Author’s response to reviews

Title: Efficacy of a Self-Management Program in Patients with Chronic Viral Hepatitis in China

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Version: 1 Date: 29 Jan 2019

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Answers to referees' comments

Reviewer 1
Comment: The authors have extensively written a good manuscript. The manuscript is well-written. Accept after minor English editing.
Response: We appreciate your kind consideration.
Yes, we acknowledge the positive feedback from the “Reviewer 1”. Yes, we made efforts to edit our manuscript. The current version of our manuscript reads much better.

Reviewer 2

Comment#1:

Abstract:
The methods section should not contain any results. Consider sending the mean age to the results section.
Response#1: We also thank the “Reviewer 2” for the positive feedback and suggestions. Yes, we have revised our manuscript according to your suggestion. We placed “the mean age” to the results section.
Comment#2: The result in the abstract is too scanty and not informative of the key findings of the study. Provide summary of results for each endpoint assessed.
Response#2: Yes, we have provided “summary of results” for each endpoint assessed.

Comment#3: Kindly have a language editor review the draft including the text in the figures as there are pockets of grammatical problems.
Response#3: Thank you. We carefully addressed the shortcomings related to typos and grammar.

Main text
Comment#4: Clearly define and differentiate between self-management and self-efficacy in the context of your study and the skills that each constitutes. Just citing a reference is not enough.
Response#4: Thank you. We added the explanation of “self-efficacy.” The requested change is on page 6.

Comment#5: Fig 1-1 is unconventional, unclear and does any covey any additional information. Either you modify the figure highlighting the relationship between the concepts or consider deleting it.
Response#5: Thank you so much for your comments. As suggested, the Figure 1 was deleted.

Comment#6: Figure 1-2 is informative. But the direction of some of the arrows seem to cloud the clarify. Showing or stratifying which activities represent input activities, outcome, etc will be helpful.
Response#6: We revised the Figure 1-2 (the revised figure was renamed as “Figure 1”). Changes made in this figure are marked in red color.

Comment#7: Rational for using the stratified sampling, open-label trial design should be stated.
Response#7: Thank you for your comments. We have added the explanation in the method section. We used “the stratified sampling, open-label trial design”, because it is difficulty of blinding either researcher or participants to the intervention method. And we selected hepatitis B and C patients; therefore, the stratified sampling was used. The requested change is shown on page 10 (Trial Design section) and on page 12 (Randomization part).

Comment#8: Nowhere in the methods is mention made of qualitative methods despite providing qualitative results. Elaborate on the study design indicating the use of mixed methods and highlight the specific designs.
Response#8: Our study is a quantitative method. We only received qualitative data about how intervention group evaluated the self-management program at the 6th month after discharge from the hospital. Therefore, our study method is not categorized as a mixed method.

Comment#9: State the number of participants selected for the qualitative study, the basis for their selection, what data were collected, how they were collected, how data was analyzed and provide details on key qualitative issues like translation.
Response#9: We have only collected the data form the intervention group (n = 30). Because the evaluation of the program was applied to the intervention group. We have revised and added the explanation of data collection and analysis procedures in the main text. The requested change is displayed on page 16 (Qualitative program evaluation part).

Comment#10: Please separate the study setting from the participants. The context of the study is inadequate. You need to give international audience more background into the characteristics (eg level, services provided, populations served, number of hospitalizations, etc) of the study facility in order for readers to conceptualize the findings.
Response#10: We have separated the study setting and participants. We have added the background information about the study facility in the main text. The requested change is on page 11 (Recruitment facility part).

Comment#11: I believe majority of patients diagnosed with HBV and HCV are treated on out-patients basis. Why did you restrict to only in-patients (hospitalized)?
Response#11: Hepatitis patients need to be admitted for treatment because of the health insurance coverage of China. Hepatitis patients’ recruitment in outpatient settings in China is very difficult. Therefore, for the study feasibility, patients with HBV and HCV needed to be recruited in-patients basis.

Comment#12: Considering that illiterates might be the ones who need the intervention the most, why were they excluded? What defines one as an illiterate?
Response#12: Thank you for your comments. You have the right perception. The illiterates need a lot of support for disease management. However, in this research study, the participants needed to answer the questionnaires by themselves, especially for the control group, and the researchers did not contact until the end since we needed to avoid bias. Therefore, we needed to consider participants who can write by themselves.

Comment#13: Exclusion criteria - What spectrum of diseases constitute 'other diseases'?
Response#13: In the Exclusion criteria, “other diseases” means which affect liver function assessed by their physicians, we have added the explanation in the main context. We already clarified in the protocol and shortened the explanation, now we have fully written in the text. The requested change is on page 10-11, part of “Participants.”

Comment#14: For a country that "has the highest number of occurrences of deaths due to hepatocellular carcinoma in the world", the sample size used is too small and the background for arriving at it is not plausible. It appears not to be representative and has implications on the validity and reliability of the study. This is a major flaw.
Response#14: Our primary endpoint is the score of Chronic Liver Disease Questionnaire (CLDQ), according to the previous study which used CLDQ, which we referred to the effect size and set alpha of 0.05 (two-tailed), and power of 90%, assuming that 20% of the participants would be lost to follow-up, the sample size was set at 30 for each group.

Comment#15: What was the size of the sampling frame from which participants were selected? How were participants selected before randomizing them into the 2 groups?
Since Mann-Whitney U test is a non-parametric test, how did you ensure that it did not affect the statistical power? Indicate which variables were analyzed using parametric and non-parametric tests?
Response#15: Because there was an ordinal scale, for comparing the difference between two groups, we have to use the Mann-Whitney U test. There was no relation to parametric and non-parametric test. The psychological data including CLDQ, depression, self-efficacy data variables were analyzed using parametric, and for the cognition of illness and behavior change data, we used non-parametric tests.

Comment#16: Table 1. Consider removing 'Interferon' and 'Ribavirin' as none of the participants were given those treatments.
Response#16: We removed them from Table 1.

Comment#17: Table 2. Please define all the acronyms
Response#17: We defined all the acronyms.
Comment#18: Table 3. Kindly state the p value to 3 decimal places and the OR to the 2 decimal places consistent with the CI. Ensure consistency of decimal places in all the tables
Response#18: We revised the “decimal places in all the tables.”

Comment#19: Consider transposing the IV and UC values in tables 4 and 5 to the table heading.
Response#19: We have transposed the IV and UC values in tables 4 and 5 to the table heading

Comment#20: Avoid repeating results in the discussion.
Response#20: We have revised the discussion section.

Comment#21: How do you ensure sustainability of the intervention beyond the project period?
Response#21: In the future we will provide continuous support to patients living with chronic viral hepatitis and regular activities related to health promotion to ensure sustainability beyond this type of intervention. We mentioned this statement in the “Implications for practice” sub-section. The new statement is on page 28.

Comment#22: Implications for practice: avoid repeating the results and state how the findings are expected to affect nursing practice both locally and globally.
Response#22: We have revised this section.

Comment#23: Kindly review the conclusions and ensure that it is reflective of the findings in your study.
Response#23: Thank you. Required changes were done.