Dear Editor,

We have made a number of changes to our manuscript (MS 1950411867850009) in the light of the reviewers’ comments. The paper is now much clearer and easier to understand. New text is shown in red in the revised manuscript for your convenience.

Reviewer's report 1

1. The primary outcome measure is agitated behavior. This study uses Cohen-Mansfield Agitation Inventory (CMAI) as a measure to represent the concept of agitation. Agitated behaviours in CMAI include three categories: aggressive, physically aggressive, verbally agitated behaviours. One of sampling inclusive criteria is a physically agitated behavior that occurred at least several time each day in daylight hours, at times other than during nursing care, to a degree that required staff intervention. This criterion shrinks recruitment of subjects and is inconsistent with the definition of agitated behaviours from Cohen-Mansfield.

Response: We set out to recruit nursing home residents with significant, demonstrable agitated behaviours. We chose to focus on physically agitated behaviours (one of the three categories of behaviour rated by the widely-used Cohen-Mansfield Agitation Inventory) because they occur most frequently and can be measured more reliably. We now list the reasons for this decision (page 6, para 1). We believe that this approach was perfectly consistent with Cohen-Mansfield’s definition of agitation.

2. The olfactory pathway and the area in the brain responsible for awareness of the ability to smell might be damaged early in Alzheimer's disease from literatures. However, neither ability of smell nor type of dementia was presented in this study. Both might confound the effect of Lavender essential oil in reducing agitation.
Response: When study participants are exposed to lavender by inhalation or topical application, it is possible that its smell activates olfactory pathways. This process is difficult to assess and has never been the subject of study in people with dementia. Lavender is readily absorbed following transdermal application and we chose to focus on this modality given its greater predictability. We now describe the evidence base for this decision in more detail (page 5, last para).

3. Figure 1 study flow chart seems inconsistent with the text of study design in p.7.

Response: In Figure 1, we have removed the text “discontinued lavender” and “discontinued placebo” from the follow-up boxes as participants were crossed from one condition to the other and could drop out in either phase.

4. MMSE was measured (p.8), but score of MMSE was not show in text or Table 1. Please add range of age, CMAI and Affect Rating Scale.

Response: We have now removed Table 1 and describe participants’ personal and clinical characteristics in the text. We now include MMSE scores and standard deviations (page 10, para 3).

5. It is recommended to compare the effects of CMAI subscales including aggressive, physically aggressive, verbally agitated behaviours between experimental and control groups.

Response: As noted above, we studied only physically agitated behaviours.

Reviewer's report 2

Some statements require citations to support the argument.

Response: We have now addressed the lack of supporting evidence regarding the relative merits of inhaled and transdermal delivery modes (page 5, para 3) by adding a reference about transdermal drug applications (ref 21). We also now state that “the amounts inhaled by an individual nursing home resident are likely to vary ....” (page 5, para 3) when comparing delivery modes.

There are sections that could be summarised more succinctly.

Response: The introduction covers a lot of ground (basic science, clinical studies, inclusion criteria, dosing, delivery mechanisms and study hypotheses in a relatively short space.

Critique of the methodologies used in some of the studies showing positive results are absent. In particular, the small sample sizes used in these studies require consideration.

Response: We state on page 4, last para that studies cannot be compared directly because of differences in lavender formulation, delivery methods, participant numbers, selection criteria, outcome measures and time frames.
Further consideration should be given to the means of application of lavender oil in the present study and in previous studies. Should there be a difference in observed effects (or not) when lavender is administered topically via massage or via olfactory mechanisms?

Response: We now state that transdermal delivery is more reliable than by inhalation and that nothing is known of olfactory delivery (page 5, last para).

The Results section should have more detail on the statistical analyses conducted, as well as the statistical results.

Response: The statistical analyses were very difficult to follow and we now show the results graphically (as well in Table form) with a Figure each for behaviour and affect (Figures 2a, 2b). Readers can grasp our results more easily while people who want the actual data can still access them. We also provide more detail in page 10, last para to help readers follow the statistical interpretation.

Some of the data referred to in the tables could be included in the text.

Response: We have deleted Table 1. Participants’ characteristics are now described in text form on page 11, para 1.

The strengths of the present study in its methodological design are not stressed adequately.

Response: The lack of a double-blind procedure where the rater was also blinded to treatment condition.

Response: Raters and nursing staff were certainly blinded to the treatment allocation (page 8, para 2). We now state that it was not practicable or even desirable to mask participants given that all had such marked cognitive impairment (page 8, para 2).

I also find the conclusion that the lack of effects in this study “does not mean that aromatherapy massage….. lacks efficacy” questionable.

Response: We have deleted the previous concluding section. The new concluding paragraph is much more robust (page 13, para 1).

Consequently, I think the authors need to revise their Conclusion paragraph, drawing from the data they collected and analysed, and using their findings to support their conclusion.

Response: See above.