



# A randomised controlled trial of Lavender (*Lavandula Angustifolia*) and Lemon Balm (*Melissa Officinalis*) essential oils for the treatment of agitated behaviour in older people with and without dementia



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## ABSTRACT

**Objective:** Lavender and Lemon Balm essential oils are popular in the management of older person agitation due to their ease of application, minimal side effects and low interaction with concurrent medications. This study addressed limitations in the literature to evaluate and compare effectiveness of Lavender and Lemon Balm essential oils on the agitated behaviour of older people with and without dementia living in residential aged care facilities [RACFs].

**Methods:** Forty-nine nursing home residents with dementia (n=39) and without dementia (n=10) exhibiting agitation participated in this study. Participants were randomised to a counterbalanced, repeated measures design experiment that tests the treatments Lavender, Lemon Balm, and Placebo (Sunflower oil). Treatments were administered once daily for two-weeks followed by a two-week washout period before commencing the subsequent treatment. All participants trialed all three treatments over a 10-week period. Data were collected on the Neuropsychiatric Inventory (NPI) and Cohen-Mansfield Agitation Inventory (CMAI).

**Results:** A significant difference was shown when essential oils effect were compared between the cognitive groups. Post hoc analysis reports Lemon Balm more effective in reducing NPI agitation (p = .04) and CMAI physical non-aggressive behaviour (PNAB) (p = .02) in residents without dementia. Lemon Balm less effective in reducing NPI irritability (p = 0.01) and Lavender more effective in reducing CMAI PNAB (p = 0.04) in dementia.

**Conclusion:** The findings support an opposing effect of Lemon Balm and Lavender in reducing agitated behaviour between the participant cognitive groups. There was no reduction in agitation with treatments when compared to placebo independent of cognitive groups.

## 1. Introduction

Agitation is recognised in the aged care literature as the most common behavioural problem in RACFs.<sup>1–3</sup> A symptom of many diseases and disorders common to older people, agitation often manifests in non-purposeful physical and verbal behaviours.<sup>4</sup> Agitation is associated with health conditions of cognitive decline, complex medical diagnosis or reliance on multiple medications.<sup>5–7</sup> Behavioural symptoms of agitation are distressing for the person exhibiting the behaviour and affects all those around them.

Nurses in RACFs are frequently challenged to manage older person agitation<sup>8</sup> while prioritising the competing demands of an already challenging workload.<sup>6,9</sup> Agitation management strategies of distraction or chemical/physical restraint often prove ineffective or unjustifiably damaging to the older person, increasing the risk of physical

and emotional decline. The need for more effective, available nurse agitation management is evident with some researchers claiming Lavender or Lemon Balm essential oils as a possible solution<sup>10,11</sup> Lavender and Lemon Balm essential oils are thought to have a calmative benefit for agitation symptoms with minimal side effects or interactions that interfere with concurrent medication regimes.<sup>12</sup> Essential oils when delivered by aromatherapy are often enjoyable to older people and come at a low cost to the facility.

Lavender and Lemon Balm constituents of terpenes, esters, and aldehydes contained in high levels are responsible for producing an anxiolytic and sedative effect. Both oils have historically been used for their calming effect to relieve feelings of distress, anxiety and insomnia.<sup>12</sup> Lavender and Lemon Balm's chemical profile is similar to pharmaceutical medications currently used to minimise agitation in older people. These essential oils may mediate serotonin in the body by

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inhibiting the main neuronal transmitter in the central nervous system to reduce neuronal excitability and regulate muscle tone.<sup>15</sup> Lemon Balm is classified as a GABA transaminase inhibitor with a broad spectrum activity in addition to a potency for 5-hydroxy-tryptamine and  $\gamma$ -aminobutyric acid receptors<sup>16</sup> and was considered by the researchers to be potentially more effective in reducing agitation than Lavender. Further research supports Lavender and Lemon Balm's effect on the GABA receptors to influence ion channels and inhibit the nervous system to produce benefits of relaxation, anti-anxiety and reduced muscular spasm.<sup>14,17,18</sup> Essential oils mechanism of action when inhaled is uncertain however constituents are believed to act upon the limbic system, principally the amygdala and hippocampus.<sup>13,14</sup>

A Cochrane systematic review of aromatherapy for agitation in dementia identified two studies<sup>16,19</sup> investigating Lemon Balm, with usable data that show conflicting outcomes. An additional five studies<sup>10,11,19–22</sup> that investigated Lavender revealed further contradictory findings for agitation in older people with dementia. Although the findings of the studies are conflicting, they do suggest that aromatherapy may assist in reducing agitation in older people. The review reported three trials that used Lavender inhalation to have a significant positive effect on behaviours in comparison to the two trials that used massage intervention.

The two papers that reported Lemon Balms effect on agitation both used massage to apply the oil to participants. The earlier study Ballard et al. (2002) reported a significant clinical effect for Lemon Balm on reducing unwanted behaviour. The second study Burns et al. (2011) sought to replicate some components of Ballards et al. (2002) study, improve on methodological limitations and add a third intervention of Donepezil medication for comparison. This second trial reports no clinically significant effect although there was some improvement in participant PAS and the oil was at least as effective as medication. Nurse compliance to intervention administration was a limitation in this study (Burns et al., 2011). This study addresses the limitations from previous literature to answer the research questions. 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. The researchers chose to administer the essential oils by inhalation based on this methods higher success for minimising agitation when compared to massage in the literature reviewed. Further, 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 dementia.

## 2. Method

### 2.1. Participants

The participants were recruited from six RACFs operated by the same large corporate provider of Aged Care in the Sydney metropolitan area. The six facilities shared commonalities of core values and care standards. The participants were required to meet the following criteria for inclusion; (i) aged 65 years or older; (ii) lived full time in the RACF for three months (iii) a cognitive level of moderate or higher as demonstrated by a score above ten on the mini-mental state examination [MMSE]; (iv) agitated behaviours recorded on at least one of the Aged Care Funding Instrument [ACFI] behaviour domains (v) 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; (vi) an ability to detect scent as demonstrated in a scent test at screening; (vii) a valid signed resident or carer consent form. Exclusion criteria included (i) a diagnosis of psychosis or agitation resulting from brain damage; or (ii) the presence of an acute life-threatening condition as reported by staff or the medical officer; or (iii) 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. Participants stable on

regular antipsychotic medication who exhibited observable agitation were included in this trial, changes to medication were monitored and reported to the researcher. The participants were also required to consent to the study design procedure of wearing a 2 x 2.5 cm dark cloth patch for two hours daily that contained two drops of treatment being either Lavender, Lemon Balm essential oil or placebo Sunflower oil.

The care managers of each facility identified potential participants for this study. Participant Information Sheets were made available to the resident and their families. Capacity to provide valid consent for people with dementia was determined in conjunction with staff and by their understanding of the information sheet provided. Consent was sought from the person responsible or next of kin for participants who could not provide valid consent.

### 2.2. Ethics

This trial complies with the principles laid down in the Declaration of Helsinki that guides research involving human subject. Ethics was approved by the Western Sydney University Human Research Ethics Committee number H10550. All participants had the right to withdraw from this study at any time without explanation to the researcher. All identifiable features were removed from the data prior to data being pooled for analysis.

### 2.3. Materials

Essential oils were of medicinal quality, Lavender chemical composition assay linalool (36%), linalyl acetate (31%), 1,8 cineole (0.6%) Camphor (0.3%) and lavandulyl acetate (3%).<sup>23</sup> Lemon Balm possessed a chemical composition of beta caryophyllene, germacrene D, citral and geraniol.<sup>24</sup> The Lemon Balm used in this trial was diluted in a 50:50 mix of 100% Lemon Balm to 100% Jojoba oil. The placebo consisted of scentless refined triglyceride Sunflower oil, with chemical composition palmitic acid, stearic acid, oleic acid and linoleic acid, the phosphatides present in the oil are lecithin and cephalin.<sup>25</sup> The essential oils were sourced from Essential Therapeutics Pty Ltd 39 Melverton Drive, Hallam, Victoria, Australia who supplied all materials for this trial.

### 2.4. Intervention

The participants were allocated a cognitive group of <sup>1</sup> with dementia or <sup>2</sup> without dementia as determined by the presence of a dementia diagnosis. Participants were randomly assigned a treatment sequence of <sup>1</sup> Lavender, <sup>2</sup> Lemon Balm and <sup>3</sup> placebo for the study duration with each older person trialing both treatments and placebo. Treatment assignment was fully counterbalanced so that one third of the older people with dementia and one third of the older people without dementia received alternate treatments simultaneously.

Consented participants were required to complete a baseline and post treatment assessment for each treatment, for the data to be included in the analysis. The allocation sequence was concealed until data collection was completed and analysis finalised. Assigned treatments were blinded in 6 bottles labeled with the letters A-F. A second researcher accessed the computer-generated assignment of each participant. Each participant was allocated a corresponding essential oil bottle letter for each treatment cycle. When the group assignment was confirmed the researcher informed the primary investigator of the assigned treatment to be implemented in each treatment period. Assigned treatments were blinded in 6 bottles and labeled with the letters A-F.

A research assistant (RA) was trained by the primary investigator in aromatherapy protocol and was responsible for administering treatment to participants. The RA was blinded to the allocation group and treatment by a nose peg and 3% Rosemary oil in Jojoba oil placed above the top lip. The RA applied two drops of oil from the correctly assigned scent bottle to a 25 mm x 20 mm dark 100% cotton patch and attached the cloth to the participants collar area. The patch was dark in

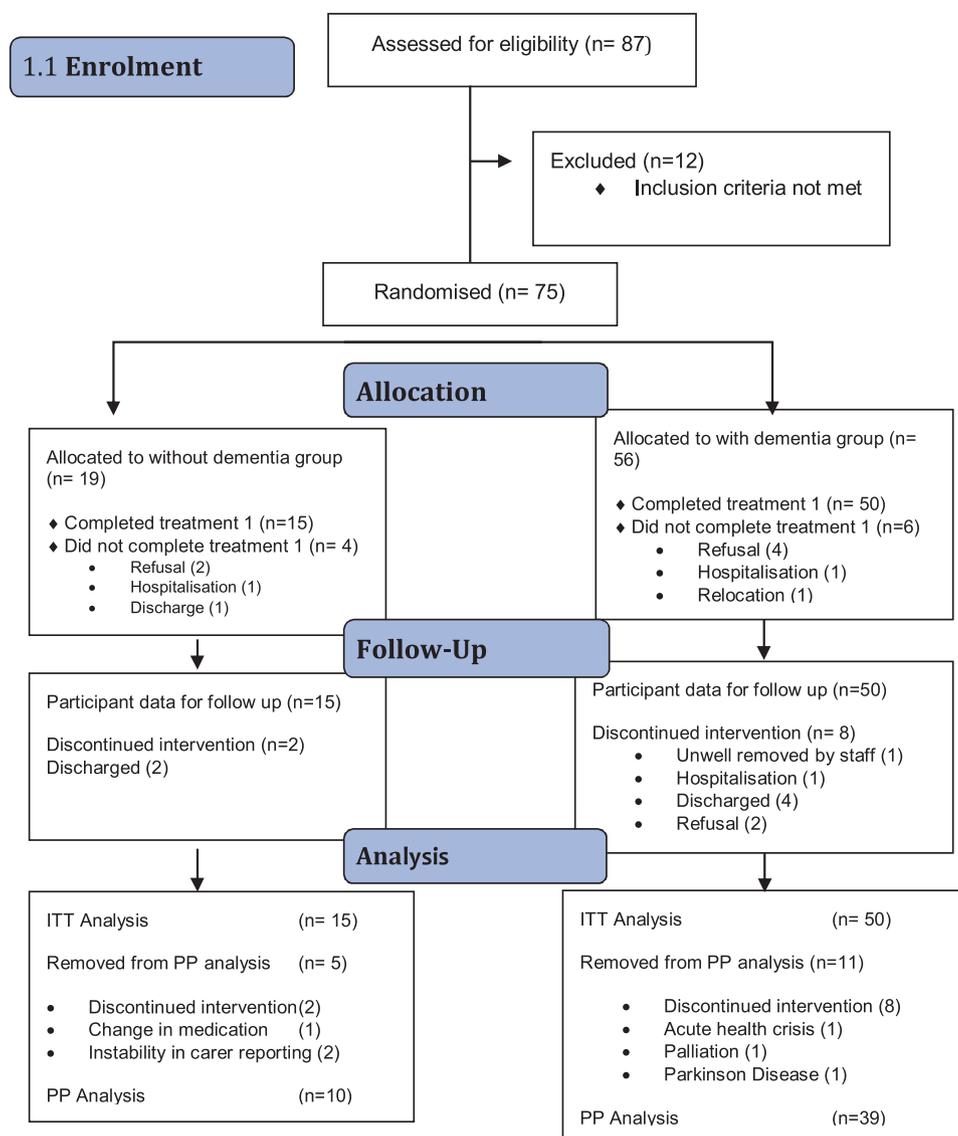


Fig. 1. Consort flow diagram.

color to obscure essential oil pigment. The RA did not engage in any non-deliberate conversation with the participant and returned after 2 h to remove the patch. Observers could not detect oil aroma from the patch at a conversational distance.

Treatment cycles consisted of 14-day consecutive intervention treatment followed by a 14-day washout period before the commencement of the next treatment. All participants were their own control and observed behaviour was reported by the nurses before as well as after each treatment cycle using the Neuropsychiatric Inventory [NPI] and Cohen-Mansfield Agitation Inventory [CMAI].

## 2.5. Data collection

Data were collected at six time points during the study, before and after each treatment cycle, on the NPI and CMAI for ten weeks. The NPI was the primary outcome measure in this study, initially developed for use in the dementia population the measure can be used in other psychological states of older person assessment. The NPI assesses frequency and severity of observable behaviour; if a behaviour was present a frequency score was given of one to four and severity one to three.<sup>26</sup> This study measured seven NPI categories, five directly related to agitation being, delusions, agitation/aggression, aberrant motor activity,

irritability/lability and night-time disturbances as well as categories of anxiety and depression, which are possible precursors to older person agitation.<sup>4,27</sup> A secondary agitation measure, the Cohen Mansfield Agitation Inventory (CMAI) measured the frequency of the agitated behaviour by monitoring 29 behaviours. Behaviours were scored with a number 1 representing a behaviour that never occurs and a number 5 if the behaviour is observed several times within the hour. CMAI outcomes are reported in three sub-categories of physical aggressive agitation, physical non-aggressive agitation and verbal agitation. Nurse observations were entered on hard copy templates then entered into Excel and checked for accuracy before transfer to Statistical Package for Social Sciences [SPSS] version 23 for analysis.

The intervention outcomes on agitation measurements are reliable and valid tools for use in this population. The internal consistency for the NPI is 0.75 to 0.89 for each category.<sup>28</sup> The reliability and validity of the CMAI demonstrates a high internal consistency and adequate inter-rater reliability<sup>29</sup> of .92, .92 and .88.<sup>30</sup>

## 2.6. Statistical analysis

Sample size was calculated with the NPI mean of the treatment groups based on the results of Lin et al., (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, NPI scores of 63.2 (placebo), 58.5 (T1) and 59 (T2) with a SD = 17.5 were used. The sample size was calculated using a  $2 \times 3$  factorial within group analysis of main effect (Placebo vs. T1 & T2). An increase of 14% was added to control for possible withdrawal of participants before completion of the study. It was estimated that a sample size of 78 participants might be needed to identify difference in treatment from baseline behaviour. Sample size calculations were conducted using GLIMMPSE (<http://glimmpse.samplesizeshop.org/#/>).

The planned analyses were conducted based on previous research that indicated the two treatments would be effective in reducing agitation for older people with and without dementia. The first planned analysis reported the change in measurement tool score between baseline and follow up for older people with dementia compared to those without dementia, independent of essential oil treatment. A second analysis evaluated the change in measurement tool score between baseline and follow up of Lavender and Lemon Balm between the with and without dementia groups. An unexpected result from the second planned analyses necessitated a focused post hoc analysis that separated essential oils and resident groups to determine cause of effect. 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 behaviour. 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 behaviour.

### 3. Results

The analysis of the forty-nine residents that completed all three treatment cycles is reported in this study. A Consort flow diagram of participant progress is shown in Fig. 1.

#### 3.1. Participant characteristics

Table 1 details the resident characteristics, the participants were

**Table 1**  
Participant characteristics.

Item	Sample (n = 49)	Percentage
Site A	10	20.41%
Facility 1	6	12.24%
Facility 2	2	4.08%
Facility 3	22	44.91%
Site B	7	14.28%
Facility 4	2	4.08%
Facility 5		
Facility 6		
Male	12	24.49%
Female	37	75.51%
Age	49	100%
65 > years		
89.31 SD6.30		
dementia	39	79.59%
without dementia	10	20.41%
MMSE (25+)	10	20.41%
MMSE (18 – 24)	2	4.08%
MMSE (10-17)	37	75.51%
Depression	28	57.14%
21 (dementia)		(42.86%)
7 (without dementia)		(14.28%)
Anxiety	17	34.69%
9 (dementia)		(18.37%)
8 (without dementia)		(16.33%)
Antipsychotic medication	18	36.73%

aged 68 years to 98 years at the time of recruitment with a mean age of 89.31 (SD6.3) years. The participants were mostly female  $n = 37$  (75.5%). A diagnosis of dementia was recorded for  $n = 39$  almost 80% of participants; a substantial percentage of this group  $n = 37$  (75.5%) scored a moderate dementia level according to Mini Mental State Examination (MMSE). A smaller percentage of participants  $n = 10$  (20.4%) were assessed by the MMSE as cognitively intact; these residents did have a dementia diagnosis. More than half of the participants  $n = 28$  (57.1%) had a diagnosis of depression, and  $n = 17$  (34.7%) were recorded as having anxiety. All participants had observable agitated behaviour with more than a third of participants  $n = 18$  (36.7%) prescribed antipsychotic medication.

#### 3.2. Planned analysis

Statistical analysis confirmed a significant interaction in planned analysis 4 between the Lavender and Lemon Balm treatment effects in older people with dementia when compared to those without dementia.

The NPI total score was reduced in residents without dementia with Lemon Balm treatment -8.9 relative to the dementia group -2.03, whereas Lavender decreased NPI total score in residents with dementia -5.33 relative to those without dementia (-0.73),  $P = 0.04$ . CMAI total score was also reduced in residents without dementia with Lemon Balm treatment -5.5 relative to the dementia group -1.62, whereas Lavender decreased CMAI total score in residents with dementia -2.82 relative to those without dementia -0.8,  $P = 0.05$ .

NPI irritability score was reduced in residents without dementia with Lemon Balm treatment -1.6 relative to the dementia group 0.31, whereas Lavender decreased NPI irritability domain score in residents with dementia -1.84 relative to those without dementia -0.01  $P = 0.02$ . CMAI physical non aggressive behaviour (PNAB) domain reduced in residents without dementia who experienced Lemon Balm treatment -1.7 relative to the dementia group -0.10, whereas Lavender decreased CMAI PNAB domain in residents with dementia -1.26 relative to those without dementia 0.3,  $P = 0.02$ .

A tabulated summary of the planned analysis 4 results for the primary measurement tools and their domains with post hoc findings reported for significant results is presented in Table 2.

Lavender or Lemon Balm did not reduce the frequency of behaviour independent of cognitive status when compared to placebo in planned analysis 1, 2 or 3 See Tables 3–5. The first planned analysis (Table 3) reported a similar reduction in behaviour score from baseline to follow up for older people with dementia and those without dementia independent of essential oil treatment. A second planned analysis (Table 4) reported similar reduction in behaviour score between baseline and follow up when essential oil treatment is compared to placebo. A third planned analysis (Table 5) reported similar reduction in behavior score between baseline and follow up when Lavender treatment was compared with Lemon Balm treatment independent of cognitive status. These results suggest Lavender or Lemon Balm did not reduce the frequency of behaviour independent of cognitive status when compared to placebo.

#### 3.3. Posthoc analysis

A focused post hoc analysis using Bonferroni test was undertaken to separate essential oils and older person cognitive groups from planned analysis 4 to determine the cause of the significant effect.

The NPI total score statistical analysis reported a significant effect by Lemon Balm (-8.9) when compared to Lavender (-1.8) and placebo (-2.7) for older people without dementia  $p = 0.04$ . No significant effect was reported between the Lavender and placebo groups  $P = 0.76$ ,  $DF27$   $T(1,0.09)$   $T_c = 2.03$  (Fig. 2). This result indicates that Lemon Balm may reduce agitation in people without dementia.

CMAI PNAB statistical analysis reported a significant effect by Lemon Balm (-1.7) when compared to Lavender (0.3) and placebo (0.6)

**Table 2**  
Planned analysis 4 results.

	Lemon Balm No Dementia	Lemon Balm Dementia	Lavender No Dementia	Lavender Dementia	p value	DF	F value	F critical
<b>NPI Total Score*</b>	-8.9	-2.03	-0.73	-5.33	0.04*	DF47	(1, 4.39)	Fc = 4.05
<b>NPI Post hoc (residents with dementia)</b>	LB -2.03	LAV -5.33	Placebo -4.95	P = 0.08	DF114	T(1,3.0)	Tc = 1.98	
<b>NPI Post hoc* (residents without dementia)</b>	LB -8.9	LAV -1.8	Placebo -2.7	P = 0.02*	DF35	T(1,5.61)	Tc = 2.03	
AA	-2.8	-0.64	-0.6	-1.71	0.07	DF46.92	(1, 3.40)	Fc = 4.05
AMB	-0.60	-0.15	0.2	-0.03	0.61	DF46.99	(1, 0.26)	Fc = 4.05
Anxiety	-1.4	-1.68	0.7	-0.54	0.20	DF46.80	(1, 1.67)	Fc = 4.05
Delusion	0.00	-0.2	0.00	-0.56	0.73	DF = 46.70	(1, 0.12)	Fc = 4.05
Depression	-1.5	-0.95	-1.8	-1.68	0.79	DF46.67	(1,0.07)	Fc = 4.05
<b>Irritability*</b>	-1.6	0.31	-0.1	-1.84	0.02*	DF37.56	(1, 5.65)	Fc = 4.11
<b>Irritability* (residents with dementia)</b>	LAV -1.84	LB 0.31	Placebo -0.77	P = 0.01*	DF113	(1,7.75)	Tc = 1.98	
<b>Irritability (residents without dementia)</b>	LAV 0.1	LB -1.6	Placebo -0.9	P = 0.20	DF27	(1, 1.75)	Tc = 2.05	
Sleep disturbance	0.00	-0.28	-0.30	-0.66	0.94	DF44.81	(1, 0.01)	Fc = 4.06
<b>CMAI total score*</b>	-5.5	-1.62	-0.8	-2.82	0.05*	DF46.72	(1,4.19)	Fc = 4.05
<b>CMAI Post hoc(residents with dementia)</b>	-2.97	-1.64	-1.72	0.14	0.94	P = 0.94	DF(1125)	T(1,0.01)
								Tc = 1.98.
<b>CMAI Post hoc (residents without dementia)</b>	-5.5	-0.8	-2.2	0.08	0.78	P = 0.08	DF29	T(1,3.3) Tc = 2.05
CMAI PAB	-1.0	-0.51	-0.90	-0.77	0.70	DF46.832	(1, 0.15)	Fc = 4.05
<b>CMAI PNAB*</b>	-1.7	-0.10	0.3	-1.26	0.02*	DF47	(1, 5.46)	Fc = 4.05
<b>CMAI PNAB* (residents without dementia)</b>	LAV 0.3	LB -1.7	Placebo 0.6	P = 0.02*	DF27	(1, 5.84)	Tc = 2.05	
<b>CMAI PNAB* (residents with dementia)</b>	LAV -1.26	LB -0.1	Placebo -0.23	P = 0.04*	DF46.63	(1,4.67)	Tc = 1.98	
CMAI VB	-2.8	-1.24	-0.8	-1.80	0.07	DF47	(1,3.42)	Fc = 4.05

**Table 3**  
Planned analysis 1 results.

	Dementia m	No Dementia m	p value	DF	F value	F critical
<b>NPI</b>	-12.31	-13.4	0.89	DF52.89	(1,2.31)	Fc = 4.03
<b>CMAI</b>	-6.33	-8.5	0.32	DF53.44	(1, 0.32)	Fc = 4.02

**Table 4**  
Planned analysis 2 results.

	Placebo m	Combined Treatment m	p value	DF	F value	F critical
<b>NPI</b>	-7.65	-9.03	0.71	DF50.81	(1, 0.141)	4.03
<b>CMAI</b>	-4.70	-4.28	0.32	DF 54.41	(1,1.01)	Fc = 4.02

groups in older people without dementia  $P = 0.02$ . No significant effect was reported between the Lavender and placebo groups  $P = 0.77$  DF27 (1,0.29) Tc = 2.05 (Fig. 3). This result indicates that Lemon Balm may reduce PNAB in people without dementia.

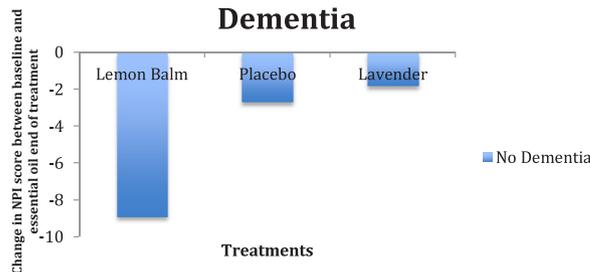
NPI Irritability statistical analysis reported a significant effect by Lemon Balm (0.31) when compared to Lavender (-1.84) and placebo (-0.77) for people with dementia  $P = 0.01$ . No significant effect was reported between the Lavender and placebo groups  $P = 0.11$  DF113 T(1,1.60) Tc = 1.98 (Fig. 4). This result indicates that people with dementia experienced less irritability when Lavender or placebo was administered when compared to Lemon Balm.

CMAI PNAB reported a significant effect by Lavender (-1.26) when compared to Lemon Balm (-0.10) and placebo (-0.23) for people with

**Table 5**  
Planned analysis 3 results.

	Lemon Balm m	Lavender m	p value	DF	F value	F critical
<b>NPI Total Score</b>	-10.93	-7.13	0.46	DF54	(1, 0.55)	Fc = 4.02
<b>CMAI total score</b>	-4.9	-3.7	0.41	DF54.38	(1,0.68)	Fc = 4.02

### Treatment effect for NPI total score in residents without Dementia



**Fig. 2.** Post hoc analysis treatment effect for NPI total score in residents without dementia.

dementia  $P = 0.04$ . No significant effect was reported between the Lemon Balm and placebo groups  $P = 1.0$ , DF114 (1, 0.00) Tc = 1.98 (Fig. 5). This result indicates that Lavender may reduce PNAB behaviour in older people with dementia.

### 4. Discussion

The essential oils investigated in this study demonstrated an opposite effect on agitation in residents with dementia when compared to residents without dementia. Lemon Balm essential oil reduced behaviour in residents without dementia when compared to Lavender. In contrast, Lavender reduced behaviours in residents with dementia when compared to Lemon Balm. This difference in the essential oil

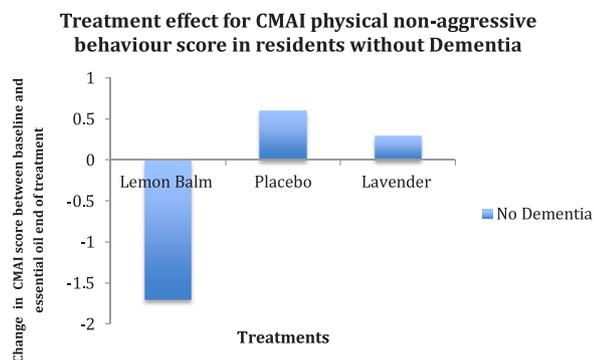


Fig. 3. Post hoc analysis treatment effect for CMAI Physical non-aggressive behaviour score in residents without Dementia.

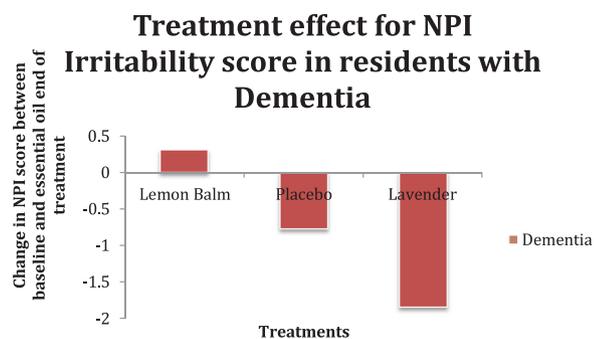


Fig. 4. Post hoc analysis treatment effect for NPI Irritability in residents with dementia.

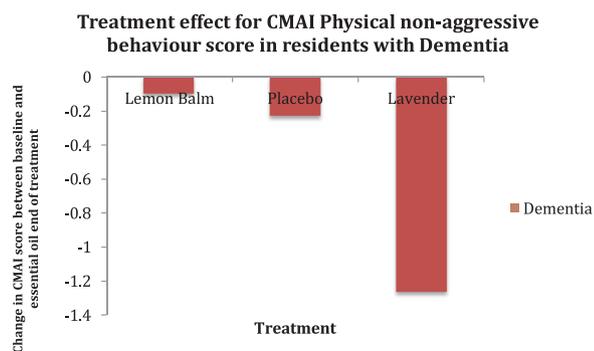


Fig. 5. Post hoc analysis treatment effect for CMAI Physical non-aggressive behaviour in residents with Dementia.

effect was observed in total agitation score, irritability and physical non-aggressive behaviour in this study, indicating the essential oils to have worked differently in each cognitive group.

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. This result is supported by Sakamoto et al. (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 essential oils were inhaled. These results conflict O'Conner et al.'s (2011) findings of 64 residents with mild to moderate dementia that reported Lavender massage did not reduce physical agitation. The previous studies<sup>11,20–22</sup> did not investigate the essential oils individual effect in people without dementia.

Lemon Balm reduced physical non-aggressive behaviour and overall agitation in residents without dementia in this study. These results are similar to the findings of Ballard et al. (2002) study that reported Lemon Balm to reduce behaviours by 30% in 71 older people living in RACFs when compared to a placebo of Sunflower oil. The results are

similar to Ballard et al., (2002) in that Lemon balm reduced non-aggressive physical behaviour, although differ in essential oil application of massage employed. This study also contrasts Ballard et al.'s (2002) results of Lemon Balm to be less effective than placebo in reducing irritability in residents with dementia. A result that is supported by Burns et al.'s (2011) study where Lemon Balm was not more beneficial than placebo in reducing agitation for 114 residents with probable or possible Alzheimers Disease.

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.<sup>31,32</sup> Olfactory dysfunction can reduce resident's ability to identify scent. In people with AD, olfactory dysfunction is estimated as high as 100% and 96% in Frontal Lobe Dementia, but lower in Vascular dementia at 15%.<sup>31,32</sup> 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.<sup>31</sup> Depending on the degree of brain dysfunction scent may be harder to discern and recognise for a person with dementia.

Hypersensitivity may responsible why Lemon Balm essential oil was less well tolerated in this study by residents with dementia. Many residents with dementia are hypersensitive to sounds, smells or temperature in their environment.<sup>33</sup> Lemon Balm's potent scent may over stimulate the residents with dementia, the oil proving an irritant rather than a calming agent. Lavender's subtler medium intensity fragrance was more effective and better tolerated in this study by residents with dementia.

Fragrances can evoke strong memories of earlier times in an older person's life.<sup>34</sup> The limbic systems amygdala governs the emotional response, while the hippocampus is involved in retrieval of memories surrounding scent.<sup>35</sup> The ability of the hippocampus to retrieve memories is impaired in dementia; however, earlier life memories rely less on the hippocampus for recollection.<sup>36</sup> Lavender was a popular herb commonly grown in gardens, used as perfumes and disinfectants in earlier years the 20th century.<sup>34</sup> 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. Lemon Balm's highly potent, less familiar scent may have been considered as having a more clinical or pharmacological basis by participants. Regardless of Lemon Balm's intense fragrance, no residents with or without dementia requested the removal of a patch during the trial.

#### 4.1. Strengths and limitations

This research was the first to compare Lavender to Lemon balm essential oils for the management of agitation in older people with and without dementia in a single study. A strength of this study was in maintaining compliance to treatment administrations throughout the 10-week trial period. The employment of a research assistant overcame issues of nurse compliance identified in previous studies and afforded the assurance that interventions were being attended consistently throughout the study.<sup>16</sup>

Dosages for this study were sort in consultation with a qualified aromatherapist. The dosage was minimal in comparison with previous studies<sup>10,19,21</sup> to limit hypersensitivity increasing unwanted behaviour. Increasing the frequency of treatments at the same dose can prolong participant exposure to the essential oil within a therapeutic range that may lead to an improved agitated behaviour reduction.<sup>11,20</sup>

The study design was a strength of this research, increasing statistical power, reducing participant variability and controlling for time-dependent factors. The repeat measure design increased statistical

power with the same number of participants relative to a between-group study design. Reduced variability between treatment groups was apparent as all participants received each treatment. Counterbalancing participant allocation also controlled for time-dependent effects such as participant fatigue or familiarity with research procedures.<sup>37</sup>

This research attempted to overcome all methodological issues identified in previous studies however, a limitation in sample size was still evident. Seventy five participants were randomised to this study however due to discharge, illness and compliance this study experienced a 34.6% withdrawal rate comparable to previous studies conducted in similar populations.<sup>16,20,21</sup> The researchers over-enrolled participants to compensate for potential withdrawal. A second trial was conducted in an attempt to improve recruitment, a third trial was abandoned due to funding restraints. Future trials may benefit from assessing an older persons physical health and psychosocial suitability to participate in the trial duration prior to recruitment.

Further large-scale studies that assess the older persons readiness to participate, investigate high quality standardised essential oils administered in approved dosages at regular intervals and include strategies that monitor participant adherence can yield reliable outcomes to guide future essential oil use in agitation management.

## 5. Conclusion

This study did not identify any improvement in participant behaviour when treatment was compared to placebo. The study does support an opposing effect of Lavender and Lemon Balm essential oils between the with and without dementia groups in overall agitation, irritability and physical non aggressive behaviours. Post hoc results indicate Lavender may be more effective in reducing agitation and physical non-aggressive behaviour in people with dementia. Lemon Balm was indicated to be more effective in reducing agitation in people without dementia. This study is important as it adds weight to the conversation that essential oils may be effective in reducing agitation in older people with and without dementia. The findings are of benefit to future researchers to consider large-scale placebo-controlled studies that monitor participant compliance with treatment in their design.

## Disclaimer

This paper reports a section of the findings from a larger PhD research. The full doctorate study is available online from the Western Sydney University ResearchDirect thesis repository at <https://researchdirect.westernsydney.edu.au/islandora/object/uws%3A44603>

## Dataset

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

## Competing interests

The authors declare they have no competing interest.

## Authors contributions

All authors have made substantial contributions to the conception and design of this study. KW coordinated the research, analysed the data and trained the RAs. AG oversaw the study design and statistical analysis. AG and DH assisted with methodological advice. All authors have contributed to the preparation of this manuscript. The authors have read and approved the final manuscript

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## Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.ctim.2018.12.016>.

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