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
Dear Editor

Thank you for the opportunity to attend to reviewers’ comments. We have addressed each of the comments below:

**Reviewer: 1**

Why do the authors have inclusion number 5, i.e currently under physical and/or chemical restraint for agitation and aggression? It is not clear why the intervention should be only used in this group?

**RESPONSE:** The intervention was targeting agitation and aggression. Therefore to ensure the best possible outcome, we chose residents who were identified as having a history of the behaviours we were interested in reducing. We have added a statement to clarify this targeted group.

Furthermore how is it assessed whether residents were restrained specifically for agitation and aggression? Furthermore how did the authors define physical restraints and how was this measured?

**RESPONSE:** A response has been added to indicate that physical restraint needed to be documented for agitation and aggression. Types of physical restraints, time they were applied and removed and reason for the use were indicated by the nursing documentation.

The data was split based on participant age. Please provide the rationale for this split up of data.

**RESPONSE:** The authors acknowledge the data split resulted in small subgroups and have therefore as requested have removed this data split.

The authors have included residents from three facilities. Why do the authors choose to analyse the data with repeated measures ANOVA. Data from the residents are nested within facilities and it is known from the literature that (disruptive) behavior has an environmental correlate. Could the authors provide more information on the variation in scores per facility?

**RESPONSE:** Due to the small number of participants (n=61) we did not look at variation in scores between facilities. We were however, careful in choosing facilities that were similar. The three facilities were owned and operated by the one operator. The building environments were based on a standard build, as were staffing models. We used Optimal Scaling (SPSS) representation of the demographic profiles of residents to indicate differences between facilities. The main difference was in gender with Facility one and three having more male participants than Facility two.

Did the authors consider a multihierarchical analyses or at least an ANCOVA analyses correcting for facility type.

**RESPONSE:** Because of sample size and as indicated above the similar environments we did not undertake multi-hierarchical analyses.
For the reasons stated above, the facilities in this current study were considered to be sufficiently homogenous that a covariate analysis controlling for facility was not required.

Furthermore it is unclear whether the authors have corrected in the analyses for disease severity of residents in their regression models.
RESPONSE: Disease severity was hypothesized to have a significant effect on cognitive ability, however since the prospective sample size was small we aimed to recruit patients with similar disease severity. Thus, a sample homogeneous on disease severity was obtained via strict inclusion criteria: (i) MMSE score of 24 out of 30 or less (ii) features of Alzheimer's disease according to American Psychiatric Association DSM-IV-TR (iii) a documented history of a minimum of two weeks of agitation or aggression in total, within the past three months.

Results p.12. The first paragraph describes results comparing outcomes in two groups based on cognitive impairment. Are these differences significant? Please add p-values and test for these results.
RESPONSE: As indicated earlier we have removed the age subanalyses from the document.

The order in which the results are currently presented might be confusing for readers. It would be helpful to structure the results section according to research questions.
RESPONSE: Results section has been restructured.

Furthermore, the results section contains information that should be presented in the method section (e.g. p.12 ‘two dimensional linear regression analyses’ and the part on the Kruskal-Wallis test and additional testing of interaction effect.
RESPONSE: These sections have been revised according to reviewer’s request.

Results: Nearly 90% relied on nursing staff to assist them with daily activities. Could the authors clarify in the methods section how this was measured.
RESPONSE: Additional information has been added to the methods section to indicate this was retrieved through an audit of residents’ documentation.

Discussion; The second paragraph (participants with severe cognitive impairment...) describes results which have not been presented in the section results. Please add this.
RESPONSE: This section has been rephrased.

CCMAI scores show a reduction from 24.68 to 17.77. Is this correct?
RESPONSE: As indicated we used the CMAI – Short Form rather than the long form. These scores are correct for this form.
Reviewer: 2

The discussion part of the abstract seems unrelated to the rest of abstract. A lot of new information is presented.  
RESPONSE: The abstract has been revised to address reviewer's concerns.

Only 2 studies using aromatherapy are presented in the introduction, with a lot of space reserved for a study describing the effects of Melissa oil, which seems less relevant because you are using Lavender oil. Three other studies are mentioned in discussion that have study the effectiveness of Lavender oil, I suggest moving these to the introduction.  
RESPONSE: Introduction and discussion have been revised.

No explanation is given about how aromatherapy may work. In the discussion it is then speculated that the olfactory system may not be intact in severely cognitively impaired individuals, whereas it also has been postulated that Lavender oil may cross the blood-brain barrier. Please, provide an overview of how aromatherapy may work in your introduction and revise discussion accordingly.  
RESPONSE: A statement referring to the lack of theoretical knowledge of how lavender oil works has been added to introduction.

Because the journal is not an aged or geriatric specific journal, I think some of the inclusion criteria need some explanation, for example inclusion criteria 1 and 2 and exclusion criteria 1.  
RESPONSE: explanation has been provided for criteria 1 and 2 and exclusion criteria 1

P8. You describe the intervention was applied in a quiet and private environment, would this have had any impact on your findings?  
RESPONSE: The quiet and private environment was necessary to avoid staff and family being aware of the intervention type. Given that residents spend lengthy periods each day alone in their room we do not believe we have isolated residents anymore than they would have each day. Frequently when residents display disruptive behaviours they are placed into their room to avoid disturbing other residents.

With the psychometric properties for the CMAI, are you reporting the inter-rater reliability in your own study? Despite remarkable properties found by the developers of the CMAI, we found in the Australian aged care setting that inter-reliability was very low for the CMAI: the perception of people's behavior seemed very individual. Because of staff rotating, I assume that during the 6 week period, it was different staff reporting CMAI scores. This deserves to be addressed as a limitation for your study as well as when discussing other studies using this outcome measure.  
RESPONSE: We indicated in the paper the reliability in this study. “In the current study, the CMAI-SF showed a high reliability the five times it was used, with a Cronbach’s alpha estimate from .87 to .91 and Guttman split-half reliability estimates
from .78 to .89”. Our previous experience has taught us of the need to use well trained and the same raters across studies. In the current study, to reduce the challenge of interrater reliability the same 15 raters were used across the six weeks. This statement has been added to the paper.

The splitting of the group into 2 age categories seems arbitrary and complicates your findings. I would suggest deleting this subgroup analysis.

RESPONSE: Age subgroup analysis has been deleted.

The discussion needs major revision and restructuring. The conclusion is very long and again contains a lot of new information. Maybe a section describing implications is in place?

RESPONSE: The discussion has been reduced and focused only on the research questions.

It think it is best to describe the recruitment/loss to follow up procedure in the text, not only in the flow chart.

RESPONSE: Further information has been added to the outcomes section

Mini Mental State Examination. The i in Mini is missing and usually capitals are used.

RESPONSE: Missing I and capitals applied.

With limitations: did you not monitor changes of medications or use of PRN medications during the study periods. This could have had a major impact on your findings.

RESPONSE: Although we were able to monitor medications we were unable to stop PRN medications hence why we have acknowledged this as a limitation of the study.

You sometimes switch between times (past and future)

RESPONSE: Paper has been reedited

I am not familiar with the term chair-fast

RESPONSE: This term is used to determine the person has no mobility. We have indicated the first time used and in the demographics table that chair-fast refers to not mobile.

The CMAI means on p 12 do not mean much when the range or labels of scores e.g are not reported.

RESPONSE: This section has been revised and additional table has been added showing the means over time as requested by reviewer 4.

I think behaviours are usually referred to as non-aggressive and aggressive. Capitals are not usually used for the CMAI groups.
Reviewer: 3
Introduction: The rationale as described in the introduction could be more convincing. The 4 example studies appear to be a bit of a random pick of studies that did something with massage and/or aromatherapy. Rather than stating limitations of single studies it would be better to describe limitations and knowledge gaps based on systematic reviews in this area and recent studies in addition to that.
RESPONSE: The introduction has been rewritten to focus only on recent studies that have shown an effect using Melissa oil or Lavender Oil.

It would be of importance to explain to the readers the exact limitations that the authors tried to overcome in their study.
RESPONSE: The limitations the researchers tried to overcome have been outlined.

The authors should explain their choice of lavender oil either make a case for it in the introduction or provide an explanation in the methods section
RESPONSE: The choice of lavender oil has been explained in the introduction.

What is meant by ‘two weeks of agitation of aggression. Two consecutive weeks or a minimum of 14 days within the past three months. Staff reporting agitation/aggression in a patient record or agitation/aggression based on outcomes of a valid instrument.
RESPONSE: This has been revised to “a documented history of a minimum of two weeks of agitation or aggression in total within the past three months.

How was it made sure that all facility managers applied this criterium in the same way?
RESPONSE: The facility managers recorded the documented episodes of agitation/aggression over the previous 3-month period. Participants in the study meet this minimum with all participants recording 2 or more episodes a week.

Staff blinding. I wonder if staff could have smelled the lavender that was sprayed onto residents chest? Could it be possible that staff was able to distinguish who was in the treatment groups and who was not by smelling lavender on residents? How was it made sure that the staff was blinded to that?
RESPONSE: Further information on this has been provided within the limitations section of the document.
I am not sure that the analysis was conducted according to the Intention to Treat approach? Five of the participants were randomized but did not finish the study because consent was withdrawn. Although there is probably not much the authors could do about it, it seems that for this reason an Intention to Treat analysis could not be conducted.

RESPONSE: Of the five participants who were randomized but did not finish the study, their relatives withdraw both consent for them to continue as well as consent to use the data. Therefore their data were not available to be included in the analysis. For all other randomized participants their data was included regardless of what subsequently occurred. The reasons for withdrawal of consent have been added to the paper.

Please explain why the outcomes of the Ballard study were chosen for the sample size calculation?

RESPONSE: An explanation has been provided that indicates the Ballard study was chosen as it had the same intention as the current study and also used the same primary outcome measure, ie the CMAI. At the time there was no suitable study that used lavender oil that we could use for the power calculation.

The paragraph about the statistical analysis does not provide a description of the statistical analysis. How were the CMAI-SF outcomes analyzed exactly, what tests were used and why? Why was the data split based on age and level of cognitive impairment.

RESPONSE: Further information has been provided.

Among the key exclusion criteria in the trial registration it reads had no documented behavioural history in the previous 3 months. This exclusion criterion is not mentioned in the manuscript and contradicts inclusion number 4 in the manuscript.

RESPONSE: We did not chose to indicate the exclusion criteria in the manuscript as participants needed to have a minimum of 14 days of agitated behavior over the previous 3 month period. It is not possible to have no history in the previous 3 months and to be included in the study.

Discussion/Conclusion

Most of the conclusions stated in the abstract and underneath the conclusion heading are not directly related to the research question. The conclusion is too long and should be more related to the primary research question and outcomes.

RESPONSE: The discussion and conclusion have been shorted to refer just to the research questions and outcomes.

The last part about treating disturbed behavior individually is in line with current knowledge in the field and probably deserves more attention in the discussion.

RESPONSE: A statement about needs driven behavior has been added to the discussion.
It is probably better to include the potential for negative effects of hand massage as part of the introduction. Participants resisted hand massage. This is not the place to mention study findings/observations for the first time.

RESPONSE: This section has been removed.

The number of allocated person is 61 according to the abstract but 67 according to the section study design and figure 1.

RESPONSE: Changed in abstract to 67

Reviewer 4
The patient who dies or data were missing should be included.

RESPONSE. There were no baseline data for the patient who died. There were 5 withdrawals of consent to continue as well as data. We were therefore unable to use the data.

The flow chart is confusing. Were there two groups of 6 participants who withdrew/died.

RESPONSE: Thank you for identifying this mistake. The flowchart has been amended so that the 6 withdrawals are clearly indicated following randomization.

Please define the primary efficacy variables and the test statistic. Please present the primary efficacy variable with SD for the 3 groups at the various time points.

RESPONSE: Table 4 presents this data and a response has been added to indicate these are the mean scores over the five time points.