Author's response to reviews

Title: Acupuncture with manual and low frequency electrical stimulation as experienced by women with polycystic ovary syndrome: a qualitative study

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Author's response to reviews:

To the editor of BMC Complementary and Alternative Medicine

We want to thank the editor and reviewers for their time and effort to assess our manuscript. We have thoughtfully considered all of the reviewers’ and editor's comments and replied to them as below. We hope that the manuscript now is suitable for publication in BMC Complementary and Alternative Medicine.

Rev 1

Major compulsory revisions

1. The introductory comments are somewhat redundant and could be strengthened by a more concise hypothesis for the present study. Additional explanation for the value of qualitative assessment of the acupuncture experience would be helpful.

Answer: Thank you for this valuable comment. We have shortened the introduction and made a more concise statement for the present study.

2. The authors should clarify if any of the subjects continued to use acupuncture after the conclusion of the randomized trial or were using any additional treatments for PCOS during the interview portion which appeared to be 4-12 months after the conclusion of the trial.

Answer: This is indeed an important point which we have clarified in the manuscript. None of the women received acupuncture, or any other treatment for PCOS, between intervention period and the interview. This has been added in the methods section.

3. First sentence should not say 5-10% of all "fertile" women but rather 5-10% of women of reproductive age since these are often not fertile women.

Answer: We agree and replaced the word "fertile" with "women of reproductive age”.

4. Page 5 under acupuncture triggered things...The subjects in the study should not be referred to as girls but rather women given the age group involved.

Answer: We apologize and agree. This has been corrected and replaced with
women.

5. It may be helpful to comment on in the discussion if there are any other quantitative studies of treatments in PCOS as this is apparently a novel area.

Answer: There are a few RCTs and these have now been referred to and brought up in the discussion. We have added a comment in the discussion section on this.

“Pharmacological treatment in PCOS is symptom oriented and often associated with negative side effects [1, 2]. In overweight and obese PCOS women, lifestyle interventions including exercise and diet is the first-line therapy for all PCOS related symptoms [2]. However, for many women this is a very difficult task and complement/alternative is warranted. Importantly, acupuncture is a treatment without unwanted side-effects.”

Rev 2

Patients:
1. You have selected eight women from a material of 84 women (the RCT study) – the rationale for choosing those eight?

Answer: We aimed to get variation in age when choosing patients from the RCT study. We ended up with a spread of 15 years (23-38) which we thought was acceptable.

2. Since you are only giving six out of eight occupations, what with the last two ones?

Answer: Occupations overlapped totaling seven occupations in the manuscript. As we checked this it turned out we missed that one informant worked as a nurse’s assistant. It is now added in the manuscript.

3. Please describe the reason for waiting up to 4-12 months before you made the interviews (it’s a long time after the last treatment, recall bias?)

Answer: We had the intention to do the interviews as soon as possible after last acupuncture treatment. However, due to various practical circumstances (such as one woman moved to another location, one woman had difficulties finding time due to work schedule etc.), we were not able to meet with the patients until a mean time of 6.75 months after the end of treatment. We have added a section in the discussion to illuminate this:

“The time from treatment to interview varied between 4-12 months. It was not possible due to practical circumstances to shorten this gap. It is possible that this may have created some recall bias.”

4. You write that the trial is registered at ClinicalTrials.gov NCT00484705, that is the same number as for your RCT – did you apply/registered for the qualitative study at the same time?

Answer: The qualitative study derives from the registered RCT. It has a separate ethical approval but the same registration number at ClinicalTrials.gov
5. Where did the interviews take place? Hospital setting? Did you have a ‘observer’ during the interviews, that is common to have someone observe the ‘unspoken words’ or body language of the participants during the interviews. If not, why?

Answer: Thank you for these valuable comments. Accordingly we added information on this issue in the method section.

"Interviews took place at the informants’ convenience, seven at the university and one at the informant’s work place."

We did not have an observer during the interviews. It is possible that an observer would pick up signals that the interviewer might have missed. We made a decision to not have an observer during the interviews and instead use dialogic validation during the interviews. The interviewer therefore asked the informant throughout the interview (where suitable) if the information given was correctly perceived. To clarify this we have added in the methods section in the manuscript:

“Dialogic validation was used throughout the interview to minimize misunderstanding.”

Data collection:

6. It is common to describe the interviews also in terms like semi-structured or in-depth, or as unstructured. Where will you place your interviews?

Answer: We would like to term our interviews as structured with the aim to get in-depth. AB did the interviews and had an opening question and thereafter, by asking follow-up questions, tried to get "behind the words" of the informant. Words such as "how did that feel" and "please tell me more" were used to get to a deeper understanding of the phenomenon. I also tried to keep an open mind and as I did not have previous experience with the patient group, I truly was surprised by their stories. We consider this as a strength as my negligible pre-understanding made me not take anything for granted.

Analysis:

7. Since you refer to Malteruds modification of Giorgi’s phenomenological research method, I think you shall describe more the analysis process related to the detextualisation/abstracting the contents of the individual meaning units.

Answer: To elaborate on this we have added under “Analysis” in the methods section:

“The process of coding was done using different colors to mark the relevant text. Codes were then decontextualized and joined with others of the same color.”

Results:

8. I find your first sentence under the results heading a bit challenging I quote: “When asked to relate their experiences of acupuncture, informants’ spoke of them in relation to the diagnosis of PCOS” – You had an open interview technique (page 3/data collection): “Please tell me about your experience of
acupuncture treatment?” - I wonder how did you invite them to only speak about their experience related to the diagnosis of PCOS? Or did you exclude them during reading your material, that's the impression I have reading your first paragraph on page 9.

In one way I find that excluding the other experiences you are more confirming your results from your RCT in the present qualitative study. A strength to qualitative studies is that it can generate new hypotheses and allow for outliers to have their ‘voice’ heard. Could you please in a sentence give the rationale for leaving out the other experiences?

Answer: Thank you for this very good point which we completely agree upon. To clarify the procedure we want to stress that the patients spoke about acupuncture in both a general sense as well as in relation to that they have PCOS. However, staying true to the aim of the study, only the material related to them receiving acupuncture and having a diagnosis of PCOS was analyzed. Our rationale for this because this study was not about experiences of acupuncture in general but specifically the experience of acupuncture for women with PCOS.

To clarify this we noted (already in the first submission) in the discussion of results:

“It is the nature of electro acupuncture to create sensations such as discomfort during needle placement, tension, relaxation and confidence in the therapist. Although the informants in this study also included such descriptions in their stories, the only results presented were those experienced in relation to the fact that the informants were diagnosed with PCOS.”

We have in no way excluded informants’ experiences (“positive” or “negative” of electro acupuncture in relation to that they have PCOS and we therefore added a section on this in the discussion (already in the first version):

“Since the interview setting was an interpersonal meeting, it is possible that informants expressed only matters that were positive and flattering. However, the informants in this study expressed scepticism and some of them related how they had gained no effect from the treatment at all, implying that their stories were trustworthy.”

9. You have given five categories reflecting the experiences. “Getting results”, nr two (page 4) – has been changed into a heading of “Acupuncture triggered things in my body” – while you refer again to “Getting results” in the discussion.

Answer: Thank you for noticing this. We have rephrased "Getting results" to "Acupuncture triggered things".

Discussion:

10. One way of increasing validity in qualitative studies is allowing to the participants read their stories as it is presented in the article. Did you consider that?

Answer: We did not consider that following Giorgi’s notion that validation by informants goes beyond their commitment. Instead, we used dialogical validation
as described above.

11. The authors are a well-known researcher in PCOS. Are the results from the present qualitative study in any way surprising to you. Or did they confirm the result from your RCT? Or?

Answer: The second author (E S-V) has vast knowledge on PCOS. However, the first author (AB) had no experience at all from the patient group. This meant that after reflection, she noticed her pre-existing notions or thoughts to bracket during the interviews or analysis. By adopting a view that nothing is definite, and keeping an open mind, she strived to systematically generate new knowledge as informants spoke of their experiences.

12. When you are discussing the transferability from your sample size (last paragraph page 8), you seem to me to be discussing this in a very quantitative way...which is not interesting in this context. Isn’t the age span you have 23-38 relevant for the “PCOS age”? In your RCT you have age span of 18-37; so you didn’t invite the ‘young ones’ to this qualitative study?

Answer: We completely agree and have therefore omitted this part of the discussion. The age span is very relevant for the PCOS population. Whoever, PCOS is a lifelong condition and there is a need for long-term follow up also of older PCOS women which is beyond the scope of this study.

13. Did it occur through your analysis that the two of you hold different position and perspectives? Different ways of approaching the same subject may result in an increased understanding of complex phenomena (?)

Answer: Yes, although we are both physical therapists, ESV is also an endocrine physiologist and we have quite different perspectives in the area of PCOS. Malterud notes that different perspectives add to the analysis as the material is viewed from different angles.

14. Maybe you shall throughout the article make clear that you have used electro acupuncture as treatment?

Answer: We agree that its an important point. However, we want to stress that it is a combination of electrical and manual stimulation of the needles that was applied in the study. We have rephrased this throughout the manuscript where applicable.

15. I know that you have not looked into the therapist/patient interaction, however do you think that your findings with regard to hope might have been influenced by the therapist?

Answer: The patient-therapist interaction may possibly have influenced the results of the study. Thank you for putting our attention to this. We have added in the discussion the following paragraph to make this clear to the reader:

"As acupuncture by nature involves a therapist, it is possible that the patient-therapist interaction have influenced the results. The treatment was administered by one therapist only, making her personality vital concerning interaction with the informants. This study did not however, investigate
patient-therapist interaction.”

Rev 3

Methods

1. Please describe the justification for including 8 participants. Is this number sufficient to fully answer your question in relation to the proposed method of analysis.

Answer: The number of 8 participants was not decided beforehand. The interviews started and continued until we estimated that we had interview material rich enough for analysis and rich enough to create new knowledge. To clarify this we added under “Participants”:

“Women included in an earlier RCT previously described in detail [9], were recruited until material rich enough for analysis was obtained. Eight women were asked to participate and all eight accepted and were included in the study.”

2. Please provide more detail on how the sample was selected, how many women were invited to participate, was it purposively undertaken, or were they volunteers? It is unclear if some women declined and why, could there be a selection bias?

Answer: We have now added a section on this under Participants:

“Eight women included in an earlier RCT previously described in detail [9], were asked to participate and all eight accepted and were included in the study. They were selected purposively to achieve variation in age.”

3. Who conducted the recruitment? Please describe the setting.

Answer: To clarify this we added under Data collection:

“Participants first received a letter containing information about the study. They were then contacted by telephone by AB to arrange interviews.”

4. In the description of the methods: please revise patients to participants throughout text.

Answer: A very good point and we have replaced patients with participants throughout the manuscript where applicable.

5. From the information given on page 3, the question asked appeared to focus on one particular aspect of having acupuncture- how did that feel. The responses reported indicated a greater depth of material gathered. Was there only one major category of questions asked?

Answer: The informants were asked to elaborate on their experience of acupuncture. However, to deepen the understanding, follow-up questions were asked. Furthermore, the interviewer was open, smooth and adaptable during the entire interview allowing the informant to elaborate freely on the experience of receiving electro acupuncture. To clarify the following sentence was added under Data collection:

“The interviewer had an open and flexible attitude towards the informant which
led the informant to elaborate freely on the phenomena.”

6. Characteristics of the study group. Are there any PCOS characteristics, or experience of conventional treatment that you can report on here to describe this population more comprehensively?

Answer: The whole population has been described in detail elsewhere. We have added information regarding the women included in this study: “All eight women had polycystic ovaries (more than 12 follicles <9 mm measured with transvaginal ultrasonography), clinical signs of hyperandrogenism (hirsutism: >8 on Ferriman Gallway score), and oligo-, amenorrhea. They were free from any medications three months entering the study and throughout the study period.”

7. Was the interview audio recorded? Was data de-identified?

Answer: Yes interviews were audio recorded and de-identified in order to protect the integrity of the informants. To make this clear to the readers, we have added under Data collection that data were de-identified.

8. Were the scripts read by researcher only. If yes please discuss the limitations of this in the discussion.

Answer: The scripts were read by both authors. We then had the possibility to discuss the analysis, challenging each other’s views and standpoints to refine the analysis.

Results

9. It is unclear from the results to get a sense of how widely some of the themes were to the sample. Maybe consider use of some,............... several women...

Answer: This is true and since we have not plotted the material in a table, we have added some... and several... in the text.

10. Page 5. Not all patients noticed great results in relation to health status. Please provide more information on how many.

Answer: Five patients noticed overlapping results in relation to health status. One patient was not sure if the results were due to the acupuncture or not. Two patients did not notice any results. To clarify this in the manuscript we added in the results that over half of the participants experienced a change in their health status.

11. Page 6, text indicates participants had various expectations. Can make it clear in methods this was a question explored in the interview. Would also help to have a sense of common participants expectations were.

Answer: The question of expectations was not decided before hand. It was something that came about as the informants spoke about their experiences.

Discretionary revisions

Introduction

12. The results indicate participants were inspired to make changes. In some
international settings PCOS guidelines strongly recommend engagement in lifestyle (diet and exercise). Please consider making reference to this, as this point might be discussed further in discussion.

Answer: We agree that the results indicate that participants were inspired to make changes in their lifestyle. The importance of lifestyle in the management of PCOS has recently been highlighted in a recent PCOS consensus workshop in which lifestyle management was recommend especially for obese women. Also the Australian PCOS alliance strongly recommends lifestyle as part of the health care of these women. However, the present study focuses on the experience of acupuncture treatment among PCOS women and the results reflect the life world as expressed by the participants. We have no substantial evidence that these women actually changed their life style. Further, they were told not to change their diet and not to change their physical exercise frequency during the RCT. Therefore we prefer not to discuss this further.

Discussion

13. Page 8 re study method, second sentence however, life-world...........................the meaning is unclear. It maybe clearer to the reader if you re-organise material and describe the text as strengths and limitations, it switches around a fair bit.

Answer: To make this section more clear we rearranged the sentences to read:
“Qualitative method is suitable for investigating the life-world of the informants. As life-world science is complex, it demands the researcher to be stringent and adhere strictly to the study method.”

14. Please consider the role of the researcher and if there are any potential biases introduced.

Answer: As this was brought up by another reviewer, we have noted:
The patient-therapist interaction may possibly have influenced the results of the study. Thank you for putting our attention to this. We have added in the discussion the following paragraph to make this clear to the reader:
“As electroacupuncture by nature involves a therapist, it is possible that the patient-therapist interaction have influenced the results. The treatment was administered by one therapist only, making her personality vital concerning interaction with the informants. This study did not however, investigate patient-therapist interaction.”

15. A point of clarification, my reading of the this section is that the interviewer attempted to engage the participant in a conversation about the experience of acupuncture ie needling, and relaxation, this wasn’t what participants spoke about. Is this correct.? Meaning of the last sentence (discussion of results) particularly in relation to the fact that the informants were diagnosed with PCOS is unclear.

Answer: As this was brought up by another reviewer, we have noted:
To clarify this we noted in the discussion of results:
It is the nature of acupuncture with manual and electrical stimulation of the needles to create sensations such as discomfort during needle placement, tension, relaxation and confidence in the therapist. Although the informants in this study also included such descriptions in their stories, the only results presented were those experienced in relation to the fact that the informants were diagnosed with PCOS.

We have in no way excluded informants’ experiences (“positive” or “negative” of acupuncture in relation to that they have PCOS and we therefore added a section on this in the discussion (already in the first version):

“Since the interview setting was an interpersonal meeting, it is possible that informants expressed only matters that were positive and flattering. However, the informants in this study expressed scepticism and some of them related how they had gained no effect from the treatment at all, implying that their stories were trustworthy.”

16. The finding that acupuncture may empower women to take responsibility for their future wellbeing is an important finding for PCOS, which is associated with other chronic conditions. Discussion this in the context of lifestyle management is important.

Answer: This is a very important finding, and we have discussed this under Discussion of results in relation to the reference Rugg et al.

“It seems that the acupuncture treatment itself in the present study gave the participants the motivation needed to take responsibility and initiate change. This is in accordance with another study reporting participants taking an active role in lifestyle changes following acupuncture treatment [18].”