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Using complementary and alternative medicine to treat pain and agitation in dementia: A review of randomized controlled trials from long-term care with potential use in critical care

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SYNOPSIS

The risk of pain in adults with dementia worsens with advancing age. Painful comorbidities may be under-assessed and inadequately treated in adults with dementia. Receiving treatment in critical care settings may indicate greater occurrences of pain, and an increased prevalence of complications. Pain may also exacerbate behavioral and psychological symptoms of dementia (BPSD), such as agitation and stress. Complementary and alternative medicine (CAM) therapies may alleviate pain and incidences of BPSD. Contiguity of therapy may bolster the therapeutic effect of CAM therapies; as such, critical care personnel should obtain a history of CAM therapy use from patients. Although this review did not reveal an apparent benefit of aromatherapy use in patients with dementia, improvements in BPSD have been shown in past studies. Of note is that massage and human interaction demonstrated efficacy in reducing BPSD and pain in individuals with dementia.

Keywords

Pain; agitation; dementia; CAM; aromatherapy; essential oil; massage; touch

Introduction

Approximately 46.8 million individuals in 2015 were living with dementia worldwide, with a new case every 3.2 seconds.¹ In the United States (US), chronic pain is considered a “problem of epidemic proportions,”² affecting around 100 million adults.³ Thus, occurrence

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The authors have nothing to disclose

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of pain and dementia will both increase with age,⁴⁻⁶ presenting challenges for pain assessment in both long-term care and adult critical care. Cognitively impaired individuals report pain less frequently and receive minimal⁷ to no pain medication,⁸ even when there is a known condition that causes pain, such as cancer.⁷ Pain at rest in the intensive care unit (ICU) is common in adult patients and contributes to complications.⁹ Although multiple tools exist to help assess pain in dementia,^{6,10,11} pain remains under assessed and inadequately treated.^{8,12,13}

Behavioral and psychological symptoms of dementia (BPSD), such as agitation, may indicate pain in people with dementia.¹⁴⁻¹⁶ Pain exacerbates agitation and may cause psychosis and delusions in dementia.¹⁷ Medications, such as anti-psychotics, are often overused and have significant adverse events in the dementia population.¹⁸ Complementary and Alternative Medicine (CAM) may offer a less invasive, safer, and more gentle option to treat BPSD,¹⁹⁻²¹ as well as pain,^{19,20,22} and improve quality of life.^{20,23,24} Reducing BPSD may also reduce the burden on the critical care nurse and support staff.²⁵ With opioid usage becoming more scrutinized,²⁶ CAM therapies may help decrease opioid use for pain.

CAM includes therapies such as aromatherapy, acupuncture, animal therapy, music, exercise, herbal medicine, massage, yoga,²³ therapeutic/healing touch,^{24,27} tai chi, meditation, dietary supplements, and others.²⁸ CAM therapies have been used by nurses for many years,²⁹ and by many people over 65 years of age in the US, Canada, United Kingdom (UK), and Australia.³⁰ In a study of 32 countries across the globe, traditional, complementary, and alternative medicine (TCAM) ranges from 10% in Eastern Europe to over 50% in Asia, with high treatment satisfaction rates over 80% in Europe, Asia, and the US.³¹ CAM has also been used in varying degrees in long-term care (LTC) for years.^{19,20,30} Increased understanding and investigating appropriate use of CAM is also a national priority in the US through the National Center for Complementary and Integrative Health (NCCIH),³² formerly known as NCCAM.

The purpose of this paper was to review CAM therapies and their effectiveness when used in older adults with pain and dementia in LTC and to explore what CAM therapies used in LTC would feasibly transition to the critical care setting. To our knowledge, no literature review has been published to address this particular question. This review was guided by the authors' beliefs that since CAM popularity will likely increase in LTC, critical care nurses receiving patients with dementia from LTC should question the communicative patient with dementia and their caregivers about current CAM use. This is especially important as BPSD may increase with hospital admission, and discontinuing currently used CAM may exacerbate these symptoms and increase pain if CAM therapy is abruptly stopped.

Search Strategy

PubMed and Google Scholar were searched for the terms: complementary, alternative, complementary alternative medicine, nursing home, residential care, long-term care, dementia, Alzheimer's, and pain. These were used in multiple combinations with each other, and with and without AND, and with and without quotes. The terms pediatric, review, systematic, and book were used with the minus sign to reduce results of some searches on

Google Scholar. Only results in English between the dates of 2002–2017 were used. Additional filters were added on PubMed for clinical trials and human trials only. Reference lists were reviewed for relevant citations. The Vanderbilt University Library was also searched for journals. Using the “contains” search option, the terms complementary and alternative, as well as dementia, were used individually to find relevant journals, such as: Journal of complementary and alternative medicine, BMC complementary and alternative medicine, Alternative & complementary therapies, Complementary therapies in clinical practice, Complementary therapies in medicine, Evidence-based complementary and alternative medicine, Journal of evidence based complementary and alternative medicine, Journal of traditional and complementary medicine, and Alzheimer’s & dementia. Notably, due to the lack of literature on CAM used to treat pain in dementia in LTC, we expanded our search for RCTs to CAM use in patients with dementia.

Using the above strategy, the final inclusion criteria for studies in this review were: 1) randomized controlled trial (RCT), 2) sample size $N > 10$, 3) written in the English, 4) published within 2002–2017, 5) participant diagnosed with dementia, and 6) study performed in a LTC facility. A larger population size was initially preferred ($n > 50$), however, due to limited results we determined that, smaller sample sizes ($N > 14$) had to be included. Exclusion criteria were: 1) articles not in English, 2) qualitative studies, 3) had a CAM therapy deemed less applicable to a critical care setting, or 4) did not meet inclusion criteria.

Results

A total of 510 records were identified and screened, with 473 being excluded as they were not applicable to BPSD or interventions that could translate to inpatient care. The remaining 37 were evaluated in detail. Of these, seven quantitative studies that best met inclusion criteria were included. Tables 1–3 detail features of each study. For the seven applicable studies, the setting and sample of each was in one or multiple long-term care facilities, located across the globe in the USA, Canada, Japan, the UK, and three in Australia. There were 364 total randomized male and female participants aged 60 and above with dementia of various types across the reviewed studies. All but two studies had over 50 participants, with sample sizes ranging from 14–94. (See Table 1.)

Review results indicate there are multiple previous studies showing improvement in dementia symptoms^{33,34} as well as reduction of pain^{33–35} and stress^{33,35} with aromatherapy, and four out of the seven studies included involve aromatherapy as an intervention.^{35–38} Intervention variables also mostly involved touch in the form of foot³⁹ or hand massage,^{36,37} reflexology,⁴⁰ therapeutic touch,²¹ and dermally applied aromatherapy.^{35–38} Outcome variables were primarily BPSD (especially agitation),^{21,35–38} but also pain,⁴⁰ changes in mood and communication,³⁷ and physiological stress responses (blood pressure, heart rate, salivary α -amylase).^{39,40} (See Table 2.)

Discussion

In contrast to previous studies, often with less rigorous designs, findings demonstrated no improvement with aromatherapy in any of the studies. However, there is a trend where

touch, interaction, and the presence of another human being improved BPSD, that other studies reflect as well.^{27,41} Reflexology, in particular, did show a reduction in pain and α -amylase, a marker of stress,⁴⁰ and while regular foot massage in another study did not show much difference outside of a larger reduction in BP, the researchers noted that the presence of another person was beneficial to all groups.³⁹ Therapeutic Touch (TT) decreased wandering and pacing, adding support for touch and presence being an important factor, however, the sham TT did not demonstrate this.²¹ Surprisingly as each of these studies showed benefit from touch and presence, which intuitively makes sense, the study on hand massage with and without aromatherapy made no statistically significant difference on agitation.³⁶ Had there been a qualitative component to that study, it would be interesting to see if it showed other improvements.

The essential oil (EO) Melissa was not superior to placebo, but the placebo revealed that touch and interaction helped, adding to the trend.³⁸ High-strength lavender oil was found to be no better than control,³⁵ as was D&H oil blend with hand massage, however, they did show safety as well as positive experiences of participants.³⁷ See Table 2 for more details. Overall, the results offered evidence for human presence and interaction as well as touch reducing BPSD, stress, and pain.

External EO or aromatherapy use has demonstrated favorable results in the past for patients, reduced caregiver distress,⁴² as well as reduced stress in nurses and staff in critical care settings.⁴³ Despite the included RCTs showing no difference from placebo, the studies showed safety and tolerability for external use. Individuals with dementia often have impaired olfactory function,^{34,36} which may explain in part the negative results of the aromatherapy studies. Also, there are anecdotal reports that too high of a dose of lavender EO can be stimulating,⁴⁴ and could therefore negate any relaxing properties, or even increase agitation. This could explain the differing results from earlier studies and the O'Connor et al. study as they used the strongest concentration per solution they could apply to the skin.³⁵ Another issue with aromatherapy trials is that there are no standardized or ideal doses or concentrations recognized,³⁵ and most studies vary widely in their demographics, methods, outcomes, etc. This is problematic as studies may miss potential benefits due to improper strength, timing, or frequency, and cross-study comparisons are difficult. Other limitations of each study are included in Table 3, including small sample sizes, questions of generalizability to larger populations, compliance with the intervention, subjective judgments by staff about scoring, and concomitant medication usage by participants that might interfere with results.

An additional article was not included in the review because it was a debate paper showed laughter and humor as a CAM treatment for dementia.²³ Takeda argues that laughter is worth trying on an individualized basis, and explains the compelling physiological basis for this option.²³ Additional articles on EO use in BPSD^{42,46,47} and cognitive function^{48,49} showed positive results, but were not reviewed, as they did not meet inclusion criteria due to study type, sample size, or applicability of the outcome variables. Other reviews that might be helpful resources for additional CAM options, are Bauer's CAM in chronic pain²² and Wardell's review on healing touch,²⁷ as well as a large review showing that music therapy and behavioral management techniques were effective for BPSD.⁴⁵ Traditional Chinese

Medicine (TCM) was not included in this review, but is widely used in Asia^{50,51} and has several compelling studies looking at cognitive function in dementia,^{52,53} as well as on BPSD and ADLs in dementia.⁵⁴ Abruptly stopping these, or other, CAM therapies upon patient admission may have unfavorable results.

Limitations and strengths

Limitations of this review include the potential for study inclusion selection bias. Though the primary author followed the inclusion and exclusion criteria outlined, including other databases and a wider date range may have yielded additional studies meeting criteria. RCTs are considered among the most rigorous findings due to reduced risk of bias, however due to the limited number of RCTs available for the current review, a more detailed quality assessment of each RCT was not performed outside of what is shown in Tables 1–3. Also, valuable information may have been found from other studies types such as qualitative and experimental studies. In addition, several articles were found during this review that had promising titles, and sometimes translated abstracts, but full-text were written in different languages such as German, Chinese, and Japanese and could not be read. In particular, TCM and other CAM therapies that are more traditionally found in Asian countries may have favorable evidence and research that is not accessible due to language barriers. More translated research findings could improve our understating of effective CAM options and use.

Despite these limitations, there are numerous strengths in the current review. First, only RCTs were included in this review. Second, the studies included represented a variety of countries. Third, five of the seven RCTs have sample sizes greater than 50 participants indicating a reasonable amount of power to detect treatment effects. Fourth, the studies demonstrated that touch, presence of another person, and interaction with other persons seem to improve BPSD. Lastly, there appear to be conceptually safe CAM therapies used in LTC that, in theory, should transfer between LTC and critical care with little disruption in continuity of treatment.

We recommend that future research in this area should involve determining dose, strength, and frequency of different EOs, including absorbed levels of compounds in the plasma levels, something other authors mentioned as well.³⁵ Even though there is preliminary evidence in this area,^{41,45} continued and further research into touch, interaction, and presence for people with dementia would be helpful, as well as comparing different types of touch (e.g., reflexology showed more favorable results than did regular foot massage).

Conclusion and Recommendations

Aromatherapy is gaining more popularity and studies show favorable experiences and attitudes from nurses, staff, and caregivers using them in dementia care,^{33,42,55} as well as improved quality of life for those with dementia.²⁵ Despite mixed results in efficacy, aromatherapy is generally safe when used externally, is inexpensive, and is rated as pleasant for the staff and patients.^{42,55} Conceptually, we believe this modality could be used in both

LTC and critical care even if only to facilitate more touch, interaction, and human presence with the patient, and create a more relaxing environment for patients and staff.

Based upon the current review and limited empirical evidence, we recommend that all acute care hospitals receiving patients from LTC facilities screen for current CAM use in people with dementia through direct questions with both communicative individuals with dementia and their caregivers. Furthermore, we recommend that critical care nurses receiving and caring for patients with dementia who normally reside in LTC should further assess for the use of CAM in persons with dementia and not rely solely on a history and physical received upon admission, especially since CAM therapies may not be a common part of intake assessments. Upon hospital admission, and when possible, patient care may be improved by continuing any CAM therapy currently used by the patient. The critical care nurse may also be able to add helpful CAM therapies that may transition back to the home or LTC setting, improving overall patient care. Modalities that can reduce stress and agitation, such as touch and massage, may also reduce pain, and vice versa.¹⁷ An open mind and thoughtful consideration of CAM therapy's effectiveness contributes to the widening variety of safer options to help improve the quality of life of people with dementia.

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KEY POINTS

- Behavioral and psychological symptoms of dementia (BPSD), such as agitation, may indicate or be exacerbated by, pain
- Pain in dementia is undertreated and there is a need for noninvasive, safe, and gentle pain management options
- Complementary and alternative medicine (CAM) therapies are becoming more popular and widely used with positive attitudes towards and satisfaction with use, and should be continued when indicated
- Although aromatherapy did not show efficacy in dementia, it was found to be safe and promotes reduced stress in nurses and staff working in critical care
- Massage, touch, and human interaction and presence have demonstrated efficacy in reducing stress, agitation, and pain in individuals with dementia and can be utilized in critical care

Study Characteristics

Table 1

Author/Year/Country	Purpose/Aim	Design	Sample/Setting	Inclusion/Exclusion Criteria
Hodgson & Andersen 2008 USA	To assess the efficacy of reflexology in treating pain, distress, and negative affect in a population suffering from mild-to-moderate dementia	Quantitative: Randomized, experimental, repeated-measures, crossover design over 8 weeks	N=21 Residents of a 324-bed nursing home in suburban Philadelphia	Inclusion: Residents of the nursing home for at least 6 months, 75 years of age or older, dementia diagnosis probable, able and willing to participate for the entire study, signed consent or verbal assent. Exclusion: Based on reflexology literature: history of deep vein thrombosis, epilepsy, bile or kidney stones, pacemaker, fever, open foot wounds, foot fractures. Also, recent hospitalization (< 1 month) preceding or during the study, and recent onset or discontinuation (< 2 weeks) of physiotherapy that included massage.
Fu, Moyle, & Cooke 2013 Australia	To examine the ability of 3% lavender oil spray aromatherapy to treat disruptive behaviors in dementia populations living in long-term care facilities	Quantitative: Single blinded randomized controlled trial of three groups with a placebo, over 6 weeks	N = 67 Residents from three long-term care facilities in Brisbane	Inclusion: To avoid persons with early onset dementia, aged 60 or over; in a nursing home for at least three months to avoid potential effects from transition to the nursing home; MMSE score of 24 out of 30 or less; features of Alzheimer's disease according to APA DSM-IV-TR; in the past 3 months documented history of at least two weeks of agitation or aggression (consecutively or 14 single days); documented physical and/or chemical restraint for agitation and aggression (including PRN medication); consent for participation from resident's family or health-attorney; no known allergic reaction to lavender oil; no recent skin tears, lacerations, bruises, or redness and swelling that might interfere with hand massage. Exclusion: Diagnosis of schizophrenia or mental retardation to avoid the complication of dual diagnoses impacting treatment effect; expectation of transfer to another facility within the next 3 months
Hawranik, et al 2008 Canada	Compared usual care to therapeutic touch therapy (including simulated) in patients with Alzheimer's disease Also to improve limitations of previous studies	Quantitative: Randomized, multiple time series, blinded, three-group experimental design	N = 51 Permanent residents from the personal care and special needs units of a long-term care facility with Alzheimer's disease (no city given)	Inclusion: Diagnosis of senile dementia of the Alzheimer type; a score of 23 or less on the MMSE; at least 65 years old; consistent agitated behavior during the past month or a history of agitated behavior; 2 or more months residence on the current unit; and the absence of an acute illness during the study Exclusion: If the resident refused verbal consent (this was not specifically stated as exclusion criteria)
O'Connor, et al 2013 Australia	To determine effectiveness of lavender (<i>Lavandula angustifolia</i>) oil as a treatment for objectively-assessed agitation in patients with dementia Also to help remedy methodological shortcomings of previous studies	Quantitative: Randomized, single-blind cross-over trial	N = 64 Residents with frequent physically agitated behaviors from eight specialist psychogeriatric nursing homes and three private nursing homes in Melbourne, between 2009 and 2011	Inclusion: Clinical Dementia Rating scale rating of mild or worse; physically agitated behavior requiring staff intervention occurring at least several times each day during daylight hours outside of nursing care; an assessment by the nursing staff, visiting medical practitioner and/or psychiatrist that the behavior was not due primarily to pain, physical illness, depression or psychosis; three or more months of residence in the facility; and consent of participation by the next of kin or guardian. Exclusion: An acute, life-threatening illness; a variable psychotropic medication use; and a medical condition that prohibited topical oil use.
Moyle, et al 2014 Australia	To determine if foot massage will decrease physiological stress in people with dementia	Quantitative: Randomized controlled trial with within-subjects, crossover design	N = 53 Residents from five LTC settings, located in South-East Queensland.	Inclusion: An age of 65 years or older; 2 months or more permanent residence in the facility; diagnosis of dementia, or met the criteria for probable AD; MMSE score < 18; PAS score > 3 during each day over a period of 1 week; two feet; appropriate informed consent

Author/Year/Country	Purpose/Aim	Design	Sample/Setting	Inclusion/Exclusion Criteria
				<p>Exclusion: Artificial legs</p>
Yoshiyama, Arita, & Suzuki 2015 Japan	To determine the effectiveness and safety of clinical aromatherapy and hand massage in people with dementia	<p>Quantitative: Randomized, single-blind crossover pilot study</p> <p>Qualitative: Observation records were collected</p>	<p>N = 14</p> <p>Residents from a nursing home in Nara</p>	<p>Inclusion: Nursing home residents; at least 65 years of age; dementia diagnosed by the International Classification of Diseases, 10th revision; mild-to-moderate dementia (score of 10–26 on the MMSE); score of III on the Independence Degree of Daily Living for the Demented Elderly scale; negative reaction on a patch test with jojoba oil and Delight & Harmony oil (D&H oil); and consent for participation from patients and their families.</p> <p>Exclusion: Any acute physical illness</p>
Burns, et al 2011 UK	Compared the use of Melissa oil (<i>M. officinalis</i>) aromatherapy with Donepezil in treating BPSD in patients with Alzheimer's disease	Quantitative: Double-blind, placebo-controlled randomized trial	<p>N = 94</p> <p>Residents from three long-term care facilities in Manchester, London, and Southampton</p>	<p>Inclusion: Four week or more of agitation; at least 60 years of age; CMAI score of 139; NHS continuing care facility or nursing home resident; clinical dementia rating of 3; no psychotropic medication use (antipsychotics and/or cholinesterase inhibitors) for a minimum of 2 weeks; written informed consent from patients when appropriate, and written assent was obtained from all caregivers</p> <p>Exclusion: Known sensitivity to cholinesterase drugs; a disability preventing completing the study; severe, unstable or poorly controlled medical conditions (particularly uncontrolled epilepsy, severe or unstable cardiovascular disease, severe asthma or severe chronic obstructive airways disease) or a history of stroke</p>

Table 2

Description of Variables and Study Results

Author/Year/Country	Intervention	Outcome Variables	Descriptive Results
Hodgson & Andersen 2008 USA	Treatment of four weeks of weekly reflexology treatments followed by four weeks of a control condition of friendly visits, or vice versa	Reduction of physiologic distress as measured by salivary α -amylase; secondary outcome was observed pain	A statistically significant decrease in observed pain ($p=0.031$) and salivary α -amylase ($p=0.049$) was found along with an improvement in sadness that nearly reached statistical significance ($p=.069$). No adverse events were found.
Fu, Moyle, & Cooke 2013 Australia	Treatment with aromatherapy spray (3% lavender oil) and hand massage or hand massage or placebo water spray twice daily for six weeks	Agitation, aggression, and cognitive function via MMSE scores	No significant effect for the reduction of aggression or agitation was found for any of the study's measures.
Hawranik, et al 2008 Canada	Treatment with therapeutic touch, sham (simulated), or usual care	Three forms of disruptive behavior: physical aggression, physical nonaggression, and verbal agitation	Physically nonaggressive behaviors were significantly reduced in the therapeutic touch group ($p<0.05$), but no significant differences were found for a reduction in physical aggression or verbal agitation in all groups. All groups showed improvement overall, but the greatest improvements were in the therapeutic touch and sham therapeutic touch groups.
O'Connor, et al 2013 Australia	Treatment with dermally-applied, neurophysiologically active, high purity 30% lavender oil in jojoba oil, or just jojoba oil	Physically agitated behaviors or affect improvement	No significant findings were reported for the efficacy of dermally-applied lavender oil in treating agitation or improving affect in this sample.
Moyle, et al 2014 Australia	Treatment with foot massage vs quiet presence	Physiological stress response (e.g., blood pressure and heart rate)	Foot massage as a therapy had no significant effect between groups, but both groups experienced an overall reduction in blood pressure with the foot massage group having a greater drop in systolic blood pressure than the control. A significant effect for the presence of human interaction was supported by a reduction in blood pressure and heart rate and remains a seemingly valid option in reducing agitation and distress in those with dementia.
Yoshiyama, Arita, & Suzuki 2015 Japan	Treatment with clinical aromatherapy with D&H oil (blend of <i>Citrus aurantium</i> leaf, <i>Cymbopogon martini</i> , <i>Picea mariana</i> , <i>Lavandula angustifolia</i> , <i>Rosa damascena</i> , <i>Citrus paradisi</i> , and <i>M. officinalis</i>) massaged gently on one hand and then the other in the following order: forearm, wrist, palm, fingers, and back of the hand, vs control therapy with jojoba oil administered in the same way	Effects on behavioral and psychological symptoms (BPSD) of dementia or activities of daily living (ADL) Changes in mood, behavior, communication (verbal and nonverbal)	Quantitative: No significant changes were found in agitation (assessed by CMAI), BPSD (assessed by NPI-Q), and ADLs (assessed by FIM). Additionally, there were no significant longitudinal improvements over four weeks for any measure. No adverse effects were found. Qualitative: Participants had positive experiences during and after therapy such as improved mood and sleep, and some experienced increases in both verbal and nonverbal communication.
Burns, et al 2011 UK	Treatment with placebo medication and active aromatherapy (Melissa oil); active medication (donepezil) and placebo aromatherapy; or placebo of both	Effects on agitation	No evidence in support of the validity of Melissa as a treatment for agitation in AD when compared to Donepezil and placebo was found. All groups, including placebo, experienced significant reduction in agitation levels after 12 weeks, providing evidence for a non-specific benefit of simple human interaction and touch in treating agitation. Adverse events for Melissa were the same as placebo.

Critique of Research

Table 3

Author/Year/Country	Threats and Biases	Limitations	Notes
Hodgson & Andersen 2008 USA	External validity: Generalizability/selection - small sample size that was homogeneous (all were white, female, Jewish, and in a nursing home, and 80% had Medicaid)	While larger than many studies on this topic, the sample size limited the ability to analyze potential interactions of affect and α -amylase, and the sample was not randomly selected. The friendly visit portion of the control condition could have been stressful if the participant felt they had to put in effort to have a conversation, though this was not required, and it appears that this interaction was positive overall.	α -amylase has been shown to be a valid physiological measure for examining changes in affect and pain, so it is important to further examine the actions by which reflexology interacts with the sympathetic nervous system. A single reflexologist provided all treatment. Welden and Yesavage's progressive relaxation exercise was used prior to intervention and control Instruments: MMSE, Checklist of Nonverbal Pain Indicators (CNPI), Apparent Affect Rating Scale (AARS), Functional Assessment Staging (FAST)
Fu, Moyle, & Cooke 2013 Australia	External validity: Generalizability/selection – limited by sample size Internal validity: Performance bias possible – single blinded; participants not blinded (because of cognitive impairment) Instrumentation – despite training in CAMI, Participant behaviors were subjectively reported by staff Selective reporting bias – MMSE scores not reported (however, this was not their objective)	Olfactory functioning was not assessed in this population known to have potential olfactory deficits. Aromatherapy was given adjunctively with standard care practices and routine medications that might allow for the presence of unknown interactions. As no standardized or ideal doses, concentrations, or forms of EO are recognized studies may miss potential benefits due to improper strength, timing, frequency, or delivery method.	Trial registration ACTRN12612000917831; Ethical and IRB approval obtained from the University Human Research Ethics Committee and the management of each aged care facility Instrumentation bias - issue reduced by inclusion of caregiver panel that rated behaviors as well Instruments: CMAI-SF, MMSE
Hawranik, et al 2008 Canada	External validity: Generalizability/selection – limited by sample size Internal validity: Instrumentation – Research staff did not directly observe behaviors before or after intervention	The proposed underlying mechanism of this modality is questionable. Did not explore the mechanisms of therapeutic touch or its interactions with behaviors oft exhibited in dementias of various types and severities or with longitudinal aspects such as time of day or year. The authors assert that since the patient is not actually touched, the benefits of touch should not be attributed to TT's effects, however, the presence, attention, and warmth of a hand close to the body may still carry similar influences the way touch might. The behaviors tracked were selected from those that at least 25% of the participants showed in the weeks leading up to the study, resulting in three categories that might not include all relevant behaviors. The reported number of participants to achieve statistical power was not obtained, and the presence of three groups indicates possible lack of sufficient data points. Therapeutic touch intervention was implemented in the evening and results were measured within 2 hours, but participants potentially experienced less behavioral symptoms because of the time of day, though the presence of the Sundowning phenomenon is noted.	Ethical approval was obtained to ensure that no coercion of participants occurred and that confidentiality and anonymity were maintained All TT providers were also RNs Instruments: CMAI, MMSE

Author/Year/Country	Threats and Biases	Limitations	Notes
O'Connor, et al 2013 Australia	Internal validity: Selective reporting bias - data not reported separately for each phase of trial Performance bias possible – single blinded; participants not blinded (because of cognitive impairment); efficacy of nose clips used is questionable	Authors note staff may have grown tired of reporting symptoms and may have recorded less of them, and there was vacation staff that did not know the residents as well (and possibly less staff than usual). As no standardized or ideal doses, concentrations, or forms of essential oils are recognized studies may miss potential benefits due to improper strength, timing, frequency, or delivery method. Dose of lavender was much higher than other studies; potential for unknown or stimulating effects. Medication use in this sample might affect results, however, efforts were made not to alter psychotropic medications.	Registered with the Australian and New Zealand Clinical Trials Registry (ACTRN 12609000569202), and approved by all relevant committees including the Monash University Human Research Ethics Committee The study was funded by the National Health and Medical Research Council (Grant #545843) and the Dementia Collaborative Research Centre administered through the University of New South Wales. "Neither funding body, nor the supplier of materials, played any part in analyzing data and preparing this report." Authors noted: "future researchers should consider measuring plasma levels of linalool and linalyl acetate as a check on absorption, and optimal dosing regimens and formulations have yet to be established;" no attempt was made to distinguish between types of dementia. Instruments: CMAI, MMSE, Philadelphia Geriatric Center Affect Rating Scale
Moyle, et al 2014 Australia	Internal validity: Instrumentation – BP and HR measurements might be inaccurate in some cases where the participant's arm was lower than recommended by the equipment's manufacturer. Data attrition – occurred when participants refused to have BP or HR taken (0.6% missing data in the study) Selective reporting bias – MMSE scores not reported (however, this was not their objective)	Medication use, as it was not altered in this sample, might affect results.	Registered with the Australian and New Zealand Trials Registry (ACTRN 1262000658819) and was granted ethical approval by the University Human Research Ethics Committee. Funding for the conduct of the study came from the National Health and Medical Research Council (NHMRC Project grant: 597415) The authors note: a future study might review medication and its influence on physiological measures; this intervention may be useful in reducing hypertension, which is acknowledged to have an influence on the progression of dementia. Took measures to avoid autonomic dysfunction issues that could be present in some forms of dementia Instruments: CMAI, MMSE
Yoshiyama, Arita, & Suzuki 2015 Japan	External validity: Generalizability/selection – small sample size (only 14) and only elderly females Internal validity: Selection – small sample size	Researchers could be influenced by single-blind crossover from initial pilot study. Qualitative analysis did not report the complete process and should be addressed in follow-up so reliability and validity statistics are obtained. As no standardized or ideal doses, concentrations, or forms of essential oils are recognized studies may miss potential benefits due to improper strength, timing, frequency, or delivery method. Effective measurement of changes in BPSD and ADLs might not have been achieved in a small timeframe of four weeks. Study methods should be compared to alternative treatments to strengthen confidence in efficacy.	Approved by Tenri Health Care University Human Research Ethics Committee and the management of the facility Instruments: CMAI, NPI-Q, Cornell Scale for Depression in Dementia (CSDD), Functional Independent Measure (FIM)
Burns, et al 2011 UK	Internal validity: Attrition bias possible – 20 participants lost, but remainder still larger than most studies of this nature.	As no standardized or ideal doses, concentrations, or forms of essential oils are recognized studies may miss potential benefits due to improper strength, timing, frequency, or delivery method.	Registered with the European trials agency (EudraCT No. 2005-003269-17) and was approved by the ethics committee (reference: 05/Q1407/213), the MHRA (CTA No. 23148/0001/001-0001)

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Author/Year/Country	Threats and Biases	Limitations	Notes
	Data attrition bias – noted only an estimated 50% compliance rate in using the interventions	Compliance rate was only estimated at 50% and only assessed by how full the returned bottles were, which could show a significant flaw. There was a greater chance of false-positive findings, acknowledged by the authors, from multiple testing for secondary outcomes. As such caution is needed with interpreting results.	Melissa oil was used instead of lavender because of the broader range of receptors upon which it acts. Numerous adverse events were reported and included combinations of donepezil, Melissa oil, and placebo, with Melissa and placebo having the same adverse events at 2 each. All three groups showed benefit, the authors feel from hand massage as noted in the results section. Instruments: PAS, NPI, Barthel scale of ADLs, Blau QOL scale