Author's response to reviews

Title: Acupressure for agitation in nursing home residents with dementia: study protocol for a randomized controlled trial

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Author's response to reviews: see over
Cover Letter

Dear Reviewer(s),

In response to the comments, we have carefully considered and made revisions. Please kindly find our responses below. I have highlighted your comments in italics and our responses and revisions are immediately below your comments. The revised manuscript extract is marked by quotation mark. The revised parts of the manuscript are highlighted in yellow with page number indicated. Thank you very much for your comments.

Sincerely,

Rick Kwan

(also on behalf of all other authors)

**Major Compulsory Revisions:**

1. Agitation in PWD is a difficult problem to solve, but the intervention period is only 2 weeks. I think it’s short. If the time is too short not enough to reflect the treatment effect?

   Thanks a lot that you highlighted the duration problem. Two-week intervention is short but we set it so with reasons:
   
   - In the expert consultation phase, experts’ consensuses on the use of duration were not strong as they reported that the TCM theory does not discuss duration of therapy. It was all by experience.
   - In the literature review, we identified two similar studies using 4-week intervention. However, they did not explain why 4-week was used.
   - In the pilot study of 24 subjects (Kwan and Lai, 2014), we purposefully compared the effect among groups with different durations within the range of durations suggested by the experts and used in the previous studies. We found that shorter-but-intense intervention produced a larger effect. Two-week intervention produced the largest significant effect.

   Therefore, after considering the experience and knowledge from the expert panel, previous similar studies, and the result of the pilot study on the same population of the clinical trial, we decided to use the duration of two weeks.

   We agree that longer treatment period hypothetically produces larger effect. However, there is no strong evidence to support this hypothesis on this kind of intervention (i.e.}
acupressure). Also, the longer intervention period is not always good because it consumes more resources and may hinder the compliance.

In response to this comment, we elaborated a bit why we set the intervention duration to be 2-week in page 9 under the heading of “Intervention”. The revised part is highlighted in the manuscript and is shown below:

“Although consensus on the intervention dosage (i.e. the duration and frequency) was reached in the Delphi process, the narrative comments from the Delphi process showed that the dosage was based on the experts’ experience only because TCM theory does not discuss dosage. A pilot study was performed to provide supporting evidence for the dosage selection. In the pilot study (Kwan and Lai, 2014), within the range of dosage suggestions given in the Delphi process, the effect of acupressure was compared among various dosages. It was found that shorter duration with higher frequency showed larger effect. The dosage that showed the largest and most significant effect was used in the intervention protocol, which is to conduct the intervention twice a day for two weeks.”

2. The intervention dosage of acupressure doesn’t have the amount of stimulation of specific criteria. It only says the optimal pressure is defined by experiencing the Deqi sensation (i.e. soreness, numbness, distention, heaviness). However, is the Deqi sensation begins to appear is the optimal pressure, or with strong sense of Deqi sensation is the optimal pressure?

Thank you very much for your very good comment. We agree that this has not been clearly specified in the manuscript. The level of pressure after the Deqi sensation being felt is arbitrary. In the literature, there is still no strong consensus for a method (e.g. pressure/subjective feelings) to quantify the Deqi sensation.

Deqi is perceived as the subjective sensation (i.e. soreness, numbness, distention, and heaviness) felt by patient receiving acupuncture that it links up with the clinical efficacy (Yang et al, 2013). Because the type and extent of sensation can largely vary among people, there is still a lack of consensus to qualify and quantify the Deqi sensation (Yang et al, 2013). In this study, we operationally, regard the pressure as optimal when the Deqi sensation begins to be obviously felt by the participants or observed by the interventionist. This decision is made according to the experts’ opinion from the expert panel.

We revised this part by adding more details on how we ensure the optimal pressure in page 10. The added part is highlighted in the manuscript and is shown below:

“The optimal pressure to achieve the Deqi sensation differs among individuals. The sensation can be confirmed by asking the participants and observing their behavior (e.g. frowning, withdrawing). When the pressure increases to a level that the Deqi sensation begins to be obviously felt by the participants or observed by the interventionist, the level of pressure is regarded as optimal.”
3. The acupressure is by manual operation. How to ensure the completely consistent of force application within the optimal pressure three minutes. If the force is not consistent, the treatment effect will inevitably be affected. Could manual operation of acupressure be changed to the machine operation?

Thank you for pointing this out. We agree that we have not clearly explained in the manuscript how we ensured the consistency of the applied pressure during intervention.

We did consider using machine operation at the time of designing the intervention of the study. From the perspective of fidelity, we totally agree that the use of machine better quantifies the level of applied pressure. However, when we tried to use a mechanical acupressure pen in round one of our pilot study on only a few subjects (people with dementia), they refused. Moreover, the nurses in the nursing homes and some family members of the subjects objected too. Therefore, it became clear that the use of the acupen was not feasible.

To ensure (with limitations) that the force is consistently applied for three minutes, we implemented a few measures. In response to this comment, we elaborated how we ensure the consistency of pressure delivered on page 12 under the heading of “Training and quality control”. The added part is highlighted in the manuscript and is shown below:

“All personnel conducting the intervention have to pass a skill examination administered by one of the six members of the TCM expert panel. The test contents included correct identification of the acupoints (e.g. skills on identifying landmarks and the Deqi sensation) and acupressure techniques (e.g. skills on sustaining the pressure by fingers). The test was performed on both the elderly volunteers and the trainer (i.e. one of the six members of the TCN expert panel). The interventionist could only pass the test when the skills were observed by the trainer to be up to standard and the pressure felt by both the elderly volunteer and the trainer to be optimal (i.e. experience the Deqi sensation sustainably for 3 minutes) as depicted in the protocol. To prevent fatigue, one interventionist was assigned to conduct acupressure for less than 10 sessions in a whole day and adequate rest time between sessions was provided.”

4. The article mentioned that this trial can provide long-term efficacy evidence. However, the last observation point is 6 weeks after treatment. I don’t think it’s a enough long time for follow-up. I suggest that this trial can be extended follow-up period.

Thank you for this comment. We agree that we have not explicated clearly on the reasons how we set the time point of measurement after the intervention. We also agree that the follow-up period is short to demonstrate the long-term efficacy evidence. We do not aim at providing evidence on “long-term efficacy” in this study. Rather, we focused on the examination of “delayed effect”. This is the term we used in the manuscript.
To estimate how long the effect could probably last, we conducted a pilot study (Kwan and Lai, 2014) with weekly repeated measurement. This pilot study provided preliminary evidence that the effect of acupressure on reducing agitation of people with dementia peaked at two weeks after the completion of the intervention. The effect diminished to very close to baseline at six weeks post-intervention. Our purpose is merely to identify whether there is a delayed effect with this intervention. If a delayed effect were observed, then it becomes justifiable to study longer-term effects.

In response to this comment, we elaborated in page 12 under the heading of “Outcome measurement” in order to explicate how we set the time point of measurement. The added part is highlighted in the manuscript and is shown below:

“The measurement at T1 aims at examining the immediate effect after the intervention, at T2 aims at examining the peak effect, and at T3 aims at examining the delayed effect. The decision of measurement interval of T2 and T3 grounded on the result of the pilot study [32] with weekly repeated measurement that the effect of acupressure peaked at the time point two weeks after the completion of intervention and diminished to very close to baseline at the time point six weeks after the completion of intervention.”

Minor Essential Revisions

1. In Figure 1 I see Trial flow chart-is the “Outcome measurements at end of 3rd, 5th, and 8th weeks”. Should it be “Outcome measurements at end of 3rd, 4th, and 8th weeks”?

Thank you very much for your comment.

What reported in the manuscript is correct. We measure T1 at the end of 3rd because we want to compare the effect immediately after the intervention among groups. We measure T2 at the end of 5th week because we want to compare the peak effect among groups as the pilot study showed the peak effect to be at the end of 5th week. This is coherent with what was described in the manuscript in p. 12 under the heading of “Outcome measurement”. The intervention lasts for two weeks. Therefore, in T1, the week immediately after the completion of the intervention (T1) is the 3rd week. The week two weeks after the completion of the intervention (T2) is the 5th week. Details can be referred to the extract of the manuscript as below:

“The outcomes will be measured at the baseline (T0), the week immediately after completion of the intervention (T1), two weeks after completion of the intervention (T2), and six weeks after completion of the intervention (T3).”
Reference
