Author’s response to reviews

Title: Immersive virtual reality as analgesia for women during hysterosalpingography: study protocol for a randomized controlled trial

Authors:

Yi-Ling Wang (wangyiling0816@163.com)
Hai-Xiang Gao (15595261976@163.com)
Jin-She Wang (wjs@nxmu.edu.cn)
Jing-Hui Wang (Guoguo050818@163.com)
Lei Bo (bosanshi@qq.com)
Ting-Ting Zhang (m18395098157@163.com)
Ya-Liang Dai (18395098157@163.com)
Lu-Lu Gao (gaolu755243@163.com)
Qiang Liu (sxliuqiang1@163.com)
Jun-Jun Zhang (15909584020@163.com)
Ju-Min Cai (caijumin1234@sina.com)
Jian-Qiang Yu (yujq910315@163.com)
Yu-Xiang Li (li_yuxiang@163.com)

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Dear Editors and Reviewers,

Thank you for your kindness reviewing and giving valuable comments concerning our manuscript entitled “Immersive virtual reality as analgesia for women during hysterosalpingography: study protocol for a randomized controlled trial” (TRLS-D-19-00783). Those comments are all valuable and very helpful for revising and improving our paper, as well as the important guiding significance to our researches. We have studied comments carefully and have made correction which we hope meet with approval. Revised portion are marked in red in the text. The main corrections in the paper and the responds to the reviewer’s comments are listed as following:
Yours sincerely,
Yu-xiang Li

Yours sincerely,
Yu-Xiang Li
School of Nursing, Ningxia Medical University, China
1160 Shengli Street, Xingqing Area, Yinchuan, China. 750004.
Tel: 0086-951-6980521
E-mail: li_yuxiang@163.com

1. Methods - Study Setting - I suggest the following sentence is restructured as follows: This institution is an urban, public, tertiary-care teaching hospital, specializing in maternal and child care, in Ningxia Hui Autonomous Region located in Northwest China.
Response: Thank you for your suggestion. We have corrected this sentence as your suggestion and highlighted it in this new submission.

2. Methods - Randomisation - Thank you for confirming stratification is not used. It would be helpful to add the type of randomisation used here (I presume simple) for the purposes of clarity.
Response: Thank you for your suggestion. Simple random sampling method will be used in our study. We have put this sentence in Randomization section and highlighted it. Thank you!

3. Methods - Randomisation - Thank you for updating this section to provide further clarity on randomisation implementation. I would suggest it would be useful to add some further clarity here with regards the use of opaque sealed envelope - is each allocation in a separate envelope, or all allocations in a single envelope?
Response: We are sorry for the ambiguity. We put all allocations in a single envelope. We have made some modifications in this sentence: A sealed opaque envelope will be used to store the randomization sequences of all allocations. Thank you!

4. Methods - Data Monitoring - Thank you for confirming no audit or interim analyses are planned. For clarity, please insert a sentence to the manuscript to confirm that this. I am also unsure that this is the correct place for information on authorship. It may be this is better placed in a brief section towards the end of the document (as per the SPIRIT checklist) to reflect dissemination plans.
Response: Thank you for your suggestion. We have put this sentence “No audit or interim analyses are planned” in this new submission and highlighted it. We had placed the information on authorship in a brief section named “Author details” at the end of this manuscript. We have referenced several manuscripts that had been published in trials. We think it is the correct place for information on authorship.

5. Methods - Sample Size - You note the use of a pilot study to inform the sample size calculation here. Is there a publication or reference which could be used to support this?
Response: Thank you for your question. According to our previous study on breakthrough pain, we use a pilot trial to determine the sample size. The article named “A fixed inhaled nitrous oxide/oxygen mixture as an analgesic for adult cancer patients with breakthrough pain: study protocol for a
randomized controlled trial” that had been published in trials use a pilot study to determine sample size. We have put this article as a reference in new submission. Thanks.

6. Methods - Statistical analysis - Many thanks for confirming your planned analyses. As noted previously it would be useful to be specific about the types of analyses used for your primary and secondary outcomes, for example will your Primary Outcome use T/Mann Whitney or Chi/Fishers test?
Response: Thank you for your suggestion.
Response: Thank you for your suggestion. A t-test will be used to assess normally distributed data, the Mann-Whitney U test for non-parametric data, and Chi-squared tests or Fisher’s exact test for categorical data. To be specific, the t-test will be applied to determine the difference between the primary outcome. Secondary outcomes like amount of time spent thinking about pain, pain unpleasantness, worst pain within 15 min after HSG, anxiety, satisfaction, and acceptance with pain management will use T/Mann Whitney tests. Chi-squared tests or Fisher’s exact test for HSG results and adverse reactions. We have put those sentence in new submission and highlighted it in red.

7. Discussion - Limitations - Thank you for confirming a larger study is not planned. The current wording suggests this is however planned. Please could you amend to reflect the current status.
Response: Thank you for your suggestion. We have made some modifications in this sentence: The study will be conducted in one setting only. The multi-center study will be more representative. In the future, we will perform the multi-center study.

8. General - It is helpful to know that you have had this proof read by a colleague. I do however suggest that some further proof reading is required, as some recent additions are not grammatically correct.
Response: Thank you for your suggestion. We have made careful proofreading, especially in recent additions. We have highlighted the modified sentences and words. Thank you!

9. There remain some elements in the SPIRIT checklist recorded as '--'. Whilst these may not be applicable, it is prudent for transparency to make this clear in your manuscript. Please could you add in relevant statements accordingly.
Response: Thank you for your suggestion. We have carefully examined every element in the SPIRIT checklist to make sure it is consistent with our modified manuscript. We have added the relevant statements to explain why those elements recorded as '--) in the SPIRIT checklist. Thank you very much.