Author’s response to reviews

Title: A randomised controlled trial of the use of aromatherapy and hand massage to reduce disruptive behaviour in people with dementia

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Author’s response to reviews: see over
A randomised controlled trial of the use of aromatherapy and hand massage to reduce disruptive behaviour in people with dementia

Response to Reviewers
Reviewer 1
Nothing to address

Reviewer 2
-Your conclusion in the Abstract now repeats your Results section.
The abstract conclusion has been modified.

-How aromatherapy works? If you believe that the mechanisms underlying aromatherapy are unknown, you cannot comment on people’s deteriorated olfactory system as a potential cause for your lack of results. Either you add a number of potential explanations of how aromatherapy may work to your introduction (I believe there is quite some evidence from animal and human studies) or you delete this explanation from your Discussion.

Information has been added/modified in the introduction to demonstrate an explanation for aromatherapy.

-Your use of the CMAI. I would expect to see Kappa’s presented if you report inter-rater reliability from your own study, including the number of sessions and raters that were included in your calculation. It is helpful that you have been able to use the same 15 raters for the study period. But did you use the same rater for each measurement per participant? In other words for each participant did the same rater complete the CMAI on the 5 occasions? And how would that work out with staff rotation? Seeing your study duration was 6 weeks and you had a baseline and a post-intervention measurements outside those 6 weeks: staff will have moved on to other wings in such a period. How can they report on agitated and aggression in the previous fortnight if they are in a different wing than the resident?

Reference to inter-rater reliability has been removed. Further information on how each individual was assessed on CMAI-SF has been added to demonstrate that there were no problems with ensuring at least 2 of the same regular carers were assessing the individual. In this organization the facilities have regular staff and they do not move between units.

-Also the CMAI scores in both your Introduction and Results section don’t mean anything as they are written now. For example, a reduction from 25 to 18 (Chinese study): does that mean 1 behavior reduced in frequency from several times an hour to never? Or several behaviours reduced from several times a day to once a day?
As indicated this refers to the mean total score of the CMAI i.e. scores of all behaviours over the fortnight. To assist readers the paper now reports a POSITIVE Reduction……

-Abstract (and Results and Discussion): the association between cognitive impairment and disruptive behaviours seems outside the scope of this paper.
Reference to the association between cognitive impairment and disruptive behaviour
Your Introduction is one-sided: you only discuss the papers that had positive outcomes (not even providing references for the negative studies). You seem to disregard all these positive studies because of design limitations, yet you still conclude there is some evidence to support the use of aromatherapy. In an Introduction I would expect a neutral overview of all the published studies, discussing limitations of both positive and negative studies. The appropriate conclusion would be that the existing evidence is mixed and many studies suffered from suboptimal methodology: that is sufficient justification for your study. If there are many studies, you can narrow it down to studies on Lavender, omitting the Melissa and combined aromas studies. You hardly discuss the evidence regarding massage in your Introduction: there is something in your Methods on page 7 (reference 12).

The introduction has been revised to include the Holt and Viggo Hansen Cochrane Review and two recent systematic reviews – as these indicate the main conclusions about aromatherapy and massage. A sentence has been added to the introduction summary to indicate why hand massage was included.

Same of your phrases are very unclear, what do you mean by the following:
page 3: ‘aroma results in psychological and physiological changes?’ How? And what changes?
This has been changed as a result of the rewriting of introduction.

page 4, 2nd paragraph: I don’t see how the reported results were compared to a control group both from reference 6 and 7. Also, was it an increase from 7.69 to 8.14 hours?
This has been removed as part of the rewriting of introduction.

page 14: an intervention that meets the needs of people with dementia? Any suggestions?
As needs are individual we do not believe it is appropriate to make any further statement here. We have changed this section to address reviewer 3’s comments.

- In our experience observations are more reliable then CMAI staff reports, so it may be best not to call this a limitation of reference 8.
This has been removed as a result of the rewrite of introduction.

- The choice to exclude people with early-onset dementia deserves a brief explanation. Do we believe there will be a different response to aromatherapy in this particular group?
Reference to different stages of cognitive impairment has now been removed.

- The point about smells in the room is only briefly mentioned. This is an important point, especially because you mention in your reply that residents spend most of their time in their rooms, so staff and family are bound to walk in. Anecdotal emarks in regards to the wrong condition do not take this concern away. I think you should admit that you attempted to blind staff, but it was highly likely to not
have worked. You should attempt to describe the potential impact on your findings in your Discussion. For future studies, you can avoid this problem by spraying another aroma into the room (not onto the participant) after all intervention and control sessions.

We believe the following, which has been added addresses, the reviewer’s concerns.

Although the intervention was performed in the private areas of the care facility staff or family may have become aware of the nature of the treatment given to participants if the lavender oil odor remained in the environment following the treatment. However, given that staff and family on occasion referred incorrectly to the treatment a participant was receiving this seemed unlikely.

-Your sample size calculation made me confused. It looks like the Balard control group had lower CMAI scores, hence less agitation than the intervention group?

Or are you presenting a difference score?
Yes this is the change in mean scores and this has been addressed in the paper.

-You have not described in the text (Methodology) how any of your demography data (Table 1.) have been established.
The following has been added: Participant demographics were obtained from the facility manager who copied information required from resident records.

Reviewer 3

Discussion
Reviewer response: The revised discussion is improved but the authors do not explain the study results. What is their explanation for finding no significant effects? Is further research needed?
A statement has been added to indicate that there is no clear explanation why the results differ but there is a question is raised re the spray application and no control over antipsychotic medication, and the need for further research.

The 2nd paragraph is about the relation between cognitive impairment on type of aggressive and nonaggressive behaviours displayed. The purpose of this paragraph is unclear. How does it relate to the interventions investigated in this study?
This has been deleted.

Conclusion: In the last sentence of the conclusion it is said that the results are important for practitioners. It would be helpful for practitioners if the authors explain why the findings are important? How should practitioners interpret the findings considering the limitations of the study? In what way are the findings important for researchers?
A statement re practitioners and researchers has been added to the conclusion.
Reviewer response: The introduction is revised but still misses an overview of scientific knowledge based on systematic reviews. For instance, Cochrane reviews from Holt et al., and Viggo Hansen. It remains unclear why the authors investigated the effect of hand massage in addition to aromatherapy?

The introduction has been revised to include the Holt and Viggo Hansen Cochrane Review and two recent systematic reviews – as these indicate the main conclusions about aromatherapy and massage. A sentence has been added to the introduction summary to indicate why hand massage was included.

Table 4 was added to the results section. Why are results described for all participants together and not for the 2 intervention groups and the control group separately? Readers are now unable to compare outcomes for each group

A comment re the results of the comparison of CMAI outcome of each group has been added to the paper.

Reviewer response: It is still unclear to me what is meant by ‘a documented history of a minimum of two weeks of agitation or aggression in total within the past three months’. Is it on a daily basis for 14 consecutive days within the past three months? Or maybe an episode of agitation or aggression on at least 14 days, but not necessarily consecutive days, within the past three months?

This has been changed to: a documented history of a minimum of two weeks of agitation or aggression in total (consecutively or 14 single days), within the past three months

Reviewer response: Please provide the references for the publications that underline this statement

Holmes et al 2002 and Lin et al. 2007 have been added as supporting references.

The statistical outcome described in the last sentence of the paragraph “Linear Regression and Goodness of Fit”. (R2 = 3E-06) seems an odd outcome? Might be typo?

Linear Regression and Goodness of Fit have been removed as a result of Reviewer 2 requesting the removal of discussion related to cognitive impairment.

Figure 1: the box that describes reasons for exclusion was amended in response to reviewer 4. Why were the numbers of persons excluded because of MMSE 24/30 and hospitalization also changed?

This was to make it clearer. One person was allocated to MMSE greater than 24 when in fact they were not excluded because of hospitalisation.

Reviewer response: Although meeting the needs of people with dementia may indeed be an important focus for future studies, this is not what I meant with this remark.
What I meant is that various reviews about the effects of non-pharmacological interventions for behavioral disturbances in dementia conclude that there is probably not 1 intervention that is effective for all dementia patients. It might be better to tailor interventions to the needs and wishes of an individual person. Aromatherapy and/or hand massage therefore might be effective for individual patients, despite the outcome of this study? What would be the opinion of the authors about that?

The following additional information has been added.

Furthermore, although this study did not demonstrate significant results there were individuals who obviously benefited from the intervention. This study supports the need to tailor interventions to the needs and wishes of individuals. Further research is required to identify if aromatherapy and/or hand massage is more effective in a particular stage of the dementia syndrome or for individuals who for example pre-dementia enjoyed aromatherapy and/or massage receive greater effect.