

## **Author's response to reviews**

**Title:** Water aerobics in pregnancy: cardiovascular response, labor and neonatal outcomes

### **Authors:**

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**Version:** 2 **Date:** 28 October 2008

**Author's response to reviews:** see over

Campinas, 28<sup>th</sup> October 2008.

Dear Dr. Kulier  
Editor of the Reproductive Health

First of all we would like to say that we very much appreciated the comments from all reviewers. Certainly they will improve the quality of the paper and we are now providing the new corrected version where we added basically all suggestions. According to your solicitation, we are explaining point by point all questions arisen by them below:

### **First referee**

**Title:** Water aerobics versus no exercise in pregnancy: cardiovascular response, labor and neonatal outcomes from a randomized controlled trial

**Version: 1 Date:** 22 August 2008

**Reviewer:** Pelle G Lindqvist

#### **Reviewer's report:**

This is a well done randomized study comparing organized water aerobics to non exercise/non-organized exercise. It is a well written sound paper on an interesting topic. A sedentary lifestyle is the cause of many obstetrical problems. Thus, I believe that research regarding exercise during pregnancy is of high priority. However I have some points that I believe might improve the paper.

Major aspects:

The authors refer their measurements of skin temperature as body temperature. They should throughout the paper use skin temperature. During exercise in pregnancy the skin temperature and measurement of body core temperature might not be identical, see Jones RL 1985 340. **OK, changed to skin temperature.**

The skin temperature rose at peak exercise and further on during the next 15 min. This is in opposition to results by Lindqvist pg 2003 152. **In fact, the skin temperature rose only until 5 minutes after peak exercise, then remaining constant until 15min. However we did accept the comparison with the results by Lindqvist 2003 and this had been included.**

The difference between skin and core temperature might be interpreted as a safety mechanism during pregnancy exercise. This would give a possible explanation to the tendency towards increased skin temperature in the exercise group. **OK, done.**

Did all women follow all scheduled water aerobics? Was it ascertained that the women not participating in the organized water aerobics did not exercise? Etc... I do miss a paragraph of the limitations of the study. **As can be seen now in the flowchart of the study, at around 25 weeks, 9 women discontinued the water aerobics and then additional 4 women discontinued at around 35 weeks. This means that around 2 thirds of them had a good compliance. However, following a intention to treat approach for analysis, all women were included in the final analysis. A new paragraph on limitations of the study was included in discussion session.**

Minor

I believe that a short description of the submaximal endurance test should be included in the paper and not only give a reference. In addition, I believe that the algorithms for VO<sub>2</sub> and MET should be given. **OK, done.**

If the authors have the BMI at partus or pregnancy weight gain during pregnancy this would **??This is subject of an in-depth analysis in another manuscript.**

Table 1: I don't understand the lines Spontaneous vag delivery / C-section **OK, corrected.**

In the results section the authors are using m1 vs. m2. This should be done throughout.  
**OK.**

I believe the design of the tables might be improved **OK, done.**

In conclusion, an interesting work that I believe add to our knowledge.

**Level of interest:** An article of importance in its field

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

**Declaration of competing interests:**

I declare that I have no competing interests

## Second referee

### Reviewer's report

**Title:** Water aerobics versus no exercise in pregnancy: cardiovascular response labor and neonatal outcomes from a randomized controlled trial

**Version: 1 Date:** 15 September 2008

**Reviewer:** Minna Aittasalo

### Reviewer's report:

The study examined the association between water aerobics, maternal cardiovascular capacity during pregnancy, labor and neonatal outcomes. It was resulted that water aerobics had no detrimental effects to the health of the mother or the child and there were fewer requests for analgesia during the labor in the water aerobics group.

The topic is of importance and the study seems carefully implemented. However, there are several issues that, in my opinion, need revision:

Major Compulsory Revisions

Abstract

- Statistical methods need to be mentioned. **OK, done..**

- Remove all p-values and replace them with between-group differences with confidence intervals. P-values convey nothing about the sizes of the between-group differences (Gardner and Altman: Statistics with Confidence 1989). In regard to some selected outcomes you may want to present both confidence intervals and p-values.

- Indicate clearly what  $\pm$  sign means. Presumably it means SD but it can also mean SE. Therefore, the sign is not generally recommended (Altman and Bland: Standard deviations and standard errors. BMJ 2005;903. bmj.com). **OK, done.**

- Replace X with vs. **OK, done.**

- Specific values are needed only on variables which show between-group differences. Those with no differences need only to be mentioned.

Background

- This part of the manuscript is too general; it should review physiological changes due to pregnancy alone in regard to outcome variables, studies on water exercise and the specific features and effects of water aerobics (e.g. Katz: Exercise in water during pregnancy. Clin Obstet Gynecol 2003;46:432-41). **OK, included a new paragraph focusing these aspects.**

- Paragraph 3: The need for supervised physical activity in sedentary or gestational diabetes is not mentioned by ACOG. The key issue is that the intensity of PA should be moderate. **OK, changed.**

- Paragraph 4: The use of RPE (Ratings of Perceived Exertion) is recommended in both the American (Artal & Toole 2003) and Canadian (Davies et al. 2003) guidelines for the intensity evaluation during pregnancy. In fact, Artal & Toole states that target heart rates cannot be used to monitor exercise intensity in pregnancy due to variability in maternal heart rate responses to exercise. Davies et al. suggests the use of a modified version of the conventional age-corrected heart rate target zone but also the use of Borg's scale is suggested. This should be added to the text. **OK, done.**

Methods

- Too many subtitles; combine issues under fewer subtitles such as "Participants", "Design", "Evaluation" and "Statistics". **OK, done.**

- Paragraph 2: The assessments methods for “regular physical activity” and “any disorders” should be explained. **OK, done.**
- I am not sure how ethical it was not to give the control group even some information on physical activity. The benefits of physical activity during pregnancy are, after all, scientifically recognized. Was this acknowledged by the research staff? **Yes, we did acknowledged! This is now included in the first paragraph of Methods session.**
- Practice of water aerobics: When was the first physical evaluation done, 18-20 weeks’ gestation? It is stated in the results that the first evaluation took place at 19 weeks’ gestation but what was the range? **The ranges are already stated at the sub-heading “Evaluations”; the value of 19 weeks written in the Summary refers to the mean age when these first evaluations were performed.** How was the intensity of the exercise determined for each participant? **OK, done** These facts should be added to the text.
- Control variables: What are these? **No, they are just baseline characteristics as presented in Table 1.** Are these confounders in the statistical analysis? If so, they should be mentioned in the statistics section. How was pre-gestational BMI measured – this should be indicated at least in Table 1. **Ok, included in the text and it was already included in Table 1.**
- Statistical analysis: Were any adjustment made for any of the baseline characteristics? **No, it was initially judged not to be necessary, considering there were no significant differences in the baseline characteristics, even taking into account the relatively small number of subjects.** It seems to me that there were differences between the groups at baseline that may have explained the findings in regard to analgesia use. For instance, in the control group there were much more nulliparous women, who may need more analgesia than women with previous deliveries. The educational level may also have been associated with analgesia use as well as previous C sections. This has to be clarified in the statistical part. If not taken into account in statistics, the issue should be thoroughly discussed in Discussion. **Considering you comments, then we did a regression analysis to control the results of request for analgesia by parity and level of schooling and the results remained exactly the same (p value of 0.0059). They are now included in the text of results session, plus the correspondent risk ratio.**

#### Results

- Too many subtitles. Confusing to read. Structure the contents according to the main outcomes. For example: “Participants” (includes information about participation and evaluation points), “Maternal cardiovascular outcomes”, “Fetal outcomes” (includes fetal heart rate and information on newborns) and “Labor outcomes”. **OK, done.**
- Remove the p-values throughout the text and replace them with between-group differences and their confidence intervals. The same thing has to be done with percentages, for example in paragraph 9, “Characteristics of labor”. P-values do not tell anything about the relevance of the findings to the reader. This is a very important change. After making the corrections you may want to reconsider the number of figures needed in the manuscript. **OK, done.**
- Paragraph 1: What was the participation in water aerobics? What about the drop-out rate? This is essential information for the interpretation of the results and should be added. **OK, this information is now included in the new Figure 1, a flowchart of the study participants.**
- Table 1: The significance testing of baseline differences is not recommended by The Consort Statement for Randomized Trials (Moher et al. 2001). Thus, remove the p-values from Table 1. Instead, use variables with notable between-group differences and variables which may have effects on outcomes as confounders in the statistical analysis. **OK, done. The second part has already been addressed above.**
- Paragraph 2: Use similar terms as in figure 1 – “Physical fitness” in the text should be “Physical Capacity” as it is in the figure. **OK, done.**
- In all the figures, you should write out “GA” **OK, done.**

## Discussion

- Compress your most important findings in the first paragraph. **OK, done.** Then structure the contents as in results. Now it is too fractured. First, briefly mention what was found out, then compare the findings with earlier studies and finally explain the reasons for your findings. **OK, done.** For instance, paragraph 4 lacks discussion about whether the increase in VO<sub>2</sub>max was comparable to the studies referred. **OK, done.** Moreover, in paragraph 12 it is difficult for the reader to compare the findings of the current study with the studies referred because no values of the current study are presented. They can only be found from the figure. **OK, this point had also been modified.**

## Conclusion

- If no baseline adjustments have been performed in statistics, I seriously doubt the conclusion on analgesia use. **Now, the adjustment has been performed and the results are exactly the same as stated in results session.**

## Minor essential Revisions

### Background

- For readability, the objective of the study should be formulated in two sentences. **OK, objective paragraph was reworded.**

### Methods

- Paragraph 1: The name of the institute should be mentioned in paragraph 1. **OK, done.**

### Results

- Indicate what the sign  $\pm$  means. **OK, done.**

- Table 2: use more familiar signs, such as a, b, c etc. to indicate the various samples and statistical methods. **OK, done.**

- Figures: ... evaluation "points", not "moments". **OK, modified.**

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.

## Third Referee

### Reviewer's report

**Title:** Water aerobics versus no exercise in pregnancy: cardiovascular response, labor and neonatal outcomes from a randomized controlled trial

**Version:** 1 **Date:** 16 September 2008

**Reviewer:** A Lucia

### Reviewer's report:

This is an interesting study (overall well done) that deals with a topic of clinical relevance. The study is compelling.

I have however numerous major and minor recommendations to make that I will just mention in chronological order. I think they are constructive and really necessary.

1. Title. Please find a more attractive, shorter one. **OK, done.**

2. Background. Please make sure that literature is totally updated, especially position stands from reference institutions. Also, a very important recent reference is missing: Barakat et al. Br J Sports Med. Freely available in the journal web (editor's free choice). Please specify in your paper what your study adds compared to the one by Barakat. **OK, done.**

3. Background, 3rd paragraph. Please specify contraindications (at least briefly). **OK, done.**

4. Same for next paragraph (what is exactly meant by 'moderate intensity'? **OK, done.**

5. Next paragraph: bad choice of references (e.g., # 4 is a review and actually the only randomized controlled trials looking at the effects of exercise training during pregnancy and allowing to establish a cause-effect relationship between exercise training and pregnancy outcomes are the one by Barakat and the present one). **At the time the current study was performed and the manuscript written this suggested study was not yet available. Indeed it is the only RCT whose main outcome is gestational age and therefore it was now included at this point as reference. However, I cannot accept that Ref.4 is a bad choice. It refers to a Cochrane review performed with very strict methodological criteria using data from 11 trials which were appraised carefully, but mainly focused on physical fitness. Certainly in the next update of this review, the paper by Barakat et al. will also be included.**

6. Methods A flowchart of subject inclusion and exclusion criteria, drop-outs etc is absolutely necessary (following CONSORT guidelines (please see the website for the CONSORT statement and use the flowchart that is freely available in the web) **OK, done in Results session.**

7. 'Practice of water aerobics'. Again, please be more specific: what HR values are we talking of? **OK, done.**

8. How did you estimate cardiac output? **OK, done.**

9. The two 1st paragraphs of the Results section should move to the Methods section. **Although this strategy is preferred by some authors, this is not a consensus. We personally prefer to maintain this in the Results section.**

10. The results section is too long and verbose (hard to read) and there is duplication with tables and Figures. Please be more concise **In fact, the only information duplicated in tables and figures were those for VO2max and physical capacity. Both were excluded from Table 1.**

11. Figures: please remove hard values from the Figures (otherwise you are really going against the 'philosophy' of using Figures instead of tables). **OK, done.**

12. End of results. Apgar scores aren't so high in the 1st min. Any explanation? **We really did not understand well this comment. Considering Apgar score is a scale (a non parametric variable) whose clinical significance is established below or above a specific cut off point (7), we prefer to use it as transformed categorical information, in terms of percentage of Apgar score  $\geq 7$ . Having 97 and 94.6% of the cases with 1<sup>st</sup> minute Apgar score above this point cannot be considered as "not so high" we think.**

13. Discussion should be much more concise and 'to the point'. The 1<sup>st</sup> paragraph should summarize the main findings and novelties of the study. There are too many short paragraphs. There is too much speculation, e.g., the authors haven't measured peripheral vascular resistance such as to really 'confirm' anything. **OK, done.**

14. The 1st sentence of the Conclusion paragraph nicely summarizes your findings which are of relevance per se. Please try to rewrite the manuscript (particularly Discussion) emphasizing its main findings and without trying to discuss every single finding. **OK, done.**

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**Level of interest:** An article of importance in its field

Sincerely yours

Rosa Ines Pereira, MD, PhD

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Brazil