Reviewer’s report

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

Version: 3 Date: 7 December 2012

Reviewer: Eva (Simone) van der Ploeg

Reviewer’s report:

Compulsory revisions

The following previous suggestions have not been addressed sufficiently in this revised paper:

- You conclusion in the Abstract now repeats your Results section.
- 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.
- 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?
- 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?

My other comments have been addressed sufficiently, however I am sorry to say that I believe overall the paper has not improved much. It must be hard to integrate the comments of 4 reviewers, but in my opinion the following still needs to be revised before this paper is acceptable for publication:

- Abstract (and Results and Discussion): the association between cognitive impairment and disruptive behaviours seems outside the scope of this paper.
- 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).

-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?

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?

page 14: an intervention that meets the needs of people with dementia? Any suggestions?

-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.

-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?

-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 remarks 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.

-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?

-The total of the mild/moderate vs. severe dementia groups does not amount to 67.

-You have not described in the text (Methodology) how any of your demography data (Table 1.) have been established.

Level of interest: An article whose findings are important to those with closely related research interests
**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.