Author's response to reviews

Title: Effect of Laser Acupuncture on Obesity: Study Protocol of a Patient-Assessor-Blinded, Randomized, Sham-controlled Crossover Trial

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Author's response to reviews: see over
Response to Comments from Reviewer 1

Comment 1:

The following paper discusses the protocol of RCT for the effect of laser acupuncture on obesity. The process of protocol, statistical method, and evidence of subject numbers are well defined. However, I think that following correction is needed.
Major Compulsory Revisions: The modification is necessary to study design. Cross over design is not suitable to evaluate an effect of intervention on obesity, because there can be a difference of obesity treatment effect between a start point and a middle point. Therefore, a simple case-control design which needs more subjects is more suitable to evaluate hypothesis of this study.

Response:
We appreciate the reviewer’s insightful comment. The reasons for using crossover design in our study are twofold. First, the crossover design has been successfully used to study the effects of interventions on obesity (Hsu CH et al., 2005; Fogarty S et al., 2015). The crossover design has reduced between-patient variation compared to the case-control design because each participant acts as his or her own matched control (Yang M et al., 2008; Mills EJ et al., 2009). Moreover, we don’t expect a difference of the obesity treatment effect between a start point and a middle point of the study because laser acupuncture doesn’t produce a noticeable sensation that would lead to order and learning effects in the patients. Therefore, we believe our crossover study design is justified.


Fogarty S, Stojanovska L, Harris D, Zaslawski C, Mathai ML, McAinch AJ. A randomised cross-over pilot study investigating the use of acupuncture to promote weight loss and mental health in overweight and obese individuals participating in a weight loss program. *Eat Weight Disord* 2015 Jan 29.


Comment 2:
Discretionary Revisions: The processing of the present study is well defined in manuscript; however, an additional mention is needed. There is no explanation on washing out period. Is there any reference for 2 weeks washing out period? or is this discretionary value? Authors should present some evidence to support this decision.

Response:
We thank the reviewer for this helpful comment. The following paragraph has been added into the revised article “A one-week washing out period between treatment sessions was used in a previous randomized crossover study of acupuncture on obesity [24]. We extended this washing out period to two weeks to further reduce potential carryover effects.”


Response to Comments from Reviewer 2

Minor Essential Revisions:

Comment 1:
2nd line: It is needed to list the model name of laser device.

Response:
Thanks for your reminder. We have listed the model name of laser device in the revised manuscript.

Comment 2:
3rd line: Power Density ---> power density
Response:
Thanks for your correction. These typographical errors have been corrected.

Comment 3:
4.17 mW/mm² ---> ???.?? W/cm² The international unit of power density is W/cm². So it is needed to recalculate the numeric data.

Response:
We thank the reviewer for pointing this out. This has been changed to “0.417 W/cm²” in the revised manuscript.

Comment 4:
The last page: Table 1 Anatomical location of acupuncture point. All acupoints names in Table 1, are should be changed to the WHO acupuncture nomenclature. The authors have used them already following to the WHO guideline of acupuncture nomenclature in Interventions, Laser Acupuncture group. (For example ‘Stomach 44’ ---> ‘ST44’)

Response:
Thanks for your correction. We have changed all acupoint names in Table 1 to the WHO acupuncture nomenclature.

Comment 5:
Discretionary Revisions: In addition, I think it is adequate to move the table 1 to the supplement data. The table 1 is not that important to list in the manuscript.

Response:
Thank you for this suggestion. We have moved Table 1 to the supplement data.
Response to Comments from Editors

1. Please include the date of registration with the trial registration number at the end of the Abstract.

Response:

The date of registration with the trial registration number has been included at the end of the Abstract.

2. Please explain that your ethical approval covers both trial sites in the Methods section.

Response:

We thank the editor for pointing this out. We have corrected it to “The trials will be conducted at the Chiayi Chang Gung Memorial Hospital.” in the Methods section. The trial site is covered by the ethical approval.

3. Please include a Trial Status section after the Discussion. This should state the status of the trial at the time of manuscript submission. The journal considers study protocol articles for proposed or ongoing trials provided they have not completed patient recruitment at the time of submission.

Response:

The Trial Status section has been included after the Discussion.

4. Please include a list of abbreviations used and their meanings after the Trial Status.

Response:
A list of abbreviations has been included after the Trial Status.

List of abbreviations

ANOVA: analysis of variance
BMI: body mass index
GaAlAs: Gallium Aluminum Arsenide
SF-36: Short-Form 36-item Health Survey
TCM: Traditional Chinese Medicine
VAS: visual analogue scale
WHR: waist-to-hip ratio

5. Please state that all authors read and approved the final manuscript in the Authors' Contributions section.

Response:

We have stated that all authors read and approved the final manuscript in the Authors' Contributions section.