. 2002) demonstrated a significant clinical effect when Lemon Balm essential oil lotion was applied, to participant’s face, hands and arms twice daily for four weeks. Frequency and severity of agitated behaviours were monitored on the CMAI and NPI during the study and a significant reduction of agitation was reported in the behaviour categories of physical aggressive, physical non-aggressive and verbal behaviours in the Lemon Balm group when compared to placebo (Ballard et al., 2002). This significant reduction in agitation was demonstrated by a 35% reduction in the Lemon Balm treatment group compared with an 11% reduction in agitation for participants in the placebo group, a Mann-Whitney U test analysis $Z = 4.1$, $p < .0001$ demonstrated this effect. Ballard et al’s (2002) study was the first essential oil study that addressed agitation in dementia to be included in the Cochrane review (Thorgrimsen et
al., 2014b) however it was criticised for its randomisation method. Participants were randomised in facilities by the toss of a coin rather than individually and therefore the results may be confounded by differences in care within each facility. Nine years later Burns et al. (2011) sought to replicate some components of Ballard’s et al. (2002) study, improve on methodological limitations and add a third intervention of Donepezil medication for comparison.

Burns et al.’s (2011) study, however, showed no significant reduction in agitation in 115 older adults with probable or possible Alzheimer’s Disease and high levels of agitation with Lemon Balm lotion. This study again compared Lemon Balm lotion to placebo with the addition of a second treatment group of Donepezil medication. The aromatherapy group received 10% Lemon Balm lotion massage plus placebo medication; the Donepezil group received medication plus placebo massage (without oil), and the placebo group received placebo medication plus placebo massage. The interventions were administered to participants twice daily by the care staff for 12 weeks. Frequency and severity of agitated behaviours were monitored on the Pittsburgh Agitation Scale [PAS] and NPI during the study.

Despite no significant clinical effect, a substantial reduction in agitation across all three intervention groups was demonstrated by improvements of 18% in the PAS score and 37% in the NPI total score over the 12 weeks trial (Burns et al., 2011). Reduction of agitation in the placebo group suggests that social contact during administration of the intervention may have a positive effect on agitation. Burns et al.’s (2011) trial concluded that Lemon Balm was at least as effective as Donepezil medication to manage older adult agitation in RACFs. A comparison of Lemon Balm and Donepezil side effects and interactions suggests Lemon Balm to be the safer management method.

Burns et al. (2011) incorporated several improvements that have advanced research into essential oils and Lemon Balm for agitation management. This study is the first
aromatherapy study to include a Quality of Life (QoL) measure to monitor participant’s wellbeing during an aromatherapy study for residents in RACFs. A clinically significant improvement in QoL was demonstrated on the Blau Quality of Life measure when participants used Lemon Balm. In contrast QoL scores decreased in participants that used the Donepezil intervention (Burns et al, 2011).

Burns et al's. (2011) study also used methods of randomisation and blinding in essential oil trials that significantly improved the validity of the findings. Randomisation of participants to one of the three intervention groups by computer-generated blocks of six that were then stratified to each RACF, overcome the randomisation limitation in the previous study. Improvements in blinding were made with the staff that administered the aromatherapy intervention using nose pegs during the procedure and applied rosemary oil above their top lip to mask the intervention scent. Nevertheless, there were limitations including a 29% participant withdrawal rate that compromised the sample size resulting in a lower than anticipated number of participants completing the trial and decreasing generalisability of outcomes. Further, staff compliance to administering the intervention was also low with an estimated only 50% of the essential oil and medication as stipulated in the study design administered to the participants. This was determined by counting the number of medications that had not been administered and weighing aromatherapy bottles to determine remaining intervention stock. The conflicting outcomes of Ballard et al. (2002) and Burns et al. (2011) Lemon Balm studies are investigated further in this study.

3.4.3 Trials of essential oils in subjects without a dementia diagnosis

Sakamoto et al’s (2012) trial was the only RCT to investigate people with and without dementia. This trial reported that 82% of participants exhibited possible or probable cognitive decline as demonstrated by a lower than 24 score on the MMSE. According to this information only 26 of the 562 participants were cognitively intact and therefore
considered not to have dementia. A breakdown of results for people with and without dementia is not reported in this trial.

The inclusion of participants without dementia experiencing agitation is essential in identifying potential effective management methods that can be practical in the RACF environment. Much research to date has focused on people with dementia due to the severity of behaviour and ease in monitoring high frequency of agitated behaviours common in the trajectory (Burns et al., 2011; Fu et al., 2013; Fujii et al., 2008; Lin et al., 2007). However, more inclusive policies for researching related health problems will provide equity and potentially improve quality of life for all residents in RACFs.

### 3.4.4 Quality of Life

Two studies (Ballard et al., 2002; Burns et al., 2011) investigated changes in quality of life score when participants were administered Lemon Balm in comparison to a placebo. Both studies reported statistically significant improvement in the quality of life on the Belau measurement scale (Burns et al., 2011) and Dementia Care Mapping (Ballard et al., 2002) when participants were treated with 10% Lemon Balm massage oil (Burns et al., 2011). Ballard et al’s (2002) study suggests the participant’s quality of life improved in the Lemon Balm group as demonstrated by reductions in time spent socially withdrawn \( Z=2.6, p=.005 \); and improvement in percentage of time engaged in constructive activities: \( Z=3.5, p=.001 \) as evidenced on the Dementia Care Mapping tool. The study also demonstrated a clinically significant difference in baseline QoL scores when compared to 12 week across groups of Placebo -2(-34,30), Donepezil -39(-63, 15) and Lemon Balm 17(-13, 47) \( p=0.03 \), with Lemon Balm showing the most marked improvement.

The Quality of Life (QoL) research into the agitation of older people needs to be investigated to identify the needs of the agitated individual without pre-empting them (Craig & Smyth, 2011; Pearson et al., 2007). Aromatherapy may resonate as a preferred healing method amongst some older people who have previously found the therapy
beneficial (Kayne, 2009). The QoL surveys can also provide accessible data for nurses in their care giving to monitor the impact essential oils have on older people and can validate the intervention effect for the nurse.

3.4.5 Nurse compliance

Nurses as primary carers are familiar to the agitated residents and are well placed to identify agitated behaviour and provide timely intervention. Interventions were initiated by care staff in five studies (Ballard et al., 2002; Burns et al., 2011; Lin et al., 2007; O’Conner et al., 2013; Sakamoto et al., 2012), nurses administered oils by massage (Ballard et al., 2002; Burns et al., 2011; O’Conner et al., 2013), patch (Sakamoto et al., 2012) and through the use of humidifiers (Lin et al., 2007). The person who delivered essential oil or placebo oil onto participants clothing in one study is unclear (Fujii et al. 2008), although a later study published by Fu et al. (2013) relied on the researcher or research assistant to administer essential oil or placebo mist spray and massage.

Direct care nurses are essential to research investigation because they are familiar with the participants and can give advice on the practicality of the intervention in a clinical environment. The reviewed studies identified the nurse’s role in research to be observing participants, administering essential oils and informing agitation measurement tools for the research. However, nurse non-compliance to essential oil administration was recognised as a limitation in two studies (Burns et al., 2011; Fu et al., 2013). Fu et al’s (2013) results were compromised by nurses not complying with the study protocols for administration of interventions, possibly due to time constraints and shifting priorities of care. Burns et al. (2014) calculated administration compliance to be 10% Lemon Balm massage oil to participants at only 50% of administrations.

Currently, it can only be speculated as to why compliance is an issue with essential oil administration in RACFs. Barriers to nurse compliance may include competing for workplace demands and priorities or knowledge deficits surrounding aromatherapy or
older person agitation (Edberg et al., 2008; King, 2012; Poole & Mott, 2003). Despite limited resources, many nurses in RACFs are challenged to meet all care needs of residents in their charge, often proving too much for the nurse with competing demands (King, 2012; Poole & Mott, 2003). Prioritising competing demands may lead to essential oil administration for agitation management being omitted from the nurse's schedule in favour of priorities the nurse perceives to be of more value. Alternatively, agitation is common in RACFs with a potential underlying perception among nurses that agitation is a normal part of ageing which cannot be remedied (Grose & Schub, 2013; King, 2012).

The literature that investigates the involvement of direct care nurses in research infers that nurses are often absent from the research process. The three studies (Akerjordet et al. 2012; Roll et al. 2013; Vedelø & Lomborg, 2011) obtained in the literature identified balancing the fluctuating volume of patient load and care demands with research commitments to be a challenge to research participation. Nurses who felt comfortable with their level of research knowledge and with the research team were more likely to participate in research (Akerjordet et al., 2012; Roll et al., 2013; Vedelø & Lomborg, 2011). To mitigate these challenges, researchers need to ensure that nurses have allocated time to participate in research which enables them to fulfil their research roles in addition to their regular care duties. Secondly, timely and transparent communication with care staff may better support the challenges they face in committing to a research project. Finally, researchers must be aware that care staff often have little experience in conducting research. Education should be provided at the appropriate level of the staff knowledge and involvement (Roll et al., 2013). Nurses are required to follow clinical procedure manuals when delivering evidence-based care to clients, therefore educating staff on research process using a similar process may improve knowledge and participation (Vedelø & Lomborg, 2011).
Researchers need to address barriers to nurse participation in research for future studies (Roll et al., 2013; Vedelø & Lomborg, 2011). The recruitment of a research assistant to administer essential oils can support the nurses by attending to the daily intervention to overcome this limitation, however this can prove expensive and defeats the purpose of a quick, effective intervention which can be provided by the nurse. Further investigation of nurse perceptions and barriers to nurse administration of essential oils is required to ensure practicality of the intervention for use in Australian RACFs (Burns et al., 2011; Fu et al., 2013).

3.4.5.1 Nurse observation reporting

Nurse perception of the effectiveness of essential oils work or an inability to distinguish agitated behaviour from an older person's rational behaviour may unintentionally bias outcomes especially if the allocation group is known. Inaccurate reporting of behaviours on the measurement tools intentionally or unintentionally, devalues outcomes obtained. Compromised nurse blinding in two studies (Fujii et al., 2008; Lin et al., 2007) increased the risk of bias and inaccurate reporting. Zuidema et al. (2011) support this view when assessing the NPI and CMAI for reliability and found poor inter-rater agreement in observed behaviours. Investigation of a nurse's preconceived inclination towards agitation, essential oil and research may identify bias in agitation management selection or bias in reporting.

Further, well-designed studies are needed to investigate the effectiveness of Lavender and Lemon Balm essential oils to manage agitation in older adults with and without dementia. Research that will address limitations in methodology, investigate the RACF environment, specifically the benefits and barriers to nurse administration of essential oils while being inclusive of all older people experiencing agitation who live in RACFs is needed.
3.5 Summary

This chapter has reviewed the suitability of essential oils as potential management for agitation in the RACF setting. The first section of this chapter explained the origin of essential oils and mode of administration to the older person. The chemistry governing essential oil formation including the locations of storage and development in the plants have been detailed. A brief history of the use of essential oils as a therapeutic intervention was provided, which included claims of low side effects and pleasant aroma. Current understanding of dermal and respiratory absorption of essential oils have been discussed with reference to key constituents of Lavender or Lemon Balm essential oil. Theories of biological or memory mechanism of action are discussed within the context of the literature.

The second section in this chapter identified constituents of Lavender and Lemon Balm that traditional observation of effect supported as having anti-agitation properties. Constituents of Lavender and Lemon Balm have been explored for anti-agitation scientific evidence as demonstrated in animal, human and in vitro studies (Burns et al. 2011; Chioca et al. 2013; O’Conner et al., 2013; Takahashi et al. 2014). Constituents in both oils have been investigated for evidence of access to neurological pathways similar to anti-agitation or antidepressant medications with conflicting results. The safety of Lavender and Lemon Balm essential oils and viability for nurse administration as an agitation management was also reported.

A literature review of RCTs on the effect of Lavender or Lemon Balm for the management of agitation in older people living in RACFs was conducted. The review identified seven RCTs, however the effectiveness of both Lavender and Lemon Balm is inconclusive from the studies results. The reviewed RCTs revealed pertinent areas of methodology, participant inclusion and nurse compliance that can be improved. The methodology of a mixed methods study to overcome limitations in the literature and provide nurse’s
scientific evidence of Lavender or Lemon Balm’s effectiveness and practicality in RACFs setting is presented in chapter 4.
Chapter 4 Methodology

4.1 Overview

This chapter presents the methodology of a mixed methods study with a three-phase sequential design. A rationale is provided that gives evidence of the effectiveness of this design to determine the effect and practicality of Lavender or Lemon Balm essential oils as agitation management in the RACF setting. The theoretical underpinning, the adapted HBM providing the framework for this inquiry is presented. The qualitative and quantitative components of this mixed method research are detailed separately with each section providing a rationale for the methods used and study objectives addressed. Finally, the rigour and ethical considerations to which this study complies are provided.

4.2 Mixed method design

Mixed methods research is a process that combines both quantitative and qualitative methods in one project to provide data that can be triangulated to provide a clearer understanding of a research problem (Treddlie & Tashakkori, 2012). The combination of methods provides a broader understanding of the research problem than either interview or statistical data could provide alone (Creswell, 2012). Quantitative and qualitative data have distinct features that when mixed can strengthen research results because the strengths of one research approach can counteract the possible limitations of the other approach (Creswell, Klasson, Clarke and Smith, 2011), for example, the ability of a quantitative study to sample a large number of people can build upon a qualitative study’s smaller sample to improve generalisability of findings (Green et al. 2015).

4.2.1 Rationale for a mixed method sequential design

This study used mixed method research to investigate the use of two essential oils, Lavender and Lemon Balm to manage agitation in older people living in RACFs. In this
research a single blind Randomised Control Trial (RCT) was conducted compare essential oils interventions for agitation management while the qualitative studies examined the issues of nurse attitudes towards essential oil research in the RACF environment in which the research was conducted. A double-blind method could not be achieved in this study as attempts to blind the resident from the essential oil scent may have reduced the effect of the intervention. The researchers participating in the administration of intervention, data collection and analysis were the not aware of resident allocation through blinding and masking strategies. The researchers kept the nurses reporting behaviours blinded to essential oil allocation. This blinding was achieved by the RA administering and removing the oils from residents before the reporting nurses started their regular work hours. However, researchers could not guarantee that resident's participating in the RCT did not identify the essential oil intervention, in particular Lavender, a commonly used herb among the older adult population. A single blind method is therefore considered to provide the most appropriate understanding of the practicality and effectiveness of using Lavender or Lemon Balm to manage agitation in older people living in RACFs.

This study employs a three-phase sequential design with exploratory and explanatory sequential research components:

**Phase I**: Qualitative interviews were conducted with nurses to explore current practices for the management of agitation at the study sites, their attitudes about agitation management and the use of essential oils as an intervention to manage agitation in the RACF setting. The interviews also explored nurse's attitudes and experiences to conducting and participating in research in the RACF setting. Findings that support nurse participation in research and the conduct of research in RACFs were incorporated into Phase II of this research.
Phase II: A single blind RCT was conducted at six residential facilities on two sites in Sydney metropolitan area to provide evidence of the effectiveness of two essential oils, Lemon Balm and Lavender, for the management of agitation in residents of RACFs. The single blind RCT design was selected for this phase as it is considered to be the gold standard according to the hierarchy of evidence in medical and biosciences (National Health and Medical Research Council, 2007) and most appropriate design for the intervention evaluated.

Phase III: Qualitative interviews were conducted with nurses to build upon the responses obtained from Phase I and identify changes in attitude after participating in the Phase II single-blind RCT. The interviews examined changes in perceptions of agitation frequency and the ability of essential oils to manage agitation. These questions also examined the ease of which the single-blind RCT was implemented into the RACF setting and facilitators to nurse participation in the research.

Table 3 presents the mixed methods three-phase sequential design that is used to guide this study.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Method</th>
<th>Description</th>
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<tbody>
<tr>
<td>Phase I</td>
<td>Qualitative</td>
<td>Exploratory semi-structured interviews with nurses to explore the factors that influence agitation management, nurse perceptions of essential and facilitators to single blind RCT implementation in the RACF environment. Phase I explored a lack of RACF nurse compliance to previous RCTs. Findings that support nurse participation in pre-trial education, intervention and data collection timing are incorporated in Phase II.</td>
</tr>
<tr>
<td>Phase II</td>
<td>Quantitative</td>
<td>A single-blind RCT of Lavender and Lemon Balm essential oils effect on agitation in sixty-five older adults living in RACF settings. Nurses who observed resident behaviour in Phase II also participated in Phase I and Phase III of this study.</td>
</tr>
<tr>
<td>Phase III</td>
<td>Qualitative</td>
<td>Exploratory semi-structured interviews with nurses monitored changes in perceptions of Lavender or Lemon Balm as an agitation management for people with and without dementia. Further examined are the influencing factors that can facilitate nurse participation in research in the RACF setting.</td>
</tr>
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Table 3 Mixed method sequential design
4.2.2 Theoretical Underpinnings

As discussed in Chapter 1 section 1.3 the theoretical underpinning for this research is the adapted Health Belief Model [HBM] (Cheung et al., 2015). The qualitative Phases I and Phase III support theoretical underpinnings of the HBM that focus on the nurse’s likelihood of changing their current agitation management strategy to essential oils application for residents in their care. The literature review established that nurses were exposed to agitation in their workplace that often seriously impeded their daily duties. When applied to the topic the HBM postulates that susceptibility and seriousness of agitation in the RACF environment should develop a cue to action among nurses to seek acceptable managements to resolve agitation in their workplace.

4.3 Qualitative studies

This section describes the qualitative design used to guide Phase I and Phase III of this research. Study methods included the use of semi-structured interviews that gave insight into nurse perceptions of agitation, its management, use of essential oils and the conduct of research in the RACF environment. The objectives explored by the qualitative study that supports this inquiry are provided. The content analysis that guided the data collection and dissemination of data into credible, reliable areas of interest are detailed.
4.3.1 Phase I and Phase III

The qualitative components of this design, Phases I and III addressed five objectives below:

Phase I

1. Explore nurse understanding of agitation and its influence on the management resident behaviour in RACFs
2. Explore nurse perception of essential oils and their use to manage agitation
3. Explore nurse attitudes towards research in RACFs, and identify barriers to research in that setting

Phase III

1. Determine if nurse's perception of the use of Lavender and Lemon Balm to manage agitation has changed by participation in Phase II
2. Determine influencing factors that can facilitate nurse participation in research conducted in the RACF setting.

The objectives in Phase I explored nurse understanding of agitation management, the perception of essential oils and their use to manage agitation, the importance of research for older people and the barriers and facilitators to the implementation of research in the RACF environment. Findings from Phase I were incorporated into Phase II of this study to address knowledge deficits and facilitate ease of research implementation to encourage nurse participation. Phase III of the study addressed changes in nurse perceptions of Lavender or Lemon Balm as an agitation management. Nurses provided opinion on the differences in Lavender and Lemon Balm's effect on agitation in older people with and without a dementia diagnosis. Nurse's observational assessment of the essential oils effect informed the scientific results obtained from the Phase II single blind RCT by verifying if results were similar to their observed experience. In addition, nurses
in Phase III reviewed their Phase II RCT research participation to reflect on factors that influence nurse participation in research conducted in the RACF environment.

### 4.3.2 Study sample

The sampling for Phases I and III included a purposive sample of 11 nurses employed in the RACFs. Purposive sampling was conducted to ensure that nurses who were potential participants for the study would be available for all three phases. Purposive sampling is non-random; residents are selected on the basis of certain characteristics that are desirable to conduct the research (Ryan & Maruyama, 2014). In this study, potential nurse participants were invited to participate if they cared for residents participating in Phase II, four days per week for at least two hours per day.

Sample bias was reduced in the study sample by ensuring that an accurate and diverse representation of the nursing staff was involved in the study. This was achieved in this study by recruiting nurses of different ages, education level and ethnic background to provide an accurate representation of a miniature sample of the nursing population in the facilities. The selection criteria for the nurse participant’s are detailed in the following section.

### Selection criteria

Participants were included in Phase I and III if they met the following criteria:

- Nursing staff that care for residents recruited to Phase II of this study, for a minimum of four days a week for at least two hours per day.

- Nursing staff who consented to monitor residents behaviour in Phase II and report these findings to the researcher for recording on agitation measurement tools NPI, CMAI and QoL-AD.
4.3.3 Recruitment

Nurse participants were initially identified in consultation with the RACF care manager as the person regularly caring for residents participating in Phase II RCT. Following this, information sheets (Appendix C) were administered to prospective participants outlining their required involvement in Phases I, II and III of the study. Prospective nurse participants were encouraged to contact the researcher by telephone if they had further questions about the study. The nurses who agreed to participate in the RCT signed a consent form (Appendix D) to participate in all three phases of the study.

In Phase I and III nurse participants agreed to take part in a semi-structured interview with the researcher and participate in subsequent phases of this trial. The setting for interviews was a quiet location of the interviewee’s choice at the RACF, to promote nurse participant comfort. The interview setting varied and included meeting rooms, lunch rooms, outside areas and nursing stations of the RACF.

4.4 Phase I and Phase III study method

The study methods for Phases I and III are guided by sequential design, use of semi-structured interviews and content analysis. The Phase I exploratory phase aimed to access information from 11 nurses observing and reporting agitation in this study. Seven semi-structured interview questions were designed to investigate preconceived ideas of agitation, use of essential oils and practicalities in the RACF setting (Greenwood & Terry, 2012). Moreover, Phase I interview questions (Appendix E) were designed to elicit an initial and comprehensive insight of the nurses perception and knowledge of agitation, including its relationship to dementia. Additionally, nurses attitudes towards the use of essential oils for agitation management were explored. Finally, the influencing factors that impede or facilitate research in RACFs were investigated.
The objective of Phase I interviews was to gain nurse foundational knowledge to be built upon and used to guide practicalities in the subsequent study phases. As nurses primarily need to administer essential oils in the RACF environment nurse attitudes towards essential oil and compliance in application are investigated. Phase I findings influenced Phase II, by identifying gaps in nurse education for the intervention and research that were addressed in Phase II prior to the commencement of the RCT. Further, Phase I findings educated the researcher on the most appropriate times for Phase II intervention administration and data collection that could best support nurse participation and the projects success in the RACF setting.

Phase III was designed to expand further upon the nurse perceptions reported in Phase I interviews and to give context to the quantitative results in Phase II. Five interview questions used in Phase III (Appendix F) were constructed from findings and anomalies of Phase I data, to review changes in 10 of the nurses attitudes after participation in Phase II.

A sequential design collects data in phases, the initial data analysed from the first phase informs or develops the second phase, a second phase then informs the subsequent phase and so on (Cameron, 2011). In addition, nurses’ perception of changes in the frequency of agitation on the ward and their opinion on the effectiveness of Lavender or Lemon Balm as an agitation management served to inform Phase II results. Phase III interview questions also built upon the Phase I findings and Phase II experience to inform the researcher of the facilitators to conducting research with nurses in the RACF setting.

4.4.1 Data collection

Data for Phases I and III was collected during 30-minute semi-structured audio recorded interview sessions with each nurse participant. The researcher in this study used reflexivity, the process of being aware of one’s own biases throughout the qualitative
interview and transcription processes. The researcher diarised thoughts and feelings before and after interviews as well as during each interview transcription to become aware of preconceived bias (Treddlie & Tashakkori, 2012) towards agitation management, effectiveness of essential oils and older person research in RACFs. The researcher listened to all 21 interviews to transcribe areas of interest and statements from the nurse's dialogue. The transcriptions were reviewed and verified as correct by all 11 nurse participants. Identifying features were removed from the data once approved by nurse participants to ensure confidentiality.

4.4.1.1 Semi structured interviews

Semi-structured interviews included 12 set questions that were asked to each nurse participant. The semi structured interview questions for Phase I semi-structured interview questions for Phase I and Phase III are found in the Appendices E and F of this thesis. The questions were followed as a guide during the interview with the nurses responses viewed as an opportunity to explore related trajectories that focus on the areas covered (Edwards & Holland, 2013). The semi-structured interview process is a means of collecting contextual information about the broad experiences of the participants with the use of predetermined questions to provide uniformity (Green et al. 2015).

Semi-structured interviews were considered the most appropriate means to obtain information from nurses in Phase I and III of this study. This form of questioning was chosen for its less formal approach and encouragement of two-way conversation (Stuckey, 2013). The questions may be rephrased or explained more fully to ensure participants understanding. The researcher considered nurses would be more receptive to the interview questions and comfortable with their responses with this relaxed approach. Further, the standardised pre-determined open questions allow the researcher to clarify what is known and probe what is currently unknown (Edwards &
Holland, 2013; Green et al. 2015). The researcher in this study constructed the questions from common themes and anomalies in the literature regarding agitation management, essential oils and research in the RACF environment.

4.4.2 Data analysis

Content analysis was considered the most appropriate method to disseminate the qualitative data into aspects of interest. Content analysis focuses on the information that was contained in the data having been used since the early 1940s to analyse large amounts of qualitative information into manageable reoccurring themes and ideas (Gondim & Bendassolli, 2014). Content analysis adheres to the principles of scientific method, systematic approach and generalisability to obtain trustworthiness in findings (Krefting, 1991).

The principle of the scientific method is achieved by conforming to a set of rules and codes that enable different researchers to duplicate results from the same transcripts. Content analysis is a systematic approach that counts word and phrase frequencies (Vaismoradi, Turunen, & Bondas, 2013). This study used QRS International NVivo 10 qualitative software to locate recurrent themes, ideas and wording in the transcripts. This systematic approach to analysis removes the researcher's interpretation from the initial data limiting bias in the raw analysis (Vaismoradi et al. 2013).

The frequency of words and phrases obtained with the NVivo software in this study was categorised through a process of information coding to establish meaning in the data (Gondim & Bendassolli, 2014). In this study, data were coded by word frequency using NVivo 10 software to avoid individual bias and singular interpretation of data. The most frequent 20 words of four letters or more from the interview responses for each question formed the codes. A researcher independently reviewed all transcripts using the pre-established coding with supervisors overseeing the process to promote consistency. All 21 transcripts were then coded into manageable areas of interest supported by key
words, phrases, sentences and areas of interest. The areas of interest are identified by patterns and relationships as well as similarities and differences in the data categories (Braun & Clarke, 2006). Any discrepancies were resolved through discussion with the researcher and two supervisors until 100% consensus was achieved.

Content analysis is bound by the principle generalisability that the findings from the interview transcripts can be generalised as correct in similar circumstances among similar populations (Macnamara, 2009). To ensure these findings are transferable the process used to obtain areas of interest must be credible, dependable and conformable, reflecting trustworthiness (Elo et al. 2014; Vaismoradi et al. 2013). The numerical method of assessing data in content analysis is often perceived as a quantitative process of qualitative data. This method of analysis was considered appropriate for this study due to the primary study being a quantitative design and in keeping with the numerical focus of the study. An example of the numerical coding is included below:

<table>
<thead>
<tr>
<th>Area of Interest</th>
<th>Types of Agitation</th>
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<tbody>
<tr>
<td>Category</td>
<td>Physical non-aggressive agitation</td>
</tr>
<tr>
<td>Sub-category</td>
<td>Wandering</td>
</tr>
<tr>
<td>Codes</td>
<td>Like Agitation</td>
</tr>
</tbody>
</table>

Table 4 Area of interest 1 - Types of agitation

A limitation in content analysis is considered to be that coding for frequency may miss or overemphasise the importance of data. It is argued that frequency of wording in some
cases does not indicate importance rather that the participant has a greater willingness to talk at length about the topic (Vaismoradi et al. 2013).

The qualitative phases of this research are situated either side of the quantitative study which is designed to evaluate essential oil effect as an agitation management in older people living in RACFs. The following section details the quantitative method.

### 4.5 Quantitative study

Phase II of this research a 2x3 factorial single blind Randomised Control Trial (RCT) was designed to measure the effect of Lavender and Lemon Balm on agitation in older people with and without dementia and who live in RACFs. The RCT is the primary focus of the study as the results will add to the body of evidence for the effectiveness of these essential oils for the management of agitation. This research phase was informed sequentially by the Phase I findings (Chapter 5) that influenced the implementation of this trial in the clinical environment.

#### 4.5.1 Phase II study

The RCT addressed two research questions (1) To examine the effectiveness of Lavender or Lemon Balm essential oils as a management for agitation in older adults and (2) To examine the differences of Lavender and Lemon Balm essential oils as a management for agitation in older adults with and without dementia.

This section addresses the research questions:

1. What is the effectiveness of Lavender compared to Lemon Balm and a placebo for the management of agitation in residents of RACFs with and without dementia?

2. What is the difference between Lavender compared to Lemon Balm and a placebo for the management of agitation in residents of RACFs with and without dementia?
4.5.1.1 *Rationale for using a RCT*

The RCT is considered the gold standard of clinical trials. The random allocation of treatment sequence to each resident and masking of assessors to essential oil scent can limit bias to overcome limitations in some previous trials. This trial was conducted as a single blind trial due to the inability to disguise scent from the resident. The researchers who assessed the outcomes in this study were blind to interventions. This research sought to determine differences in Lavender and Lemon Balms effect on agitated behaviour in residents with and without dementia. A placebo of 100% Sunflower oil was used in this trial. The placebo was considered to provide no therapeutic effect on resident agitation. The active treatment effects of Lavender and Lemon Balm were compared to the placebo effect for differences in the residents agitation. An RCT was necessary to provide evidence for Lavender and Lemon Balm essential oils potential as an agitation management. Previous studies (Ballad et al., 2002; Burns et al., 2011; Lin et al., 2007; O’Conner et al., 2011; Sakamoto et al., 2013) investigating either Lavender or Lemon Balm have argued that there is evidence for the use of these products to reduce agitation. This study is the first to use both Lavender and Lemon Balm in the one study enabling a comparison of the oils to determine if one is more effective than the other in reducing agitation.

4.6 *Phase II study method*

As stated above, a 2x3 factorial single blind design was used for the RCT component of the study. The repeated measure design permitted all residents to receive each of the three interventions: Lavender, Lemon Balm and the sunflower oil placebo, and to compare to the resident’s baseline behaviour for effect, as such residents, acted as their own behaviour control. Participant agitated behaviours were assessed on the NPI and CMAI standardised agitation measurement tools, between each treatment to monitor for condition progression and changes to baseline behaviour. The nurses reporting resident observed behaviours were interviewed in Phase I and II of this study. Nurses were
provided education on the measurement tools at the commencement of Phase II. This data collection process was considered most appropriate to measure difference of effect between the essential oils in comparison to placebo.

The first factor was the degree to which the residents had dementia and consisted of two groups: dementia and without dementia. The second factor was the essential oil treatment and consisted of three groups: Lemon Balm (A), Lavender (B) and placebo sunflower oil (C). The second factor is the within group factor, as all residents received all three treatments separately during the trial. This repeated measures design allowed residents to act as their own control. Participants were allocated to either the dementia or without dementia group based on diagnosis and cognitive score on MMSE and this ensured residents within each group contained similar cognitive characteristics, the only difference being interventions. Participants were then randomly allocated a treatment sequence A, B or C giving a total of six groups for comparison. Participant allocation between groups of dementia and without dementia and treatment sequences are outlined in Table 5. A factorial design allowed the comparison of within resident groups for intervention effect and also examination between the independent groups, dementia and without dementia (Polit & Beck, 2014).

<table>
<thead>
<tr>
<th></th>
<th>A-B-C</th>
<th>A-C-B</th>
<th>B-A-C</th>
<th>B-C-A</th>
<th>C-A-B</th>
<th>C-B-A</th>
</tr>
</thead>
<tbody>
<tr>
<td>With dementia (30)</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Without dementia (30)</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 5 Participant allocations between 2-group dementia split and within group treatment sequence

This repeated measure design study is a modification of Lin et al’s (2007) study with the improvement made in attention to counterbalancing treatment sequence. An inhalation method was chosen to administer essential oils as this method proved most effective in the literature reviewed (Lin et al., 2007; Fuji et al., 2008).
4.6.1 Participants

Potential participants were identified in consultation with the RACF care manager and regular permanent nursing staff. Participant information sheets (Appendix G) were administered to these residents outlining their required involvement in the RCT. In those instances (68) where cognitive impairment prevented residents providing informed consent, the researcher approached the person responsible for the resident, usually a family member, explained the study giving the Carer Information Sheet (Appendix H) and sought their consent to include the resident. Residents or their carers were encouraged to contact the researcher if they had further questions pertaining to the study. The 87 residents recruited to this RCT were required to complete the consent form prior to study commencement (Appendix I and resident consent for a carer in Appendix J).

4.6.1.1 Participant Selection

Participants were selected for inclusion in this trial if they met the following criteria:

Inclusion Criteria

- Participants were aged 65 years or older.
- Participants must have lived full time in a residential aged care facility (RACF) for three months to ensure they are familiar with the daily processes and settled into their environment.
- A cognitive level of moderate or higher as demonstrated by a score above ten on the mini-mental state examination [MMSE].
- Recorded agitated behaviours on at least one of the Aged Care Funding Instrument [ACFI] behaviours domain questions. Behaviour questions being question 7 wandering, question 8 verbal behaviours and question 9 physical agitations.
- Be stable on medication for three months as confirmed by medication charts. Any changes in psychotropic medications need to be reported to the investigator.
- At least one agitated behaviour with a frequency of at least six occurrences observed by the nurse in the last two weeks, assessed on the NPI at baseline.
- Ability to detect scent as demonstrated in a scent test at screening.
• The resident or the carer have provided consent.

Participants also consented to:

• Wear a 2x2.5cm dark cloth patch for two hours daily for a duration of six weeks.
• Understood the patch contained two drops of treatment being either Lavender, Lemon Balm essential oil or placebo sunflower oil.
• Participate in a Quality of Life survey conducted by the primary investigator every two weeks for the 10-week duration of the trial.

Exclusion Criteria

• Diagnosis of psychosis or agitation resulting from brain damage.
• The presence of an acute life-threatening condition as reported by staff or the medical officer.
• Any condition that was likely to confound the study such as schizophrenia, Parkinsons disease or another medical condition as determined by the researcher to interfere with interpretation of study results.

4.6.2 Study Setting

This study was conducted in conjunction with a large not for profit provider of aged care assisted accommodation in NSW. The setting for the study was six residential aged care facilities that provided assisted living to the older adult participants on two Sydney metropolitan sites. These facilities share commonalities of core values and care standards. All facilities were assisted living facilities with 24 hour nursing care. Site A contained three facilities; the first being a mixed cognition accommodation of 68 beds; the second facility was mixed cognition accommodation of 66 beds that contained a secure dementia unit. The third facility contained 94 beds with two secure dementia units. Site B contained three facilities; the first being a mixed cognition accommodation of 112 beds and the second facility containing three secure dementia units of 75 beds. A third facility of 96 beds and two secure dementia units commenced this study. However due to the relocation of the nurse participant from this facility during the RCT and failure to secure a suitable replacement, data collection was not completed on this site.
The RACFs were typical of the assisted living facilities targeted to older people in Australia. The facilities offered recreational and social activities in addition to services common to RACFs of similar standards. Activities offered included craft, live entertainment, music, social events and exercise. Services provided were 24 hour nursing care, personal care, podiatrist, hairdressing and meals. These RACFs were chosen because they represented a typical facility that encompassed approximately 500 residents, the majority being over 65 years of age and had ample older residents from which to obtain willing participants that met inclusion criteria for this study.

4.6.3 Intervention

This study included three interventions consisting of two treatment oils; Lavender and Lemon Balm, and one placebo, sunflower oil. The within group design ensured all residents trialled two drops of oil for each intervention in this way residents acted as their own control. All essential oil dosages for this trial were determined in consultation with a qualified aroma therapist from the Australian College of Aromatherapy (ACOA).

**Lavender (Lavandula Angustifolia)** an essential oil with a chemical composition of linalool (>28%), linalyl acetate (>35%), 1,8 cineole (<1%) and β-caryophyllene (Essential Therapeutics, 2013) was used in this trial. Lavender has medium scent intensity with a sweet woody aroma; dosages were 100% concentration at two drops each treatment.

**Lemon Balm (Melissa Officinalis)** an essential oil with chemical composition of Geranial (>22%), Neral (>18%), β-caryophyllene (14-30%), y-muurolene (≤20%) (Bagdat & Cosge, 2006; Huang et al. 2008) was used in this trial (Essential Therapeutics, 2013). Lemon Balm has strong scent intensity with a sweet citrus aroma. Lemon Balm used in this trial was diluted in a 50:50 mix of 100% Lemon Balm to Jojoba oil, dosages were two drops each treatment.
Sunflower Oil (Placebo) is a triglyceride with chemical composition of palmitic acid, stearic acid, oleic acid and linoleic acid. The phosphatides present in the oil are lecithin and cephalin (Elvers, 2013). Sunflower oil when refined is scentless; dosage was two drops each treatment.

Forty-nine participants received all the allocated treatment sequences for 14-consecutive days followed by a 14-day washout period before the commencement of the next treatment. A research assistant (RA) was trained by the researcher in aromatherapy protocol and was responsible for administering treatment to residents. Each treatment was administered daily and consisted of two drops of essential oil or placebo oil applied on a 25mm x 20mm dark coloured 100% cotton patch daily and attached via double sided Velcro to the resident’s collar area. The patch was removed by the RA after being in situ for two hours. During the 14-day washout period, no patches were applied to the residents. Interventions were administered to residents during their normal daily activities at a regular time negotiated with the RACF nurses to provide the least disruption to routine.

4.6.4 Measurement tools
Tools used to measure cognition (MMSE) and agitation (NPI; CMAI) had been validated reliable for a credible outcome when used in this population and within the timeframes specified (Cohen-Mansfield et al. 1989; Cummings et al. 1994; Tombaugh & McIntyre, 1992). An assessment test of scent to screen for anosmia was also performed.

4.6.4.1 Smell test
Inhalation was the mode of administration for the essential oils Lavender and Lemon Balm in this study. The mechanism of action for essential oils as described in Chapter 2 may rely on identification of scent. A smell test of identification and discrimination was
conducted in all participants (residents). As olfactory dysfunction has been predicted among those with cognitive decline, the smell test was essential to rule out anosmia (Sohrabi et al., 2012). The smell test consisted of three scent sticks, two with sweet orange essential oil and one with sandalwood essential oil. The resident was asked to identify which scent stick smell was different to the other two. A positive result proved identification of scent present and ability to distinguish one scent from another. A negative result was considered a possible olfactory dysfunction excluding the potential participant from this trial (6). In addition residents were also excluded from the trial if they had advanced dementia as indicated by MMSE score (6).

4.6.4.2  Mini Mental State Examination [MMSE]

MMSE is a widely recognised measurement which screens for cognitive impairment. This tool is commonly used clinically to screen for cognitive decline. The MMSE was used to support the separation of residents into dementia and without dementia groups based upon their level of cognitive decline. The MMSE consists of a 30-point questionnaire which tests arithmetic, memory and orientation taking approximately 10 minutes to complete. The MMSE is scored out of 30; a score below 24 indicates a possibility of mild impairment, below 18 moderate and below ten severe cognitive decline (Fu, 2009). Residents in this study who achieved a score of 25 or more were placed in the without dementia group unless a diagnosis of dementia was concurrent. Those who achieved a score of 10-24 with a dementia diagnosis were placed in the dementia group. Participants who score below ten on the MMSE were excluded from the study due to possible severe dementia. Table 22 phase II participant characteristics reports the MMSE score for the residents that were included for analysis in this study. Good test/retest reliability 0.89 and internal consistency of 0.83 (Tombaugh & McIntyre, 1992) have been achieved with the MMSE. The MMSE was obtained at baseline to screen for resident and support group allocation.
4.6.4.3 **Neuropsychiatric Inventory**

The NPI was the primary outcome measure for agitation in this study. The NPI was initially developed for use in the dementia population, however it can be used in other psychological states of older person assessment. The NPI assesses frequency and severity of behaviour through observation of 10 behaviour categories and two neurovegetative states. Behaviour categories consist of delusions, hallucinations, dysphoria, anxiety, agitation and aggression, euphoria, disinhibition, irritability and lability, apathy, aberrant motor activity, and nighttime behaviour disturbances (Smart et al., 2011). A yes or no is recorded, dependent on where the behaviour is present. If the behaviour is present, a number is allocated for frequency and severity of the behaviour. Frequency is scored one to four and severity scored one to three (Smart et al., 2011). The internal consistency for this measure is 0.75 to 0.89 for each category (Cummings et al., 1994).

This study measured seven NPI categories only, five directly related to agitation being, delusions, agitation/aggression, aberrant motor activity, irritability/lability and nighttime disturbances. Also measured were the two categories of anxiety and depression which are possible precursors to the older person experiencing agitation (Grose & Schub, 2013; Volicer, Frijters, & Van der Steen, 2012). The full NPI is considered to take approximately 15 minutes to administer. The NPI with the omission of three categories and the two-neurovegetative states was anticipated to take approximately eight minutes to administer. As nurses were reporting behaviour on the NPI this time saving measure was a necessary compromise with stakeholders. A secondary measure used to monitor agitation was the Cohen-Mansfield Agitation Inventory.

4.6.4.4 **Cohen-Mansfield Agitation Inventory**

The Cohen-Mansfield Agitation Inventory (CMAI) is another measurement tool for agitation, which features heavily in the literature among dementia populations. The
CMAI measures frequency of agitated behaviour only and was used as a second agitation measure in this study. The CMAI monitors 29 behaviours for frequency; each behaviour is scored a numerical frequency between 1 and 5. A number 1 score indicates the behaviour was not observed in the previous two weeks and a 5 score indicating the behaviour occurs several times within the hour. The outcomes of the CMAI in this study were subcategorised into three categories of verbal, physical non-aggressive and physical aggressive agitation. The reliability and validity of the CMAI tool was studied in residents of a long-term care facility and determined to be a valid measure for this population. The CMAI demonstrates a high internal consistency and adequate inter-rater reliability (Finkel et al., 1992) of 0.92, 0.92 and 0.88 at three nursing home units (Cohen-Mansfield et al., 1989). The administration of the CMAI took approximately 10 minutes for each resident. Participants were also screened for Quality of Life during the trial.

4.6.4.5 Quality of Life Measure

The QoL-AD is a brief, 13-item measure designed specifically to obtain a residents’ quality of life that is informed by either the resident or their caregiver. The questionnaire has 13 measures of physical health, energy, mood, living situation, memory, family, marriage, friends, chores, fun, money, self and life as a whole (Delaney, Cullen, & Dolphin, 2011). The resident or the nurse rate each item as either excellent, good, fair or poor accordingly. The validity of the QoL-AD is supported by a correlation with the dementia quality of life scale (0.69) and on the Euroqol-%D scale (0.54) and indicates a good criterion concurrent validity between resident and carer responses (Thorgrimsen et al., 2003a). The QoL-AD is not validated in the people without dementia population. In this study, a quality of life measure that was validated in dementia populations was preferable for use as one quality of life measurement tool only was chosen for ease of comparison.
A timeline of measurement and the patient/nurse timeline of events is presented in table 6 schedule of events.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Baseline Week 0</th>
<th>Treatment 1 Week 1-2</th>
<th>Washout Week 3-4</th>
<th>Treatment 2 Week 5-6</th>
<th>Washout Week 7-8</th>
<th>Treatment 3 Week 9-10</th>
<th>Follow up Week 11</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPI</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CMAI</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>QoL-AD</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>MMSE</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scent Test</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 6 Schedule of events

### 4.6.5 Sample Size

An appropriate resident sample size for this study was calculated at 75 residents for Phase II (RCT) of this study. This was calculated using the NPI means of the treatment groups based on the results of Lin et al's (2007) study that reported patients’ mean NPI scores as 63.2 (placebo) and 58.5 (treatment) with a standard deviation of 17.5. For the present sample size calculation, we used NPI scores of 63.2 (placebo), 58.5 (T1) and 59 (T2) with an SD=17.5 were used. The sample size was calculated using a 2x3 factorial within group analysis of main effect (Placebo vs. T1 & T2). An increase of 14% was added to control for the possible withdrawal of residents before completion of the study, increasing the sample size to 75 randomised residents. Sample size calculations were conducted using GLIMMPSE (http://glimmpse.samplesizeshop.org/#/). Two previous studies (Burns et al. 2011; Fu et al. 2013) reported high resident withdrawal due to the investigated populations frailty, with one researcher (Svansdottir & Snaedal, 2006) suggesting an overestimation of the sample size by 30% was necessary to protect the sample size.
4.6.6 Randomisation

Participants were randomly assigned a treatment sequence of Lavender, Lemon Balm and placebo sunflower oil for the study duration. Treatment assignment was fully counterbalanced such that one-third of each dementia and without dementia group received alternate treatments simultaneously. An independent researcher performed the study randomisation using a block randomisation of the three facilities and a randomised number table to allocate resident sequence. The independent researcher was invaluable in minimising selection bias and ensuring research staff were kept blinded to group allocation. The randomisation process used in this study took into account the previous limitation in Lin et al's (2007) study. In that study care was taken to counterbalance groups to protect results from being attributed to intervention order or disease progression. In the interest of full disclosure, this study clearly outlines the process of randomisation that ensured residents were given equal opportunity to be allocated to each group at any stage of the trial. Allocation bias in this study was also protected through the use of blinding and masking techniques.

4.6.7 Blinding

An independent researcher was responsible for essential oil preparation in bottles for administration which kept staff blinded to allocation assignment. Essential oils were stored in dark glass bottles fitted with a dropper for accurate dosage. Bottles were clearly labelled A, B or C and kept in a dry locked environment when not in use. A research assistant (RA) responsible for administering essential oils to the residents minimised researcher assessor and allocation bias. In addition, this study made use of masking techniques to blind the RA from the scent being administered to residents. The RA was masked to the allocation group, and treatment by nose peg and three percent Rosemary Oil in Jojoba oil placed above the top lip. The RA did not engage in any non-deliberate conversation with the resident during administration.
The RA was responsible for checking the resident’s identity, bottle assignment and documentation of treatments administered. The RA applied two drops of oil from the correctly labelled bottle to the dark 100% cotton patch and attached the patch to the residents collar. The patch was dark in colour to obscure essential oil colour. The RA then signed and dated the resident’s logbook as treatment was administered from the correctly lettered bottle. The RA returned after two hours to remove the patch from the resident, sign the logbook as removed and discard the patch appropriately.

4.6.8 Data Collection

The researcher responsible for collecting data was blinded to treatment allocation and not present when treatment was administered to residents. An independent researcher was responsible for randomising resident treatment and the RA for administering resident treatment.

The blinded researcher recorded observations of agitated behaviour as reported by the nurse, checked medication records and completed the Quality of Life score with residents fortnightly. Nurses who participated in monitoring behaviour in this study also participated in Phase I and II of this study. Nurses were provided with pre-trial training on the research being conducted including the measurement tools used that took between 15-25 minutes to complete. Due to the nurses demanding workload, education was carried out by the researcher with one or two nurses at a time, agreeable to the nurses during their work day. A regular data collection time when the workload was least likely to impact on the nurses time was negotiated with the nurse that was also agreeable to the researcher. The researcher also provided a phone number should the nurse have further questions or require additional support in the research process.

Data were collected at the conclusion of each two-week treatment period to assess for changes in agitation and after each washout period to gain new baseline measures. Therefore information for the NPI, CMAI and QoL-AD was collected at six stages.
throughout the study. There were no active treatment sessions during the data collection however, as an added precaution the researcher wore rosemary oil upon the top lip to confound any residue scent when interviewing residents.

A second researcher collected behavioural observations from the clinical staff and recorded the information on the NPI and CMAI. This researcher was also responsible for collecting Quality of Life information from the clinical staff or directly from the resident, dependent on their level of dementia. The researcher collected data pre and post treatment cycles fortnightly obtaining six measurement sets on each resident.

4.6.9 Statistical analysis

An analysis of variance (ANOVA) was used to determine the degree of agitation present between the groups of dementia and without dementia in the absence of intervention. An ANOVA was then performed for a within group subject comparison of the effect of Lavender intervention and Lemon Balm intervention; both interventions were then independently compared to placebo irrespective of the level of dementia among residents. Finally, a within-between subjects comparison of the interaction between level of dementia and the effect of both Lavender and Lemon Balm essential oils compared to the placebo group was investigated using ANOVA. The NPI data were collected in categories of delusion, agitation/aggression, irritability/lability, aberrant motor behaviours, sleep time disturbance, anxiety and depression. Data from CMAI and NPI was then correlated with changes in the three constructs of physically aggressive, physical non-aggressive and verbal agitations.

Data were analysed with adherence to Per Protocol (PP) guidelines, a PP analyses valid cases only or a subset of residents that were more compliant with the research protocol. These residents completed all treatment cycles, were available for all measurement periods and did not violate inclusion criteria throughout the trial. The researchers remained blinded in this study until all analyses were finalised. An intention-to-treat
(ITT) analysis was also conducted to minimise type one error or false positives and withdrawal bias. ITT included all available completed outcome data for all randomised residents (Jadad, To, Emara, & Jones, 2011). A full report of the PP analyses is presented in Chapter 6 with the outcomes for ITT analyses tabulated in Appendix K of this thesis.

In addition to monitoring for essential oils effect on agitation, a major focus of the analyses compared for a difference in treatment effect between the two cognitive groups. Contrasts between these two groups provided greater insight into the relationship between essential oil agitation management.

## 4.7 Study Rigour

An investigation of study quality relies on how strictly the researcher follows the protocol that eliminates bias and how the study adds knowledge to the emerging body of research (Grove, Burns, & Gray, 2013). Rigour in mixed method studies is dependent on the quality of the qualitative and quantitative studies that it combines (Creswell, 2012). Therefore attention to rigour was required for both the quantitative and qualitative components of the study.

### 4.7.1 Scientific Rigour

Scientific rigour is determined for quantitative research by how scrupulously a protocol is followed in addition to how objective and precise the design and analysis techniques conform to the research. This study used a RCT. That design is governed by strict guidelines that evaluate an intervention for accuracy against a blinded comparison treatment within a population that has similar characteristics and an identifiable clinical presentation (NHMRC, 2007). The RCT is considered the gold standard of evaluation with a Level II evidence on the NHMRC level of evidence scale. This level of evidence is superseded only by the systematic review that compares similar Level II evidence studies for consistency in the outcome. This study complies with the Consolidated Standards of Reporting (CONSORT) that promotes strict adherence to protocol through
the complete and transparent reporting of all trial procedures (Schulz, Altman, Pocock & Evans, 2010).

This study used a single-blind RCT, in that both resident and researcher were blinded to the intervention allocation. Participants were randomised to a treatment sequence to compare essential oils with a placebo for effectiveness and safety in agitation management (Stevely et al. 2015). Random allocation by an independent researcher assigned similar resident demographics between treatments to ensure the treatment groups were comparable except for intervention. The treatment sequence was counterbalanced among residents to ensure the outcomes were not attributed to treatment order.

The agitation measurement tools that were used in this study held validity and reliability for assessment in the older adult population and within the timeframe of use. The RCT evaluation contained manipulation, randomisation and a control condition that together minimised uncertainty and increased the reliability of outcomes (Moher et al. 2016). The RCT was necessary when considering whether a) Lavender and Lemon Balm are effective in reducing agitation and b) if one essential oil is more effective than the other and therefore more appropriate to introduce into RACF clinical practice (Buchanan, 2015; Moher et al. 2016). The differing definition of rigour in qualitative research, when compared to quantitative, is indicative of the opposing data they capture in mixed methods research.

4.7.2 Trustworthiness

The concept of rigour in qualitative research is referred to as the trustworthiness of research or how closely it follows research protocols so that results are reproducible. Rigour is defined in qualitative research by its adherence to a philosophical perspective, thoroughness in data collection and how open the data collection method is to scrutiny (Grove et al. 2013). The researcher practised reflexivity during the qualitative
interviewing process in that the thoughts and feelings of the researcher were diarised. This self-referencing technique was conducted before and after the interview process as well as during the transcription period. This process assisted the researcher to become aware of any existing bias and remove them from the qualitative data process (Treddlie & Tashakkori, 2012).

Qualitative rigour requires trustworthiness in that attention to reciprocity, the validity strategy and reflexivity that have been practised throughout the qualitative process. Reporting of interview questions, the types of data collected, how the data were prepared including processes for multiple coders and the steps taken in data analysis can assist in providing trustworthiness. Rigour is important in qualitative research due to the lack of experimental design and opportunity for researcher interpretation. Table 7 reports the criteria for the assessment of trustworthiness that promotes rigour in qualitative research.

<table>
<thead>
<tr>
<th>Truth value/credibility</th>
<th>Degree to which researcher has established “confidence in the truth of the findings for the subjects and the context in which the study was undertaken”.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicability</td>
<td>Degree to which the findings can be applied to other contexts, settings or groups</td>
</tr>
<tr>
<td>Consistency</td>
<td>Extent to which the findings would be consistent if inquiry were replicated with same subjects or similar context</td>
</tr>
<tr>
<td>Neutrality</td>
<td>Degree to which the findings are a function of the subjects/informants and condition of the research and not of other biases, motivations, and perspectives.</td>
</tr>
</tbody>
</table>

Table 7 Rigour in qualitative research: The assessment of trustworthiness (Krefting, 1991 Pg. 214-222)

4.8 Ethical considerations

This trial adheres to the ethical considerations of informed consent, confidentiality and avoiding harm to do good (Israel & Hay, 2006). All nurse participants, residents or persons responsible for the resident, granted consent for participation in this study with the full knowledge of the study aims, participation expectations and possible consequences of involvement. Capacity to provide valid consent for people with dementia was determined by a dementia diagnosis and the residents score on the evaluation to consent form (Resnick et al., 2007). Consent was obtained in compliance
with ethical considerations and good clinical practice regulations that have an origin in the Declaration of Helsinki (ICH GCP, 1996). Informed consent and ethics approval was obtained for the researcher to access the medical records of the participants. The researcher is competent to conduct this research with qualifications and experience in older adult nursing, naturopathy and research (ICH GCP, 2011). Further, the researcher holds several publications in complementary therapies and older adult healthcare.

Confidentiality of the resident and nurse participants was protected during all stages of this research. Data collected on older person characteristics during the trial were attributed a numerical value and resident's name and identifying details removed. Similarly, nurse interviews once transcribed and verified as correct had all identifying features removed and a pseudonym assigned. Data was entered and stored on the primary researcher's password protected computer. A trial master file managed by the primary researcher contained all essential documentation regarding the trial, including ethics approval and source protocol documents with residents identifying criteria such as consent and conforming with inclusion criteria. The master file is located in the researcher's locked filing cabinet; information will be kept for five years from publishing at which time information will be erased and destroyed (NHMRC, 2007).

The safety of the essential oils used in this study was of primary concern to the researcher. In Australia, essential oils are recognised as chemical substances defined as medicines in Section 3.1 of the TGA (TGA, 2015). Both essential oils of Lavender (Lavandula Angustifolia) and Lemon Balm (Melissa Officinalis) hold evidence of safety in research (EMA, 2011, 2012) when used in higher dosages in the older adult dementia population (Ballard, O'Brien, Reichelt, & Perry, 2002; Burns et al., 2011; O'Connor et al. 2013). Lavender and Lemon Balm hold assessment reports with the European Medicines Agency (EMA), the European Union for the evaluation of medicinal products. The EMA provides a summary of non-clinical and clinical data along with an evaluation of clinical
efficacy and safety (EMA, 2011, 2012) that promote the oils safety when used as directed in this study.

This research conforms with the NHMRC Australian Code for the Responsible Conduct of Research, the National Statement on Ethical Conduct in Human Research (2007) and other relevant legislation and guidelines that apply to this study. Ethical clearance was obtained from the Western Sydney University Human Research Ethics Committee for the study Essential oils for agitation management in older adults: A mixed method study, with registration approval number H10550 14/009176. This ethics approval ensured that the research protected the rights and interests of all residents in the study.

This trial also holds registration with the Australian New Zealand Clinical Trial Registrar [ANZCTR]. The ANZCTR is an online registrar of National Health and Medical Research clinical trials that is accountable to the public. As such this research meets the appropriate content, quality and validity that is required by the World Health Organisation [WHO] registry network standards. The trial registration number is ACTRN12614000130662-Essential Oils for Agitation Management in Older Adults: A Mixed Method Study (ICH Tripartite, 2011).

### 4.9 Summary

This chapter has described the methodology for a mixed method study comprising qualitative and quantitative data to provide evidence for the use of Lavender or Lemon Balm to manage agitation in the RACF setting. A rationale for a mixed method sequential design with three phases that included an RCT in phase II proposed to establish the effect essential oils as an agitation management. Nurse interviews, phase I and phase III, either side of the phase II RCT inform the conduct of the RCT in the facility. Theoretical underpinnings of the HBM that guides this research were discussed within the study context. The nurse interviews were designed to identify the attitudes of nurses towards essential oils that may influence their likelihood to adopt this strategy as an agitation
management. The RCT was designed to provide aspherical evidence of effectiveness what could be used by nurses to support selection of essential oils for use with agitation in older people.

Qualitative Phases I and III have been designed to explore nurses understanding of agitation management, their perception of essential oils to manage aggression, the importance of research for older people and the barriers and facilitators to the implementation of research in the RACF environment. The qualitative phases of the study were detailed, including study sample, selection criteria, recruitment, methods of semi-structured interviews and content analysis to analyse the data. The primary focus of the RCT was to examine the effect of Lavender and Lemon Balm essential oil on agitation in residents with and without dementia in RACFs. The quantitative randomised controlled trial was presented with a rationale provided for the 2x3 factorial design. The quantitative methods detailed recruitment, randomisation, sample size, blinding, measurement tools, data collection and analysis processes.

Finally, the rigor of the study was examined, and the ethical considerations to which the study complies are presented. The findings obtained from this study are presented in Chapter 5 Phase I Qualitative Findings, Chapter 6 Phase II Quantitative Results and Chapter 7 Phase III Qualitative Findings.
Chapter 5 Phase I Qualitative Findings

5.1 Overview

This chapter reports the findings of 11 exploratory, semi-structured interviews conducted with nurses caring for older people living in six RACFs and who exhibit signs of agitation. The interviews sort to understand (1) Nurse perceptions of agitation and its relationship to dementia (2) Current agitation management of agitation at the study sites including resident characteristics that influence the type of strategy used by the nurse to manage behaviour (3) Nurse perceptions of essential oils and their efficacy; and (4) Nurse perceptions of and compliance with research in the RACF environment. This section presents the findings of the semi-structured interviews, and includes a profile of the nurse participant demographics and attributes relevant to this study. The findings are reported as areas of interest identified from the analysis accompanied by the frequency of occurrence and percentage of data coverage. Responses by the nurses were grouped into the following themes: types of agitation, agitation management, perceptions of essential oils and nurse perceptions of research in the RACFs. All areas of interest are supported by categories and subcategories with quotes from the nurse transcripts.

5.2 Data Collection and Analysis

Data were collected in responses from the nurses interviewed were analysed using content analysis (discussed in Chapter 4), which is often employed as an analytical tool in nursing research (Vaismoradi et al., 2013). In the current study content analysis was employed as a means of inquiry to explore nurse assumptions and situational circumstances of the environment in which this study was conducted. It is a process of organising and integrating narrative from the semi-structured nurse interviews according to key concepts and areas of interest (Polit & Beck, 2014). The interviews were audio recorded and listened to several times before being transcribed by the researcher. Before including data in the analysis, each nurse verified a hard copy transcription of the interview as correct. The frequency of keywords in the interviews, were used to code
responses into manageable categories to identify key areas of interest in the nurse responses. The coded content was analysed by pattern and sequence of occurrence to identify relationships in the interviews (Braun & Clarke, 2006). The findings are presented for each area of interest supported by corresponding categories. Categories are supported by sub-categories from the interview transcripts. Each sub-category is supported by a code frequency along with the percentage of interview coverage being the number of interviewees that reported this sub-category topic in response to the interview questions. A detailed table of codes for the area of interest 1, types of agitation is presented in table 4.

5.2.1 **Participant Characteristics**

This section focuses on the characteristics of the 11 nurses who took part in this study. All nurses were full-time care staff employed by the same aged care organisation operating on two sites in the Sydney metropolitan area. Qualifications of the nurses included seven registered nurses (RNs) who held Australian Health Practitioner Regulation Agency (AHPRA) registration. The remaining four assistants in nursing (AINs) had obtained a qualification of Certificate IV through an accredited provider.

The length of experience varied significantly between the nurses with employment in the aged care sector ranging from six months to 25 years. Five RNs (Gabi, Jasmine, Rosemarie, Sabrina, and Sam) were new graduate nurses who held six months to three years aged care experience. The remaining two RNs had been employed for 18 years (Kaye) and 22 years (Jess) as registered nurses and both held managerial positions that also provided direct care to residents. The four AINs also varied in length of employment being four years (Sanaya), 16 years (Natasha), 19 years (May) and 25 years (Abbie) respectively. All 11 nurses held direct care responsibilities for the resident with agitation in their positions. Aged care role, area of specialty and level of responsibility differed between the 11 nurses. Six nurses were employed in mixed cognition wards and five
nurses were employed in specialty dementia secured facilities. Two nurses held managerial positions in the facility with one being a care manager and the other a clinical nurse educator. All nurses were exposed to the same core values, training and education materials endorsed by the organisation. The nurses were 91% female. The language of origin differed among the nurses with 73% not having English as their first language. Each of the nurses also participated in the RCT Phase 11 of the research. Pseudonyms were assigned to protect participant confidentiality. The names allocated were Abbey, Gabi, Jasmine, Jess, Kaye, May, Natasha, Rosemarie, Sabrina, Sam and Sanaya. The characteristics of Phase I nurse participants are presented in Table 8.

<table>
<thead>
<tr>
<th>Item</th>
<th>Sample (n=11)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Site A facility</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unit 1</td>
<td>3</td>
<td>27%</td>
</tr>
<tr>
<td>Unit 2</td>
<td>2</td>
<td>18%</td>
</tr>
<tr>
<td>Unit 3</td>
<td>1</td>
<td>9%</td>
</tr>
<tr>
<td><strong>Site B facility</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unit 4</td>
<td>2</td>
<td>18%</td>
</tr>
<tr>
<td>Unit 5</td>
<td>1</td>
<td>9%</td>
</tr>
<tr>
<td>Unit 6</td>
<td>2</td>
<td>18%</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
<td>9%</td>
</tr>
<tr>
<td>Female</td>
<td>10</td>
<td>91%</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30+ years</td>
<td>5</td>
<td>45%</td>
</tr>
<tr>
<td>30&lt; years</td>
<td>6</td>
<td>55%</td>
</tr>
<tr>
<td><strong>Designation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Care Manager</td>
<td>1</td>
<td>9%</td>
</tr>
<tr>
<td>CNC</td>
<td>1</td>
<td>9%</td>
</tr>
<tr>
<td>RN</td>
<td>5</td>
<td>46%</td>
</tr>
<tr>
<td>AIN (Certificate IV)</td>
<td>4</td>
<td>36%</td>
</tr>
<tr>
<td><strong>Years Experience</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 3 years</td>
<td>5</td>
<td>45%</td>
</tr>
<tr>
<td>3-10 years</td>
<td>1</td>
<td>9%</td>
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<tr>
<td>11-20 years</td>
<td>3</td>
<td>27%</td>
</tr>
<tr>
<td>over 20 years</td>
<td>2</td>
<td>18%</td>
</tr>
<tr>
<td><strong>Aged Care Area</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dementia Specific</td>
<td>5</td>
<td>45%</td>
</tr>
<tr>
<td>Mixed Cognition</td>
<td>6</td>
<td>54%</td>
</tr>
<tr>
<td><strong>Language background</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Native English speakers</td>
<td>3</td>
<td>27%</td>
</tr>
<tr>
<td>NESB</td>
<td>8</td>
<td>73%</td>
</tr>
</tbody>
</table>

Table 8 Phase I nurse characteristics
5.3 Summary of areas of interest

During data analysis similar responses were first assigned to categories that were then grouped into four areas of interest. These areas of interest and categories are:

- **Area of interest 1: Types of agitation**
  - Physical non-aggressive agitation
  - Physical aggressive agitation
  - Verbal agitation
  - Physical and verbal agitation

- **Area of interest 2: Agitation management**
  - Types of agitation management
  - Differences in agitation management for residents with and without dementia.

- **Area of interest 3: Perceptions of essential oils**
  - Individual use of essential oils
  - Clinical experience of essential oils
  - Perceived effectiveness of essential oils

- **Areas of interest 4: Nurse perceptions of research in RACF’s**
  - Importance of research
  - Nurse compliance
  - Recommendations for future research

5.4 Area of interest 1 - Types of agitation

This section describes the four categories of agitated behaviours identified in the transcripts using content analysis. These behaviours include physical non-aggressive agitation, physical aggressive agitation, verbal agitation, and physical and verbal agitation. The four categories were further divided into six subcategories of wandering, restlessness, aggression, shouting, swearing and repetitive behaviour. The most frequently reported types of agitation identified by the participating nurses are tabulated into categories and subcategories in Table 9 below.
<table>
<thead>
<tr>
<th>Area of interest</th>
<th>Types of Agitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Physical non-aggressive agitation</td>
</tr>
<tr>
<td>Subcategory</td>
<td>Wandering</td>
</tr>
</tbody>
</table>

Table 9 Types of Agitation

A central focus of the semi-structured interviews was nurse’s understanding of the types of agitation. The most frequently reported agitated behaviours were wandering and restlessness, which was identified by seven nurses, followed by aggression, identified by six nurses. Five nurses also identified the behaviours of shouting and three identified swearing as agitation. The agitation related behaviours of aggression, swearing and shouting were also considered to be problematic in the RACF environment. Further, four nurses considered the characteristic of repetitive behaviour indicative of agitation. Table 10 presents the behaviours identified by these nurses, reporting frequency and percentage of interview coverage.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wandering</td>
<td>7</td>
<td>64%</td>
</tr>
<tr>
<td>Restlessness</td>
<td>7</td>
<td>64%</td>
</tr>
<tr>
<td>Aggression</td>
<td>6</td>
<td>54%</td>
</tr>
<tr>
<td>Shouting</td>
<td>5</td>
<td>45%</td>
</tr>
<tr>
<td>Swearing</td>
<td>3</td>
<td>27%</td>
</tr>
<tr>
<td>Repetitive behaviour</td>
<td>4</td>
<td>36%</td>
</tr>
</tbody>
</table>

Table 10 Nurse identified behaviours of agitation

5.4.1 Physical non aggressive agitation

Nurses identified non-aggressive behaviours of wandering and restlessness to be the most frequent behaviours they considered as agitation. Wandering was identified by seven nurses, describing this behaviour as originating from internal unease that results in ambulating behaviour and requires close monitoring. This is illustrated in some of their comments:
"When they get cranky... and there is something not feeling well inside... and they feel like, where to go, what to do and they just start wandering." Sanaya AIN

"... trying to get into inappropriate places... because they just cannot sit still." Gabi RN

Restlessness, described as the constant physical movement that interferes with the resident’s routine, was also identified by seven nurses as an agitated behaviour. The following are examples of behaviours the nurses identified as agitation:

"... like they cannot sit down to finish their meals they(sic) constantly want to get up and do something." Gabi RN

"... fidgeting and... a lot of non-verbal’s." Kaye RN

### 5.4.2 Physically aggressive agitation

Just over half, six nurses interviewed identified physically aggressive behaviour as the agitation related behaviour of most concern in the RACF environment. Nurses observed aggression to be impulsive behaviour that posed serious safety concerns for other residents and staff in the RACF environment. This is demonstrated by the following nurse comments:

“Like kicking, hitting, pulling the hair, my hair. It’s been pulled so many times even if I have short hair, because sometimes if I put on their socks and they just pull my hair. And grabbing, grabbing my arm and then sometimes they twist my fingers.” Natasha AIN

“They just want to do something without thinking and that usually involves violence... some people have a... you know
they have like a fight or flight response where people usually just fight it.” Sam RN

“... a lot of behaviours in here like punching some of the resident’s... physical aggression towards staff and residents as well.” Jasmine RN

5.4.3 Verbal agitation

Five nurses also associated shouting and three nurses associated swearing with agitation. Nurses described the residents shouting as disruptive vocal behaviour that was used by the resident to air grievances. This is outlined in the following comments:

“... and sometimes shouting at you like go away, just leave me alone, stuff like that but it’s not really, really severe.” Jasmine RN

"Mrs. X she is quite agitated... because of the yelling.” Sabrina RN

“... verbally abruptly telling the staff that they are not happy with this and they are not happy with that.” Jess RN

A smaller proportion of nurses (3) identified swearing as a verbal agitated behaviour that was common in the RACF environment as shown by the following comment:

“... verbal agitation, yes swearing, most of this side [of facility] swears.” Natasha AIN

5.4.4 Physical and verbal agitation

Four nurses indicated repetitive behaviour to be a characteristic of agitation that often accompanied physical or verbal behaviour. Nurses described repetitive behaviour as
repeating the same verbal or physical agitation, with or without aggression, several times without resolve. The nurse comments below demonstrate their understanding of resident repetitive behaviour:

“Agitation is people constantly coming up to you with some being aggressive and some verbally abusive.” May AIN

“… coming to the trolley repeatedly asking the same question.” Sabrina RN

“Like tapping tapping the door or the wall.” Jasmine RN

Physical non-aggressive, physical aggressive, verbal and a mix of physical and verbal behaviours require the nurse’s attention for management in the RACF environment. Management strategies commonly used by the nurses to reduce agitation in the RACF environment are discussed under the second area of interest agitation management in the following section.

5.5 Area of interest 2 - Agitation management

This section presents the findings for nurse’s perceptions of agitation management in RACFs. The area of interest agitation management includes the two categories, types of agitation management and differences in agitation management in residents with dementia compared to agitated behaviours exhibited by residents who do not have dementia. The first category, Types of agitation management contains six subcategories including distraction, providing space, knowing the resident, medication, causative factors, and individual time that represent the most common strategies nurses used to manage agitative behaviours by residents. The second category differences in agitation management for residents with and without dementia, includes four subcategories: ease of agitation management, communication, comprehension and preference based care.
Table 11 presents the interventions most frequently used to manage agitation, presented by category and subcategory.

<table>
<thead>
<tr>
<th>Area of Interest</th>
<th>Agitation Management</th>
<th>Differences in agitation management for dementia and without dementia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Types of agitation management</td>
<td></td>
</tr>
<tr>
<td>Subcategory</td>
<td>Distraction</td>
<td>Providing space</td>
</tr>
</tbody>
</table>

Table 11 Agitation management

### 5.5.1 Types of agitation management

Nurses were asked what management strategies they used to reduce agitation in residents at the RACF. The most frequent response reported by ten nurses was distraction. Seven nurses also identified giving the resident space to settle down as a common strategy. Six nurses acknowledged the importance of knowing what triggers a resident’s agitation and the interventions that assist in calming episodes of agitation. Further, five nurses described medication, four nurses attested to identifying the underlying causative factors or providing individual time as strategies used to reduce agitation in the RACF environment. These management strategies are discussed separately and supported by nurses comments from the interviews. Table 12 presents the types of agitation management as reported by nurses, presented as frequency and percentage of respondents.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distraction</td>
<td>10</td>
<td>91%</td>
</tr>
<tr>
<td>Providing space</td>
<td>7</td>
<td>64%</td>
</tr>
<tr>
<td>Knowing the resident</td>
<td>6</td>
<td>55%</td>
</tr>
<tr>
<td>Medication</td>
<td>5</td>
<td>45%</td>
</tr>
<tr>
<td>Causative Factors</td>
<td>4</td>
<td>36%</td>
</tr>
<tr>
<td>Individual time</td>
<td>4</td>
<td>36%</td>
</tr>
</tbody>
</table>

Table 12 Types of agitation management

Ten nurses identified distraction as the most frequently used agitation management in the RACF setting. Nurses described the diversion of a resident’s attention away from the cause by replacing it with another idea or activity. Distraction when individually tailored
to the resident’s preference was considered by the nurses as an effective short-term management for agitation. This is shown in the following comments:

“the best way is just to distract them, there is one resident, if she’s getting really angry I just make her sing because she loves singing... that really calms her down... another one (resident) if he gets really agitated you can just hold his hands and give a cup of tea or I just say I’ll give you a massage and if you give a massage for 20 seconds he’s fine. Pretty effective.” Sam RN

“But it [distraction] can not continue for the whole day you know the agitation starts of course after the activity is over” Gabi RN

Seven nurses identified providing space as a common response when a resident is agitated. Nurses described providing space as the process of removing themselves from the vicinity of the agitated resident for 5-10 minutes to allow the resident to calm down. The nurse would then re-enter the relationship once the situation had de-escalated in an attempt to establish the causative issues for the behaviour. Nurses described this process as preferable to using touch, which they believed sometimes increases agitation and places staff and residents at risk of harm. This is shown in the following comments:

“... we use the five-minute rule which is coming back again later so that is re-entering the relationship... I try to avoid tactile interventions because it puts the staff member at risk and often increases the agitation... we come back later with a cup of tea or come back with a different face and also try and problem solve it.” Kaye RN
“…if they become really agitated and we really only have one
or two [staff] you are best to leave them.” May AIN

Six nurses identified knowing the resident as a type of agitation management method commonly used in RACFs. Nurses recognised that being familiar with or knowing the resident’s usual behaviour can assist to determine how they approach the resident and manage agitation. Nurses reported that when they have knowledge of situations or events that trigger unease in a resident, agitation can often be pre-empted. In addition, a nurse’s knowledge of the resident’s preferences can be quickly implemented to address the behaviour appropriately. This is shown in the following comments:

“We know the behaviours so… we know how to approach”
Sabrina RN

“…we have to watch for the triggers and I’m aware of the
triggers... I see that someone has a certain look in their eyes
and I think, oh, they’re going to go off.” Abbey AIN

“They know the residents well because everything is in their
file and before you are on the floor probably a majority of
our staff have worked here for many years so they know.”
Rosemarie RN

Five nurses interviewed in this study reported that medication is commonly used to manage agitation in RACFs. Almost half of the nurses believed that medication was an appropriate management for agitation, specifically when agitation was disruptive or not resolving by other management methods, describing medication as a necessary measure for the welfare of the resident and others on the ward. Medication was also described as necessary to manage behaviour in cognitive decline:
“... there are some medication management as well from the doctors... if the agitation is really disturbing them and disturbing other people, well then we get medical help.”
Gabi RN

“... with dementia it is different, cause it’s cognitive impairment so therefore we have to deal with the doctors and deal with the medications... anything that can manage the behaviour.” Rosemarie RN

“We know the behaviours so it can be with the staff that we know how to approach and we can give them medications.”
Sabrina RN

However, nurses also suggested that excessive doses of medication administered to some resident’s is ineffective, with side effects impairing resident mobility.

“I think it’s not helping... they give too much (medication)... the way they walk leaning you can tell on their face”
Natasha AIN

Four nurses described the importance of identifying the causative factors for agitation in RACFs. Nurses attempted to find physiological causes for agitation and to encourage the resident to verbalise the causes of their agitation, considered to be pivotal in calming the resident. This is shown by the comments below:

“First of all we have to find out how and why, what is the cause of agitation so that we can resolve it.” Jess RN
“Do they need to go to the toilet? Are they hungry? Are they thirsty? Are they in pain?... have they had a change in medication or are they becoming increasingly unwell?” Kaye RN

“We will talk to them calmly... and we ask them what do you feel? Why do you feel like this? Why are you angry? If they couldn’t actually tell you, you need to look for the non-verbal cues.” Jasmine RN

Four nurses also recognised that providing individual time with an agitated resident is a suitable management strategy. Nurses described that providing individual time with an older person gave the resident personal attention to voice their concerns. This is shown by the following comments:

“... spend one on one [time] with them, talking to them, allow them to express their feelings and let them air whatever is not happy, and provide lots of reassurance and emotional support.” Jess RN

“We have one on one sessions... we will try to manage the agitated behaviours on the ward face to face, spending time with them.” Gabi RN

5.5.2 Differences in agitation management for dementia and without dementia

Nurses were asked if agitation was managed differently in residents with dementia compared to residents without dementia. Nine nurses reported a difference in management. The reason for difference in agitation management approach was reported by six nurses to be impaired communication or comprehension that is often associated
with dementia. Impaired ability to communicate undermines the nurse’s attempts to identify factors influencing the behaviour, and impaired comprehension reduces the resident’s ability to follow instructions aimed to modify behaviour. Four nurses identified agitation management strategies for residents without dementia to most often involve changes to care delivery to better align with the residents needs. Table 13 presents the number of nurses who reported the approach to managing agitation varies for people with dementia compared to residents without dementia.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ease of agitation management</td>
<td>8</td>
<td>72%</td>
</tr>
<tr>
<td>Communication difficulties</td>
<td>6</td>
<td>55%</td>
</tr>
<tr>
<td>Comprehension level</td>
<td>6</td>
<td>55%</td>
</tr>
<tr>
<td>Preference based care</td>
<td>4</td>
<td>36%</td>
</tr>
</tbody>
</table>

Table 13 Differences in agitation management for dementia and without dementia

Nurses were asked if there was a difference in the way agitation was managed in residents with dementia compared to residents without dementia. Nurse’s acknowledged there to be a difference in the management of agitation between people with and without dementia. This is supported by the following comments:

“Well there is definitely a difference.” Rosemarie RN

“Yes of course there is a big difference.” Jess RN

Nurses were asked if agitation was easier to manage in people without dementia compared to those who have dementia. An analysis of the comments revealed eight nurses believed there was a difference in the ease of agitation management between residents with and without dementia. Not surprisingly, the majority, nine of these responses described agitation as being more easily managed in people without dementia. Six nurses considered symptoms common to the dementia trajectory that impair communication or comprehension to adversely affect the ease in which contributing factors can be quickly identified and agitation effectively managed. This is shown in the following comment:
“... it might be a little easier [residents without dementia] because you can just ask them what’s wrong and can just say if their care (needs) are not met. We can make sure (future needs are met) we can reassure them... that it will not happen again... the problem would be solved immediately and it will be faster.” Sam RN

Alternatively, one nurse explained that regardless of the residents diagnosis, interventions were more effective and easier to implement when the resident has insight into why they are feeling agitated:

“Also on the flip side of it, when someone is verbal they [nurses] are less likely to look at the non-verbal’s. So I think sometimes the words of ‘No, no, no I’m fine’ when actually all the non-verbal’s are saying that they are not fine at all... can add a layer of complication... it depends on their insight.” Kaye RN

Six nurses identified difficulties with communication to be a frequent reason for the differences in agitation management between residents with and without dementia. Residents with dementia were considered to be less verbally able to articulate the causes of their agitation. Nurses expressed their frustration at not being able to find the cause of agitation quickly in residents with dementia. Agitation was assumed to be more easily managed in residents who could communicate their reasons for agitation. This is shown in the comments below:

“People who don’t have dementia, we will find the cause, it will be easier as they can describe the cause and we will try to fix the problem... But with dementia, it is not necessarily
that we will definitely get a cause. We can only guess the trigger.” Gabi RN

“I think that the main difference would be the ability for the resident to verbally identify what is happening for them. But other than that basically not, the reliance upon non-verbal’s, the reliance of knowing the resident, their medical condition, their social condition, where they are at the time makes no difference as to whether they have dementia or not. It’s the ability of the resident to be able to verbally articulate what is giving them agitation.” Kaye RN

Six nurses reported that comprehension deficits often seen in residents with dementia result in an impaired ability to recognise their own emotional state, understand nurses questions or follow instructions, necessitating a different approach to agitation management. Nurses described the need to repeat instructions, remind them or modify language for resident’s with dementia to be the main difference in agitation management between those with and without dementia. This is shown by the following comments:

“... with dementia they don’t understand what we are talking about. You need to constantly be reminding them or doing something if they may be agitated.” May AIN

“People who have dementia... in a sense you have to keep repeating yourself all the time... and it doesn’t always work because they are so forgetful.” Gabi RN

Four nurses identified meeting residents needs for care to be more commonly used as an agitation management of older adults without dementia compared to those with dementia. Nurses reasoned that residents without dementia often became agitated when
the care was of low quality or does not meet their needs. Providing care that aligns with older persons preferences to fit within the persons routine was considered to reduce agitation in residents without dementia. This is shown in the following comments:

“... without dementia, they always come [to the nurse] when the care is not provided properly. We will try to deliver or make it change so that we can deliver the care properly, you know, or according to their needs.” Jess RN

“Like we have residents like [Mr X] he is quite agitated about his medication and he is always asking about his medication and you need to have his catheter bag right at 7pm. If you don’t he does get agitated. He doesn’t have dementia so we try to do things on time for them.” Sanaya AIN

The types of agitation management commonly used in the RACF and the differences in management strategies required between resident cognitive groups have been described in this section. Strategies for agitation management in older people with impaired communication or comprehension have been reported as time consuming offering only short-term resolve in behaviour. More effective long-term agitation managements are required with some promoting essential oils as a possible alternate management (Lin et al, 2007; Sakamoto et al. 2013). Nurse perceptions of essential oils as possible agitation managements for resident’s are reported in the following section.

5.6 Area of interest 3 - Perceptions of essential oils

This section presents the area of interest nurse perceptions of essential oils as identified in the transcripts using content analysis. Nurse perceptions of essential oils are categorised into three categories nurse's individual use of essential oils, nurse's clinical
experience of essential oils and perceived effectiveness of essential oils. Within these three categories are nine subcategories. The first category individual use of essential oils has three subcategories potential for nurse self use, no experience and motivators for use. The second category, clinical experience of essential oils consists of three subcategories previous clinical use, dementia setting and palliative care setting. The final category perceived effectiveness of essential oils contains three subcategories positive effect, resident selective and uncertain. Table 14 presents the most frequent reported nurse perceptions of essential oils under the third area of interest.

<table>
<thead>
<tr>
<th>Area of interest</th>
<th>Nurse Perceptions of Essential Oils</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Individual use of essential oils</td>
</tr>
<tr>
<td></td>
<td>Clinical experience of essential oils</td>
</tr>
<tr>
<td>Subcategories</td>
<td>Potential for nurse self use</td>
</tr>
<tr>
<td></td>
<td>No experience</td>
</tr>
<tr>
<td></td>
<td>Motivators for use</td>
</tr>
<tr>
<td></td>
<td>Previous clinical use</td>
</tr>
<tr>
<td></td>
<td>dementia setting</td>
</tr>
<tr>
<td></td>
<td>Palliative care setting</td>
</tr>
<tr>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>Resident selective</td>
</tr>
<tr>
<td></td>
<td>Uncertain</td>
</tr>
</tbody>
</table>

Table 14 Nurse perception of essential oils

5.6.1 Individual use of essential oils

Nurses were asked if they would consider using essential oils for their own health. Ten nurses agreed they would use essential oils for their own health conditions. Nurses were asked if they had used essential oils previously with six nurses indicating they had no previous experience with essential oils. Three nurses claimed the motivators for their individual use of essential oils included a belief that the oils provided a positive effect or the oils pleasing scent. Table 15 presents the reported nurse experience of using essential oils for their own health conditions.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential for nurse self use</td>
<td>10</td>
<td>91%</td>
</tr>
<tr>
<td>No experience</td>
<td>6</td>
<td>55%</td>
</tr>
<tr>
<td>Motivators for use</td>
<td>4</td>
<td>36%</td>
</tr>
</tbody>
</table>

Table 15 Nurse individual use of essential oils

A significant majority of ten nurses agreed they would try essential oils to manage their health and well being. Several nurses were already using essential oils for their own health and some owned home diffusers. This is illustrated by the following comments:
“Yes. I have got a diffuser in my bedroom.” Sabrina RN

“I find it quite relaxing.” Sanaya AIN

A slight majority of six nurses interviewed had not used essential oils previously for various reasons. One nurse identified a need for education of essential oil properties and effects before committing to using the oils. Allergies prevented another nurse from using essential oils.

“ Well it depends on what does it do though, like well I’m not really sure what it does?” Sam RN

“No... I need to be quite wary because I get a bit of asthma” May AIN

Four nurses used essential oil for their perceived benefit including pleasant aroma or relaxing effect. Nurses reported that essential oils have a greater effect on resident’s. The following comments portray this:

“I like trying the smells...” Gabi RN

“... have had education about it, that it’s quite soothing and calming especially to the older people.” Rosemarie RN

5.6.2 Clinical experience of essential oils

Seven nurses had used essential oils previously in the clinical environment, three nurses for people with dementia and two nurses for people receiving palliative care (18%). Table 16 presents the previous clinical use of essential oil and settings as reported by the nurses.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=11)</th>
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</thead>
<tbody>
<tr>
<td>Previous clinical use</td>
<td>5</td>
<td>45%</td>
</tr>
<tr>
<td>Dementia setting</td>
<td>3</td>
<td>27%</td>
</tr>
<tr>
<td>Palliative care setting</td>
<td>2</td>
<td>18%</td>
</tr>
</tbody>
</table>

128
Table 16 Previous clinical use of essential oil

This is demonstrated in the responses below:

“... we have a client who... was prescribed Lavender oil to go on the pillow, a few drops on the pillow before he went to bed.” Gabi RN

“... the answer is no, I haven’t seen anybody using it.” Sam RN

“No I haven’t seen it but I heard about it.” Sanaya AIN

Three nurses who reported using essential oils in a dementia care setting in their clinical practice, had administered Lavender hand massage in their current facility, while others had been involved with essential oil use for residents with dementia at other organisations. This is shown by their comments:

“Oh about five years ago in another organisation in our dementia specific unit. I used aromatherapy” Kaye RN

“... then I used, they gave us aroma oil... it smells nice, Lavender, I massaged it into their hands.” Natasha AIN

Two nurses reported they had used essential oils in a palliative care setting in their clinical practice. These essential oils were used for patient relaxation at the end of life. This is shown by the following comments:

“Yes, I have for palliative care, aromatherapy.” Jess RN

“[Essential oil use] in palliative care patients as they get restless too... they get very agitated in that end of life stage.” Gabi RN
5.6.3 Perceived effectiveness of essential oils

Nurses were asked how effective they perceived essential oils to be in managing agitation in older adults. Eight nurses reported that essential oils would be effective in managing agitation in residents. Seven nurses believed that essential oils would reduce agitation in some residents only, that effect would be dependent on pre-existing conditions or personal situations. Another two nurses were unsure as to the effect of essential oils, preferring to wait for the RCT results. Table 17 reports nurse perceptions of essential oils effectiveness as an agitation management in residents.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive effect</td>
<td>8</td>
<td>80%</td>
</tr>
<tr>
<td>Resident selective</td>
<td>7</td>
<td>70%</td>
</tr>
<tr>
<td>Uncertain</td>
<td>2</td>
<td>20%</td>
</tr>
</tbody>
</table>

Table 17 Perceived effectiveness of essential oils as agitation management

Nurses who described essential oils to have a positive effect on managing agitation, believed effectiveness was assisted by the pleasing fragrance, comforting touch and one on one communication during the application process:

“It is good, aromatherapy smells nice and people always love the nice things, so I think it’s good for them. And when you do the aromatherapy you... like, comforting and touching them and then talking with them.” Sanaya AIN

Nurses who cared for residents in a palliative care setting believed the essential oils were effective as they created a comfortable homely environment in the clinical setting that was important to both resident and their families. This is shown by the following comment:

“The oils calm the client and the visitors, it creates a really nice environment and it really feels like it’s not a nursing home or it’s not a hospital, it feels like home where actually
there is something meaningful to them. I had a feeling like that." Gabi RN

Nurses reported essential oils promoted relaxation and enhanced appetite in some residents, and this effect was observed in residents regardless of dementia diagnosis. This is demonstrated in the following nurse comments:

“... it certainly created a more comfortable ambience whether we were using the Lavender based relaxing type things or the citrus type based appetite enhancers.” Kaye RN

“I found it calming, even for the staff with their approach. Even with normal residents without dementia background sometimes they get agitated, restless or because of anxiety level... essential oil usually able to calm, you feel more comfortable in that environment, it feels good.” Jess RN

Seven nurses perceived essential oils would be beneficial in reducing agitation in some residents only. These nurses considered the effect to be dependent on a residents pre-existing health condition or individual circumstance. Nurses considered that should essential oils reduce agitation in dementia, lower levels of medication might be prescribed. This is shown by their following comments:

“I don’t think it will work for everyone but some people sure it will work.” Sabrina RN

“Maybe people who don’t have dementia will get benefits out of it because it will relax them.” May AIN
“… if it is working on dementia patients that would really be a breakthrough and that would help in terms of managing their behaviour rather than medication.” Jess RN

A minority of two nurses were uncertain of the effect of essential oils on agitation, preferring to observe the clinical trial further before providing an opinion. This is demonstrated in Jess’s comment:

“I want to see how effective it is. Actually I want to see whether its really working on dementia patients’.” Jess RN

Nurse’s previous experience through individual or clinical use, in conjunction with their perceptions of the essential oil’s effectiveness have been explored in this section. Research on the effect of essential oils on agitation conducted in the RACF setting can provide nurses evidence for the use of oils as an agitation management. Nurse perceptions of research in the RACF environment are discussed in the following section.

5.7 Area of interest 4 - Nurse perceptions of research in RACF’s

This section presents the area of interest, nurse perceptions of research in RACFs as identified in the transcripts using content analysis. Nurse perceptions of research in RACFs are categorised into three categories importance of research, nurse compliance and recommendations for future research. Within these three categories are 11 subcategories. The first category importance of research has three subcategories older adults living in RACFs, dementia behaviours and barriers to research. The second category nurse compliance consists of five subcategories: supportive of research, demanding workload lack of belief fear of reprisal and lack of education. The final category recommendations for future research contains three subcategories education communication and researchers expectations. Table 18 presents the most frequent
reported nurse perceptions towards research in the RACF environment under the fourth area of interest. Tabulated are the categories and subcategories from the frequency codes from the nurse transcripts.

<table>
<thead>
<tr>
<th>Area of interest</th>
<th>Perceptions of research in RACF's</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Importance of research</td>
</tr>
<tr>
<td>Subcategories</td>
<td>Older adults living in RACFs</td>
</tr>
<tr>
<td>Frequency</td>
<td>Percentage</td>
</tr>
<tr>
<td>Older adults living in RACFs</td>
<td>10</td>
</tr>
<tr>
<td>Dementia behaviours</td>
<td>4</td>
</tr>
<tr>
<td>Barriers to research</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 18 Perceptions of research in the RACF's

**5.7.1 Importance of Research**

An additional focus of the semi-structured interviews was the nurses understanding of the importance of research in the RACF environment. Nurses were asked how important they perceived research to be in RACFs. Ten nurses believed that research in aged care facilities to establish an evidence base for care of residents was important and could assist understanding of the experiences of people living in RACFs. Four nurses did not believe enough research was being conducted into resident behaviours, specifically those common in the dementia trajectory. However two nurses identified barriers to the research process that required addressing. Table 19 presents the responses to the importance of research in the RACF environment as reported by the nurses.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Older adults living in RACFs</td>
<td>10</td>
<td>91%</td>
</tr>
<tr>
<td>Dementia behaviours</td>
<td>4</td>
<td>36%</td>
</tr>
<tr>
<td>Barriers to research</td>
<td>2</td>
<td>18%</td>
</tr>
</tbody>
</table>

Table 19 Importance of research

Ten nurses perceived research for residents in RACFs could improve care and quality of life. Nurses believed that increased research could provide awareness of dementia issues in RACFs and give value to the older person’s experiences. This is shown in the comments below:
"I think it’s a good benefit for research to see how dementia people are living in aged care, it’s very important for some other people as they don’t have an understanding." May AIN

"I think it’s pretty important... there is not enough research on older people being... valued by research teams." Sam RN

Four nurses specifically identified research into behaviours to be an important area of research for the RACF setting. Nurses admitted difficulty in managing agitation and had concerns for the safety of residents, family or staff. Nurses described a need for additional effective strategies to manage agitation in the RACF setting, they hoped essential oils would provide an alternative management. In addition nurses spoke of the detrimental effect agitation had on residents, being lack of sleep or appetite that often resulted in health deterioration and hospitalisation. This is shown by the following comments:

"I think it’s quite important to do the research in the aged care... It’s really getting hard to control their behaviours and then if we do the research and we can control their behaviours it will be beneficial for resident and everyone in aged care. I have seen a lot of residents because of their agitation, they don’t eat, they don’t sleep and that is how they get sick and end up in hospital." Sabrina RN

"It’s very important because at the moment... we are managing dementia behaviour by using distraction and by using other alternatives but if essential oil helps that will make a big difference." Jess RN
Two nurses identified barriers to research in RACFs including confidentiality, workload and resident or family non-compliance. Nurses considered many residents and their families to be in crisis during the RACF placement, with the realisation that services or family members can no longer support the older person to live in the community. Some staff concluded that the additional burden of research participation may not be a priority for the resident or family during this time. This is shown below:

“It’s essential and it’s extremely difficult... the laws of confidentiality, access and having staff that are so flat chat trying to complete their daily tasks. To add any additional workload or even any change to their work process... its met with a lot of stonewalling.” Kaye RN

“I don’t know 50:50, probably the clients themselves, if they don’t want to participate or don’t understand and things like that. Probably the families too, if they don’t want to be involved in this kind of thing, because it’s extra isn’t it, to what is already happening. Most of the families here, they come here, they have a kind of guilt as to why their family members are here, they are already in such an emotional trap. So researchers I think... there are some boundaries.”

Gabi RN

5.7.2 Nurse compliance

Nurses were informed of staff non-compliance with research in previous studies and asked to identify underlying factors that may affect compliance. Five nurses stated they were supportive of nurse participation in research. However nurses reported demanding workload (n=5), lack of belief in intervention (n=3), fear of managerial reprisal (n=3) and a lack of research education (n=2) to influence nurse compliance with
research. Table 20 presents the subcategories identified as reasons influencing nurse compliance with research.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supportive of research</td>
<td>5</td>
<td>50%</td>
</tr>
<tr>
<td>Demanding workload</td>
<td>5</td>
<td>50%</td>
</tr>
<tr>
<td>Lack of Belief</td>
<td>3</td>
<td>30%</td>
</tr>
<tr>
<td>Fear of reprisal</td>
<td>3</td>
<td>30%</td>
</tr>
<tr>
<td>Lack of education</td>
<td>2</td>
<td>20%</td>
</tr>
</tbody>
</table>

Table 20 Nurse compliance

Five nurses were supportive of research regardless of their non-compliance to the protocol. Nurses concurred that if staff agreed to participate in a research study that they should endeavour to comply with that investigation process for the approved timeframe.

Nurses considered compliance to research necessary to improve staff workload, quality of care and to provide best practice alternatives to manage current difficulties in the RACF environment. This is shown in the following comments:

“If something comes here that is going to benefit the residents and the staff, I don’t think staff should have any problem cooperating with the interventions...” Sanaya AIN

“I suppose if we do it in that time period I think all the nurses if they are participating, we should all be participating and compliant to that research for the sake of older people to get the best results of the research.” Sam RN

“I would love to have research because I want to see what other alternative we can do to improve the care for the patient.” Jess RN

Five nurses identified workload as the most frequent reason nurses may be non-compliant with research. Nurses described an increasing number of scheduled and unscheduled tasks that impact on their work day. These demands require prioritising to ensure they are all completed during a shift. Research tasks to be completed by the nurse
are additional demands to the already heavy work schedule that extend their work day. Nurses described that higher priority care demands could lower the priority of research tasks leading staff to forget their research commitments. This is shown in the following comments:

“Multiple demands from management down. We have constant demands on us and they are ever increasing so any change to routine means it’s going to take me longer to complete my day which means I won’t get my work done” 
Kaye RN

“… sometimes they might forget, sometimes they get really busy and they’ve got other stuff to do and they might not be compliant with the intervention.” Sam RN

Three nurses identified that a lack of belief that a research intervention will benefit or improve the situation being investigated is a common reason for nurse non-compliance. Nurses reasoned if they believe the research will not be successful in improving the situation being investigated, the time and effort to comply with research is of low priority. This is shown in the following comments:

“Well it depends what kind of intervention it was and whether, I believe” Sam RN

“Maybe they don’t believe essential oils (are effective).” Jess RN

“Maybe they are thinking that it won’t help first of all. Aromatherapy won’t help the resident, maybe lack of time, lack of interest.” Sabrina RN
Three nurses identified a fear of providing the researcher with information that may not be acceptable to their supervisors as a reason for non-compliance. Some nurses believed their employment would be at risk if their responses showed limited knowledge or deviated from correct procedures. This is shown by the comments below:

“... some of them, they don't want to say anything and I think in my opinion because sometimes when you say research some people think maybe you are going to tell our manager. They are going to tell the big boss maybe I am going to lose my job. They are scared.” Natasha AIN

“... fear they are going to do the wrong thing they are going to make a mistake.” May AIN

Two nurses identified that a lack of staff education about the benefits and expected staff involvement of research could lead to non-compliance. Nurses reasoned if staff were not aware of their responsibilities in the research project they could not be expected to comply. Further, nurses described that education needs to be provided at different levels for managers, registered nurses and personal care workers as they have differing levels of knowledge, responsibilities and expectations for their work day. This is shown in the comments below:

“... probably some of the staff, they're not aware of this so saying this we need to actually talk to all of the other staff to make sure they are aware of this or what is happening so they can cooperate.” Jasmine RN

“I think mostly if there is new research and there isn't education, no one will know. And starting from a staff or
carer, it is totally different to being a manager or an RN because no perspective. We will look into things differently but I think you need education otherwise there will be a barrier, there will be a gap there and conflict, so education plays a role.” Rosemarie RN

5.7.3 Nurses Recommendations for future research

Nurses were asked how future research could be better implemented in the RACF environment. Nurse’s recommendations for future research in RACFs included improved education (n=7) and more effective communication between researcher and service provider (n=5). In addition nurses (n=5) perceived researchers had limited understanding of the nurses demanding workload and limited time available for research collaboration. Table 21 presents the subcategories for nurse recommendations for future research in the RACF environment as reported by the nurses.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education</td>
<td>7</td>
<td>70%</td>
</tr>
<tr>
<td>Communication</td>
<td>5</td>
<td>50%</td>
</tr>
<tr>
<td>Researcher’s expectations</td>
<td>5</td>
<td>50%</td>
</tr>
</tbody>
</table>

Table 21 Recommendation for future research

Seven nurses identified education as the most important recommendation for improvement when implementing new research in the RACF environment. Nurses believed education targeted at different levels of staff to outline the benefits that are relevant to each group could improve research commitment. The high prevalence of English as a second language among nursing staff was also cited as reasons to why staff may need education. This is shown by their comments:

“… it could be that probably they need to train the staff, they need to explain more of the research, like how the intervention was actually developed and things like that. They have to give a background to the staff.” Gabi RN
“I think that can only be done by encouraging or educating nurses because I think that nurses are the only ones that are in touch with their residents.” Sam RN

“The staff that work on the floor, we shouldn’t forget that they only have a limited qualification and they are only trained to do certain things, they need lots of education... with most staff I have seen, with an overseas background, limited English this could be the problem as well, so I think they need more education” Sanaya AIN

Five nurses identified improved communication between the researcher and service provider as pivotal to research success in the RACF environment. Nurses considered a policy on disclosure of information to be shared between researcher and the nurse would assist in promoting transparent communication. This is shown in the following comment:

“I think very important is the communication between the researcher and the service provider. Disclosure of information and communication effectively in terms of how much the researcher... or how much the company is allowed to disclose to the researcher.” Jess RN

Five nurses identified the need to reduce the researcher’s expectations of staff involvement in research, as adding work to an already demanding workload is often met with resistance from staff. Nurses considered it necessary for researchers to take ownership of the workload created by their research by providing their own team to perform research related tasks. This is shown in the following comment:
“The problem is it’s an institution and it is an institution with a limited budget so we are all trying to eek [gain] out of our budget the best that we can. So we say that this will be good for you and we will do research that will give you best care and no one disputes that. The problem is that unfortunately the only way to do that is to bring in the team that are going to do the research and make sure when it’s ready to roll it is going to make the staff members day faster, more effective and meaningful for their residents.” Kaye RN

5.8 Summary
This chapter has reported the findings from 11 semi-structured interviews with nurses. A content analysis obtained information relating to four areas of interest; Types of agitation, Agitation management, Perceptions of essential oils and Nurse perceptions of research in RACFs. The 12 categories and 36 subcategories supporting the four areas of interest were described. Subcategories were identified by content analysis coding and supported by nurse quotes from the Phase I interviews.

Nurses understood agitation to be physical or verbal behaviours that could be aggressive or non-aggressive. Nurses identified behaviours of shouting, restlessness, wandering and repetitive behaviours to be agitation that they regularly managed in their facilities. Nurses understood behaviours to be distressing to the resident and disruptive to others in the facility.

Current agitation management included distraction, providing space, knowing the resident’s triggers or providing medications. Nurses explained that by identifying causative factors for the agitation, the behaviour could be more readily resolved. However, impaired communication or comprehension associated with a dementia diagnosis hindered the nurse’s ability to manage behaviour in this group. Nurses were
concerned by the escalating level of agitation on the ward and the limited effective management strategies at their disposal.

A majority of nurses believed in Lavender and Lemon Balms ability to reduce agitation in the residents. A small percentage had worked with essential oils previously in the clinical setting. Several nurses were also using the oils for their own well-being. Some nurses, however did not believe the oils would be effective on all residents agitation, considering the agitation in dementia to be intractable in the conditions trajectory.

Nurses perceived research to be important for residents in the RACF. The nurses suggested that lack of compliance in research can stem from a lack of belief in the intervention or the nurses demanding workloads. They suggested nurse compliance to research could be improved with pretrail education, and better communication between researcher and nurses, in addition to researcher's having realistic expectations of what can be achieved by the nurses in the RACF environment.

The findings from Phase I nurse interviews informed the practicalities of the RCT in Phase II of this study and the implementation of essential oils into the aged care environment. The additions to Phase II from the Phase I results are discussed in chapter 8 of this thesis. The results of Phase II RCT are presented in chapter 6.
Chapter 6 Phase II Quantitative Results

6.1 Overview
This chapter presents the results of the Phase II single blind RCT of the effectiveness of Lavender and Lemon Balm to reduce agitation in resident's people living in RACFs. As previously described in Chapter 4, resident data was collected using the Neuropsychiatric Inventory (NPI), the Cohen-Mansfield Agitation Inventory (CMAI) and the Quality of Life AD (QoL-AD). Planned analyses and post hoc analyses were conducted; the planned analyses was based on previous research, which indicated that the two treatments would be effective in reducing agitation in elderly people with and without dementia. Significant effect is reported in the planned analysis for the NPI, CMAI and QoL-AD measures. The outcomes of the NPI and CMAI are reported in full followed by analyses of instrument specific behaviour categories. NPI categories reported are aggression/agitation, aberrant motor activity, anxiety, delusions, depression, irritability and sleep disturbance. The CMAI categories reported are physical aggressive behaviour, physical non-aggressive behaviour and verbal agitation. The QoL-AD total score is reported incorporating the categories of physical health, energy, mood, living situation, memory, family, marriage, friends, self as a whole, ability to do chores, things for fun, money and life as whole. All results are reported for the per protocol (PP) analyses which is a standard analysis that includes only those residents that completed all allocated treatment within the study protocol guidelines (Shah, 2011).

6.2 Data Analysis
This section reports the details results, including details of the four planned and post hoc analyses. Data were recorded for behaviour on the NPI, CMAI and for quality of life on the QoL-AD measurement instruments. The measurement tools are validated for use in this population within the timeframes specified in this study (Cohen-Mansfield et al. 1989; Cummings et al. 1994; Tombaugh & McIntyre, 1992). Data were collected before and after the three treatment periods, a total of six data collection occasions for each
Each resident trialled each of the two essential oil treatments, being Lavender and Lemon Balm and the placebo therefore each resident acted as their own control. The treatment cycles consisted of a 14-day treatment period followed by a 14-day washout period. Measurements were taken before treatment to obtain baseline and again after treatment to compare the effect in each of the three treatment periods. Data were collected on hard copy templates in conjunction with the regular carer. Once collected resident data were entered into an Excel spread sheet checked for accuracy and transferred to statistical software SPSS for analysis.

The statistical software SPSS Version 23 conducted an Intention to Treat (ITT) and PP analyses for collected resident data in this study. An ITT standard analysis that compared treatments from the data of all residents who were randomised and completed at least one observable treatment was conducted (Shah, 2011) to provide a complete picture of resident results. Data from the 65 residents who had completed at least one treatment cycle were analysed by statistical software SPSS Version 23, the details of the ITT analysis can be found in Appendix K.

Of the 65 residents who completed at least one treatment period, only 49 completed all treatment periods within the study protocol guideline and were included in the PP analysis reported in this Chapter. Reasons for the withdrawal of the 16 residents, included changes in health status (6), refusal of treatment (2), discharge from the RACF (6) and unavailability of carers to report behaviours (2).

### 6.2.1 Participant Characteristics
This section reports the characteristics of the 49 older adult participants whose data was analysed in the PP analysis for this study. The residents were permanent aged care residents recruited from six RACFs on two sites operated by the same aged care provider in the Sydney area. The residents were aged 65 years or older at the time of recruitment with the mean resident age being 89.31 (SD6.3) years. Forty (62.7%) were female and
15 (27.3%) were male. All residents experienced agitated behaviour as documented on the Aged Care Funding Instrument [ACFI] behaviour domain. The ACFI is a government funding instrument that is used to appraise the care needs of older people living in RACFS across the three domains of activity of daily living [ADL], behaviour [BEH] and complex health care [CHC]. Older people included in this study, were residents at the facility with observable behaviours as recorded in the BEH domain categories of wandering, verbal behaviours or physical agitations (Department of Social Services, 2007). Resident behaviours were routinely observable to the nurse three or more times during their regular working week. Resident’s in this trial were assigned to either the dementia or without dementia based on dementia diagnosis and cognitive level as determined by the Mini Mental State Examination (MMSE).

The MMSE, is a 30-point measurement scale commonly used to screen for cognitive decline that was used in this study to evaluate cognitive status in residents (Fu, 2009; Tombaugh & McIntyre, 1992). Forty two residents in this study had been diagnosed with dementia and an MMSE score of 10 to 18 was documented for 39 residents indicating moderate cognitive decline and a further three residents scored 19 to 23 indicating a mild cognitive decline. The thirteen residents included in the without dementia group scored 24 to 30 on the MMSE measurement scale indicating no cognitive decline.

A diagnosis of depression was also indicated for 28 residents, both with dementia (n=21) and without dementia (n=7). Anxiety was documented as a symptom in nursing notes for 18 residents, both with dementia (n=10) and without dementia (n=8), however only 10 of these residents were medically diagnosed. All participating residents experienced agitated behaviour with 19 residents taking antipsychotic medications either regularly or as needed to manage behaviour. Antipsychotic medication changes in all residents were monitored throughout the study. The characteristics for the 49 residents whose
data was analysed in this study are tabulated in Table 22 Phase II resident characteristics.

<table>
<thead>
<tr>
<th>Item</th>
<th>Sample (n=49)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility 1</td>
<td>10</td>
<td>20.41%</td>
</tr>
<tr>
<td>Facility 2</td>
<td>6</td>
<td>12.24%</td>
</tr>
<tr>
<td>Facility 3</td>
<td>2</td>
<td>4.08%</td>
</tr>
<tr>
<td>Site B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility 4</td>
<td>22</td>
<td>44.91%</td>
</tr>
<tr>
<td>Facility 5</td>
<td>7</td>
<td>14.28%</td>
</tr>
<tr>
<td>Facility 6</td>
<td>2</td>
<td>4.08%</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12</td>
<td>24.49%</td>
</tr>
<tr>
<td>Female</td>
<td>37</td>
<td>75.51%</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>65 &gt; years</td>
<td>49</td>
<td>100%</td>
</tr>
<tr>
<td>89.31 SD6.30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dementia Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dementia</td>
<td>39</td>
<td>79.59%</td>
</tr>
<tr>
<td>Without Dementia</td>
<td>10</td>
<td>20.41%</td>
</tr>
<tr>
<td>Cognitive Score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMSE (25+)</td>
<td>10</td>
<td>20.41%</td>
</tr>
<tr>
<td>MMSE (18 – 24)</td>
<td>2</td>
<td>4.08%</td>
</tr>
<tr>
<td>MMSE (10-17)</td>
<td>37</td>
<td>75.51%</td>
</tr>
<tr>
<td>Depression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>57.14%</td>
<td></td>
</tr>
<tr>
<td>20 (dementia)</td>
<td>(40.82%)</td>
<td></td>
</tr>
<tr>
<td>6 (without dementia)</td>
<td>(12.24%)</td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>34.69%</td>
<td></td>
</tr>
<tr>
<td>9 (dementia)</td>
<td>(18.37%)</td>
<td></td>
</tr>
<tr>
<td>8 (without dementia)</td>
<td>(16.33%)</td>
<td></td>
</tr>
<tr>
<td>Antipsychotic medication</td>
<td>18</td>
<td>36.73%</td>
</tr>
</tbody>
</table>

Table 22 Phase II participant characteristics

A Consolidated Standards of Reporting Trials (CONSORT) flow diagram details the randomisation process and withdrawal of residents on the trial see Figure 2 CONSORT flow diagram. Seventy-five residents having met all of the inclusion criteria were randomised to a treatment sequence and allocated to either the dementia (n=56) or without dementia (n=19) group according to MMSE score. Ten residents with dementia (n=6) and without dementia (n=4) allocated withdrew before completing the first treatment period and prior to data collection. Due to limited exposure, post-treatment data for baseline comparison was unable to be collected and these residents were removed from the analysis. Reasons for withdrawal in the initial treatment period include refusal (n=7) hospitalisation (n=2) and discharge (n=1). Five residents with dementia were recruited and consented by family members, refused participation in the
first treatment period. Of the two residents with without dementia who withdrew in the first treatment period, one was concerned with their behaviour being monitored and data collected, the other resident did not provide a reason. The 65 resident's that completed the first treatment cycle were analysed using statistical software SPSS version 23 to report the ITT (Appendix K).

Of the 65 residents who completed one treatment period, a further ten residents withdrew from the trial prior to completing all treatment periods; six residents discharged through death or relocation, two residents refused treatment, one was hospitalised and one resident was withdrawn by staff due to a suspected respiratory infection. All ten residents partial data were removed from the PP analysis. A further six residents were withdrawn from the PP analysis as they had not adhered to key aspects of the study protocol. Reasons for the withdrawal of the six residents included changes to medication (n=1), unavailability of carer to monitor behaviours (n=2), violation of inclusion criteria, Parkinson Disease (n=1), knowledge of a life-limiting condition (n=1) and palliation in the last treatment period (n=1). A Consort flow diagram of resident numbers is shown in Figure 2.
6.2.2 Analysis for CMAI, NPI and QoL-AD

Planned analyses based on previous literature is presented with orthogonal contrasts that compared treatments against placebo and then treatments to each other across both the with and without dementia groups. The planned analyses measured the change in NPI, CMAI and QoL-AD score between baseline and treatment evaluation. Planned analyses are reported for the total score and specified behavioural categories for each measurement tool. The planned analyses were designed to provide evidenced answers to the research questions: (1) What is the effectiveness of Lavender compared to Lemon...
Balm and a placebo for the management of agitation in residents of RACF with and without dementia (2) What are the differences between Lavender compared to Lemon Balm and a placebo for the management of agitation in residents of RACF with and without a dementia diagnosis. The four planned analyses considered necessary to answer the research questions were:

- The first planned analysis reported the change in measurement tool score between baseline and follow up for the with dementia group compared to the without dementia group independent of essential oil treatment.

- A second planned analysis reported the change in measurement tool score between baseline and follow up when Lavender and Lemon Balm essential oils are compared to placebo.

- A third planned analysis compared the change in measurement tool score between baseline and follow up in residents treated with Lavender to residents treated with Lemon Balm independent of cognitive status.

- The fourth planned analysis evaluated the change in measurement tool score between baseline and follow up of Lavender and Lemon Balm on the with and without dementia groups.

6.2.3 Post hoc Analyses for CMAI, NPI and QoL-AD

An unexpected result from planned analyses necessitated a focused post hoc analysis that separated essential oils and resident groups to determine cause of effect. The post hoc analyses are detailed below.

- A first post hoc analysis reported the findings for Lavender when compared to Placebo and Lemon Balm with a supplementary analysis comparing Placebo to Lemon Balm. This analysis was designed to determine the effect of Lavender essential oil on agitation or quality of life.
• A second post hoc analysis reported the findings for Lemon Balm when compared to Placebo and Lavender with a supplementary analysis comparing Placebo to Lavender. This analysis was designed to determine the effect of Lemon Balm essential oil on agitation or quality of life.

6.2.4 Summary of Significant Effects

This section reports the statistically significant findings of the planned and post hoc analyses from the 2x3 factorial design single blind RCT that comprises the Phase II component of this mixed methods study.

• The analysis demonstrated a statistically significant reduction in the overall NPI score between baseline and follow up by Lemon Balm when the groups of with and without dementia were compared. This result reported a significant decline in NPI total score when Lemon Balm was administered to residents without dementia in comparison to those with dementia. This result suggests Lemon Balm may affect NPI behaviours differently in residents without dementia compared to those with dementia.

• A post hoc analysis demonstrated a statistically significant decrease in NPI total score between baseline and follow up by Lemon Balm when compared to Lavender and placebo in the without dementia group. No statistically significant difference was reported between baseline and follow up when Lavender and placebo groups were compared. This result reported Lemon Balm reduced agitation significantly more compared to Lavender or placebo in residents without dementia. Indicating that Lemon Balm may reduce agitation in residents without dementia.
• The analysis demonstrated a statistically significant reduction in the NPI irritability score between baseline and follow up by Lavender and Lemon Balm when the groups of with and without dementia were compared. This result reported a significant decline in NPI Irritability when Lemon Balm was administered to residents without dementia in comparison to those with dementia. This result suggests Lemon Balm may affect NPI irritability differently in residents without dementia compared to those with dementia.

• Post hoc analyses demonstrated a statistically significant difference in NPI irritability between baseline and follow up by Lemon Balm when compared to Lavender and placebo in the residents with dementia group. No statistically significant difference was reported in the NPI irritability between baseline and follow up when Lavender and Placebo group were compared. This result reported a significant decrease in NPI irritability between baseline and follow up when Lavender is administered to residents with dementia. Indicating that residents with dementia may experience less improvement in irritability when Lemon Balm is treatment is administered relative to Lavender or placebo treatment.

• The analysis demonstrated a statistically significant difference in the CMAI reduction between baseline and follow up by Lemon Balm when the groups of with and without dementia were compared groups. This result reported a decline in CMAI total score between baseline and follow up when Lemon Balm is administered to residents without dementia in comparison to those with dementia. This result suggests Lemon Balm affects CMAI behaviours differently in residents without dementia compared to those with dementia. Indicating that
Lemon Balm may reduce agitation in residents without dementia more effectively than those with dementia.

- The analysis demonstrated a statistically significant reduction in the CMAI physical non-aggressive behaviour between baseline and follow up by Lavender and Lemon Balm when the groups of with and without dementia were compared. This result reported a significant decline in CMAI physically non-aggressive behaviour when Lemon Balm was administered to residents without dementia in comparison to those with dementia. Contrastingly a significant decline in CMAI physical non-aggressive behaviour when Lavender was administered to residents with dementia in comparison to those without dementia. This result suggests Lavender and Lemon Balm may affect CMAI physical non-aggressive behaviour differently in residents without dementia compared to those with dementia.

- A post hoc analysis demonstrated a statistically significant decrease in CMAI physical non-aggressive behaviour between baseline and follow up by Lemon Balm when compared to Lavender and placebo in the without dementia group. No statistically significant difference was reported between baseline and follow up when Lavender and placebo groups were compared. This result reported Lemon Balm reduced CMAI physical non-aggressive behaviour significantly more compared to Lavender or placebo in residents without dementia. Indicating that Lemon Balm may reduce physical non-aggressive behaviour in residents without dementia.

- A post hoc analysis demonstrated a statistically significant decrease in CMAI physical non-aggressive behaviour between baseline and follow up by Lavender when compared to Lemon Balm and placebo in the dementia group. No statistically significant difference was
reported between baseline and follow up when Lemon Balm and placebo groups were compared. This result reported Lavender reduced CMAI physical non-aggressive behaviour significantly more compared to Lemon Balm or placebo in residents without dementia. Indicating that Lavender may reduce physical non-aggressive behaviour in residents with dementia.

- The analysis demonstrated a statistically significant reduction in the CMAI PNAB domain score between baseline and follow up by Lavender and Lemon Balm when compared to placebo. This result reported a significant reduction in PNAB domain scores between baseline and follow up when essential oils of Lavender and Lemon Balm were administered to residents. These results suggest Lavender and Lemon Balm may affect PNAB behaviours differently in dementia people.

- A post hoc analysis demonstrated a statistically significant decrease in CMAI PNAB score between baseline and follow up by Lavender when compared to Lemon Balm and placebo in the dementia group. No significant difference was reported between baseline and follow up when Lemon Balm and placebo were compared. This result reports that Lavender decreased physical non-aggressive behaviour in residents with dementia more effectively than Lemon Balm or placebo treatment. Lavender may decrease PNAB behaviour in residents with dementia.

- The analysis demonstrated a statistically significant increase in overall QoL-AD overall score between baseline and follow up for the without dementia group when compared to dementia group. Results suggest that residents with dementia have a higher QoL than residents without dementia independent of essential oils treatment. Indicating that
residents without dementia may have a lower quality of life than people with dementia living in RACFs.

A tabulated summary of the results for planned analyses and the attributing post hoc’s is presented for planned analysis 1 (table 23), planned analysis 2 (table 24), planned analysis 3 (table 25) and planned analysis 4 (table 26).

<table>
<thead>
<tr>
<th></th>
<th>Dementia</th>
<th>No Dementia</th>
<th>p value</th>
<th>DF</th>
<th>F value</th>
<th>F critical</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPI PP</td>
<td>-12.31</td>
<td>-12.33</td>
<td>0.85</td>
<td>DF47</td>
<td>(1.0.04)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>AMB</td>
<td>-0.44</td>
<td>-1.1</td>
<td>0.67</td>
<td>DF47</td>
<td>(1.0.18)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>AA</td>
<td>-4.07</td>
<td>-2.9</td>
<td>0.53</td>
<td>DF46.9</td>
<td>(1.0.39)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>Anxiety</td>
<td>-1.62</td>
<td>-2.4</td>
<td>0.62</td>
<td>DF46.66</td>
<td>(1.0.24)</td>
<td>Fc= 4.05</td>
</tr>
<tr>
<td>Delusion</td>
<td>-1.46</td>
<td>-0.2</td>
<td>0.35</td>
<td>DF46.91</td>
<td>(1.0.90)</td>
<td>Fc= 4.05</td>
</tr>
<tr>
<td>Depression</td>
<td>-3.52</td>
<td>-3.4</td>
<td>0.96</td>
<td>DF46.90</td>
<td>(1.0.00)</td>
<td>Fc= 4.05</td>
</tr>
<tr>
<td>Irritability</td>
<td>-4.70</td>
<td>-2.4</td>
<td>0.99</td>
<td>DF42.60</td>
<td>(1.0.00)</td>
<td>Fc= 4.05</td>
</tr>
<tr>
<td>Sleep disturbance</td>
<td>-1.09</td>
<td>-0.5</td>
<td>0.57</td>
<td>DF46.12</td>
<td>(1.0.33)</td>
<td>Fc= 4.05</td>
</tr>
<tr>
<td>CMAI</td>
<td>-6.03</td>
<td>-8.5</td>
<td>0.45</td>
<td>DF46.99</td>
<td>(1.0.57)</td>
<td>Fc= 4.05</td>
</tr>
<tr>
<td>CMAI PAB</td>
<td>-1.86</td>
<td>-1.80</td>
<td>0.93</td>
<td>DF46.80</td>
<td>(1.0.01)</td>
<td>Fc= 4.05</td>
</tr>
<tr>
<td>CMAI PANB</td>
<td>-1.59</td>
<td>-0.8</td>
<td>0.61</td>
<td>DF47</td>
<td>(1.0.37)</td>
<td>Fc= 4.05</td>
</tr>
<tr>
<td>CMAI VB</td>
<td>-3.34</td>
<td>-4.87</td>
<td>0.52</td>
<td>DF47</td>
<td>(1.0.42)</td>
<td>Fc= 4.05</td>
</tr>
<tr>
<td>CMAI PAB</td>
<td>-2.02</td>
<td>-5.80</td>
<td>0.03*</td>
<td>DF34.23</td>
<td>(1.5.07)</td>
<td>Fc= 4.13</td>
</tr>
<tr>
<td>QOL-AD Post hoc (residents with dementia)</td>
<td>LAV 2.59</td>
<td>LB 0.44</td>
<td>Placebo - 0.66</td>
<td>P=0.07</td>
<td>(1.77)</td>
<td>T(1.3.77) Tc=1.99</td>
</tr>
<tr>
<td>QOL-AD Post hoc (residents without dementia)</td>
<td>LAV -3.80</td>
<td>LB -1.0</td>
<td>Placebo - 1.0</td>
<td>P=0.18</td>
<td>DF25</td>
<td>T(1.1.92) Tc=2.06.</td>
</tr>
</tbody>
</table>

Table 23 Planned analysis 1 NPI, CMAI and QoL-AD outcome
<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Combined Treatment</th>
<th>p value</th>
<th>DF</th>
<th>F value</th>
<th>F critical</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPI Total Score</td>
<td>-7.65</td>
<td>-8.49</td>
<td>0.66</td>
<td>DF47</td>
<td>(1, 0.20)</td>
<td>4.05</td>
</tr>
<tr>
<td>AMB</td>
<td>-1.03</td>
<td>0.06</td>
<td>0.55</td>
<td>DF47.04</td>
<td>(1, 0.30)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>AA</td>
<td>-1.22</td>
<td>-2.88</td>
<td>0.27</td>
<td>DF46.91</td>
<td>(1, 1.23)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>Anxiety</td>
<td>-2.88</td>
<td>-0.57</td>
<td>0.09</td>
<td>DF46.75</td>
<td>(1, 3.07)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>Delusion</td>
<td>-0.9</td>
<td>-0.38</td>
<td>0.57</td>
<td>DF47.00</td>
<td>(1, 0.33)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>Depression</td>
<td>-1.0</td>
<td>-2.80</td>
<td>0.15</td>
<td>DF46.96</td>
<td>(1, 2.20)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>Irritability</td>
<td>-1.67</td>
<td>-1.59</td>
<td>0.91</td>
<td>DF45.73</td>
<td>(1, 0.13)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>Sleep disturbance</td>
<td>-0.35</td>
<td>-0.81</td>
<td>0.61</td>
<td>DF45.83</td>
<td>(1, 0.26)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>CMAI total score</td>
<td>-3.79</td>
<td>-5.37</td>
<td>0.48</td>
<td>DF46.97</td>
<td>(1, 0.51)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>CMAI PAB</td>
<td>-0.48</td>
<td>-1.59</td>
<td>0.26</td>
<td>DF47.03</td>
<td>(1, 1.29)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>CMAI PANB*</td>
<td>0.37</td>
<td>-1.38</td>
<td>0.02*</td>
<td>DF47</td>
<td>(1,6.38)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>CMAI PANB post hoc</td>
<td>LAV 1.26</td>
<td>LB -0.05</td>
<td>Placebo</td>
<td>0.02*</td>
<td>DF124</td>
<td>T(15.49)</td>
</tr>
<tr>
<td>(residents with dementia)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tc=1.98</td>
</tr>
<tr>
<td>CMAI PANB post hoc</td>
<td>LAV 0.6</td>
<td>LB -1.7</td>
<td>Placebo</td>
<td>0.07</td>
<td>DF29</td>
<td>T(13.63)</td>
</tr>
<tr>
<td>(residents without dementia)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tc=2.05</td>
</tr>
<tr>
<td>CMAI VB</td>
<td>-1.46</td>
<td>-3.3</td>
<td>0.24</td>
<td>DF47</td>
<td>(1, 0.06)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>QoL-AD</td>
<td>-1.67</td>
<td>-1.06</td>
<td>0.86</td>
<td>DF36.20</td>
<td>F1, 0.03</td>
<td>Fc=4.11,</td>
</tr>
</tbody>
</table>

Table 24 Planned Analysis 2 NPI, CMAI and QoL-AD outcomes

<table>
<thead>
<tr>
<th></th>
<th>Lemon Balm</th>
<th>Lavender</th>
<th>p value</th>
<th>DF</th>
<th>F value</th>
<th>F critical</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPI Total Score</td>
<td>-10.93</td>
<td>-6.06</td>
<td>0.46</td>
<td>DF45</td>
<td>(1, 0.58)</td>
<td>Fc=4.06</td>
</tr>
<tr>
<td>AMB</td>
<td>-0.75</td>
<td>0.17</td>
<td>0.49</td>
<td>DF46.99</td>
<td>(1, 0.49)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>AA</td>
<td>-3.44</td>
<td>-2.31</td>
<td>0.53</td>
<td>DF46.92</td>
<td>(1, 0.41)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>Anxiety</td>
<td>-1.68</td>
<td>-0.54</td>
<td>0.15</td>
<td>DF46.80</td>
<td>(1, 2.17)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>Delusion</td>
<td>-0.2</td>
<td>-0.56</td>
<td>0.73</td>
<td>DF46.70</td>
<td>(1, 0.12)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>Depression</td>
<td>-2.45</td>
<td>-3.48</td>
<td>0.50</td>
<td>DF46.67</td>
<td>(1, 0.45)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>Irritability</td>
<td>-1.29</td>
<td>-1.74</td>
<td>0.76</td>
<td>DF37.56</td>
<td>(1,0.10)</td>
<td>Fc=4.10</td>
</tr>
<tr>
<td>Sleep disturbance</td>
<td>-0.28</td>
<td>-0.95</td>
<td>0.47</td>
<td>DF44.81</td>
<td>(1,0.53)</td>
<td>Fc=4.06</td>
</tr>
<tr>
<td>CMAI total score</td>
<td>-7.12</td>
<td>-3.62</td>
<td>0.23</td>
<td>DF46.72</td>
<td>(1,1.48)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>CMAI PAB</td>
<td>-1.51</td>
<td>-1.67</td>
<td>0.86</td>
<td>DF46.32</td>
<td>(1,0.03)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>CMAI PANB</td>
<td>-1.8</td>
<td>-0.96</td>
<td>0.44</td>
<td>DF47</td>
<td>(1,0.61)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>CMAI VB</td>
<td>-4.04</td>
<td>-2.6</td>
<td>0.22</td>
<td>DF47</td>
<td>(1,0.05)</td>
<td>Fc=4.05</td>
</tr>
<tr>
<td>QoL-AD</td>
<td>-0.56</td>
<td>-1.5</td>
<td>0.83</td>
<td>DF37.04</td>
<td>(1,0.05)</td>
<td>Fc= 4.11,</td>
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</table>

Table 25 Planned Analysis 3 NPI, CMAI and QoL-AD outcomes
<table>
<thead>
<tr>
<th>Measurement Tool</th>
<th>Dementia</th>
<th>No Dementia</th>
<th>DF</th>
<th>Tc</th>
<th>Fc</th>
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<tbody>
<tr>
<td>NPI Total Score*</td>
<td>-8.9</td>
<td>-2.03</td>
<td>4</td>
<td>1.39</td>
<td>4.05</td>
</tr>
<tr>
<td>NPI post hoc (residents with dementia)</td>
<td>LB -2.03</td>
<td>LAV -5.33 Placebo -4.95</td>
<td>11</td>
<td>1.98</td>
<td>4.05</td>
</tr>
<tr>
<td>NPI Post hoc* (residents without dementia)</td>
<td>LB -8.9</td>
<td>LAV -1.8 Placebo -2.7</td>
<td>35</td>
<td>2.03</td>
<td>4.05</td>
</tr>
<tr>
<td>AA</td>
<td>-2.8</td>
<td>-0.64</td>
<td>4</td>
<td>0.7</td>
<td>4.05</td>
</tr>
<tr>
<td>AMB</td>
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<td>-0.15</td>
<td>4</td>
<td>0.61</td>
<td>4.05</td>
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<tr>
<td>Anxiety</td>
<td>-1.4</td>
<td>-1.68</td>
<td>4</td>
<td>0.20</td>
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<tr>
<td>Delusion</td>
<td>0.00</td>
<td>-0.2</td>
<td>4</td>
<td>0.73</td>
<td>4.05</td>
</tr>
<tr>
<td>Depression</td>
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<td>-0.95</td>
<td>4</td>
<td>0.79</td>
<td>4.05</td>
</tr>
<tr>
<td>Irritability*</td>
<td>-1.6</td>
<td>0.31</td>
<td>4</td>
<td>0.02</td>
<td>4.11</td>
</tr>
<tr>
<td>Irritability* (residents with dementia)</td>
<td>LAV -1.64</td>
<td>LB 0.31 Placebo -0.77</td>
<td>11</td>
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<td>4.05</td>
</tr>
<tr>
<td>Irritability* (residents without dementia)</td>
<td>LAV 0.1</td>
<td>LB -1.6 Placebo -0.9</td>
<td>11</td>
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<td>4.05</td>
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<tr>
<td>Sleep disturbance</td>
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<td>-0.28</td>
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<td>0.94</td>
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<td>-1.62</td>
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<td>0.05</td>
<td>4.05</td>
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<td>CMAI Post hoc* (residents with dementia)</td>
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<td>-1.64</td>
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<td>4.05</td>
</tr>
<tr>
<td>CMAI Post hoc* (residents without dementia)</td>
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<td>-0.8</td>
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<td>0.08</td>
<td>4.05</td>
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<td>CMAI PAB</td>
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<td>-0.51</td>
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<td>0.70</td>
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<td>CMAI PNAB*</td>
<td>-1.7</td>
<td>-0.10</td>
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<td>0.02</td>
<td>4.05</td>
</tr>
<tr>
<td>CMAI PNAB* (residents without dementia)</td>
<td>LAV 0.3</td>
<td>LB -1.7 Placebo 0.6</td>
<td>11</td>
<td>2.05</td>
<td>4.05</td>
</tr>
<tr>
<td>CMAI PNAB* (residents with dementia)</td>
<td>LAV -1.26</td>
<td>LB -0.1 Placebo -0.23</td>
<td>11</td>
<td>1.98</td>
<td>4.05</td>
</tr>
<tr>
<td>CMAI VB</td>
<td>-2.8</td>
<td>-1.24</td>
<td>4</td>
<td>0.07</td>
<td>4.05</td>
</tr>
<tr>
<td>QoL-AD</td>
<td>-1.0</td>
<td>0.44</td>
<td>4</td>
<td>0.15</td>
<td>4.11</td>
</tr>
</tbody>
</table>

Table 26 Planned Analysis 4 NPI, CMAI and QoL-AD outcomes

The following section provides a detailed report of the planned and post hoc analysis for the NPI, CMAI and QoL-AD measures. The four planned analysis are reported for each measurement tool as a total score, as well as each CMAI behaviour domain and the seven
NPI domains that are reported in this study. The four planned analysis are reported as PP, with post hoc and graphs included analysis with significant findings.

6.3 **Neuropsychiatric inventory [NPI]**

This section reports the findings of the observable agitated behaviours measured on the NPI. Behaviours were observed and recorded by nursing staff in conjunction with the researcher on the NPI measurement tool. Data were collected before and after the three treatment periods, a total of six data collections occasions were observed for each resident. Data were entered into statistical software SPSS v23 for analysis using Analysis of Variance [ANOVA] for planned analyses and T-test for post hoc analyses. Statistically, significant findings in the data sets include an opposite effect of Lavender to Lemon Balm essential oils in residents without dementia when compared to residents with dementia on NPI total behaviour score. This unexpected result from the planned analysis required a detailed post hoc analysis to describe the full set of findings from the clinical study. A post hoc analysis of effect between dementia and without dementia groups follows the planned analysis of statistically significant findings. Reported is the total NPI score, and seven NPI behaviour categories of aberrant motor behaviour, agitation/aggression, anxiety, delusion, depression, irritability and sleep disturbance.

6.3.1 **NPI Total Score**

This section provides the four planned analyses and relevant post hoc analyses for the NPI total score. The NPI total score consists of a combined tally of the seven associated behaviour categories of aberrant motor behaviour, agitation/aggression, anxiety, delusion, depression, irritability and sleep disturbance. The NPI total score reports frequency and severity of agitated behaviours in older adults.
**NPI Total Score Planned Analysis 1**

The NPI total score analysis confirmed no significant change between baseline and follow up in dementia (-12.31) compared to the without dementia (-12.33) group P=0.85 DF47 F(1, 0.04) Fc=4.05. This result reports no significance difference in the NPI score between the dementia and without dementia groups. Findings indicate NPI total score to be similar for the with and without dementia resident groups in this study independent of essential oil treatment.

**NPI Total Score Planned Analysis 2**

The analysis reported no significant change in NPI total score between baseline and follow up when residents received placebo (-7.65) compared to treatment (-8.49), P=0.66 DF47 F(1, 0.20) Fc=4.05. The finding indicates that the essential oils did not improve NPI total score for residents in this study independent of cognitive status.

**NPI Total Score Planned Analysis 3**

Analysis confirmed no significant difference in NPI total score change between baseline and follow up when residents received Lavender (-6.06) compared to Lemon Balm (-10.93) treatment P=0.46 DF54 F(1, 0.58) Fc=4.05. The change in NPI total score was similar for residents receiving Lavender when compared to Lemon Balm. This result indicates that the essential oil were comparable in effect on the NPI total score in this study independent of cognitive status.

**NPI Total Score Planned Analysis 4**

Statistical analysis of the data set confirmed a statistically significant difference in NPI total score from baseline to treatment evaluation, between the Lemon Balm treatment effects in the dementia group compared to the without dementia group see Figure 3. NPI total score between baseline and follow up was reduced in residents with without
dementia who experienced Lemon Balm treatment -8.9 relative to the dementia group -2.03, whereas Lavender decreased NPI total score between baseline and follow up in the dementia group -5.33 relative to the without dementia group -0.73. Statistical analysis of the NPI total score confirmed a significant interaction between the groups $P=0.04$, $DF_{47} F(1, 4.39) Fc=4.05$. This result indicates Lemon Balm may effect NPI behaviours differently in people without dementia when compared to residents with dementia.

![Effect of Lavender when compared to Lemon Balm in the cognitive groups on NPI total score](image)

**Figure 3** Effect of Lavender when compared to Lemon Balm in the cognitive groups on NPI total score.

### 6.3.1.1 NPI Total Score Post hoc analysis

A focused post hoc analysis was undertaken to separate essential oils and resident groups to determine the cause of the significant effect in planned analysis 4. The planned analysis 4 evaluated change between baseline and treatment effect of Lavender and Lemon Balm in the with and without dementia groups.

A statistically significant effect was confirmed in the post hoc analysis for Lemon Balm compared to Lavender and placebo in the without dementia groups see Figure 4. Within the planned analysis 4 change in NPI total score between baseline and follow up for Lemon Balm was -8.9 compared to Lavender -1.8 and placebo -2.7. Statistical analysis reported a significant effect by Lemon Balm when compared to Lavender and placebo groups $P=0.01 DF27 T(1,7.04) Tc=2.03$. No significant effect was reported between the
Lavender and placebo groups $P=0.76$ DF 27 $T(1,0.09)$ $T_c=2.03$. This result indicates that Lemon Balm may reduce agitation in people without dementia.

\[ \text{Treatment effect for NPI total score in residents without Dementia} \]

There was no significant effect in a post hoc analysis for Lavender (-5.33) compared to Lemon Balm (-2.03) and placebo (-4.95) in the dementia groups $P=0.08$ DF(1,114) $T(1,3.0)$ $T_c=1.98$. There was also no significant effect between Lemon Balm and placebo groups $P=0.94$ DF(1,125) $T(1,0.01)$ $T_c=1.98$. Demonstrating that in this study, neither Lemon Balm or Lavender were more effective that the placebo on NPI behaviours in people with dementia.

### 6.3.2 NPI Aberrant Motor Behaviour

This section reports the four planned analyses for the NPI aberrant motor behaviour category. Aberrant motor behaviours were recorded as present if the older person was observed pacing, performing repetitive actions, repeatedly picking at things or winding imaginary string or thread. The NPI measure tallied frequency and severity of aberrant motor behaviour in older adults.
**NPI Aberrant Motor Behaviour Planned Analysis 1**

The NPI aberrant motor behaviour analysis confirmed no significant change between baseline and follow up in dementia (-0.44) compared to the without dementia (-1.1) group $P=0.67$ $DF47$ $F(1, 0.18)$ $Fc= 4.05$. This result reports no significance difference in NPI aberrant motor behaviour score between the dementia and without dementia groups. Findings indicate aberrant motor behaviour score to be similar for the with and without dementia groups in this study independent of essential oil treatment.

**NPI Aberrant Motor Behaviour Planned Analysis 2**

The analysis reported no significant change in NPI aberrant motor behaviour score between baseline and follow up when residents received placebo (-1.03) compared to the treatment (-0.06), $P=0.55$ $DF47.04$ $F(1, 0.30)$ $Fc=4.05$. This result indicates that the essential oils did not improve NPI aberrant motor behaviour in this study independent of resident’s cognitive status.

**NPI Aberrant Motor Behaviour Planned Analysis 3**

Analysis confirmed no significant change in NPI aberrant motor behaviour score between baseline and follow up when residents received Lavender (0.17) compared to Lemon Balm (-0.75) treatment $P=0.49$ $DF46.99$ $F(1,0.49)$ $Fc=4.05$. The change in NPI aberrant motor behaviour was similar for residents receiving Lavender when compared to Lemon Balm. This result indicates that the essential oil were comparable in effect on the NPI aberrant motor behaviour in this study independent of cognitive status.
NPI Aberrant Motor Behaviour Planned Analysis 4

Statistical analysis confirmed no significant change in NPI aberrant motor behaviour score between baseline and follow up in the Lavender and Lemon Balm interventions. Within the analysis the change in NPI aberrant motor behaviour score between baseline and follow up for residents in the without dementia group receiving Lemon Balm scored -0.60 relative to its effect in the dementia group -0.15, where as those in the dementia group receiving Lavender scored -0.03 relative to the without dementia group 0.2. Analysis confirmed the groups did not significantly differ in NPI aberrant motor behaviour score between baseline and follow up P=0.61 DF46.99 F(1, 0.26) Fc=4.05. The change in NPI aberrant motor behaviour score was similar for residents receiving Lavender or Lemon Balm intervention indicating no significant interaction between essential oils and cognitive status on NPI aberrant motor behaviour.

6.3.3 NPI Agitation/Aggression

This section reports the four planned analysis for the NPI agitation/aggression behaviour category. Agitation/aggression behaviours were recorded as present if the older person demonstrated physical or verbal behaviour that was uncooperative, resistive or threatening. The NPI measure tallied frequency and severity of agitation/aggression in older adults.

NPI Agitation/Aggression Planned Analysis 1

The NPI agitation/aggression confirmed no significant change in the score between baseline and follow up in the dementia (-4.07) compared to the without dementia (-2.9) groups P=0.53 DF46.9 F (1, 0.39) Fc=4.05. This result reports no significant difference in NPI agitation/aggression score between the dementia and without dementia groups. Findings indicate agitation/aggression score to be similar for the with and without dementia resident groups in this study independent of essential oil treatment. NPI Agitation/aggression Planned Analysis 2
The analysis reported no significant change in NPI agitation/aggression score between baseline and follow up when residents received placebo (-1.22) compared to treatment (-2.88), P=0.27 DF46.91 F(1,1.23) Fc=4.05. The finding indicates that the essential oils did not improve agitation/aggression in this study independent of resident's cognitive status.

**NPI Agitation/aggression Planned Analysis 3**

Analysis confirmed no significant change in NPI agitation/aggression scores between baseline and follow up when residents received Lavender (-2.31) compared with Lemon Balm (-3.44) treatment P=0.53 DF46.92 F(1, 0.41) Fc=4.05. The change in NPI agitation/aggression score was similar for residents receiving Lavender when compared to Lemon Balm. This result indicates that the essential oil treatments were comparable in effect on the agitation/aggression in this study independent of cognitive status.

**NPI Agitation/aggression Planned Analysis 4**

Statistical analysis confirmed no significant change in NPI agitation aggression score between baseline and follow up in the Lavender and Lemon Balm interventions. Within the analysis the change in NPI agitation/aggression score between baseline and follow up for residents in the without dementia group receiving Lemon Balm scored -2.8 relative to its effect in the dementia group -0.64, where as those in the dementia group receiving Lavender scored -1.71 relative to the without dementia group -0.6. Analysis confirmed the groups did not significantly differ in NPI agitation/aggression score between baseline and follow up P=0.07 DF46.92 F(1, 3.40) Fc=4.05. The change in NPI agitation/aggression score was similar for residents receiving Lavender or Lemon Balm intervention indicating no significant interaction between essential oils and cognitive status on NPI agitation/aggression.
6.3.4 NPI Anxiety

This section reports the four planned analysis for the NPI anxiety behaviour category. Anxiety was recorded as present if the older person was observed to be nervous, anxious or frightened for no apparent reason. Anxiety was also recorded if the older person appeared tense or shaky. The NPI measure tallied frequency and severity of anxiety in older adults.

NPI Anxiety Planned Analysis 1

The NPI anxiety analysis confirmed no significant change between baseline and follow up in the dementia (-1.62) compared to the without dementia (-2.4) group P=0.62 DF46.66 F(1, 0.24) Fc= 4.05. This result reports no significant difference in anxiety score between the with and without dementia groups. Findings indicate anxiety score to be similar for the with and without dementia resident groups in this study independent of essential oil treatment.

NPI Anxiety Planned Analysis 2

The analysis reported no significant change in NPI anxiety score between baseline and follow up when residents received placebo (-2.88) or treatment (-0.57), P=0.09 DF47 F(1, 0.33) Fc=4.05. The finding indicates that the essential oils did not improve NPI anxiety for residents in this study independent of cognitive status.

NPI Anxiety Planned Analysis 3

Analysis confirmed no significant change in NPI anxiety score between baseline and follow up when residents received Lavender (-0.54) compared to Lemon Balm (-1.68) treatment P=0.27 DF46.8 F(1, 2.17) Fc=4.05. The change in NPI anxiety score was similar for residents receiving Lavender when compared to Lemon Balm. This result indicates that the essential oil treatments were comparable in effect on the NPI anxiety score independent of cognitive status.
**NPI Anxiety Planned Analysis 4**

Statistical analysis confirmed no significant change in NPI anxiety score between baseline and follow up in the Lavender and Lemon Balm interventions. Within the analysis the change in NPI anxiety score between baseline and follow up for residents that received Lemon Balm in the without dementia group is -1.4 relative to its effect in the dementia group -1.68 while those receiving Lavender in the dementia group scored -0.54 relative to the without dementia group 0.00. Analysis confirmed the groups did not significantly differ in the NPI anxiety score between baseline and follow up P=0.20 DF46.80 F(1, 0.90) Fc=4.05. The change in NPI anxiety score was similar for residents receiving Lavender or Lemon Balm indicating between essential oils have no significant effect on cognitive status on NPI anxiety.

### 6.3.5 NPI Delusion

This section presents the four planned analyses for the NPI delusion behaviour category. Delusions were recorded as present if the older person had beliefs, which were known to be untrue, insisted that people were trying to harm them, steal from them or claimed that people were not who they said they were. Delusion behaviour was marked as present if the resident was convinced that these things were happening to them. The NPI measure tallied frequency and severity of delusion in older adults.

**NPI Delusion Planned Analysis 1**

The NPI Delusion analysis confirmed no significant change in the score between baseline and follow up in dementia (-1.46) compared to the without dementia (-0.2) group P=0.35 DF46.91 F(1, 0.90) Fc=4.05. This result reports there was no significant difference in delusion between the with and without dementia groups. Findings indicate delusion score to be similar for the with and without dementia resident groups in this study independent of essential oil treatment.
**NPI Delusion Planned Analysis 2**

The analysis confirmed no significant change in NPI delusion score between baseline and follow up when the placebo (-0.9) was compared to treatment (-0.38), $P=0.57$ DF47 F(1, 0.33) Fc=4.05. The finding indicates that the essential oils did not improve NPI delusion independent of cognitive status in this study.

**NPI Delusion Planned Analysis 3**

Analysis confirmed no significant change in NPI delusion score between baseline and follow up when residents received Lavender (-0.56) compared to Lemon Balm (-0.2) intervention $P=0.73$ DF46.7 F(1, 0.12) Fc=4.05. The change in NPI delusion score was similar for residents receiving Lavender when compared to Lemon Balm. This result indicates that the essential oil treatments were comparable in effect on the NPI delusion score independent of cognitive status in this study.

**NPI Delusion Planned Analysis 4**

Statistical analysis confirmed no significant change in NPI delusion score between baseline and follow up in the Lavender and Lemon Balm interventions. Within the analysis the change in NPI delusion score between baseline and follow up for residents that experienced Lemon Balm in the without dementia group is 0.00 relative to its effect in the dementia group -0.2, where as Lavender in the dementia group scored -0.54 relative to the without dementia group 0.7. Analysis confirmed the groups did not significantly differ in the NPI delusion score between baseline and follow up $P=0.94$ DF=53.84 (1, 0.00) Fc=4.02. The change in NPI delusion was similar for residents in the Lavender or Lemon Balm intervention indicating that essential oils have no significant effect on cognitive status.
NPI Depression

This section presents the four planned analysis for the NPI depression behaviour category. Depression was recorded as present if the resident voiced they were sad or depressed, or was observed to be crying or sad. The NPI measure tallied frequency and severity of depression in older adults.

NPI Depression Planned Analysis 1

The NPI depression analysis confirmed no significant change in score between baseline and follow up in dementia (-3.52) compared to the without dementia (-3.4) group P=0.96 DF46.90 F(1,0.00) FC=4.05. This result indicates there was no significant difference in NPI depression score between the dementia and without dementia groups. Findings indicate NPI total score to be similar for the with and without dementia resident groups in this study independent of essential oil treatment.

NPI Depression Planned Analysis 2

The analysis reported no significant change in NPI depression score between baseline and follow up when residents received placebo (-1.0) compared to treatment (-2.8), P=0.15 DF46.96 F(1,2.20) FC=4.05. The finding indicates that the essential oils did not improve NPI depression for residents in this study independent of cognitive status.

NPI Depression Planned Analysis 3

Analysis confirmed no significant change in NPI depression score between baseline and follow up when residents received Lavender (-3.48) compared to Lemon Balm (-2.45) treatment P=0.48 DF46.67 F(1,0.45) FC=4.05. The change in NPI depression score was similar for residents receiving Lavender when compared to Lemon Balm. This result indicates the essential oil treatments were comparable in effect on NPI depression independent of cognitive status in this study.
NPI Depression Planned Analysis 4

Statistical analysis confirmed no significant change in NPI depression score between baseline and follow up in the Lavender and Lemon Balm interventions. Within the analysis the change in NPI depression score between baseline and follow up for residents that experienced Lemon Balm in the without dementia group is -1.5 relative to its effect in the dementia group -0.95, where as Lavender in the dementia group scored -1.68 relative to the without dementia group -1.8. Analysis confirmed the groups did not significantly differ in the NPI depression score between baseline and follow up \( P=0.79 \) DF46.67 \( F=(1, 0.07) \) \( Fc=4.05 \). The change in NPI depression score was similar for residents in the Lavender or Lemon Balm intervention indicating that essential oils have no significant effect on cognitive status.

6.3.6 NPI Irritability

This section presents the four planned analyses and relevant post hoc analyses for the NPI irritability behaviour category. Irritability was marked as present if the resident tended to be easily disturbed with resultant anger or argumentative behaviour. Irritability was also recorded if carers perceived the resident to be impatient or displaying rapid mood changes contrary to their usual behaviour. The NPI measure tallied frequency and severity of irritability in older adults.

NPI Irritability Planned Analysis 1

The NPI irritability analysis confirmed no significant change in score between baseline and to follow-up in dementia (-4.70) when compared to the without dementia (-2.4) group \( P=0.99 \) DF42.80 \( F(1, 0.00) \) \( Fc=4.07 \). This result reports no significant difference in irritability between the dementia and without dementia groups. Findings indicate irritability score to be similar for the with and without dementia resident groups in this study independent of essential oil treatment.
NPI Irritability Planned Analysis 2

The analysis reported no significant change in NPI irritability score between baseline and follow-up when residents received placebo (-1.67) compared to treatment (-1.59), P=0.91 DF45.73 F(1, 0.13) Fc=4.05. The finding indicates that the essential oils did not improve NPI irritability for residents independent of cognitive status in this study.

NPI Irritability Planned Analysis 3

Analysis confirmed no significant difference in NPI irritability scores between baseline and follow-up for residents receiving Lavender (-1.74) when compared to Lemon Balm (-1.29) treatment P=0.76 DF37.56, F(1,0.10) Fc=4.10. The change in NPI irritability was similar for residents receiving Lavender when compared to Lemon Balm. This result indicates the essential oils to be comparable in effect on NPI irritability independent of cognitive status in this study.

NPI Irritability Planned Analysis 4

Statistical analysis of the data set confirmed a statistically significant difference in NPI irritability score between baseline treatment evaluation, between the Lemon Balm treatment effects in the dementia group compared to the without dementia group see Figure 5. NPI irritability score between baseline and follow up was reduced in residents without dementia who received Lemon Balm treatment -1.6 relative to the dementia group 0.31, where as Lavender decreased NPI irritability score between baseline and follow up in the dementia group -1.84 compared to the without dementia group -0.01. Statistical analysis of the NPI irritability score confirmed a significant interaction between the groups P=0.02 DF37.56 F(1, 5.65) Fc=4.11. This result indicates that the essential oil treatments may effect irritability differently in residents without dementia when compared to residents with dementia.
A focused post hoc analysis was undertaken to separate essential oils and resident groups to determine the cause of the significant effect in planned analysis 4. The planned analysis 4 evaluated change between baseline and treatment effect of Lavender and Lemon Balm in the with and without dementia groups.

A statistically significant effect Lemon Balm was confirmed in the post hoc analysis when compared to Lavender and placebo in the dementia group see Figure 6. Within the planned analysis 4, change in NPI total score between baseline and follow up in Lemon Balm was 0.31, Lavender -1.84 and placebo -0.77. A statistically significant effect was reported for Lemon Balm compared to Lavender and placebo P=0.01 DF113 T(1,7.75) Tc=1.98. No significant effect was found in the difference between Lavender and Placebo groups P=0.11 DF113 T(1,1.60) Tc=1.98. This result suggests Lemon Balm maybe less effective than Lavender or placebo in reducing irritability in people with dementia. Indicating that residents with dementia experienced less agitation when Lavender treatment was administered compared to Lemon Balm.
There was no significant effect in a post hoc analysis for Lemon Balm (-1.16) compared to Lavender (-0.1) and placebo (-0.9) in the without dementia groups $P=0.20$ DF(1,27) $T(1.175)$ $T_c=2.05$. There was also no significant effect between Lavender and the placebo group $P=0.35$ DF(1,27) $T(1,0.91)$ $T_c=2.05$. Demonstrating that in this study, neither Lemon Balm or Lavender were more effective than the placebo on NPI irritability in residents without dementia.

**NPI Sleep Disturbance**

This section reports the four planned analysis for the NPI sleep disturbance behaviour category. Sleep disturbance was recorded if the older person had difficulty sleeping apart from getting up and going to the bathroom. Sleep disturbance was also recorded if the older person was up at night, wandered during the night, got dressed or disturbed others sleeping. The NPI measure tallied frequency and severity of sleep disturbance in older persons.

**NPI Sleep Disturbance Planned Analysis 1**

The NPI sleep disturbance analysis confirmed no significant change in the NPI score between baseline and follow-up in dementia (-1.09) compared to the without dementia.
(-0.5) group P=0.57 DF46.12 F(1,0.33) Fc=4.05. This result reports no significant difference in sleep disturbance between the dementia and without dementia groups. Findings indicate NPI irritability to be similar for the with and without dementia groups in this study independent of essential oil treatment.

**NPI Sleep Disturbance Planned Analysis 2**

The analysis reported no significant change in NPI sleep disturbance score between baseline and follow-up when residents received placebo (-0.35) compared to treatment (-0.81), P=0.61 DF45.83 F(1,0.26) Fc=4.05. The finding indicates that the essential oils did not improve NPI sleep disturbance for residents independent of cognitive status in this study.

**NPI Sleep Disturbances Planned Analysis 3**

Analysis confirmed no significant change in NPI sleep disturbance score between baseline and follow-up for residents receiving Lavender (-0.95) when compared to Lemon Balm (-0.28) treatment P=0.47 DF44.81 F(1,0.53) Fc=4.06. The change in NPI total score was similar for residents receiving Lavender when compared to Lemon Balm. This result indicates that the essential oil treatments were comparable in effect on the NPI sleep disturbance in this study independent of cognitive status.

**NPI Sleep Disturbances Planned Analysis 4**

There was no significant change in NPI sleep disturbance score between baseline and follow-up for residents receiving Lavender or Lemon Balm in either the dementia or without dementia groups. The change in NPI sleep disturbance score between baseline and follow-up for residents receiving Lemon Balm in the without dementia group was 0.00 compared to the dementia group of -0.28 where as residents in the dementia group receiving Lavender scored -0.66 compared to the score for the without dementia group of -0.30. There was no statistically significance difference between the groups P=0.94
DF44.81 F(1, 0.01) Fc=4.06. The change in NPI sleep disturbance was similar for residents in the Lavender or intervention indicating that the essential oils had no significant effect on the cognitive status on NPI sleep disturbance.

### 6.4 Cohen Mansfield Agitation Inventory (CMAI)

This section reports the findings of the observable agitation behaviours measured on the Cohen Mansfield Agitation Inventory (CMAI). Behaviours were observed and recorded by nursing staff in conjunction with the researcher on the CMAI measurement tool. Data were collected before and after the three treatment periods, with a total of six data collections were attended for each resident. As described in Chapter 4 Methods, the CMAI monitors twenty-nine behaviours, frequency is recorded numerically with a 1 score being never to a 5 score representing several times within the hour. Data were entered into statistical software SPSS version 23 for analyses using Analysis of Variance (ANOVA) for planned analyses and T-test for post hoc analysis. Statistically significant findings include an opposite effect of Lavender and Lemon Balm essential oils in residents with without dementia when compared to residents with dementia on CMAI total score. There was also a significant difference for PNAB score in the treatment groups when compared to placebo. A post hoc analysis of effect in dementia and without dementia groups follows the planned analysis of statistically significant findings. Reported is the CMAI total score and the three CMAI behaviour categories of physical aggressive behaviour, physical non-aggressive behaviour and verbal agitation.

#### 6.4.1 CMAI Total Score

This section presents the four planned analyses and relevant post hoc analyses for the CMAI total score. As described in Chapter 4 Methods, the CMAI total score reports the combined score tally for the three CMAI categories of physical aggressive behaviour, physical non-aggressive behaviour and verbal agitation. The CMAI total score reports frequency of agitated behaviours in older adults.
**CMAI Total Score Planned Analysis 1**

The CMAI total score analysis confirmed no significant change between baseline and follow-up in dementia (-6.03) compared to the without dementia (-8.5) group $P=0.45$ DF46.99 F(1,0.57), Fc=4.05. This result indicates no significant difference in CMAI agitation between the dementia and without dementia groups. Findings indicate CMAI total score to be similar for the with and without dementia resident groups in this study independent of essential oil treatment.

**CMAI Total Score Planned Analysis 2**

The analysis reported no significant change in CMAI total score between baseline and follow-up when residents received placebo (-3.79) compared to treatment (-5.37), $P=0.48$ DF46.97 F(1,0.51) Fc=4.05. The finding indicates that the essential oils did not improve CMAI total score in residents independent of cognitive status in this study.

**CMAI Total Score Planned Analysis 3**

Analysis confirmed no significant change in CMAI total score between baseline and follow-up when residents received Lavender (-3.62) compared to Lemon Balm (-7.12) treatment ($P=0.23$ DF46.72 F(1,1.48) Fc=4.05). The change in CMAI total score was similar for residents receiving Lavender when compared to Lemon Balm. This result indicates that the essential oil treatments had a comparable effect on CMAI total score independent of cognitive status in this study.

**CMAI Total Score Planned Analysis 4**

There was a statistically significant change in CMAI total score between baseline and follow-up in the Lavender and Lemon Balm interventions see Figure 7. Within the analysis the CMAI total score between baseline and follow-up for residents receiving Lemon Balm in the without dementia group was -5.5 compared to its effect in the dementia group of -1.62, where as residents receiving Lavender in the dementia group scored -2.82 compared to the without dementia group that scored -0.8 ($P=0.05$ DF46.72
F(1,4.19) Fc=4.05. This result suggests that Lemon Balm may affect CMAI behaviours differently in residents with dementia compared to those who do not have dementia.

**Figure 7 Effect of Lavender when compared to Lemon Balm in the cognitive groups on CMAI Total Score**

**CMAI Total Score Post hoc analyses**

A focused post hoc analysis was undertaken to separate essential oils and resident groups to determine the cause of the significant effect in planned analysis 4 between baseline and treatment effect of Lavender and Lemon Balm in the dementia and without dementia groups.

Analysis confirmed no significant effect in a post hoc analysis by Lemon Balm when compared to Lavender and placebo in the without dementia groups. Within the planned analysis 4 change in CMAI total score between baseline and follow up in Lemon Balm was -5.5, for Lavender -0.8 and placebo -2.2. A statistical analysis reported no significant effect for Lemon Balm when compared to Lavender and placebo P=0.08 DF29 T(1,3.32) Tc=2.05. No significant effect was found in the difference between Lavender and placebo groups P=0.78 DF29 T(1,0.08) Tc=2.05. In this study neither Lemon Balm or Lavender were more effective that the placebo on CMAI behaviours in people with without dementia.
There was no significant effect in a post hoc analysis for Lavender (-2.97) compared to Lemon Balm (-1.64) and placebo (-1.72) in the dementia groups $P=0.14 \ DF(1,125) F=2.02$. There was also no significant effect between Lemon Balm and placebo groups $P=0.94 \ DF(1,125) T(1,0.01) Tc=1.98$. Demonstrating that in this study, neither Lemon Balm or Lavender were more effective that the placebo on CMAI behaviours in people with dementia.

6.4.2 CMAI Physical Aggressive Behaviours

This section presents the four planned analysis for the CMAI physical aggressive behaviour category. Physical aggressive behaviours were recorded if the older person was observed hitting, kicking, pushing, scratching, tearing things, or grabbing, biting and spitting. The CMAI measure tallied frequency of aggressive behaviours in older adults.

CMAI Physical Aggressive Behaviours Planned Analysis 1

The CMAI physical aggressive behaviour analysis confirmed no significant change between baseline and follow up in dementia (-1.86) compared to the without dementia (-1.80) group $P=0.93 \ DF46.80 F(1, 0.01) Fc= 4.05$. This result indicates no significant difference in physically aggressive behaviours between the dementia and without dementia groups independent. Findings indicate CMAI physical aggressive behaviour score to be similar for the with and without dementia resident groups in this study independent of essential oil treatment.

CMAI Physical Aggressive Behaviours Planned Analysis 2

The analysis reported no significant change in CMAI physical aggressive behaviour score between baseline and follow up when residents received placebo (-0.48) compared to treatment (-1.59), $P=0.26 \ DF47.03 \ F(1, 1.29) Fc=4.05$. The finding indicates that the essential oils did not improve CMAI in residents independent of cognitive status in this study.

CMAI Physical Aggressive Behaviours Planned Analysis 3
Analysis confirmed no significant change in CMAI physical aggressive behaviour score between baseline and follow up when residents received Lavender (-1.67) compared with Lemon Balm (-1.51) treatment $P=0.86$ DF46.32 $F(1,0.03) F_c=4.0$. The change in CMAI physical aggressive behaviour score was similar for residents in the Lavender and Lemon Balm. This result indicates that the essential oil treatments were comparable in effect on CMAI physical aggressive behaviours independent of cognitive decline in this study.

**CMAI Physical Aggressive Behaviours Planned Analysis 4**

Analysis confirmed no significant change in CMAI physical aggressive behaviour score between baseline and follow up in the Lavender and Lemon Balm interventions. Within the analysis the change in CMAI physical aggressive behaviour score between baseline and follow up for residents that experienced Lemon Balm in the without dementia group is -1.0 relative to its effect in the dementia group -0.51, where as Lavender in the dementia group scored -0.77 relative to the without dementia group -0.90, confirming the groups did not significantly differ in the CMAI physical aggressive behaviour score between baseline and follow up $P=0.70$ DF46.83 $F(1, 0.15) F_c=4.05$.

### 6.4.3 CMAI Physical Non-Aggressive Behaviour

This section presents the four planned analysis for the CMAI physical non-aggressive behaviour category. Physical non-aggressive behaviours were recorded if the older person was observed pacing, inappropriately robing or disrobing, wandering, handling things inappropriately, general restlessness or repetitious mannerisms. The CMAI measure tallied frequency of physical non-aggressive behaviour in older adults.

**CMAI Physical Non-aggressive Behaviour Planned Analysis 1**

The CMAI physical non-aggressive behaviour analysis confirmed no significant change between baseline and follow up in dementia (-1.59) compared to the without dementia
(-0.80) group P=0.61 DF47 F(1,0.37) Fc=4.05. This result indicates no significant
difference in physical non aggressive behaviours between the dementia and without
dementia groups. Indicating CMAI physical non-aggressive behaviour score to be similar
for the with and without dementia resident groups in this study independent of essential
oil treatment.

**CMAI Physical Non-aggressive Behaviour Planned Analysis 2**

There was a significant difference in the CMAI physical non-aggressive behaviour score
between baseline and follow up in the placebo (0.37) and treatment (-1.38) groups
P=0.02 DF47 F(1, 6.38) Fc=4.5 see Figure 8. This result indicates that essential oils have
a significant reduction on CMAI physical non-aggressive behaviour for people with and
without dementia.

![Figure 8](image)

**CMAI Physical Non-aggressive Behaviour Planned Analysis 3**

Analysis confirmed no significant difference in CMAI physical non-aggressive behaviour
scores between baseline and follow up when residents received Lavender (-0.96)
compared with Lemon Balm (-1.8) treatment (P=0.44 DF47 F(1,0.61) Fc=4.05). The
change in CMAI physical non-aggressive behaviours was similar for residents receiving
Lavender when compared to Lemon Balm. This result indicates that the essential oil
treatments were comparable in effect on CMAI physical non-aggressive agitation independent of cognitive status in this study.

**CMAI Physical Non-aggressive Behaviour Planned Analysis 4**

Statistical analysis of the data set confirmed a statistically significant difference in CMAI physical non aggressive behaviour score between baseline treatment evaluation, between the Lemon Balm treatment effects in the dementia group compared to the without dementia group see Figure 9. CMAI PNAB score between baseline and follow up was reduced in residents without dementia who received Lemon Balm treatment -1.7 relative to the dementia group -0.10, where as Lavender decreased NPI irritability score between baseline and follow up in the dementia group -1.26 compared to the without dementia group 0.03. Statistical analysis of the NPI irritability score confirmed a significant interaction between the groups \( P=0.02 \) DF37.56 \( F(1, 5.65) \) \( Fc=4.11 \). This result indicates that the essential oil treatments may effect irritability differently in residents without dementia when compared to residents with dementia.

![Figure 9 Effect of Lavender when compared to Lemon Balm in cognitive groups on the CMAI PNAB score](image)

**6.4.3.1 CMAI Physical Non-aggressive Behaviour Score Post hoc analysis**

A focused post hoc analysis was undertaken to separate essential oils and resident groups to determine the cause of the significant effect in planned analysis 4. The planned
analysis 4 evaluated change between baseline and treatment effect of Lavender and Lemon Balm in the with and without dementia groups.

A statistically significant effect for Lavender was confirmed in the post hoc analysis when compared to Lemon Balm and placebo in the dementia groups see figure 10. Within the planned analysis 4, change in CMAI physical non-aggressive behaviour between baseline and follow up in Lavender was -1.26, Lemon Balm was -0.1 and placebo -0.23. A statistically significant effect was reported when Lavender was compared to Lemon Balm and placebo P=0.04, DF114 (1, 4.49) Tc=1.98. No significant effect was found in the difference between Lemon Balm and placebo P=1.0 DF114 (1,0.00) Tc=1.98. This finding indicates that residents with dementia experienced less PNAB when Lavender treatment was administered compared to Lemon Balm, Lavender may reduce PNAB in residents with Dementia.

A statistically significant effect for Lemon Balm was confirmed in the post hoc analysis when compared to Lavender and placebo in residents without dementia see figure 11. Within the planned analysis 4, change in CMAI physical aggressive behaviour between baseline and follow up in Lemon Balm was -1.7, Lavender 0.3 and placebo 0.6. A statistically significant effect was reported when Lavender was compared to Lemon
Balm and placebo P=0.02, DF27 (1, 5.84) Tc=2.05. No significant effect was found in the difference between Lemon Balm and placebo P=0.77 DF27 (1,0.29) Tc=2.05. This finding indicates that residents without dementia experienced less physical non-aggressive behaviour when Lemon Balm treatment was administered compared to Lavender, Lemon Balm may reduce physical aggressive behaviour in residents without Dementia.

![Figure 11 Post hoc analysis treatment effect for CMAI Physical non-aggressive behaviour score in residents without Dementia](image)

### 6.4.4 CMAI Verbal Agitation

This section presents the four planned analysis for the CMAI verbal agitation behaviour category. Verbal agitation was recorded as present if the older person was constantly complaining, cursing, requesting attention, verbalising negativity, repetitious questions or screaming. The CMAI measure tallied frequency of verbal agitation in older adults.

**CMAI Verbal Agitation Planned Analysis 1**

The CMAI verbal agitation analysis confirmed no significant change between baseline and follow up in dementia (-3.34) compared to the without dementia (-4.87) groups.
This result reports no significant difference in verbal agitation between the dementia and without dementia groups. Findings indicate CMAI verbal agitation score to be similar for the with and without dementia resident groups in this study independent of essential oil treatment.

**CMAI Verbal Agitation Planned Analysis 2**

The analysis reported no significant change in CMAI verbal agitation score between baseline and follow up when residents received placebo (-1.46) compared to treatment (-3.3), \( P=0.24 \) \( DF=47 \) \( F=4.05 \). The finding indicates that the essential oils did not improve CMAI verbal agitation for residents independent of cognitive status in this study.

**CMAI Verbal Agitation Planned Analysis 3**

Analysis confirmed no significant difference in CMAI verbal agitation scores between baseline and follow up when residents received Lavender (-2.6) compared to Lemon Balm (-4.04) treatment \( P=0.22 \) \( DF=47 \) \( F=4.05 \). The change in CMAI verbal agitation score was similar for residents receiving Lavender when compared to Lemon Balm. This result indicates that the essential oil treatments were comparable in effect on CMAI verbal agitation independent of cognitive status in this study.

**CMAI Verbal Agitation Planned Analysis 4**

Analysis confirmed no significant change in CMAI verbal agitation score between baseline and follow up in the Lavender and Lemon Balm interventions. Within the analysis the change in CMAI verbal agitation score between baseline and follow up for residents that experienced Lemon Balm in the without dementia group is -2.8 compared to its effect in the dementia group -1.24, whereas Lavender in the dementia group scored -1.80 compared to the without dementia group -0.8. The statistical analysis of the dataset confirmed the groups did not significantly differ in the CMAI verbal agitation score.
between baseline and follow up $P=0.07$ DF47 $F(1,3.42)$ $F_c=4.05$. The change in CMAI verbal agitation score was similar for residents receiving both essential oils indicating no significant effect regardless of cognitive status.

### 6.5 Quality of Life – Alzheimer’s Disease [QoL-AD]

This section reports the findings of resident quality of life as measured on the QoL-AD. Data collected was entered into statistical software SPSS Version 23 for analyses using Analysis of Variance [ANOVA] for planned analyses and T-test for post hoc analyses. There was a statistically significant difference in QoL-AD score between the dementia and without dementia groups independent of essential oil treatment, which is not an unexpected finding when comparing people with dementia to those who do not. A post hoc analysis of effect in dementia and without dementia follows the planned analysis of statistically significant findings. Reported are the QoL-AD measures for quality of life in older adults participating in this study.

**QoL-AD Planned Analysis 1**

Analysis confirmed a significant change in the QOL-AD quality of life score between baseline and follow up in the dementia compared to the without dementia group see Figure 12. The analysis, QoL-AD score change between baseline and follow up for the dementia group was 2.02 compared to -5.80 in the without dementia group. Statistical analysis of the data set confirmed there was a significant difference in QoL-AD quality of life score between the dementia and without dementia groups $P=0.03$ DF34.23 $F(1, 5.07) F_c=4.13$. The result indicates that QoL differs significantly for those with dementia and those without independent of intervention effect. Results indicate that residents who have agitation without a dementia diagnosis living in RACFs have a lower QoL than people with dementia who experience agitation.
A focused post hoc analysis was undertaken to separate essential oils and resident groups to determine the cause of the significant effect in planned analysis 1. The planned analysis 1 evaluated change between baseline and follow up effect for quality of life in the dementia group compared to the without dementia group independent of essential oil treatment.

A statistical analysis confirmed no significant effect in a post hoc analysis by Lavender (2.59) when compared to Lemon Balm (0.44) and placebo (-0.66) in the dementia group (P=0.07 DF(1,77) T(1,3.37) Tc=1.99). Likewise, no significant effect was reported in the difference between the Lemon Balm and Placebo groups P=0.47 DF77 T(1,0.53) Tc=1.99. This result suggests that neither Lavender or Lemon Balm improved QoL-AD score in residents without dementia.

Analysis confirmed no significant effect in a post hoc analysis by Lavender (-3.80) when compared to Lemon Balm (-1.0) and placebo (-1.0) in the without dementia group (P=0.18 DF25 T(1,1.92) Tc=2.06). There was also no significant effect between Lemon Balm and Placebo groups P=1.0 DF25 T(1,0.00) Tc= 2.06. This result suggests that
neither Lavender of Lemon Balm improves QoL-AD score in people with without dementia.

**QoL-AD Planned Analysis 2**

Analysis confirmed no significant change in QoL-AD quality of life score between baseline and follow up when residents received placebo (-1.67) compared to treatment (-1.06), \( P=0.86 \) DF36.20 F(1, 0.03) Fc=4.11. The finding indicates that the essential oils did not improve quality of life for residents independent of cognitive status in this study.

**QoL-AD Planned Analysis 3**

Analysis confirmed no significant change in QoL-AD quality of life score between baseline and follow up in the Lavender (-1.5) and Lemon Balm (-0.56) groups (\( P=0.83 \) DF37.04 F(1,0.05) Fc= 4.11), indicating that essential oils had no significant effect on QoL-AD quality of life regardless of cognitive status.

**QoL-AD Planned Analysis 4**

Analysis confirmed no significant change in QoL-AD quality of life score between baseline and follow up in the Lavender and Lemon Balm interventions. Within the analysis the change in QoL-AD quality of life score between baseline and follow up for residents that experienced Lemon Balm in the without dementia group is -1.0 compared to its effect in the dementia group 0.44, where as Lavender in the dementia group scored 2.25 compared to the without dementia group -3.80. The statistical analysis of the dataset confirmed the groups did not significantly differ in the QoL-AD quality of life score between baseline and follow up \( P=0.15 \) DF37 F(1,2.16) Fc=4.11., indicating essential oils did not improve QoL-AD quality of life for residents included in this study.
6.6 Summary

This chapter has presented the results of Phase II of this mixed methods study, a single-blind RCT comparing the effectiveness of Lemon Balm and Lavender to reduce agitation. The characteristics of the 49 residents have been described, and results of the trial of Lemon Balm and Lavender essential oils presented. The four planned analyses have been reported for the measurements NPI and CMAI as total score and for associated behaviour categories. The quality of life results as reported on the QoL-AD have also been presented in this section. The data demonstrated that neither Lavender nor Lemon Balm reduced total agitated behaviour regardless of cognitive decline when compared directly to placebo in this study.

Significant findings have been reported for opposing the effect of Lavender and Lemon Balm interventions between the with and without dementia groups on the NPI and CMAI total score and the domains of NPI irritability and CMAI.

A post hoc analysis indicated Lemon Balm to be significantly more effective in reducing NPI total score compared to placebo and Lavender in the without dementia groups. This result indicates that Lemon Balm may reduce agitation in residents without dementia.

This chapter has reported that Lavender and Lemon Balm interventions to significantly reduce physical non-aggressive behaviour independent of cognitive decline when compared to placebo independent of cognitive groups.

A post hoc reported Lemon Balm to be significantly more effective in reducing CMAI score compared to Lavender and placebo in the without dementia groups. This result indicates Lemon Balm may reduce physical non-aggressive behaviour in residents without dementia.

A posthoc analysis confirmed Lavender significant decrease in CMAI physical non-aggressive behaviour when compared to Lemon Balm and placebo, with no difference
indicated between placebo and Lavender. This result indicates that Lavender may reduce physical non-aggressive behaviours in residents with dementia.

Further, a post hoc analysis has demonstrated Lemon Balm to be significantly less effective in reducing NPI irritability when compared to placebo and Lavender in residents with dementia. This result indicates that Lemon Balm decreases irritability in residents with dementia less than placebo or Lavender.

A final significant difference between with and without dementia groups was reported for Quality of Life. Results indicate that residents without dementia experience a lower quality of life in comparison to residents with dementia independent of essential oil treatment.

The results presented in this chapter will be further explored in conjunction with the qualitative findings from Chapter 5 and 7, in Chapter 8 Discussion of this thesis.
Chapter 7 Phase III Qualitative Findings

7.1 Overview
This chapter reports the findings from semi-structured interviews with 10 nurses conducted following their participation in the RCT reported in Chapter 6. These interviews sort nurses’ perceptions of: (1) Frequency of agitation on the ward; (2) The effectiveness of essential oils as agitation management in older adults; (3) Nurse’s perception and use of essential oils for health conditions, and (4) Factors influencing the conduct of research in the RACF environment. The findings are reported as areas of interest identified from the analysis accompanied by the frequency of occurrence and percentage of data coverage. Areas of interest evidenced by the nurse interview responses were change in frequency of agitation; effectiveness of essential oils for agitation; nurse use of essential oils, and influencing factors that support research. All areas of interest are supported by response categories and subcategories with quotes from the nurse interviews.

7.2 Data Collection and Analysis
Data were collected through individual interviews and analysed using the content analysis process detailed in Chapter 4 of this thesis. The processes of data collection and analysis including the interviewing process, transcription of data, verification of transcripts, coding content and frequency analysis are duplicated from Chapter 5. A detailed table of evidence for the data analysis process is reported in table 4 of this thesis.

7.2.1 Participant Characteristics
Ten nurses who had previously participated in Phase I interviews and Phase II RCT of this study were interviewed to obtain information about whether their perception of essential oils had changed having experienced a research project in their clinical area. This information adds a further dimension to the quantitative results of the RCT. One nurse (Rosemarie) from the original 11 nurses who participated in the interviews in
Phase I left the organisation during the RCT and did not participate in the Phase III interviews. All 10 nurses in Phase III were assigned the same pseudonyms as in Chapter 5 Phase I including Abbie, Gabi, Jasmine, Jess, Kaye, May, Natasha, Sabina, Sam and Sanaya. Full details of pseudonyms and nurse characteristics are presented under pseudonyms in Chapter 5.

7.3 Summary of areas of interest

The four areas of interest identified from the Phase III post-trial nurse responses are described in this section. Nurse responses are classified into categories and subcategories under each area of interest. These areas of interest and categories are outlined below:

- **Area of interest 1: Change in frequency of agitation**
  - No change in agitation frequency
  - Reduction in frequency of agitation
- **Areas of interest 2: Effectiveness of essential oils for agitation**
  - Essential oils as an agitation management
  - Effect of essential oils on older people
  - Importance of essential oil research
- **Area of interest 3: Nurse use of essential oils**
  - Essential oils for health conditions
  - Motivators for using essential oils
- **Area of interest 4: Influencing factors that support research**
  - Researcher’s conduct of research
  - Staff attitude towards research

7.4 Area of interest 1 - Change in frequency of agitation

This section provides evidence for the two categories describing a change in frequency of agitation as identified in the transcripts using content analysis. These findings include no change in agitation frequency and reduction in the frequency of agitation. The two categories include three subcategories of frequency unchanged, all residents and some
residents. Table 27 presents in categories and subcategories the most frequently reported differences in agitation identified by the nurses.

<table>
<thead>
<tr>
<th>Area of interest</th>
<th>Change in frequency of agitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>No change in agitation frequency</td>
</tr>
<tr>
<td>Subcategory</td>
<td>Frequency unchanged</td>
</tr>
</tbody>
</table>

Table 27 Change in frequency of agitation

Nurses were asked if they had observed any changes in the frequency of agitation in residents during the essential oil RCT. Nurses were divided in opinion with five nurses reporting no change and four nurses describing a reduction in the frequency of agitation on the ward. A further four nurses believed reduction in frequency of agitation to be observed in some residents only. Table 28 illustrates the common responses to changes in the frequency of agitation on the ward as reported by the nurses.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency unchanged</td>
<td>5</td>
<td>50%</td>
</tr>
<tr>
<td>All residents</td>
<td>4</td>
<td>40%</td>
</tr>
<tr>
<td>Some residents</td>
<td>1</td>
<td>10%</td>
</tr>
</tbody>
</table>

Table 28 Change in frequency of agitation on the ward

**7.4.1 No change in agitation frequency**

Responses to changes in the frequency of agitation were based on nurse perceptions of increases and decreases in overall agitation on the ward. Four nurses reported frequency of agitation to be unchanged on their wards during the trial; their comments are documented below:

"*We have noticed no changes in agitation frequency.*" Kaye RN

"*Have I seen any difference? No, not really.*" May AIN

**7.4.2 Reduction in frequency of agitation**

The four nurses who reported a change had observed a reduction in the frequency of agitation on their ward during the trial as shown below:
“I have noticed with a few residents I have seen some changes.” Sabrina RN

“Mrs Y is still the same wandering around the same as before. She is hard to shower, but for a couple of weeks there she was compliant.” May AIN

The four nurses who reported a reduction in the frequency of agitation on the ward also perceived the frequency to be reduced in some residents only while frequency of agitation remained the same in others. Nurses also acknowledged that they were unaware of whether a resident was having active essential oil treatment or placebo at the time of their observations. This is shown in the following comments:

“I am pretty sure I’ve seen some positive changes among the residents but for some of the residents I don’t think there is much change. Then I don’t know whether they were having the real medication or the placebo medication.” Sam RN

This section has provided nurse responses to changes of frequency observed in their facility during the phase II RCT. Nurses were divided in opinion, some nurses observing no change other claiming a reduction in agitated behaviour. The following section presents the nurse perceptions of how effective Lavender or Lemon Balm were in managing resident agitation.

### 7.5 Area of interest 2 - Effectiveness of Essential Oils for Agitation

This section provides evidence for the three categories describing the effectiveness of essential oils on agitation as identified in the transcripts using content analysis. Three categories were identified under this theme: essential oils as an agitation management, effect of essential oils on older people, and the importance of essential oil research. These
three categories are divided into five subcategories: effective; not effective; older person inclusive; older person specific; and reducing agitation in RACFs. Table 29 presents the most frequent reported nurse responses for Area of interest 2 the effectiveness of essential oils for agitation. Tabulated are the categories and subcategories from the frequency codes taken from the nurse transcripts.

<table>
<thead>
<tr>
<th>Area of interest</th>
<th>Effectiveness of Essential oils for agitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Essential oils as an agitation management</td>
</tr>
<tr>
<td></td>
<td>Effect of essential oils on older people</td>
</tr>
<tr>
<td></td>
<td>Importance of essential oil research</td>
</tr>
<tr>
<td>Subcategory</td>
<td>Effective</td>
</tr>
<tr>
<td></td>
<td>Not effective</td>
</tr>
<tr>
<td></td>
<td>Older person inclusive</td>
</tr>
<tr>
<td></td>
<td>Older person specific</td>
</tr>
<tr>
<td></td>
<td>Reduced agitation in RACFs</td>
</tr>
</tbody>
</table>

Table 29 Post trial nurse perception of effectiveness of essential oils for agitation

7.5.1 Essential oils as agitation management

Nurses were asked post RCT for their perceptions of the effects of essential oils for managing agitation in older people. Nine Nurses agreed that Lavender and Lemon Balm essential oils were successful in managing agitation in older people, and one nurse did not observe any change. Table 30 presents the most common responses of nurse perceptions of essential oils effectiveness in older people post-RCT as reported by the nurses.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective</td>
<td>9</td>
<td>90%</td>
</tr>
<tr>
<td>Not Effective</td>
<td>1</td>
<td>10%</td>
</tr>
</tbody>
</table>

Table 30 Effectiveness of essential oils for agitation management in older adults

The nine nurses who agreed that essential oils were effective in reducing agitation in residents disagreed as to whether this reducing effect extended to every resident or every agitated behaviour. Nurses described the oils as having a relaxing effect with reductions of agitated behaviours and anxiety in some older people. This is demonstrated in the following comments:

“As far as Mrs X, I think it made a small amount of difference... her anxiety levels did decrease.” May AIN
“I was there most of the time, before and after, I could see a bit of difference in some of the residents... Because that smell can sooth them down and comfort them.” Sam RN

Another nurse described a lack of observable change in behaviours when the older people were trialling the oils. This left her with the belief that the oils were not effective in reducing agitation. This is demonstrated by the following comment:

“I can't really see any effectiveness because the behaviour is still the same as before without this or with this aromatherapy oil.” Jasmine RN

7.5.2 Effect of essential oils on older people
Of the nine nurses who reported that the essential oils did effectively reduce agitation in older people, five nurses reported that the oils appeared to reduce agitation in some residents only while four nurses credited the oils as being effective in reducing agitation in all residents trialled. Table 31 presents the most common responses of nurse perceptions of essential oils effectiveness in the older people that participated in the RCT.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Older person specific effect</td>
<td>5</td>
<td>50%</td>
</tr>
<tr>
<td>Older person inclusive effect</td>
<td>4</td>
<td>40%</td>
</tr>
</tbody>
</table>

Table 31 Effectiveness of essential oils on agitation in resident RCT participants

Of the nurses interviewed, five considered oils to be effective in some older people. Nurses considered that essential oils were more effective on certain individuals, and appeared to reduce some agitation behaviour more effectively. Their comments are illustrated below:

“There has been a change for some but for some they are still the same.” Natasha AIN
“I have seen some changes like with Mrs Y her agitation has reduced and also in Mrs Y she is also much better. So I think there is an effect but that effect depends on the individual person.” Sabrina RN

“Yeah I think it is working. Last week I noticed Mrs Z more settled because before she was fighting and really non compliant with care but wandering is still the same.” Sanaya AIN

Nurses also considered that essential oils were not effective for residents with dementia. The following comment states:

*People in the last stages of dementia it is not effecting.*

Sabrina RN

Four nurses expressed a firm belief in the calming effect of essential oils as shown in the comments below:

“ I think very mild [effect]... the patch, usually they have a very calming effect.” Jess RN

“ I think it’s working... I think it’s [the oils] getting good results.” Gabi RN

### 7.5.3 Importance of essential oil research

Two nurses stressed the importance of undertaking further rigorous research on use of essential oil in RACFs. Table 32 presents the common responses for the perceived significance of essential oils research for agitation management in RACFs.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced agitation in RACFs</td>
<td>2</td>
<td>20%</td>
</tr>
</tbody>
</table>

Table 32 Significance of essential oil research for agitation management in RACFs
Nurses advocated for essential oils calming effect on older people and for increased numbers of older people trialling the oils effect:

"I think I am where we were at the beginning I think that certain essential oils create a pleasant aroma and people feel good... this is a very small sample... I still think it generates a sense of wellbeing in the environment." Kaye RN

The problematic nature of agitation on the ward was evident as nurses described reducing agitation could decrease the number of ward related unplanned mishaps. In addition, family distress at having an agitated person in care was clear as nurses described in the following comment:

“... the smell can soothe them... we can handle the residents more effectively... if the residents agitation is reduced. I think this is the most important thing in caring for people on a dementia ward. This is especially important for the care staff so they can achieve a better level of cooperation. Reducing agitation can also reduce the incidents and accidents that happen around the ward, and I'm pretty sure the families would... be happier if they see any reduction in agitation.”

Sam RN

This section has reported nurse perceptions of Lavender or Lemon Balm's ability to manage resident agitation. Nurses generally agreed that essential oils were effective in reducing resident agitation. Nurse opinion varied in the ability of essential oils to reduce behaviour in all residents or only some residents. The following section discusses nurse use of essential oils and the motivators for the adoption of this health practice.
7.6 Area of interest 3 - Nurse use of essential oils

Nurses were asked about their personal use of essential oils. The area of interest nurse use of essential oil included the two categories: use of essential oils for health conditions, and motivators for using essential oils. These categories were further divided into five subcategories; belief in benefit, lack of belief in benefit, current use, sense of wellbeing, and pleasant aroma. Table 33 presents the most frequently reported responses from the nurses interviews presented by category and subcategory.

<table>
<thead>
<tr>
<th>Area of interest</th>
<th>Nurse use of essential oils</th>
</tr>
</thead>
<tbody>
<tr>
<td>Categories</td>
<td>Essential oils for health conditions</td>
</tr>
<tr>
<td>Subcategories</td>
<td>Belief in benefit</td>
</tr>
</tbody>
</table>

Table 33 Nurse use of essential oils

7.6.1 Essential oils for health conditions

Nurses were asked if they would consider using essential oils for their health conditions. Nine nurses claimed that they would use essential oils for a health complaint and one would not. Four of the nurses interviewed confirmed they were currently using essential oils for health conditions of insomnia, anxiety and relaxation. The most frequent responses by nurses are shown in Table 34 below.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belief in benefit</td>
<td>9</td>
<td>90%</td>
</tr>
<tr>
<td>Lack of belief in benefit</td>
<td>1</td>
<td>10%</td>
</tr>
<tr>
<td>Current use</td>
<td>4</td>
<td>40%</td>
</tr>
</tbody>
</table>

Table 34 Essential oils for health conditions

The nine nurses who reported they would use essential oils for health conditions, would do so because of the health benefits of the oils, while one nurse was ambivalent about the benefit but would consider using essential oils in future. This is shown in the following comments:

“Oh yes definitely. Because I have been (using essential oils),
I know that it works... usually it works.” Jess RN
“Well, not at the moment but maybe in the future if I needed too.” Sam RN

Four nurses were using oils for a variety of different health conditions including anxiety, insomnia, migraines and pain. This is demonstrated in the following comments:

“I am using musk oil at home, which is promoting my sleep, it helps reduce my pain.” Sabrina RN

“I actually do have some essential oils in my top drawer that I spray on myself because I suffer from anxiety.” Kaye RN

“I sometimes suffer migraine and I... use some oil, especially the Lavender, I like the smell it calms me down.” Natasha AIN

7.6.2 Motivators for using essential oils

Ten nurses reported using essential oils themselves, six because the oils provide a sense of wellbeing and relaxation and four because of the pleasant aroma. Table 35 presents the most common nurse responses for motivators for essential oil use as identified by these nurses, reporting frequency of coding and percentage of interview coverage.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sense of wellbeing</td>
<td>6</td>
<td>60%</td>
</tr>
<tr>
<td>Pleasant aroma</td>
<td>4</td>
<td>40%</td>
</tr>
</tbody>
</table>

Table 35 Motivators for essential oil use

Six nurses believed the agreeable fragrance could create a feeling of relaxation and wellbeing regardless of whether the effect was attributed to a pharmacokinetic or psychosomatic origin. They commented:

“... certain essential oils create a pleasant aroma and people feel good... I think that a general feeling of wellbeing is
achieved... Is it psychosomatic? I don't know. Does it make me feel better when I smell it. Yes.” Kaye RN

“... sometimes you feel frustrated, you are not agitated you are frustrated. If you are frustrated your body is tight... if you use essential oils, it calms you down. I like Lavender.” May AIN

This section reported nurse self-use of essential oils with a majority of nurses agreeing they would consider essential oils for their own health conditions. Several nurses currently using essential oils stated motivators for use to be pleasant aroma and the benefits the oils produced. The following section presents nurses opinion of the influencing factors that can support research in the RACF environment.

7.7 Area of interest 4 - Influencing factors that support research

This section reports nurses' responses to interview questions relating to the conduct of research in RACFs. Nurses reported a variety of factors influencing research in the facilities, broadly categorised as researchers conduct of research and staff attitude to research. These categories were further divided into seven subcategories influencing factors include: unobtrusive research, routine timing, effective communication, staff workload, pre-trial education, researcher's attributes, and research value. Table 36 presents the most frequently reported influencing factors for research under Area of interest 4.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Influencing Factors that Support Research</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Categories</td>
</tr>
<tr>
<td></td>
<td>Subcategories</td>
</tr>
</tbody>
</table>

Table 36 Influencing factors that support research
7.7.1 Researcher’s conduct of research

A central focus of this research was to identify factors that support and influence the success of research in the RACF environment. Nurses were asked if there were any difficulties in implementing the essential oil study on their ward. On analysing their comments, the most frequent responses by six of the nurses were that the research was unobtrusive and presented no obstacle for staff or residents and that the research was routinely timed to adequately prepare staff for the researchers arrival. Of the ten nurses interviewed, four suggested effective communication between researcher, staff and the residents would increase research success. Table 37 presents the subcategories for Researcher’s conduct of research as reported by the nurses.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unobtrusive</td>
<td>6</td>
<td>60%</td>
</tr>
<tr>
<td>Routine timing</td>
<td>6</td>
<td>60%</td>
</tr>
<tr>
<td>Effective communication</td>
<td>4</td>
<td>40%</td>
</tr>
</tbody>
</table>

Table 37 Researcher conduct of research

7.7.2 Unobtrusive research

Of the ten nurses interviewed, six were pleased with the unobtrusive way in which the research was implemented in the facility. Staff described the research as having minimal or no impact on them and the intervention as being largely unnoticed by the participating residents. The research staff in the RACF environment were described by the nurses as unassuming in their duties and amenable with the residents. This is shown in the following comments:

“No impact on the nursing staff, she (research assistant) came in explained what she was doing... some people come in and don’t explain what they’re doing and just start.” May AIN

“So they [resident] don’t even notice the little black thing on their clothes.” Sam RN
“No she (research assistant) was ok. She was just going around on the list; I think she had a list. She likes the residents she is very good with the residents.” Sanaya AIN

Further, when nurses were asked what suggestions or recommendations they would have for the future implementation of research in RACFs they described unobtrusive research that was well accepted by the residents and families as a preferred method of conducting research:

“... it was a smooth running process.” Kaye RN

“I think the trial went really really well we didn’t have any problems... nobody has complained... the family members were happy that their loved ones were getting treatment.”

Sam RN

7.7.3 Routine Timing

Six Nurses identified routine timing to be the most important factor in future research success in the RACF environment. Nurses were aware of the fortnightly on/off timeframe for the research and daily routine of the researcher. They were aware in advance of the activity to be conducted on the ward during these times. Researchers who adhere to regular timing provide consistency for staff and the resident, in their expectations of ward procedure or their daily routine at this time. This is shown in the nurses comments below:

“I think the way you did it was good. You came in and put on patches for two weeks and then you came back.” Abbie AIN

“I think the trial went well, I’ve seen who does the patches she (research assistant) comes at the same time, she removes the patch at the same time.” Sam RN
Some nurses also recommended a change in the routine timing of the research to better meet the needs of the nurse and residents. Nurses described changing the intervention time to the afternoon during “sundowning” behaviour may be more beneficial to the resident and possibly easier for the nurse to monitor behaviours. This is shown in the following comment:

“I was thinking if we could also try for you to come in the afternoon so you can also observe the resident in the afternoon. Especially with the residents with sundowning, they are really bad in the afternoon but in the morning they are good.” Jasmine RN

7.7.4 Effective Communication

Four nurses identified effective communication among researchers, staff and the resident as an influencing factor in the success of the research. Nurses described effective communication as crucial to the success of future research. Nurses described the research assistant as approachable and knowledgeable. They acknowledged the research assistant as having a genuine interest in the resident and a willingness to explain procedures thoroughly. Further, the families of residents who tried to assist the researcher in completing the research duties appreciated this care. This is shown in the following nurse comments:

"She was very good and very friendly, and the resident and the family started knowing her and they were quite interested to help her, and they looked forward to her coming, I saw very enjoyed (sic) family members.” Gabi RN

“... [the researcher] was wonderful, came in, said why she was here and spoke beautifully to the clients. The loveliest girl, she was terrific, explained everything, ‘I’m just going to change your
patch today, and this is what I am going to do’. Because they wouldn’t remember.” May AIN

“[research assistant] giving the aromatherapy with them and talking with them and then they go back and when we [staff] approach that person they say ‘oh that lady is good, she is good and nice, she gave us nice smells.” Sanaya RN

7.7.5 Staff attitude towards research
Nurses were asked to suggest how researchers could approach future research projects in RACFs to increase acceptability and success of the research. Staff recognised researcher’s awareness of the nurses current workload and the need to minimise research impact on their work day was deemed to be pivotal to future research success. In addition to pre-trial education, research team attributes and a perceived research value were deemed necessary to foster acceptance and compliance to the research among staff. Table 38 presents the staff attitudes towards research as reported by the nurses.

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Frequency</th>
<th>Percentage (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff workload</td>
<td>3</td>
<td>30%</td>
</tr>
<tr>
<td>Pre-trial education</td>
<td>2</td>
<td>20%</td>
</tr>
<tr>
<td>Research team attributes</td>
<td>2</td>
<td>20%</td>
</tr>
<tr>
<td>Research value</td>
<td>1</td>
<td>10%</td>
</tr>
</tbody>
</table>

Table 38 Staff attitudes towards research

7.7.6 Staff workload
Of the ten nurses interviewed, three identified staff workload to be a barrier in performing research duties. Nurses were aware that the research assistant was performing the trial interventions in the clinical environment to minimise the research impact on nursing staff. Nurses described limited time for research duties in addition to their current workplace functions. Nurses generally felt disappointed that they could not contribute more to the research process. This is illustrated by the following statements:
“It was a bit sad because I was quite busy on the ward and I really couldn’t concentrate that much on the study purpose, just generally the observing behaviour was all I could do.”

Gabi RN

“...it is hard to get time [to report behaviours] when I am busy on the ward.” Sabrina RN

Some nurses recognised the difficulty committing to the time required to monitor a resident’s behaviour. A shorter timeframe was suggested to be easier for the nurse to monitor older person behaviour. The is shown in the nurse response below:

“I think that you need to shorten it because two weeks is a very long time to monitor someone but if it’s a week, the days are quick, then you can see if there is any changes for the residents... I think it’s better one week than one week off and then one week.” May AIN

7.7.7 Pre-trial Education

Several nurses identified a short pre-trial staff education session as beneficial when introducing research into the clinical environment. Nurses acknowledged that pre-trial education describing the objectives, benefits and intentions may increase staff participation because if staff were aware of the effect and procedures, they are more likely be interested and be in a position to participate in the research. This is shown in the following comments:

“Researchers need to tie into the pre-trial an education package, only very small maybe 10-15 minutes long because that is as long as our staff have. So all the staff are
knowledgeable of the benefits, what we are looking for and some of the objectives of the research.” Kaye RN

“... and spend a little bit more time explaining what essential oils are and how they will be reacting on residents. Because not everyone knows about this very well and if you explain it to them they might help to do the things and they can also notice how it is affecting the residents.” Sanaya AIN

### 7.7.8 Research Team Attributes

Several Nurses identified the personal characteristics of the research team as being pivotal to the success of the research. Researchers who are polite to staff, acknowledge that routine care has priority over the research and make efforts to organise the research around usual activities are more likely to have the cooperation and support of clinical staff:

“I really do think it is the persons you employ to conduct the study... The research assistant always came to the door and said ‘I’m here to change the patch is that ok? And I might say, can you come back in half an hour because one resident is really uptight?’ Very obliging... So if you want to do any more studies that is fine as long as I like the person coming in.”

Jasmine RN

### 7.7.9 Research value

One nurse identified the capacity for the research to add value and a feeling of importance to the resident and nurse as a facilitator of research in the RACF environment. Participating in research provided a sense of importance to the resident, that researchers valued them and were interested in what they could contribute. This is shown in the following comment:
“It was actually a good thing for the residents and the staff, to have research on the ward, it made them feel important.”

Natasha AIN

This section has reported of factors described by nurses that can support research in the RACF setting. Nurse perceptions had been informed by their participation in the essential oil RCT conducted in this study.

### 7.8 Summary

This chapter has reported the findings from 10 semi-structured interviews with nurses. A content analysis identified four areas of interest; Change in frequency of agitation, Effectiveness of essential oils for agitation; Nurse’s use of essential oils; and Influencing factors that support research. The nine categories and 20 subcategories were identified from the four areas of interest. Subcategories were identified by the content analysis and illustrated by nurse’s statements from Phase III interviews.

Nurses were divided in their responses to Change in frequency of agitation in their facility. Nurses who claimed to have observed a change in frequency stated agitation had reduced on the ward with the majority claiming a behaviour reduction in all residents participating on the RCT. Other nurses claimed to have not observed a change in frequency on the ward or were unsure.

A majority of nurses interviewed agreed that essential oils were effective in reducing resident agitation. However, nurses remained divided on whether essential oils would be effective in managing agitation in all residents or only some residents, with some nurses advocating for further essential oil research.

A majority of nurses agreed they would consider using essential oils for their own health conditions. Almost half the nurses interviewed were currently using essential oils for
their health, stating motivators for essential oils to be pleasant aroma and the sense of well-being that the oils created.

Nurses described research that was unobtrusive in the RACF, routinely timed and provided good communication with the researchers to facilitate a projects success. Nurses advised researchers to be mindful of the nurses existing workload and need for pre-trial education. In addition, nurses also described pleasing research team attributes and conducting research considered valuable to the nurse to be beneficial to a research project.

The findings from Phase III nurse interviews are discussed in conjunction with Phase I interview findings pre RCT and the results of the intervention phase II RCT for this study in Chapter 8.
Chapter 8 Discussion

8.1 Overview

This final chapter discusses the findings of this research the implications for the evolving understanding of agitation management, essential oil investigation and research involving residents living in RACFs. The findings are discussed within the context of the HBM, that predicts and explains behaviours that lead to the adoption of new health management strategy (Hayden, 2014; Hochbaum, Kegels & Rosenstock, 1952). The findings as they relate to the research questions and objectives are discussed (1) How nurse understanding of agitation influences the management of older persons behaviour in RACFs? (2) Nurse's perception of essential oils and their use to manage agitation (3) What is the effectiveness of Lavender compared to Lemon Balm and a placebo for the management of agitation in residents of RACF with and without dementia, and (4) What are the influencing factors that can facilitate nurse participation in research conducted in the RACF setting. Implications for education, practice, policy, management and research are discussed. The final section of this chapter includes an account of the strengths and limitations of the quantitative and qualitative components of the study in addition to the author’s concluding remarks

8.2 Research findings

This research examined the effectiveness of Lavender or Lemon Balm essential oils as alternative approaches to the management of agitation for residents living in RACFs. While there are publications describing the effect of both Lavender and Lemon Balm oils in separate trials, this study was the first to compare Lavender to Lemon Balm essential oil in a single study for the management of agitation. The inclusion of residents with and without dementia has also not been reported previously. Further, the design of the RCT phase of this research overcame some of the methodological limitations of previous studies investigating essential oils for agitation in older people. The main findings are summarised in Table 39.
Explore nurse understanding of agitation and its influence on the management of resident behaviour in RACFs

Main Findings

- Nurses considered some agitated behaviours to be intractable to the dementia condition.
- Agitation is often managed differently when communication is impaired.
- Nurses held a strong belief in the ability of essential oils to reduce agitation (new).

What is the effectiveness of Lavender compared to Lemon Balm and a placebo for the management of agitation in residents of RACFs with a dementia diagnosis?

- Lavender or Lemon Balm, did not reduce agitated behaviour independent of cognitive status when compared to placebo.
- Lavender and Lemon Balm reduced physical non-aggressive behaviour independently of cognitive status when compared to placebo (new).
- Quality of life in residents without dementia was significantly less when compared to dementia independent of essential oil treatment (new).

What are the differences of Lavender compared to Lemon Balm and a placebo for the management of agitation in residents of RACF with and without a dementia diagnosis?

- A significant opposing effect of Lavender and Lemon Balm between the without dementia and dementia groups on NPI and CMAI total score and in the domains of NPI Irritability and CMAI physical non-aggressive behaviour (new)
- Lavender was significantly more effective in reducing physical non-aggressive behaviour compared to Lemon Balm and placebo in residents with dementia (new).
- Lemon Balm was significantly more effective in reducing NPI total score and physical non-aggressive behaviour compared to Lavender and placebo in residents without dementia (new).
- Lemon Balm was significantly less effective in reducing irritability on the NPI Irritability score when compared to Lavender or placebo in residents with dementia (new).

Influencing factors for Research

- Research is vital to providing optimum care to residents in RACFs
- Collaboration between researcher and nurse can promote and sustain research capacity
- Practical research achievable in the RACF setting is most beneficial in sustaining interventions long-term
- Staff education of research processes can encourage compliance with research

Table 39 Summary of main findings

The following sections discuss the major findings as they relate to each research aim or question within the context of the literature.

8.3 How does nurse understanding of agitation influence the management of resident behaviour in RACFs?

Nurse's understanding of agitation influenced the strategies selected to manage behaviour in residents with and without dementia in RACFs. Nurses interviewed acknowledged being susceptible to agitation in the RACF environment. The nurses
considered agitation to be a serious problem to the older person, staff and other residents in the setting. Most nurses perceived essential oils would be effective in managing agitation, however perceived barriers to effectiveness of the management between people with and without dementia. The nurses who were interviewed considered agitation in people without dementia to be preventable, therefore they may be more likely to persevere to identify triggers for the behaviour that once rectified could resolve the agitation. In contrast, nurses identified impaired communication, common in older people with dementia, hindered the nurse attempts to find reasons for agitation which results in nurses adopting short-term managements of distraction or restraint to contain behaviour. Nurses perception that agitation is difficult to treat in people with dementia does influence their clinical decision making.

8.3.1 Nurses experiences of agitation

Nurses reported that residents frequently experienced episodes of agitation and in many cases, attempts by nurses to calm the resident often resulted in limited success. This creates a stressful environment for other residents and staff. This finding is similar findings by Zwigsen et al. (2014) involving 432 nursing home residents. That study found that agitation and aggressive behaviours were the most prevalent behaviours displayed by residents and the most disturbing to nurses. A New South Wales Nursing Midwifery Association [NSWNMA] (2016) survey also confirmed agitation and aggression to be a frequent occurrence in RACFs with 90% of nurses having experienced physical or verbal agitation from a person in their care. Concerns were expressed about the increasing level of agitation and aggression in the RACF environment and a lack of resources available to effectively manage the behaviour. Nurses in this study relied on their education and the residents non-verbal cues to negotiate in an attempt to resolve the situation and ensure the safety of the person, other residents and staff in the immediate environment. Nurses in this study expressed frustration at the lack of effective agitation management.
resources, the limited time available to manage agitation and meet the care needs of all residents in their charge.

Edberg et al's (2008) study resonates the frustration of the nurses in this study claiming that the unpredictable nature and time required to manage agitated behaviour created difficulties in balancing competing demands in the workplace, resulting in nurse/carer strain. When a resident is agitated, other residents and nurses are affected. The serious nature of the behaviour and limited effectiveness of interventions such as distraction provides a cue to action for nurses to investigate alternate approaches to managing agitation in residents with and without dementia.

Nurses interviewed in this study reported physical aggression, wandering and repetitive behaviour are more frequently exhibited in residents with dementia than those who do not have dementia. Several recent studies (Burns et al. 2011; O'Conner, Eppingstall, Taffe, & van der Ploeg, 2013) and the International Psychogeriatric Association [IPA] agree that some agitated behaviours are specific to the dementia trajectory and the IPA has recently formed a working party to develop an agreed definition for agitation that will include dementia specific behaviours (Cummings et al. 2015).

Nurses in this study reported agitation in residents without dementia most frequently originated from incongruences in resident care preferences. They perceived agitation in residents without dementia to be easier to manage than in people with dementia. This agitation was more often attributed to frustration, irritability or as a symptom of an anxiety or depressive condition. Results of Drageset et al's (2013), cross-sectional observation study of 227 residents without dementia supports this finding, reporting the conditions of anxiety and depression to be a precursor to agitation in residents without dementia. These studies are consistent with the findings of interviews from Phases 1 and 111 of the study reported in this thesis, however nurses need to exercise caution when attributing behaviours or their origins based on cognitive level. Australian statistics
predict that 40-50% of people with dementia also experience depression in addition to 49% displaying the symptoms of anxiety (Neville & Teri, 2011). The presumption that an agitated behaviour is related solely to the cognitive status may result in anxiety or depression being overlooked and left untreated in older people with dementia.

### 8.3.2 Nurses understanding of agitation management

Nurses understanding of agitation management in this study focused on identifying the factors that contribute to the behaviour, which is greatly assisted by a residents ability to communicate grievances, comprehend questions and have insight into their behaviour, as well as the nurses awareness of the resident's health, usual behaviour patterns and preferences. When triggers for behaviour are identified, care can be modified, assessment arranged or processes put in place to mitigate or eliminate the triggers of episodes of agitation. Nurses allocated individual time to older people when they were agitated, to assess agitation level, identify triggers and select appropriate management strategies (NSW Health, 2006). When residents were excessively agitated, nurses in this study agreed that it was best practice to remove themselves from the situation until the resident was calm and more able to communicate their grievances or participate in management strategies.

The impaired capacity of older people with dementia to communicate effectively is often an obstacle to identifying causes of agitation and further escalates the agitation (Edberg et als. 2008; Duxbury, Pulsford, Hadi, & Sykes, 2013). Nurses also exhibit a high level of frustration when residents are unable to communicate (Duxbury, Pulsford, Hadi, & Sykes, 2013). Nurses interviewed in this study reported similar feelings when residents could not articulate the cause of their behaviour and noted resident’s frustration escalated their agitation. Nurses interviewed agreed that agitation was most difficult to manage in residents with dementia primarily due to impaired communication.
As a consequence of the cycle of poor communication, Runci, Eppingstall and O’Connor (2012) found that agitation was often the reason psychiatric medications are prescribed in RACFs and recommended that responses to residents’ agitation should be monitored to ensure that medications are not inappropriately selected due to difficulty in communicating the causes.

8.3.2.1 Short-term management strategies
In an attempt to ease agitation and relieve distress in residents who could not communicate the reason for their agitation, nurses used short-term strategies of distraction, deception and monitoring. Residents with dementia were frequently managed in that way. However, short-term management provides temporary relief only and rarely saves the nurse’s time or decreases frustration in managing behaviours (Dombeck, 2015; Hofmann & Hahn, 2014). Nurses’ perception that agitation in dementia is intrinsic may pose a barrier to selecting strategies considered to permanently reduce unwanted behaviours in this population.

Distraction was the most common approach used by nurses interviewed. Distracting the resident with an activity or conversational topic of their preference often resulted in the reduction of agitation. However, once the distraction ceased the behaviour was observed to reoccur necessitating the nurse to re-assess the resident and repeat the distraction technique.

Nurses in this study also combined deception with distraction to calm residents using approaches such as placebo medications, telling residents a bus was due or that family would be visiting later. This approach has been used widely across RACFs. Tullo et al’s, (2015) study found that medical staff considered deception to be an acceptable clinical management for people with dementia largely because this group have lowered capacity for understanding, retaining and emotional processing of information.
Wandering was the most frequently mentioned agitated behaviour by nurses. The constant movement of the resident from one area to another required nurses to keep a watchful eye on the resident to monitor their safety, protecting them from their own actions and external threats in the environment (DoHA, 2010). Wandering residents require not only monitoring for safety but also ensuring they receive adequate amounts of sleep and nutrition to support their activity. Wandering is easier for the nurse to monitor when the resident is contained in a ward or area in easy view of the nurse’s station. This type of containment is considered restraint and is commonly used in dementia wards in RACFs nationally and internationally (DoHA, 2014).

Nurses in this study considered pharmacological restraint to be an acceptable management for agitation that was unresolved by other non-pharmacological methods. Chemical restraint, the use of medication for the sole purpose of managing behaviour, often increases sedation that can further impair communication in the older person (Jeste & Maglione, 2013). Morley’s (2010) investigation of clinical practice in RACFs found that nurses were aware of the detrimental effects and limited efficacy of restraints. They understood non-pharmacological methods to be more effective approaches, however restraint was still used in the RACFs. Chemical restraint has a negative impact on the resident increasing the risk of pressure areas, physical decline, incontinence, depression, anxiety, confusion, injury, aggression, falls and death (Gulpers et al. 2013; Hill & Fauerbach, 2014). Restraints that restrict a person’s movement are degrading, violate human rights and are often perceived as punishment by the older person. These factors increase the resident’s distress and can contribute to injury as the individual often attempts to free themselves from their circumstance (NSW DoH, 2014).

While some of the nurses in this study believed chemical restraint is acceptable to manage agitation, opinions about the appropriate use of chemical restraint varied from a first line management strategy for unresolved agitation to a last resort measure. Some
nurses suggested lowering of medication dosage to reduce side effects. Similarly, Boase et al’s (2012) study found that regular use of medications to reduce agitation could further compromise a nurses ability to assess agitation as side effects often remove the resident’s voice and limit use of alternate methods in favour of medications (Boase, Kim, Craven, & Cohn, 2012).

Morley (2010) contends that nurses considered restraint a safer option than unresolved agitation, with the short-term benefits of restraint outweighing the long-term detriment to the older person. Mohler and Meyers’ (2014) study further demonstrates that despite a reported lack of benefit to the older person and evidence of detrimental effect, nurses still favoured restraint for agitation management. A small qualitative study investigating restraint use in the clinical environment by Duxbury et al. (2013) contradicts these findings reporting that nurses prefer to use strategies of distraction rather than medication in aggressive physical agitation and as expected, relatives were also supportive of this non-coercive approach.

In contrast, Haut, Kolbe, Strupeit, Mayer and Meyer (2010) found attitudes of staff and family towards restraint to be rather positive and comparable between groups. The family perceived their relatives situation to be less distressing when the family member was calm even for a short time. Hoffman ‘s (2015) investigation of clinical practice in RACFs found that use of all forms of restraint promote more autonomy for the nurses in their role.

8.4 Nurse perceptions of essential oils and their use to manage agitation

This study found that nurses believed in the benefits of Lavender and Lemon Balmto reduce agitation in the residents. A small percentage of nurses had worked with essential oils previously in the clinical setting. Several nurses were also using the oils for their own wellbeing. Some nurses, however, did not believe the oils would be effective on all
residents agitation, considering the agitation in dementia to be intractable in the conditions trajectory. This belief supports Azermai et al’s (2014) findings that nurses held strong beliefs in complementary therapies as effective management, despite their opinion being in opposition to the GPs who perceived complementary therapies to be ineffective.

Several nurses interviewed were currently or had previously used essential oils for their own health conditions. Nurses perceived a relaxation benefit, pleasing aroma and safety in use that they considered would be beneficial for others. Nurses in this study’s experiences with essential oils either clinically in palliation or dementia care, or through self-use had been positive. These positive experiences coupled with knowledge of essential oils low interaction with medications and minimal side effects may have led nurses to advocate their use for the residents in agitation management.

However, a substantial amount of the nurses interviewed did not believe that essential oils would be effective in managing agitation in residents with dementia. Nurses in this study perceived agitation in dementia to be an incurable side effect of the condition. This lack of belief in inventions effect can compromise compliance with research in essential oil trials that focus solely on dementia populations. Burns et al. (2011) estimated nurse compliance to administering essential oils to agitated residents with dementia at only 50% through measuring the returned bottles. If nurses perceive the intervention to be ineffective, they will feel their time is better spent elsewhere rather than supporting the research.

The nurses interviewed in this study were aware that scientific evidence on the effectiveness and safety of essential oil will be required to support policy and practice change in facilities. To that end, nurses were supportive of further trials using essential oils being conducted in their facilities.
8.5 What is the effectiveness of Lavender or Lemon Balm essential oils as a management for agitation in residents with and without dementia?

Although some of the nurses reported that the essential oils did appear to improve agitation in some residents, primarily those without dementia, results of this RCT did not demonstrate a statistical reduction in agitation when results were independently compared to placebo. These findings are consistent with previous research by Burns et al. (2011), Fu et al. (2013) and O’Conner et al. (2013) that reported no significant difference when Lavender or Lemon Balm essential oils were used to reduce agitation in people with dementia. They contradict the findings of Sakamoto et al. (2012), Lin et al. (2007), Fuji et al. (2009) and Ballard et al. (2002) that reported the use of Lavender or Lemon Balm did significantly reduce agitation in older people living in RACFs.

Timing of the application of the essential oils may also influence their effectiveness. The essential oils in this trial were administered once daily, at the same time in the morning. Administering a second dose in the afternoon when behaviours in dementia peak may have increased the effect. This assertion is supported by Fuji et al.’s (2009) Lavender study and Ballard et al.’s (2002) Lemon Balm study, where essential oil interventions were administered twice daily, with both studies reporting a significant reduction in agitated behaviour in people with dementia. A more frequent small dose of essential oils may minimise adverse side effects associated with higher doses of essential oils and may maintain a therapeutic level of effect for a longer period.

A statistically significant reduction was reported in the CMAI domain of physical non-aggressive behaviour when Lavender and Lemon Balm treatment groups were compared to placebo in this study. This result indicates that the essential oils may reduce this behaviour. Non-aggressive physical behaviours include restlessness, repetitious mannerisms and wandering among other behaviours. This result supports findings by Lin et al. (2007) and Fuji et al. (2008) who also reported a clinically significant reduction
in motor activity on the NPI with the use of Lavender in dementia residents. The post hoc analysis in this study revealed that Lavender was more effective in reducing physical non-aggressive behaviour than Lemon Balm for people with dementia, further supporting Lin et al.’s (2007) and Fuji et al.’s (2009) findings. Similar to this RCT, Fuji et al., (2009) used two drops of 100% Lavender essential oil applied to residents clothing for inhalation as an intervention. Lin et al.’s (2007) study used two drops of 100% Lavender essential oil applied to a cotton ball to be inhaled by a humidifier during sleep. The frequency of treatments in Lin et al.’s(2007) study was once daily, the same dose frequency used in this study. While Fuji et al., (2009) applied the oils three times a day. These results suggest that increasing the dose and frequency of Lavender treatments may lead to an increased reduction in physical non-aggressive behaviour in older people with dementia.

A significant reduction in physical non-aggressive behaviour as revealed by the analysis in this study contradicted the reports of nurses in this study who perceived that non-aggressive physical behaviour, specifically wandering to have remained the same throughout the trial. This perception may indicate a bias by the nurses towards behaviours they considered specific to dementia. Physical non-aggressive behaviours such as wandering were considered by nurses to be intractable in dementia and not expected to be influenced by essential oil intervention. This bias can affect the reporting of behaviours by nurses, bias was minimised from reporting in this trial, by low scent doses and counterbalancing treatments coupled with the nurses challenging workload nurses may not have been aware when residents were taking a active treatment or placebo.

8.5.1 What are the differences in Lavender or Lemon Balm essential oils
The essential oils investigated in this study demonstrated an opposite effect in residents with or without dementia. Lemon Balm essential oil consistently reduced behaviour in
residents without dementia when compared to Lavender. In contrast, Lavender was consistently more effective in reducing behaviour in residents with dementia when compared to the Lemon Balm treatment. This difference in the essential oil effect was significant between the with and without dementia groups in total agitation score, irritability and physical non-aggressive behaviour in this study, demonstrating the intervention to have worked differently in each group.

Lemon Balm demonstrated an ability to reduce NPI agitation and CMAI physical non-aggressive behaviours in residents without dementia in post hoc analyses featured in this research. These results are similar to the findings of Ballad et al (2002) where Lemon Balm reduced behaviours by 30% in 71 older people living in RACFs when compared to a placebo of sunflower oil. This trial however conflicts with the results of this study as participants in Ballad et al’s (2002) trial all had a diagnosis of dementia.

In further contrast to Ballad et al’s (2002) results, this study demonstrated a significant difference with Lemon Balm being less effective than placebo in reducing irritability in residents with dementia. This result is supported by Burns et al’s (2011) study that reported Lemon Balm was not more beneficial than placebo for 114 residents with probable or possible AD as reported on the NPI measure.

Lavender was significantly more effective in reducing physical non-aggressive behaviours in residents with dementia when compared to Lemon Balm and placebo in this study. The result in this study is supported by Sakamoto et al’s (2012), Fuji et al (2008) and Lin et al. (2007) studies, which also reported a reduction in agitated behaviour in residents with Dementia when Lavender is administered. The result in this study are in contrast to O’Conner et al’s (2011) study of 64 residents with mild to moderate dementia which reported Lavender massage did not reduce physical agitation. O’Connor et al’s study did not investigate the Lavender treatments effect in people without Dementia.
This difference in essential oil effect between the cognitive groups may be attributed to impaired brain function in dementia, and the associated symptoms of olfactory dysfunction, memory impairment, and hypersensitivity to environmental stimuli or diminished neurotransmitter processes. Olfactory dysfunction in AD is estimated at high as 100% and 96% in Frontal Lobe dementia, but lower in Vascular dementia at 15% (DeYoung, Just, & Harrison, 2002; Raetz, 2013). A scent discriminate test was performed in this study to assess the ability to detect and distinguish between scents. The test did not determine odour identification or level of olfactory dysfunction. Scent detection relies on immediate memory while scent recognition is more a delayed memory processing. Depending on the degree of brain dysfunction scent may be harder to discern and recognise for a person with dementia.

Lemon Balm essential oil was not well tolerated in this study by residents with dementia. A rationale for this outcome may be attributed to Lemon Balm being a less recognisable and highly potent fragrance (Duda et al. 2015). Many residents with dementia are hypersensitive to sounds, smells or temperature in their environment (Tyrrell, 2014). Lemon Balm’s potent scent may over stimulate the residents with dementia, the oil proving to have an irritant rather than a calming agent. Lavender’s more subtle medium fragrance was more effective and better tolerated in this study by residents with dementia. Lavender statistically reduced physical non-aggressive behaviour in comparison to Lemon Balm and placebo in the dementia groups.

Fragrances can evoke strong memories of earlier times in an older person’s life when they recollect having smelled the scent previously (Halcon, 2010). The limbic systems amygdala governs the emotional response, while the hippocampus is involved in retrieval of memories surrounding scent (Fontaine, 2014). The ability of the hippocampus to retrieve memories is impaired in dementia; however earlier life memories rely less on the hippocampus for recollection (Simons, 2014). Lavender was a
popular herb commonly grown in gardens, used as perfumes and disinfectants in earlier years (Halcon, 2010). It is highly likely that some older people with dementia would recognise and may be comforted by this scent.

Conversely, the fragrance of Lemon Balm was more effective in people without dementia, and its highly potent, less familiar scent as having more of a pharmacological effect. However, treatment with Lavender did reduce agitation and the total score on NPI from baseline behaviour for people without dementia. Lemon Balm significantly reduced agitation on the NPI total score when compared to Lavender and placebo. Regardless of Lemon Balm’s intense fragrance, no residents with or without dementia requested the removal of a patch during the trial.

A final consideration for the difference in the effect of the essential oils between people with and without dementia, may be impaired pharmacodynamics effect. Lemon Balm is considered to influence GABA processes to create an anxiolytic, sedative and muscle relaxant effect (Awad, et al., 2009; Duda et al., 2015; Koulivand, et al., 2013). Lavender may affect the serotonin pathways, in addition to GABA pathways, which are thought to increase mood and social behaviour (Chioca et al., 2013). Diminished neurotransmitter processes in dementia may impair pharmacodynamic effect in comparison to the intact brain in the without dementia groups.

In addition, older people with dementia commonly take antipsychotics and benzodiazepines that also affect the GABA and serotonin pathways (Banjee, 2009; Alzheimer’s Australia 2012). Lavender may elicit a synergistic effect on people who are already taking medication that engages these neurological pathways, providing a greater calming effect than Lavender essential oil may exert alone. Further investigation is required into the synergistic effect with pharmacology and the mechanism of action of essential oils.
8.5.2 Quality of Life independent of essential oil treatment

As could be expected, there was a significant difference in Quality of Life (QoL) for people without dementia compared to those with dementia, however the study did not find that essential oils improved QoL.

Quality of life for older people is often determined by their ability to remain independent, individual and autonomous (Lee et al., 2009). Capacity to maintain these three factors can be problematic in a RACF due to communal living, structured routines and protocols that guide the furnishing of living areas. Before many people enter RACF they have already experienced losses to one or more of the factors that underpin their QoL (Anderson, 2011). However, QoL for people living in RACFs is closely related to the quality of care provided and how well the older person suits this care environment (Lee et al., 2009). Many people with dementia thrive on routine and structured environments (Alzheimer's Australia, 2015), making them more suitable candidates for aged care living. This may contribute to a higher quality of life found in people with dementia when compared to older people without dementia in this study.

8.6 What are the factors that influence research in the RACF environment?

This section addresses the final research question to provide information on the factors that influence research in the RACF environment. There are barriers to change in clinical settings, including reluctance by staff to change that can influence the adoption of a new health management strategy in the clinical setting (Hayden, 2014). This research sought to overcome barriers to using essential oils in the clinical setting and to encourage nurses to value and take responsibility for research in RACFs.

This study is the first to investigate influencing factors of a RCT for essential oils in the RACFs environment. Findings of this study were similar to other studies that investigated nurse research compliance in different clinical settings (Akerjordet, Lode, & Severinsson, 2012; Roll et al. 2013; Vedelø & Lomborg, 2011).
Nurses interviewed in this study aspired to provide the best evidence-based care to the residents in their charge and understood that research is a vital component in delivering care, however they also believed that research for residents in RACFs was often overlooked in government funding. Nurses were aware that the ageing population was impacting on the role of aged care nurses, with greater numbers of people presenting to facilities with increased levels of frailty and complex comorbidities. Nurses specifically identified research into managing agitation to be a crucial area for investigation in the RACF setting. Nurse’s were concerned about the increasing difficulty of managing agitation among residents in the absence of effective management.

Three factors emerged from this study that influenced research including collaboration between researcher and nurse to promote and sustain research capacity, practical research that is relevant to direct care and achievable in the RACF to sustain interventions long-term and staff education of research processes to encourage compliance when research.

Nurses in this study highlighted a need for improved communication between the researcher and nurse. Nurses were the best informants of the daily practical difficulties encountered by residents and staff in their facilities. This knowledge coupled with the researchers skill in developing strong arguments for evidence based practice can produce change for residents and RACF staff. Akerjordet, Lode and Stevensons’s (2012) investigation of 364 clinical nurses in a university teaching hospital in Norway support theses findings concluding that a conscious effort is required by the researcher to build collaborative relations with clinical staff to promote a sustainable capacity for research in the clinical environment.

Nurses in this study warned researcher’s should have realistic expectations about the research they seek to implement in RACFs. Researchers have skills to design robust
studies that will provide reliable and valid results, and frontline nurses can advise on the feasibility of implementing the protocol in clinical settings (O’Keeffe, 2014). Vedlo and Lomborg (2010) reported that for research to be successful, the design and logistics of the research must be flexible in the clinical environment to accommodate for an unexpected environment or care priority changes in the day to day running of the RACF.

Smith et al. (2016) found communication between nurse and researcher to be pivotal to the success of a study. The nurses interviewed in this study indicated in this study that staff were often challenged to trust the researchers with sensitive client information and at times, workplace information. They were aware that withholding such information could jeopardise the validity of the research outcomes. Similarly, when researchers withheld details of the research being conducted at the facility, often to reduce prejudicial outcomes, an element of distrust was created. Alt-White and Pranulas (2006) similarly demonstrated that inadequate communication by researchers of a study’s progress and findings was common feedback received from nurses following a research project completion and requires the researchers attention.

A positive attitude towards research was acknowledged by the majority of nurses interviewed in this study despite recognising substantial barriers to their participation. Akerjordek et al.’s (2012) study also reported a positive attitude among nurses towards research regardless of frequently not being actively involved in research projects. Support for research in RACFs was evident from the interviews completed for this research, however several nurses emphasised the difficulties of conducting research in the RACF environment, in part because of the requirement to follow a rigid protocol for clinical trials.

Nurses in this study consistently advocated for practical research relevant to direct care and achievable in the RACF setting as being the most beneficial factors in sustaining interventions long-term. O’Keeffe’s (2014) review of research in RACFs supports this
finding also claiming that many of the well-designed studies that researchers want to conduct in RACFs are impractical in the clinical environment.

### 8.6.1 Nurse identified barriers to research in the RACF setting

Recruitment of suitable residents has been identified as a barrier by nurses in this study and is supported by other researchers. Vidello and Lomborg (2011) reported that researchers faced major challenges in recruitment for over 50% of the studies they reviewed. Nurses in this study explained that residents and their families in the RACF setting were often distressed and emotionally fragile during an older persons placement, claiming that for physical, emotional and social reasons, often participation in research was far down their list of priorities. O'Keeffe (2014) also acknowledges that researchers may well be out of date with their current view of RACF residents, warning prospective researchers that residents are no longer the low care relatively active older people that were willing to support research of 10 years earlier. Rather, many of the residents included in this study had complex care needs and were at increased levels of frailty, often palliative or experiencing advanced dementia.

Demanding workloads, competing care priorities and staff shortages were also identified as barriers making it difficult for nurses to comply with research (Burns et al. 2011). The nurses interviewed in this study stated their appreciation of the research assistant who applied the intervention during the RCT, as many felt that essential oils would not have been administered if the study relied on the nurses to deliver the intervention as part of their care. Nurses interviewed also claimed it was difficult to find time once per fortnight to report the observed behaviours of residents in their care to the researcher. Nurses reasoned due to time constraints in an already busy work schedule that without strong scientific evidence of the effect of essential oils research was not a high priority.

Researchers can often overestimate the knowledge clinical staff have of the research process. Akerjordet et al’s (2012) findings support nurses lack of knowledge in research
processes as a possible reason for nurse non-compliance with research. Videlo and Lomborg's (2011) found nurses in over half the studies they reviewed failed to follow the research protocols correctly. Nurses in this study recommended that increasing education and providing encouragement to staff during the research process could increase compliance. They suggested including information about the background to the research and potential benefits to the older person and the nurses daily routine would increase staff support for research projects.

Nurses in this study emphasised a need to be provided with research training at the staff member's educational and English level, which has also been identified by other researchers in RACFs (O'Keefe 2014).

8.7 Implications for the nursing profession

This section discusses the implications of this research for nurse education, practice and policy, facility management and research in RACFs.

8.7.1 Implications for Education

Aged care nurses are required to be knowledgeable of the management of a variety of health conditions associated with old age and to provide best practice, evidence-based care. This research has identified areas for nurse education improvement in agitation management and research processes that validate best practice.

The findings from this research identify a need for effective education on agitation management for nurses in RACFs. Nurses in this study relied on their knowledge of the older person and agitation management training to alleviate behaviours; however many felt ill equipped to cope with the increasing levels of agitation on the ward. Agitation management training is currently a mandatory training initiative for all aged care nursing staff. However, many nurses in this study considered current agitation
management strategies to be short-term measures that merely alleviated behaviour intermittently in many older people.

Nurses in this study reported a fear of management reprisal for not effectively managing agitation after training, which can lead to a lack of incident reporting or unsuitable agitation management. The NSWNMA (2016) survey reports that the frequency of agitation, in particular aggression, to be underreported in RACFs and also reported that 61% of staff feared managerial repercussions of reporting injury resulting from resident agitation. More effective education with practical strategies for managing agitation in residents is required for nursing staff working in RACFs. The appropriateness of education provided for nurses can be assisted by greater transparency between staff and management in addressing the increasing realities of agitation in RACFs.

Nurse education on research processes was identified as a strategy that could enhance the success of research in the RACF environment. Educating nurses of the importance of adherence to research processes can foster a collaborative culture of best practice and improvement in the facility. Nurse non-compliance to research has been associated in the literature with a lack of knowledge and support in research processes (Akerjordet et al. 2012). Education of nurses on research methods can lessen the divide between clinician and researcher for the betterment of care. Suitable nurses interested in research may be identified by management for further training in the research process coupled with support for postgraduate education in this area.

### 8.7.2 Implications for Practice and Policy

This research has implications for RACF nursing practice in three pertinent areas. The first being that increased allocation of nurses time and resources are necessary for the identification of factors that trigger agitation in dementia. The second, relates to vigilance in conforming to legal guidelines in the use of restraints through the documenting, monitoring and reviewing of restraint necessity for older people. The
third, being the allocation of frontline clinical nurses to be research champions for the facility in collaboration with researchers on areas of RACF improvement.

Nurses currently spend less time assessing causative factors of agitation in people with dementia than they do for people without dementia, reporting that impaired communication makes identification of the causes difficult. As a consequence, nurses were more likely to use distraction and restraint in dementia which increases confusion and the likelihood of recurrent agitation. Strategies need to be developed within individual facilities to ensure residents with impaired communication be allocated the necessary time and resources to identify causative factors for agitation. A clinical nurse that specialises in agitation management may provide support to older people and nurses on the wards at a minimal cost to the facility.

Strict adherence is required to monitor, document and review the use of all types of restraints in RACFs. Nurses reported that reoccurring or severe agitation that was difficult to resolve was often managed with chemical restraint. The use of restraint is legal in NSW and serves to contain the behaviour while the nurse can continue with duties. Adherence to monitoring ensures the contained resident is safe, and care needs are being met (DoHA, 2012). Spot checks performed by management can ensure that the restraint registers are completed in a timely and correct manner. In addition, the regular review of a residents need for chemical restraint and dose regularly can limit unnecessary use or overdose of the older person (Hill & Fauerbach, 2014).

Implications for policy include the review of clinical guidelines for the management of agitation, such as the NSW Department of Health Working with People with Challenging Behaviours guide, to ensure transparent, equitable and consistent instruction is given for the management of agitation for all residents regardless of cognitive status (NSW DoH, 2014).
Nurses interviewed were keen to be involved in research, however they were limited in the available time they could contribute to the research. Nurses who show aptitude and interest in research should be encouraged by management to participate in research through the allocation of additional time and educational support. Implications for policy include guidelines that support frontline nurses participation in research. The policy should include specific instructions for delegated time away from direct care duties to fulfil research responsibilities and attend education to support nursing staff to improve research knowledge. In addition, future policy that specifies information that can be shared with researchers can promote greater confidence among staff in disclosing sensitive facility or resident information.

### 8.7.3 Implications for Facility Management

Implications for organisational management from the findings of this research include the consideration of additional agitation specialist staff to provide support to nurses and older people with agitation and management support of a restraint free RACF environment to promote dignity in ageing. High levels of anxiety and depression represented in RACF residents coupled with disparity in care provision found in this research, requires investigation to ensure residents are provided with adequate opportunities for physical, mental and timely-care provision. Support by management for staff opportunities to be involved in research can promote a culture of evidence based best practice in facilities.

The employment of a specialist nurse to manage agitation within the facility to support staff and residents requires consideration from facility management. The creation of such a position would relieve frontline nurses of agitation management responsibilities and free up their time to provide essential care to all residents. In addition, the specialist nurse can ensure that agitation is managed consistently across the organisation and within evidence-based guidelines (Fu et al. 2013). Such an initiative would demonstrate
management’s acknowledgement of the increasing levels of agitation within facilities and their commitment to improving care provision for residents and staff work conditions.

This research recommends management to take a proactive role in the promotion of restraint free environment in RACFs. Recommended measures include the support of mandatory staff education and changes to policy that prohibit the use of restraint in RACFs (Testad et al. 2016). The benefits of a restraint free policy in RACFs protect the human rights of one of societies most vulnerable populations (Decker & Castle, 2011).

Essential oils were found in this study to be well tolerated and safe for older people, with a potential to reduce agitation. A progressive step for managers in aged care would be to promote a chemical restraint free environment that encourages the use of complementary therapies to manage symptoms in residents in their facilities. Essential oils were currently used by a majority of nursing staff in this study with good effect, therefore incorporating essential oil therapy may be supported by the staff and improve behaviours and QoL of residents.

This study also found high levels of depression and anxiety among residents in addition to a difference in care standard offered to those with agitation who have dementia compared to those without dementia and this requires investigation by facility managers. A review of policy, in particular older adults rights for independence, participation, care, self-fulfilment and dignity that underpin minimum care standards (UN, 1991) is warranted. Facility managers are accountable for the service they are promoting to older adults in ensuring that residents have access to physical activity, mental stimulation and timely care provision.

Implications for facility managers also include the need to support nurse participation in research through education, policy and clinical time. Managers can assist nurses by supporting in-service training to inform staff of research being conducted in the facilities.
Alternatively, a designated nurse research officer supported by policy can be appointed to assist the researchers in their investigation process. Researchers need to be mindful of fiscal costs to facilities that can limit the amount of available time the researcher can spend collaborating and educating staff on research processes. However, support from organisational management for nurses to participate in research can only benefit an organisation through improved knowledge and care provision.

8.7.4 Implications for Research

Implications for future research from the findings of this thesis include further investigation of potential agitation management for residents of RACFs. Additional research to identify optimal doses, methods for administration, and pharmacological and pharmacokinetic properties of essential oils and mechanisms of action of Lavender and Lemon Balm to reduce agitation in older people with and without dementia is required. Further investigation is required into the essential oils synergistic effect with pharmacology and the mechanism of action. Research investigating olfactory dysfunction and scent identification in older people with dementia may explain the clinically significant difference in scent effect identified in this study.

Research investigation of how to best support nurses in the research process can improve compliance, while an inquiry potential resident psychosocial readiness to be involved in research can guide future recruitment processes and may protect samples from withdrawal.

Further investigation of appropriate agitation management for older people that is safe and provides effective relief from symptoms is needed to improve care delivery to residents in RACFs. This research has shown nurses to be susceptible to the consequences of agitation in the RACF environment that seriously impact on their ability to prioritise and provide care to all residents. Nurses frustration was compounded by a lack of effective or safe available agitation management for older people in RACFs.
Further research that provides scientific evidence of agitation management effectiveness and practicality can assist nurses in the management of agitation in RACF. Although this study did not provide the scientific evidence for effect that nursing management requires for Lavender or Lemon Balm positive effects on agitation, this study does, however, recommend further research necessary to comprehensively evaluate Lavender or Lemon Balm’s potential as an agitation management.

Finally, recruitment concerns identified by nurses hold implications for greater collaboration between researchers, residents and their families to assess their psychosocial readiness for involvement in research (O’Keeffe, 2014). Research investigating the understanding of the residents and family's experiences can further direct the recruitment approaches.

8.8 Strengths and limitations of this study

A strength of this study was the investigation of influencing factors that support research in the RACF setting. The interviews of 11 nurses with varying qualifications and workplace demands provided information on factors that influence the success of research in the RACF setting that will direct future research in the aged care sector. Another strength provided by the research was the insight into the differences in nurses perceptions of agitation and management provided to residents with dementia compared to those without dementia. Further research is needed to provide standardisation and equity in agitation management for all residents in RACFs regardless of cognitive decline.

A major strength of this study was the implementation of the RCT and maintaining of resident compliance to treatment throughout the 10-week study. The employment of a research assistant overcame issues of nurse noncompliance identified in previous studies and afforded the assurance that interventions were being administered consistently throughout the study (Burns et al. 2011). Dosages for this trial were sort in
consultation with a qualified aroma therapist and dosages were minimal in comparison with previous studies. However, scent can often increase agitation and unwanted behaviour, especially with high scent intensity oils such as Lemon Balm. As low doses were used in this trial, it was imperative that compliance to treatment was maintained.

Another strength of this trial was that the within groups study design provided increased statistical power with the same number of residents compared to a between group design study. In addition, the study design facilitated a reduction in variability between treatment groups as all subjects received each treatment and acted as their own control. Participants were assigned to treatments in a counterbalanced manner to control for time-dependent effects such as resident fatigue or familiarity with research procedures.

This research attempted to overcome all methodological issues identified in previous studies, however limitations in sample size was still evident in this study. To ensure statistical power, 87 residents were approached and consented, however after screening only 75 residents remained and were randomised to the study. A further 10 residents had withdrawn from the study before treatment data was collected. Sixty-five residents completed at least one essential oil treatment cycle and their data was included in the ITT analysis (Appendix K). Ten residents withdrew after one treatment due to departure, relocation, refusal or illness. A further six residents who violated inclusion criteria over the duration of the trial were removed from the analysis. This thesis has reported the PP analysis for the 49 residents that met resident inclusion throughout the study and concluded all three treatment cycles. The unexpected resident withdrawals in this study have reduced sample size limiting the generalisability of the outcomes. More detail on the residents withdraw process can be found in Figure 2 Consort diagram flow chart.

Further increasing the dose or frequency of dose may have resulted in a more substantial reduction in agitation. However, a higher dosage of Lavender was used by O’Conner et al., (2013) and Lemon Balm by Burns et al., (2011) and both studies failed to show any
clinical significant reduction in agitation among people with dementia. Increasing the frequency of doses may be a more viable alternative to increasing the quantity of oil used.

8.9 Conclusion

Several directions for nursing including clinical practice, education, organisational management and policy are addressed in this study. This study is the first study to compare Lavender and Lemon Balm for agitation management in older people without dementia. This study is also the first study to compare the effect of Lemon Balm to Lavender in the same study. Increased frequency of dosage could decrease the declining trend in behaviours. Dosages were given in the morning between 8-10am and a second patch at 4 pm when sundowning behaviours occur may facilitate this trend. Despite reductions in behaviours, Lavender or Lemon Balm did not significantly reduce agitation independent of cognitive decline. A significant difference was shown in the comparison of treatment effect between the cognitive groups on the NPI and CMAI. This opposing clinically significant effect requires further investigation. Specifically further investigation is recommended for Lavender essential oils for the reduction of PNAB behaviours. In addition, research of Lavender’s anti-agitating effects on people without dementia and Lemon Balm’s anti-agitation effect in those without dementia warrants further investigation.

This study has been the first study to investigate nurses perceptions of agitation in people with dementia and without dementia. Nurses perceptions that agitation is intractable in the dementia trajectory led to a difference in management approaches provided to older people dependent on dementia diagnosis and communication ability. This difference in care provision warrants further investigation to ensure standardisation and equity in agitation management provided. Further, this study is the first to investigate a RCT in the RACF environment with findings of influencing factors that support research in this environment to guide future research in aged care.
This study was conducted within an adapted HBM theoretical framework. This study has found nurses to be susceptible to the carer and workplace stresses of residents agitation in the RACF environment. This study shows that the influence of agitation seriously impedes the nurse’s ability to prioritise and conduct care for all older adults in the RACF setting. A lack of available effective and safe management for agitation has provided a cue to action for staff to seek, investigate and possibly adopt new agitation management for residents in the RACF environment. The HBM states for new management to be adopted benefits of the health practice must outweigh the barriers associated with its implementation.

This study has investigated the essential oils of Lavender and Lemon Balm as possible alternatives for nurse-initiated agitation management. In such, nurses perceptions of essential oil were investigated for benefit and barriers as agitation management for residents. Regardless of limited scientific effect, nurses held strong beliefs in the ability of essential oils to reduce agitation in residents without dementia residents. Nurses noncompliance with essential oils administration observed in previous trials alerted researchers to the possibility of barriers to essential oil implementation in the RACF environment. The RACF environment was investigated for influencing factors that could support essential oil research and nurse self-efficacy to adopt and implement essential oils into RACFs.

It is the researchers opinion that despite the nurse’s best intentions, workload demands and competing clinical priorities hinder the use of essential oils to the resident in the RACF environment. This study recommends a specialist nurse be employed by the facility to manage and monitor resident agitation. Specialist nurses can assist the resident with evidence and individual preference based agitation management. The nurse would relieve the burden from the frontline nursing staff allowing them to provide care to other residents. Such a measure by organisational management could be seen as
a positive step towards creating a restraint free culture in the RACF environment that promotes QoL for older people.
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Appendix A Search Strategy

**Academic Search Complete via EBSCO (3)**

- S1 Randomised controlled trial
- S2 Randomized controlled trial
- S3 Clinical trial
- S4 Systematic review
- S5 Random allocation
- S6 Single blind method
- S7 Single blind method
- S8 Comparative study*
- S9 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8
- S10 Agitation
- S11 dementia
- S12 Bpsd
- S13 Neuropsychiatric symp*
- S14 Agitated behavi*
- S15 Irritability
- S16 Inappropriate behavi*
- S17 Aggressive behavi*
- S18 Problem behavi*
- S19 Disruptive behavi*
- S20 Verbally disrupt*
- S21 S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20
- S22 Residential aged care facility*
- S23 Nursing home*
- S24 Homes for the age*
- S25 Institution*
- S26 Care home*
- S27 Special care unit*
- S28 Long term care
- S29 S22 or S23 or S24 or S25 or S26 or S27 or S28
- S30 Over 65 years
- S31 Over 80 years
- S32 Older adult
- S33 Older people
- S34 Resident*
- S35 Seniors
- S36 S30 or S31 or S32 or S33 or S34 or S35 or S36
- S37 Lavender*
- S38 Lemon Balm
- S39 Lavandula Angustifolia
- S40 Melissa Officinalis
- S41 Melissa oil
- S42 S37 or S38 or S39 or S40 or S41
- S43 S42 and S36 and S29 and S21 and S9

**CINAHL via EBSCO (2)**

- S1 Randomised controlled trial
- S2 Randomized controlled trial
- S3 Clinical trial
- S4 Systematic review
- S5 Random allocation
- S6 Single blind method
- S7 Single blind method
- S8 Comparative study*
- S9 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8
- S10 Agitation
- S11 dementia
- S12 Bpsd
- S13 Neuropsychiatric symp*
- S14 Agitated behavi*
- S15 Irritability
- S16 Inappropriate behavi*
- S17 Aggressive behavi*
- S18 Problem behavi*
- S19 Disruptive behavi*
- S20 Verbally disrupt*
- S21 S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20
S22 Residential aged care facility*
S23 Nursing home*
S24 Homes for the age*
S25 Institution*
S26 Care home*
S27 Special care unit*
S28 Long term care
S29 S22 or S23 or S24 or S25 or S26 or S27 or S28
S30 Over 65 years
S31 Over 80 years
S32 Old adult
S33 Older people
S34 Resident*
S35 Seniors
S36 S30 or S31 or S32 or S33 or S34 or S35 or S36
S37 Lavender*
S38 Lemon Balm
S39 Lavandula Angustifolia
S40 Melissa Officinalis
S41 Melissa oil
S42 S37 or S38 or S39 or S40 or S41
S43 S42 and S36 and S29 and S21 and S9

COCHRANE (27)

#1 Randomised controlled trial
#2 Randomized controlled trial
#3 Clinical trial
#4 Systematic review
#5 Random allocation
#6 Single blind method
#7 Single blind method
#8 Comparative study*
#9 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8
#10 Agitation
#11 dementia
#12 Bpsd
#13 Neuropsychiatric symp*
#14 Agitated behavi*
#15 Irritability
#16 Inappropriate behavi*
#17 Aggressive behavi*
#18 Problem behavi*
#19 Disruptive behavi*
#20 Verbally disrupt*
#21 S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20
#22 Residential aged care facility*
#23 Nursing home*
#24 Homes for the age*
#25 Institution*
#26 Care home*
#27 Special care unit*
#28 Long term care
#29 S22 or S23 or S24 or S25 or S26 or S27 or S28
#30 Over 65 years
#31 Over 80 years
#32 Old adult
#33 Older people
#34 Resident*
#35 Seniors
#36 S30 or S31 or S32 or S33 or S34 or S35 or S36
#37 Lavender*
#38 Lemon Balm
#39 Lavandula Angustifolia
#40 Melissa Officinalis
#41 Melissa oil
#42 S37 or S38 or S39 or S40 or S41
#43 S42 and S36 and S29 and S21 and S9

EBSCO (7)

S1 Randomised controlled trial
EMBASE (9) via Ovid

1. Randomised controlled trial.mp. [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
2. Randomized controlled trial.mp. [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
3. Controlled clinical trial.mo. [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
4. Random allocation.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
5. Systematic review.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
6. Single blind method.mp. [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
7. Single blind method.mp. [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
8. Comparative stud*.mp. [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
9. or/1-8
10. Agitation.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
11. BPSD.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
12. Irritability.mp. [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
13. Neuropsychiatric behavior.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
14. Inappropriate behavior.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
15. Disruptive behavior.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
16. Agitated behavior.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
17. Aggressive behavior.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
18. Problem behavior.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
19. Dementia.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
20. or/10-19
21. Nursing home.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
22. Homes for the aged.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
23. Residential aged care facility.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
24. Long term care.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
25. Special care unit.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
26. Care home.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
27. Long term care mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
28. (aged 65 and over).mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
29. (aged 80 and over).mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
30. Resident.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
31. Senior.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
32. Old adult.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
33. Lavender.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
34. Melissa oil. Mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
35. Lavandula Angustifolia.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
36. Melissa officinalis.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
37. 9 and 20 and 29 and 36 and 42
an, ui]
4. Random allocation.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
5. Systematic review.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
6. Single blind method.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
7. Single blind method.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
8. Comparative stud*.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
9. or/1-8
10. Agitation.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
11. BPSD.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
12. Irritability.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
13. Neuropsychiatric behav$ mp. [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
14. Inappropriate behav$.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
15. Disruptive behav$.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
16. dementia.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
17. Agitated behav$ mp. [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
18. Aggressive behav$.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
19. Problem behav$.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
20. or/10-19
21. Nursing home$.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
22. Homes for the aged$.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
23. Residential aged care facility$.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
24. Long term care.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
25. Special care unit$.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
26. Institution mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
27. Care home$ mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
28. Long term care mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
29. or/21-28
30. (aged 65 and over).mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
31. (aged 80 and over).mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
32. Resident$.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
33. Senior$.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
34. Older adult.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
35. Older people.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
36. or/30-35
37. Lavender.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
38. Lemon Balm.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
39. Melissa oil. Mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi,
40. Lavandula Angustifolia.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
41. Melissa officinalis.mp [mp=tx, bt, ed, ot, ab, ct, sh, hw, sa, ca, mi, mx, nt, de, tn, dm, mf, dv, kw, id, ta, te, nm, kf, px, rx an, ui]
42. or 37-41
43. 9 and 20 and 29 and 36 and 42

MEDLINE via EBSCO (5)
S1 Randomised controlled trial
S2 Randomized controlled trial
S3 Clinical trial
S4 Systematic review
S5 Random allocation
S6 Single blind method
S7 Single blind method
S8 Comparative study*
S9 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8
S10 Agitation
S11 dementia
S12 Bpds
S13 Neuropsychiatric symp*
S14 Agitated behavi*
S15 Irritability
S16 Inappropriate behavi*
S17 Aggressive behavi*
S18 Problem behavi*
S19 Disruptive behavi*
S20 Verbally disrupt*
S21 S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20
S22 Residential aged care facility*
S23 Nursing home*
S24 Homes for the age*
S25 Institution*
S26 Care home*
S27 Special care unit*
S28 Long term care
S29 S22 or S23 or S24 or S25 or S26 or S27 or S28
S30 Over 65 years
S31 Over 80 years
S32 Older adult
S33 Older people
S34 Resident*
S35 Seniors
S36 S30 or S31 or S32 or S33 or S34 or S35 or S36
S37 Lavender*
S38 Lemon Balm
S39 Lavandula Angustifolia
S40 Melissa Officinalis
S41 Melissa oil
S42 S37 or S38 or S39 or S40 or S41
S43 S42 and S36 and S29 and S21 and S9

OVID (24)
S1 Randomised controlled trial
S2 Randomized controlled trial
S3 Clinical trial
S4 Systematic review
S5 Random allocation
S6 Single blind method
S7 Single blind method
S8 Comparative study*
S9 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8
S10 Agitation
S11 dementia
S12 Bpds
S13 Neuropsychiatric symp*
S14 Agitated behavi*
S15 Irritability
S16 Inappropriate behavi*
S17 Aggressive behavi*
Problem behavi*
Disruptive behavi*
Verbally disrupt*
S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20
Residential aged care facility*
Nursing home*
Homes for the age*
Institution*
Care home*
Special care unit*
Long term care
S22 or S23 or S24 or S25 or S26 or S27 or S28
Over 65 years
Over 80 years
Older adult
Older people
Resident*
Seniors
S30 or S31 or S32 or S33 or S34 or S35 or S36
Lavender*
Lemon Balm
Lavandula Angustifolia
Melissa Officinalis
Melissa oil
S37 or S38 or S39 or S40 or S41
S42 and S36 and S29 and S21 and S9

PROQUEST (16)
Randomised controlled trial
Randomized controlled trial
Clinical trial
Systematic review
Random allocation
Single blind method
Single blind method
Comparative stud*
S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8
Agitation
dementia
Bpsd
Neuropsychiatric symp*
Agitated behavi*
Irritability
Inappropriate behavi*
Aggressive behavi*
Problem behavi*
Disruptive behavi*
Verbally disrupt*
S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20
Residential aged care facility*
Nursing home*
Homes for the age*
Institution*
Care home*
Special care unit*
Long term care
S22 or S23 or S24 or S25 or S26 or S27 or S28
Over 65 years
Over 80 years
Older adult
Older people
Resident*
Seniors
S30 or S31 or S32 or S33 or S34 or S35 or S36
Lavendula Angustifolia
Melissa Officinalis
S37 or S38 or S39
S40 and S36 and S29 and S21 and S9

255
Randomised controlled trial
Randomized controlled trial
Clinical trial
Systematic review
Random allocation
Single blind method
Single blind method
Comparative study
S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8
Agitation
dementia
Bpsd
Neuropsychiatric symptoms
Agitated behavior
Irritability
Inappropriate behavior
Aggressive behavior
Problem behavior
Disruptive behavior
Verbally disruptive
Residential aged care facility
Nursing home
Homes for the age
Institution
Care home
Special care unit
Long term care
S22 or S23 or S24 or S25 or S26 or S27 or S28
Over 65 years
Over 80 years
Older adult
Older people
Resident
Seniors
S30 or S31 or S32 or S33 or S34 or S35 or S36
Lavender
Lemon Balm
Lavandula Angustifolia
Melissa Officinalis
Melissa oil
S37 or S38 or S39 or S40 or S41
S42 and S36 and S29 and S21 and S9
Residential aged care facility
Nursing home
Homes for the age
Institution
Care home
Special care unit
Long term care
S22 or S23 or S24 or S25 or S26 or S27 or S28
Over 65 years
Over 80 years
Older adult
Older people
Resident
Seniors
S30 or S31 or S32 or S33 or S34 or S35 or S36
Lavender
Lemon Balm
Lavandula Angustifolia
Melissa Officinalis
Melissa oil
S37 or S38 or S39 or S40 or S41
S42 and S36 and S29 and S21 and S9

SCOPUS (12)

#1 TITLE-ABS-KEY(randomised controlled trial*)
#2 TITLE-ABS-KEY(randomized controlled trial*)
#3 TITLE-ABS-KEY(clinical trial*)
#4 TITLE-ABS-KEY(systematic review*)
#5 TITLE-ABS-KEY(random allocation)
#6 TITLE-ABS-KEY(single blind method)
#7 TITLE-ABS-KEY(single blind method)
#8 TITLE-ABS-KEY(comparative study*)
#9 (TITLE-ABS-KEY(randomised controlled trial*)) or (TITLE-ABS-KEY(randomized controlled trial*)) or (TITLE-ABS-KEY(clinical trial*)) or (TITLE-ABS-KEY(systematic review*) or (TITLE-ABS-KEY(random allocation)) or (TITLE-ABS-KEY(single blind method)) or (TITLE-ABS-KEY(comparative study*))
#10 TITLE-ABS-KEY(agitation)
#11 TITLE-ABS-KEY(dementia)
#12 TITLE-ABS-KEY(Bpsd)
#13 TITLE-ABS-KEY(neuropsychiatric symp*)
#14 TITLE-ABS-KEY(agitated behav*)
#15 TITLE-ABS-KEY(irritability)
#16 TITLE-ABS-KEY(inappropriate behav*)
#17 TITLE-ABS-KEY(aggressive behav*)
#18 TITLE-ABS-KEY(problem behav*)
#19 TITLE-ABS-KEY(disruptive behav*)
#20 TITLE-ABS-KEY(verbals disrupt*)
#21 (TITLE-ABS-KEY(agitation)) or (TITLE-ABS-KEY(dementia)) or (TITLE-ABS-KEY(bpsd)) or (TITLE-ABS-KEY(neuropsychiatric symp*)) or (TITLE-ABS-KEY(agitated behav*)) or (TITLE-ABS-KEY(IRRITABILITY))
#22 TITLE-ABS-KEY(AGGRESSIVE behav*) or (TITLE-ABS-KEY(problem behav*)) (TITLE-ABS-KEY(disruptive behav*)) or (TITLE-ABS-KEY(verbals disrupt*)) or (TITLE-ABS-KEY(agitation)) or (TITLE-ABS-KEY(dementia)) or (TITLE-ABS-KEY(bpsd)) or (TITLE-ABS-KEY(neuropsychiatric symp*)) or (TITLE-ABS-KEY(agitated behav*)) or (TITLE-ABS-KEY(IRRITABILITY))
#23 TITLE-ABS-KEY(residential aged care facilit*)
#24 TITLE-ABS-KEY(nursing home*)
#25 TITLE-ABS-KEY(homes for the age*)
#26 TITLE-ABS-KEY(institution*)
#27 TITLE-ABS-KEY(care home*)
#28 TITLE-ABS-KEY(special care unit*)
#29 TITLE-ABS-KEY(long term care)
#30 (TITLE-ABS-KEY(residential aged care facilit*)) or (TITLE-ABS-KEY(nursing home*)) or (TITLE-ABS-KEY(homes for the age*)) or (TITLE-ABS-KEY(institution*)) or (TITLE-ABS-KEY(care home*)) or (TITLE-ABS-KEY(special care unit*)) or (TITLE-ABS-KEY(long term care))
#31 TITLE-ABS-KEY(aged 65 years or over)
#32 TITLE-ABS-KEY(aged 80years or over)
#33 TITLE-ABS-KEY(older people)
#34 TITLE-ABS-KEY(older people)
#35 TITLE-ABS-KEY(older adult)
#36 TITLE-ABS-KEY(resident*)
#37 TITLE-ABS-KEY(senior)
#38 TITLE-ABS-KEY(geriatric)
#39 (TITLE-ABS-KEY(aged 65 years or over)) or (TITLE-ABS-KEY(aged 80years or over)) or (TITLE-ABS-KEY(older people)) or (TITLE-ABS-KEY(older people)) or (TITLE-ABS-KEY(older adult)) or (TITLE-ABS-KEY(resident*)) or (TITLE-ABS-KEY(senior))
#40 TITLE-ABS-KEY(geriatric)) or (TITLE-ABS-KEY(aged 65 years or over)) or (TITLE-ABS-KEY(aged 80years or over)) or (TITLE-ABS-KEY(older people)) or (TITLE-ABS-KEY(older people)) or (TITLE-ABS-KEY(older adult)) or (TITLE-ABS-KEY(resident*)) or (TITLE-ABS-KEY(senior))
#41 TITLE-ABS-KEY(Lavender)
#42 TITLE-ABS-KEY(lemon Balm)
#43 History Search TermsTITLE-ABS-KEY( Lavandula angustifolia)
#44 History Search TermsTITLE-ABS-KEY( Lavandula angustifolia)
#45 History Search TermsTITLE-ABS-KEY( melissa officinalis)
#46 History Search TermsTITLE-ABS-KEY ( melissa oil)
#47 History Search TermsTITLE-ABS-KEY ( lemon Balm) OR ( TITLE-ABS-KEY ( Lavandula angustifolia)) OR ( TITLE-ABS-KEY ( melissa officinalis)) OR ( TITLE-ABS-KEY ( melissa oil))
# Appendix B Tabulated Summary of Studies

<table>
<thead>
<tr>
<th>Author/Country</th>
<th>Essential Oil</th>
<th>Study design/Setting</th>
<th>Treatment</th>
<th>Measurement</th>
<th>Outcomes</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sakamoto 2013, Japan</td>
<td>Lavender</td>
<td>Randomised Controlled trial</td>
<td>Lavender patch or unscented patch applied daily to lavender intervention group for 365 days. The patch was changed daily and worn for a 24-hour period. The old patch was removed by the nursing staff and replaced for 360 days.</td>
<td>Barthel Scale of Daily living, MMSE, CMAI</td>
<td>Significant decrease in CMAI, Fewer falls in the Lavender group. The CMAI score for the Lavender group was 24.3 +/- 5.47 at baseline compared with 22.9 +/- 2.3 at the study conclusions giving a significant reduction in agitation with p-value 0.04.</td>
<td>Oil concentration was not reported. CMAI collected twice only once at Baseline and again at 12 months. The old patch was removed by the nursing staff and replaced for daily for 360 days. CMAI was a secondary measure to falls prevention. Agitation measured pre and post trial only with 12month interval. Scent only detectable to the participant when wearing the suggests the essential oil dosage was low.</td>
</tr>
<tr>
<td>Burns et al, 2013, United Kingdom</td>
<td>Lemon Balm</td>
<td>Double blinded parallel group placebo trial</td>
<td>Twice daily treatments from RA blinding with nose peg.</td>
<td>PAS, NPI</td>
<td>Neither Lemon Balm nor Doneprizel was more beneficial than placebo.</td>
<td>50% nurse compliance of intervention administration was estimated by measuring the returned bottles.</td>
</tr>
</tbody>
</table>
Confounding scent and nose peg blinded assessors from allocation groups.

**Three Groups**
Lemon Balm 10% massage oil and placebo medication.
Medication and Placebo massage oil (no Lemon Balm)
Placebo medication and Placebo massage oil

Participants **60 years** or older

All participants were antipsychotic medication free for two weeks prior to trial

Barthel Scale of Daily Living
Blau Quality of life (QOL) measure.

**Significant improvement in week 12 QOL for Lemon Balm group.**

NPI depression scale showed a significantly smaller change for the donepezil group when compared to aromatherapy and placebo groups.

Sample size was compromised. 35% withdrawal. 81 participants completed the study.

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>O’Conner, Eppingstall, Taffe, van der Ploeg, Australia</td>
<td>Lavender</td>
<td>High dosage 30% Lavender oil massage</td>
<td>Blinded repeated measures design with random cross-over between lavender oil and placebo oil.</td>
<td>Total of 6 treatments over a two-week period. Each treatment given in a week block of three treatments with at least 2-day washout between treatments. Treatment swap occurs week 2.</td>
<td>Direct behaviour monitoring was used to count prominent behaviour 30 minutes prior to intervention and 60 minutes after.</td>
<td>Lavender did not significantly reduce physically agitated behaviours. Sample size is below power calculation.</td>
</tr>
<tr>
<td></td>
<td>High dosage 30% Lavender oil massage</td>
<td>Masking scent and nose peg was used to blind assessors. 64 Participants with moderate to severe dementia in RACF</td>
<td></td>
<td></td>
<td>Direct behaviour monitoring was used to count prominent behaviour 30 minutes prior to intervention and 60 minutes after.</td>
<td>Lavender did not significantly reduce physically agitated behaviours. Sample size is below power calculation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Two groups: Lavender 30% massage oil</td>
<td></td>
<td>Direct behaviour monitoring was used to count prominent behaviour 30 minutes prior to intervention and 60 minutes after.</td>
<td>Physical agitation was only tested and only behaviour.</td>
</tr>
<tr>
<td>Author/Country</td>
<td>Essential Oil</td>
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<tr>
<td>Fu 2009 Australia</td>
<td>Lavender</td>
<td>Single blind randomised controlled trial 61 older people with Dementia 48% with severe dementia <strong>Three groups</strong> Combination aromatherapy spray (3% oil) and hand massage (5ml). Aromatherapy spray (AS) (3% Oil) Placebo water spray</td>
<td>Treatments were twice daily for three weeks. Aromatherapy spray and Placebo spray consisted of three sprays too the chest area. Massage consisted of 5minute hand massage.</td>
<td>CMAI MMSE Revised Memory and Behaviour Problems checklist (RMBPC)</td>
<td>No significant effect in decreasing agitation among groups. Increases in agitation were reported in the combination aromatherapy with hand massage group Aromatherapy plus Massage increased agitation</td>
<td>Nurse compliance in administering was low. Withdrawals led to a lower than anticipated sample size.</td>
</tr>
<tr>
<td>Fuji 2008 Japan</td>
<td>Lavender</td>
<td>Double blind randomised controlled trial. 28 participants with mild to moderate dementia <strong>Two groups:</strong></td>
<td>2 drops of 100% Lavender oil placed on the participants collar area 3 times daily for Placebo group received usual care.</td>
<td>NPI MMSE</td>
<td>Significant improvement in NPI score especially in agitation/agression, motor activity, irritability/lability categories.</td>
<td>Unclear randomization, medication changes and blinding processes.</td>
</tr>
<tr>
<td>Author/Country</td>
<td>Essential Oil</td>
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<tr>
<td>Lin 2007 Hong Kong</td>
<td>Lavender</td>
<td>Randomised controlled single blinded crossover trial</td>
<td>2 drops of 100% Lavandula Angustifolia lavender oil or placebo sunflower oil applied to cotton wool. Two humidifiers placed either side of participant containing treatment for one hour daily while sleeping. Treatment blocks of 3 weeks followed by 2-week washout then 3 weeks alternate treatment.</td>
<td>Chinese forms of the measurements were used. MMSE CMAI NPI</td>
<td>Significant decrease in CMAI and NPI for in the lavender group. particularly those of depression, as well as irritability/lability and aberrant motor behaviours (33) Mean score on the CCMAI was 63.17 (SD=17.81) to 58.77 (SD=16.74) and on the CNPI a reduction of 24.68 to 17.77 (p&lt;.001)</td>
<td>Inadequate blinding as staff/assessors are not blinded to treatment group. Unreported baseline after washout at the start of each treatment.</td>
</tr>
<tr>
<td>Ballard 2002 Australia</td>
<td>Lemon Balm</td>
<td>Single blind Placebo controlled trial</td>
<td>10% essential oil cream or 10 % placebo cream applied to face and arms twice a week for four weeks.</td>
<td>Barthel scale, NPI CMAI</td>
<td>Significant reduction in agitation on CMAI with 60% of Lemon Balm group reducing behaviours by 30% and an overall</td>
<td>Participants were randomised by facility, which may have led to differences in care confounding results.</td>
</tr>
<tr>
<td>Author/Country</td>
<td>Essential Oil</td>
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</tr>
<tr>
<td>Bowles 2002</td>
<td>Lavender blend (Lavender, Sweet marjoram, Vetiver)</td>
<td>Cross-over design</td>
<td>3.5% blended oil cream massaged neck, shoulders back and arms five times daily with five minute durations</td>
<td>MMSE</td>
<td>Improvement of MMSE in 7 residents.</td>
<td>Assessors were aware of group allocation.</td>
</tr>
<tr>
<td>Australia</td>
<td></td>
<td>56 residents with dementia</td>
<td>Alternate oil treatment by week. Oil massage first week massage no oil second week. 10-week study with a cross over of treatment occurring in week 7.</td>
<td>CMAI</td>
<td>Decreases in resistance of care frequency and severity in both placebo and oil blend group.</td>
<td>36% of data was missing at the study conclusion.</td>
</tr>
<tr>
<td></td>
<td>Two Groups</td>
<td>Massage with oil</td>
<td></td>
<td>Nursing notes documenting resistance to care.</td>
<td></td>
<td>Baselines or interater reliability was not established for measurement.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Massage without oil</td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td>Residents were aged over 60 years.</td>
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</tr>
</tbody>
</table>
Appendix C Nurse participant information sheet

Human Research Ethics Committee

Office of Research Services

Nurse Participant Information Sheet

Project Title: Essential Oils for Agitation Management in Older Adults: A Mixed Method Study

Who is carrying out the study?

Primary Investigator

Ms. Karen Watson BHlthSc(Nat) BNGE BN(Hons.) PhD candidate, School of Nursing and Midwifery, University of Western Sydney, Telephone: 0455578279 Email: Karen.Watson@uws.edu.au

Supervisors

Professor Esther Chang Professor of Nursing, Director of Higher Degree Research School of Nursing and Midwifery University of Western Sydney Telephone: 02 96859046 Facsimile: 02 96859023 Email: e.chang@uws.edu.au

Assoc. Prof. Amanda Johnson Senior Lecturer Director of Academic Programs - Undergraduate, School of Nursing and Midwifery University of Western Sydney Telephone: 0296859115 Facsimile: 02 96859023 Email: amanda.johnson@uws.edu.au

Dr. Anthony Good Senior Lecturer/Head of Clinical Development, Centre for Complementary Medicine Research, School of Science and Health, University of Western Sydney. Telephone: 02 46203345 Facsimile: 02 46203291 Email: a.good@uws.edu.au

You are invited to participate in a study conducted by Karen Watson PhD candidate, under her supervisors with the School of Nursing and Midwifery, University of Western Sydney.

What is the study about?

The purpose of this study is to investigate the effect of the essential oils Lavender and Lemon Balm on agitation in older adults. The use of essential oils to promote health benefit is commonly known as aromatherapy. Lavender and Lemon Balm are used in aromatherapy traditionally for their relaxing properties. This calming effect of Lavender and Lemon Balm may assist in relieving or reducing agitation in older adults. Essential oils can be administrated by an accredited aged care nurse and may provide an expedient management tool for health conditions. This study also provides foundation for future
research examining mechanisms of action and the types of people or conditions which best respond to aromatherapy management.

What does the study involve?

Should you agree to participate:

- The researcher will ask you to attend two semi-structured audiotaped interviews, once at study commencement and again at the study conclusion. The interview questions are designed to explore perceptions towards agitation and complementary therapies. The aged care setting will also be explored for barriers and facilitators to nurse initiated aromatherapy.
- As a nurse participant you will be asked to observe agitated behaviours of the older adults in your regular care. A research assistant will attach a patch containing treatment to older adult participants in your care daily and remove the patch after two hours. The nurse participant will report observed behaviours of older adult participants fortnightly. Observations will be recorded on the Cohen Mansfield Agitation Inventory [CMAI] and the Neuropsychiatric Inventory [NPI] in conjunction with the primary investigator.

How much time will the study take?

<table>
<thead>
<tr>
<th></th>
<th>Approximate Time</th>
<th>What will be done</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Interview</strong></td>
<td>20-30 minutes</td>
<td>Semi structured audiotaped interview investigating perceptions of agitation, complementary therapies and their feasibility as managements in RACFs.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Interviews will be conducted during normal nursing activities or at a time convenient to the nurse and primary investigator.</td>
</tr>
<tr>
<td><strong>Agitation observing and reporting</strong></td>
<td>5-20 minutes fortnightly. 5 times during the 10-week study.</td>
<td>Nurses will be asked to observe the agitated behaviour of older adult participants who are in their regular care. They will report what they have observed to the researcher every two weeks. The time taken in this task is variable and dependent on the nurse's familiarity with the resident and knowledge of their behaviours.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Observation reporting can be attended during normal nursing activities or at a time convenient to the nurse and primary investigator.</td>
</tr>
<tr>
<td>Concluding Interview</td>
<td>20-30 minutes</td>
<td>Semi structured audiotaped interview investigating perceptions of agitation, complementary therapies and their feasibility as managements in RACFs. Interviews will be conducted during normal nursing activities or at a time convenient to the nurse and primary investigator.</td>
</tr>
</tbody>
</table>

**Will the study benefit me?**

This study aims to further nursing knowledge and may improve future treatment for agitation of older adults living in residential aged care facilities. Reductions in agitation can lead to increased nurse productivity and improve morale among staff, residents and their families creating a less stressful workplace environment. Your contribution in this study will allow better guidance on essential oil management of agitation in the future. Benefits may also include the knowledge that you are furthering the investigation into quality healthcare management practices for older adults in residential aged care facilities.

**Will the study have any risks?**

All health care management procedures involve some risk. The researchers anticipate risks to be few and unlikely for nurse participants in this study. However essential oils are proven low irritants and may exacerbate allergy symptoms in some people. Additionally nurse participants may become uncomfortable during the interview process; at this point the interview will be ceased at the resident’s request and rescheduled. There may also be risks associated with the study that are presently unknown or unforeseen. If you at any time have concerns regarding anticipated or actual risks or discomforts, please raise them with the aged care nurse and the investigator directly.

**How is this study being paid for?**

The study is supported by the School of Nursing and Midwifery, University of Western Sydney.

**Will anyone else know the results? How will the results be disseminated?**

All aspects of the study, including results, will be confidential and only the researchers will have access to information on residents. Data will be recorded and stored on the primary researchers password protected computer and destroyed once results are finalised. Any identifiable information collected about you will remain confidential and can only be disclosed with your permission or as required by law.

Nurse interviews will be audiotaped. The researcher will listen to the interview to transcribe themes and significant statements from the interviewee. The transcription will then be reviewed by the nurse participant, amended and elaborated upon before the
information is pooled. Identifying features will be removed from the data once approved by nurse participants to ensure confidentiality.

The primary researcher plans to use this data in preparing a thesis, report and further publications. Be assured information provided is treated in the strictest confidence and you will not be personally identifiable in the resulting documents.

**Can I withdraw from the study?**

Your participation in this study is voluntary. Your decision not to participate will not affect the relationship you have with your place of work or the researchers. If you do commence this study you have the right to withdraw at anytime without requiring an explanation. However if you do withdraw from the study at a late stage it may not be possible to withdraw your data from the study results if these have already had your identifying details removed.

**Can I tell other people about the study?**

Yes, you can tell other people about the study by providing them with the chief investigator's contact details. They can contact the chief investigator to discuss their participation in the research project and obtain an information sheet.

**What if I require further information**

If you would like to know more at any stage, please feel free to contact Karen Watson, PhD Candidate, School of Nursing and Midwifery, University of Western Sydney on 0455578279 or Karen.Watson@uws.edu.au.

**What if I have a complaint?**

This study has been approved by the University of Western Sydney Human Research Ethics Committee and NSW Department of Health Area Health Service. The Approval number is H10550.

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through the Office of Research Services on Tel +61 2 4736 0229 Fax +61 2 4736 0013 or email humanethics@uws.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome. If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for the resident to keep and the consent form is retained by the researcher.
Appendix D Nurse participant consent

Human Research Ethics Committee
Office of Research Services

Nurse Participant Consent Form

This is a project specific consent form. It restricts the use of the data collected to the named project by the named investigators.

**Project Title: Essential Oils for agitation management in older adults: A mixed methods study.**

I, ........................................, consent to participate in the research project titled Essential Oils for Agitation Management in Older Adults: A Mixed Methods Study.

I acknowledge that:

I have read the resident information sheet and have been given the opportunity to discuss the information and my involvement in the project with the researcher.

The procedures required for the project and the time involved have been explained to me, and any questions I have about the project have been answered to my satisfaction.

I consent to two semi structured interviews with the researcher, once at the study commencement and again at the study's conclusion. I consent to these interviews being audiotaped and understand that I will be required to approve a transcript of my interview prior to this information being included in the study. I understand that interviews and recording times will be scheduled at a time convenient to both the researcher and myself. I consent to observe older adults residents in my regular care to monitor agitation and record my findings, in conjunction with a researcher on the Neuropsychiatric Inventory [NPI] and the Cohen Mansfield Agitation Inventory [CMAI] once every two weeks for ten weeks.

I understand that my involvement is confidential and that the information gained during the study may be published but no information about me will be used in any way that reveals my identity.

I understand that I can withdraw from the study at any time, without affecting my relationship with the researchers now or in the future.

Signed:  
Name:  
Date:  

Return Address:  
Karen Watson  
School of Nursing and Midwifery  
Locked Bag 1797  
Penrith NSW  2567  

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Appendix E Phase I Interview questions

Agitation

- What behaviours do you consider to be agitation?
- How often do you see agitation on the ward?

dementia

- Are their differences in the way agitation is managed in people with dementia compared to people who have without dementia? Can you some examples?
- In your view is agitation managed more effectively in people with without dementia compared to those who have dementia?

Essential oils

- Have you used essential oils previously? Have you found them effective? Would you consider using essential oils for a health condition or problem? Why?
- How effective do you perceive essential oils will be in managing agitation in older adults? Can you give me an example?

RACF Environment

- How important do you see research for older people living in RACFs?
- It has been said in other research studies that the staff are not compliant or not cooperatively when implementing an intervention or research study in RACF. What do you think are the underlying issues surrounding this statement?
- How do you think future research can be better implemented in the RACF environment?
Appendix F Phase III interview question

Interview questions

- Have there been any changes in the frequency of agitation in the residents participating in the trial?
- Do you think essential oils are effective for agitation management?
- Would you consider using essential oils for your own health conditions?
- Were there any challenges or problems associated with conducting the trial in your facility?
- Can you suggest better ways to implement future trials into this facility and future facilities?
Appendix G
Participant information Sheet

Human Research Ethics Committee
Office of Research Services

Participant Information Sheet

Project Title: Essential Oils for Agitation Management in Older Adults: A Mixed Method Study

Who is carrying out the study?

Primary Investigator
Ms. Karen Watson BN, BHIthSc (Nat), PhD candidate School of Nursing and Midwifery, University of Western Sydney, Telephone: 0455578279 Email: Karen.Watson@uws.edu.au

Supervisors
Professor Esther Chang Professor of Nursing, Director of Higher Degree Research School of Nursing and Midwifery University of Western Sydney Telephone: 02 96859046 Facsimile: 02 96859023 Email: e.chang@uws.edu.au
Dr Amanda Johnson Senior Lecturer Director of Academic Programs - Undergraduate, School of Nursing and Midwifery University of Western Sydney Telephone: 0296859115 Facsimile: 02 96859023 Email: amanda.johnson@uws.edu.au
Dr Anthony Good, Head of Clinical Development, National Institute of Complementary Medicine (NICM), School of Science and Health, University of Western Sydney. Telephone: 02 46203345 Facsimile: 02 46203291 Email: a.good@uws.edu.au

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What is the study about?

The purpose of this study is to investigate the effect of the essential oils Lavender and Lemon Balm on agitation in older adults. The use of essential oils to improve health is commonly known as aromatherapy. Lavender or Lemon Balm have traditionally been used in aromatherapy for their relaxing properties. This calming effect may assist in relieving or reducing agitation. This study will provide valuable scientific evidence of Lavender and Lemon Balm’s effects on agitation in older adults. This study also provides
a foundation for future investigations into how aromatherapy works and the type of people or conditions that best respond to aromatherapy management.

**What does the study involve?**

If you agree to participate:

- The researcher will require access to your medical records and information on agitation as provided by their regular carers.
- You will be asked to take part in a Mini Mental State Evaluation (MMSE) questionnaire prior to study commencement.
- You will be asked to take part in a simple scent identification test. This test will consist of three scent sticks two with the same scent and one with a different scent. You will be asked to identify the stick with the different scent. **NOTE:** Potential residents who cannot identify the different scent will not continue in this study, however may be included in subsequent studies resulting from this research.
- You will be asked to wear a 2x2.5cm dark cloth patch for two hours daily for duration of ten weeks. The patch will contain 2 drops of treatment being Lavender essential oil or Lemon Balm essential oil, placebo sunflower oil or no oil.
- A researcher will attach the patch with double-sided velcro to your collar area daily and remove the patch after two hours. The treatment scent will be changed every two weeks so residents can trial all scents.
- The researcher will meet with you and your carers every fortnight for 10 weeks to monitor progress. At this time information on agitation will be collected from carers and information on quality of life [QoL] will be collected from you, as the resident.

**How much time will the study take?**

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<tr>
<th></th>
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<tbody>
<tr>
<td><strong>Initial Interview</strong></td>
<td>20 minutes</td>
<td>Mini Mental State examination [MMSE] questionnaire.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Scent Identification Test</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quality of Life questionnaire</td>
</tr>
<tr>
<td><strong>Daily patch administration and removal</strong></td>
<td>5-10 minutes daily for 6 weeks.</td>
<td>A research assistant will attach the patch to the residents collar area and remove the patch after 2 hours.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>This will be done during residents normal activities or at a time convenient to the resident and research assistant</td>
</tr>
<tr>
<td><strong>Progress monitoring</strong></td>
<td>10-15 minutes fortnightly.</td>
<td>Quality of Life questionnaire.</td>
</tr>
<tr>
<td></td>
<td>5 times during the 10-week study.</td>
<td>Progress monitoring will be scheduled at a time convenient to the resident and the researcher.</td>
</tr>
</tbody>
</table>

**Will the study benefit me?**
This study aims to further medical knowledge and may improve future treatment for agitation of older adults living in residential aged care facilities. While this study seeks to reduce agitation and improve quality of life in residents, the study may not directly benefit you. Your contribution in this study will, however, allow better guidance on essential oil management of agitation in the future. Benefits may also include the knowledge that you are furthering the investigation into quality healthcare management practices for older adults in residential aged care facilities.

**Will the study have any risks?**

All health care management procedures involve some risk. The researchers anticipate risks to be few and unlikely in this study. Skin irritation is a known risk, however uncommon in essential oils. The risk of skin irritation is further reduced as there is no contact between essential oil and skin in this study. However, in the unlikely event you experience skin irritation please alert the aged care nurse and or researcher immediately.

There may also be risks associated with the study that are presently unknown or unforeseen. If you at any time have concerns regarding anticipated or actual risks or discomforts, please raise them with the aged care nurse and the researcher directly.

**How is this study being paid for?**

The study is being supported by the School of Nursing and Midwifery, University of Western Sydney.

**Will anyone else know the results? How will the results be disseminated?**

All aspects of the study, including results, will be confidential and only the researchers will have access to information on residents. Data will be recorded and stored on the primary investigators password protected computer and destroyed once results are finalised. Any identifiable information collected about you will remain confidential and can only be disclosed with your permission or as required by law. The primary investigator plans to use this data in preparing a thesis, report and further publications. Be assured information provided is treated in the strictest confidence and you will not be personally identifiable in the resulting documents.

**Can I withdraw from the study?**

Your participation in this study is voluntary. Your decision not to participate in this study will not effect the care you receive now or in the future. Your decision not to participate will not affect your relationship with the staff who care for you or the researchers. If you commence this study you have the right to withdraw at anytime without requiring an explanation. However, if you decide to withdraw from the study at a late stage it may not be possible to withdraw your data from the study results if these have already had identifying details removed.

**Can I tell other people about the study?**

Yes, you can tell other people about the study by providing them with the chief investigator’s contact details. They can contact the chief investigator to discuss their participation in the research project and obtain an information sheet.

**What if I require further information?**

If you would like to know more at any stage, please feel free to contact the primary
investigator Karen Watson PhD Candidate School of Nursing and Midwifery, University of Western Sydney on 0455578279 or Karen.Watson@uws.edu.au

What if I have a complaint?

This study has been approved by the University of Western Sydney Human Research Ethics Committee and NSW Department of Health Area Health Service. The Approval number is H10550.

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through the Office of Research Services on Tel +61 2 4736 0229 Fax +61 2 4736 0013 or email humanethics@uws.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome. If you agree to participate in this study, you may be asked to sign the Participant Consent Form.
Appendix H Participant Information Sheet - Caregiver

Human Research Ethics Committee
Office of Research Services

Participant Information Sheet - Caregiver

Project Title: Essential Oils for Agitation Management in Older Adults: A Mixed Method Study

Who is carrying out the study?

Primary Investigator

Ms. Karen Watson BN, BHIthSc (Nat), PhD candidate School of Nursing and Midwifery, University of Western Sydney, Telephone: 0455578279 Email: Karen.Watson@uws.edu.au

Supervisors

Professor Esther Chang Professor of Nursing, Director of Higher Degree Research School of Nursing and Midwifery University of Western Sydney Telephone: 02 96859046 Facsimile: 02 96859023 Email: e.chang@uws.edu.au

Dr Amanda Johnson Senior Lecturer Director of Academic Programs - Undergraduate, School of Nursing and Midwifery University of Western Sydney Telephone: 0296859115 Facsimile: 02 96859023 Email: amanda.johnson@uws.edu.au

Dr Anthony Good, Head of Clinical Development, National Institute of Complementary Medicine (NICM), School of Science and Health, University of Western Sydney. Telephone: 02 46203345 Facsimile: 02 46203291 Email: a.good@uws.edu.au

The person in your care is invited to participate in a study conducted by Karen Watson PhD candidate, under her supervisors with the School of Nursing and Midwifery, University of Western Sydney.

What is the study about?

The purpose of this study is to investigate the effect of the essential oils Lavender and Lemon Balm on agitation in older adults. The use of essential oils to improve health is commonly known as aromatherapy. Lavender or Lemon Balm have traditionally been used in aromatherapy for their relaxing properties. This calming effect may assist in relieving or reducing agitation. This study will provide valuable scientific evidence of Lavender and Lemon Balm’s effects on agitation in older adults. This study also provides a foundation for future investigations into how aromatherapy works and the type of people or conditions that best respond to aromatherapy management.
What does the study involve?

If you agree to the person in your care participating in this study:

- The researcher will require access to resident’s medical records and information on agitation as provided by their regular carers.
- Participants will take part in a Mini Mental State Evaluation (MMSE) questionnaire prior to study commencement.
- Participants will take part in a simple scent identification test. This test will consist of three scent sticks two with the same scent and one with a different scent. Participants will be asked to identify the stick with the different scent. **NOTE:** Participants who cannot identify the different scent will not continue in this study, however may be included in subsequent studies resulting from this research.
- Participants will wear a 2x2.5cm dark cloth patch for two hours daily for a duration of ten weeks. The patch will contain 2 drops of treatment being Lavender essential oil or Lemon Balm essential oil, placebo sunflower oil or no oil.
- A researcher will attach the patch with double-sided velcro to the resident’s collar area daily and remove the patch after two hours. The treatment scent will be changed every two weeks so the resident can trial all scents.
- The researcher will meet with the resident and their facility carers every fortnight for 10 weeks to monitor progress. At this time information on agitation will be collected from carers and information on quality of life [QoL] will be collected from resident.

How much time will the study take

<table>
<thead>
<tr>
<th>Approximate Time</th>
<th>What will be done</th>
</tr>
</thead>
</table>
| **Initial Interview** | 20-30 minutes | Mini Mental State examination [MMSE] questionnaire.  
Scent Identification Test  
Quality of Life questionnaire |
| **Daily patch administration and removal** | 5-10 minutes daily for 10 weeks. | A research assistant will attach the patch to the residents collar area and remove the patch after 2 hours.  
This will be done during residents normal activities or at a time convenient to the resident and research assistant |
| **Progress monitoring** | 10-15 minutes fortnightly.  
5 times during the 10-week study. | The resident will be asked to fill out a [QoL] questionnaire with the assistance of the researcher. Progress monitoring will be scheduled at a time convenient to the resident and the researcher. |
Will the study benefit me?

This study aims to further medical knowledge and may improve future treatment for agitation of older adults living in residential aged care facilities. While this study seeks to reduce agitation and improve quality of life in residents, the study may not directly benefit the person in your care. Their contribution in this study will, however, allow better guidance on essential oil management of agitation in the future. Benefits may also include the knowledge that you and the person in your care are furthering the investigation into quality healthcare management practices for older adults in residential aged care facilities.

Will the study have any discomforts?

All health care management procedures involve some risk. The researchers anticipate risks to be few and unlikely in this study. Skin irritation is a known risk, however uncommon in essential oils. The risk of skin irritation is further reduced as there is no contact between essential oil and skin in this study. However, in the unlikely event you experience skin irritation please alert the aged care nurse and or researcher immediately.

There may also be risks associated with the study that are presently unknown or unforeseen. If you at any time have concerns regarding anticipated or actual risks or discomforts, please raise them with the aged care nurse and the researcher directly.

How is this study being paid for?

The study is being supported by the School of Nursing and Midwifery, University of Western Sydney.

Will anyone else know the results? How will the results be disseminated?

All aspects of the study, including results, will be confidential and only the researchers will have access to information on residents. Data will be recorded and stored on the primary investigators password protected computer and destroyed once results are finalised. Any identifiable information collected about you will remain confidential and can only be disclosed with your permission or as required by law. The primary investigator plans to use this data in preparing a thesis, report and further publications. Be assured information provided is treated in the strictest confidence and you will not be personally identifiable in the resulting documents.

Can I withdraw the person in my care from the study?

Your participation in this study is voluntary. Your decision not to participate in this study will not effect the care the person in your care receives now or in the future. Your decision not to participate will not affect the person in your care’s relationship with the staff who care for them or the researchers. If the person in your care does commence this study you have the right to withdraw that person at any time without requiring an explanation. The person in your care will be monitored daily to their progression in the study by the research assistant and nursing staff.

The person in your care will be removed from the study if they are deemed to experience verbal or non-verbal discomfort due to the study processes. If the person in your care withdraws from the study at a late stage it may not be possible to withdraw their data from the study results if these have already had identifying details removed.
Can I tell other people about the study?

Yes, you can tell other people about the study by providing them with the chief investigator’s contact details. They can contact the chief investigator to discuss their participation in the research project and obtain an information sheet.

What if I require further information?

If you would like to know more at any stage, please feel free to contact the primary investigator Karen Watson, PhD Candidate, School of Nursing and Midwifery, University of Western Sydney on 0455578279 or Karen.Watson@uws.edu.au

What if I have a complaint?

This study has been approved by the University of Western Sydney Human Research Ethics Committee and NSW Department of Health Area Health Service. The Approval number is [enter approval number]

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through the Office of Research Services on Tel +61 2 4736 0229 Fax +61 2 47360013 or email humanethics@uws.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome. If you agree to participate in this study, you may be asked to sign the Participant Consent Form.
Appendix I Participant Consent Form

Human Research Ethics Committee
Office of Research Services

Participant Consent Form

Project Title: Essential oils for agitation management in older adults: A Mixed Methods study

I, ........................................, consent to participate in the research project titled Essential Oils for Agitation Management: A Mixed Methods Study.

I acknowledge that:

I have read the resident information sheet and have been given the opportunity to discuss the information and my involvement in the project with the researcher.

The procedures required for the project and the time involved have been explained to me, and any questions I have about the project have been answered to my satisfaction.

I consent to the researchers accessing my medical records and information on my agitation as provided by my regular carers.

I consent to take part in a Mini Mental State Evaluation (MMSE) questionnaire to participate in a simple scent identification test consisting of three scent sticks for the purpose of identifying scent. Also to meet with the researcher every fortnight for 6 weeks for the purpose of completing a quality of life [QoL] questionnaire.

I consent to wear a 2x2.5cm cloth patch for two hours daily for a duration of ten weeks. I understand the patch will contain 2 drops of treatment being Lavender essential oil or Lemon Balm essential oil, placebo sunflower oil or no oil.

I consent to a research assistant attaching the patch with double-sided velcro to my collar area daily and removing the patch after two hours. I understand treatment scent will be changed every two weeks so I can trial all treatment scents.

I understand that my involvement is confidential and that the information gained during the study may be published but no information about me will be used in any way that reveals my identity.

I understand that I can withdraw from the study at any time, without affecting my relationship with the researchers now or in the future.

Signed: ........................................................................................................

Name: ........................................................................................................

Date: ........................................................................................................
This study has been approved by the University of Western Sydney Human Research Ethics Committee. The Approval number is: H10550.

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through the Office of Research Services on Tel +61 2 4736 0229 Fax +61 2 4736 0013 or email humanethics@uws.edu.au. Any issues you raise will be investigated fully, and you will be informed of the outcome.
Appendix J Participant Consent Form for Carers

Human Research Ethics Committee
Office of Research Services

Participant Consent Form for Carers

Project Title: Essential Oils for Agitation Management in Older Adults: A Mixed Methods Study.

I…………………………, give consent for ……………………………to participate in the research project titled Essential oils for agitation management in older adults: a mixed methods study.

I acknowledge that:

I have read the resident information sheet. The person in my care and I, have been given the opportunity to discuss this information with the researcher. I have also been given the opportunity to discuss the involvement of the person in my care with the researcher.

The procedures required for the project and the time involved have been explained to me, and the person I care for. Any questions I have about the project have been answered to my satisfaction.

I consent to the researchers accessing the medical records of the person in my care and information on their agitation as provided by the regular carers.

I consent to the person in my care taking part in a Mini Mental State Evaluation (MMSE) questionnaire, participating in a simple scent identification test consisting of three scent sticks for the purpose of identifying scent. Also to meet with the researcher every fortnight for 10 weeks for the purpose of completing a quality of life [QoL] questionnaire with the researcher’s assistance.

I consent to the person in my care wearing a 2x2.5cm cloth patch for two hours daily for a duration of ten weeks. I understand the patch will contain 2 drops of treatment being Lavender essential oil or Lemon Balm essential oil, placebo sunflower oil or no oil.

I consent to a research assistant attaching the patch with double-sided velcro to the collar area daily of the person in my care and removing the patch after two hours. I understand treatment scent will be changed every two weeks so they can trial all treatment scents.

I have discussed participation in the project with the person in my care and they agree to their participation in the project.

I understand that the involvement of the person in my care is confidential and any information gained during the study may be published but no information about the
person in my care will be used in any way that reveals their identity.

I understand that I can withdraw the person in my care from this study at any time, without affecting their medical care or relationship with their carers or the researchers now or in the future.

Signed (caregiver): ........................................
Name: ..........................................................
Date: ..............................................................

Signed (resident): ..............................
Name: ..........................................................
Date: ............................................................

Return Address:  Karen Watson
                 School of Nursing and Midwifery
                 University of Western Sydney
                 Locked Bag 1797
                 PENRITH NSW 2571

This study has been approved by the University of Western Sydney Human Research Ethics Committee. The Approval number is H10550.

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through the Office of Research Services on Tel +61 2 4736 0229 Fax +61 2 4736 0013 or email humanethics@uws.edu.au. Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
## Appendix K Phase II Intention to Treat (ITT) Results

<table>
<thead>
<tr>
<th></th>
<th>Dementia (m)</th>
<th>without Dementia (m)</th>
<th>P value</th>
<th>DF</th>
<th>F value</th>
<th>F critical</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPI</td>
<td>-13.62</td>
<td>-14.08</td>
<td>0.97</td>
<td>DF81</td>
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<td>Fc=3.95</td>
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<tr>
<td>Irritability</td>
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<tr>
<td>CMAI</td>
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<tr>
<td>CMAI PANB</td>
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<td>DF56</td>
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<td>Fc=4.01</td>
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<tr>
<td>QoL-AD</td>
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<td>-2.91</td>
<td>0.22</td>
<td>DF42.11</td>
<td>1.159</td>
<td>Fc=4.07</td>
</tr>
</tbody>
</table>

Planned analysis 1 NPI, CMAI and QoL-AD outcomes

<table>
<thead>
<tr>
<th></th>
<th>Placebo (m)</th>
<th>Treatment (m)</th>
<th>P value</th>
<th>DF</th>
<th>F value</th>
<th>F critical</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPI</td>
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<td>-9.00</td>
<td>0.86</td>
<td>DF87.09</td>
<td>1.103</td>
<td>Fc=3.98</td>
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<tr>
<td>NPI Irritability</td>
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<td>-1.69</td>
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<td>DF73</td>
<td>1.002</td>
<td>Fc=3.97</td>
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<td>CMAI</td>
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<td>-5.46</td>
<td>0.99</td>
<td>DF60</td>
<td>1.000</td>
<td>Fc=4.00</td>
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<td>CMAI PANB</td>
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<td>0.10</td>
<td>DF57</td>
<td>1.298</td>
<td>Fc=4.00</td>
</tr>
<tr>
<td>QoL-AD</td>
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<td>-0.50</td>
<td>0.92</td>
<td>DF38.6</td>
<td>1.001</td>
<td>Fc=4.10</td>
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</table>

Planned analysis 2 NPI, CMAI and QoL-AD outcomes

<table>
<thead>
<tr>
<th></th>
<th>Lavender (m)</th>
<th>Lemon Balm (m)</th>
<th>P value</th>
<th>DF</th>
<th>F value</th>
<th>F critical</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPI</td>
<td>-9.11</td>
<td>-8.89</td>
<td>0.86</td>
<td>DF70.89</td>
<td>1.215</td>
<td>Fc=3.95</td>
</tr>
<tr>
<td>NPI Irritability</td>
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<td>DF73</td>
<td>1.018</td>
<td>Fc=3.97</td>
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<tr>
<td>CMAI</td>
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<tr>
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<td>DF57.9</td>
<td>1.012</td>
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<td>DF40</td>
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<td>Fc=4.09</td>
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</table>

Planned analysis 3 NPI, CMAI and QoL-AD outcomes

<table>
<thead>
<tr>
<th></th>
<th>Dementia</th>
<th>Without Dementia</th>
<th>Dementia</th>
<th>Without Dementia</th>
<th>P value</th>
<th>DF</th>
<th>F value</th>
<th>F critical</th>
</tr>
</thead>
<tbody>
<tr>
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<td>-1.88</td>
<td>-7.23</td>
<td>0.15</td>
<td>DF87.18</td>
<td>1.215</td>
<td>Fc=3.96</td>
</tr>
<tr>
<td>NPI Irritability</td>
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<td>-1.33</td>
<td>0.04</td>
<td>DF73</td>
<td>1.455</td>
<td>Fc=3.97</td>
</tr>
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<td>CMAI</td>
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<td>DF59.26</td>
<td>1.003</td>
<td>Fc=4.00</td>
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<tr>
<td>CMAI PANB</td>
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<td>-1.28</td>
<td>-0.15</td>
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<td>0.14</td>
<td>DF57.9</td>
<td>1.223</td>
<td>Fc=4.01</td>
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<td>QoL-AD</td>
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<td>-3.0</td>
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<td>-0.17</td>
<td>0.22</td>
<td>DF42.11</td>
<td>1.159</td>
<td>Fc=4.07</td>
</tr>
</tbody>
</table>

Planned analysis 4 NPI, CMAI and QoL-AD outcomes