Review report

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

**Version**: 2  **Date**: 16 October 2012

**Reviewer**: Emmelyne Vasse

**Reviewer’s report:**

Review report

The manuscript could be of interest to other researchers and care professionals in the area of dementia care. At this moment, however, it lacks essential information about the rational for the intervention/research question and the methods used. This makes it very difficult to establish soundness of the data and to interpret the results.

**Major compulsory revisions**

**Introduction**

1. The research question itself seems clear but the rational as described in the introduction should 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.

   In the final paragraph of the introduction it is said that the current study was performed ‘to overcome some of these limitations’, it would be of importance to explain to the readers the exact limitations that the authors tried to overcome in their study.

**Methods**

The following aspects need clarification:

2. One of the limitations of previous studies as identified by the authors is that some of the studies did not provide a clear explanation of the essential oil used. I would therefore expect that the authors would explain their choice for lavender oil. Either make a case for it in the introduction or provide an explanation in the methods section.

3. Inclusion criterium no. 4 # What is meant by ‘two-weeks of agitation or 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? How was it made sure that all facility managers applied this criterium in the same
4. Staff blinding # I wonder if staff could have smelled the lavender that was sprayed on to the 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?

5. I am not certain 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.

If possible, please provide information about the reasons why consent was withdrawn in these cases.

6. Please explain why the outcomes of the ‘Ballard-study’ were chosen for the sample size calculation? Why not one of the other studies mentioned in the introduction and discussion?

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

8. Inclusion criterium no. 5 # Why was this selection criterium used for the study? Why would one expect significant effects of the intervention in persons who already are ‘treated’ with restraints for aggression or agitation? How was dealt with the effects/influence of the chemical restraints on study outcomes?

9. The trial was registered:

Among the key exclusion criteria mentioned in this registration it reads “Had no documented behavioral history in the previous three months”. This exclusion criterium is not mentioned in the manuscript and contradicts inclusion criterium no 4. in the manuscript/no. 3 in the registration file. Please provide clarity about this?

Discussion/Conclusion/Abstract

10. Most of the conclusions stated in the abstract and underneath the conclusion heading are not directly related to the research question or primary study outcome. I am not sure what to make of the present conclusions as they appear to be also based on indications about how staff handles residents with disruptive behavior and research by others. In my opinion, the conclusion is too long and should be more related the primary research question and outcomes.

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

11. Several paragraphs in the discussion contain explanations about why specific behavior might or might not be expected in the age and cognitive function subgroups. This is too long and not clearly linked to the research question or primary outcome of the study.

12. The last paragraph underneath the discussion heading sort of makes a case why one could expect negative effects from hand massage in residents with severe dementia. This leads the reader to wonder why the massage was part of the intervention in the first place? It is probably better to include this in the introduction and make a case why additional research was needed, despite negative findings from previous studies.

It also states that ‘participants with dementia resisted the hand massage treatment’. This is new information for the reader and it is not clear if this was an objective or subjective finding? The discussion is not the correct section to mention study findings/observations for the first time.

Minor essential revisions

13. The number of allocated persons is 61 according to the abstract but 67 according to the section ‘Study design’ and in figure 1. I suggest that this number is changed to 67 in the abstract.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests