Author’s response to reviews

Title: Evaluating the feasibility of a nurse-led self-management support intervention for kidney transplant recipients: a pilot study

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Author’s response to reviews:

Reply to the editor and reviewers

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Title: Evaluating the feasibility and preliminary results of a nurse-led self-management support intervention for kidney transplant recipients: a pilot study

Response to the editor

We are grateful to the editor and reviewers for their thoughtful comments and their valuable suggestions for improvement. We have carefully addressed their concerns and added the adapted parts of the manuscript in this rebuttal letter. Changes in the manuscript are highlighted in red.

Editor comments: Please consider in details that in which aspects intervention had impact for patients instead of general.
Response: In general, the intervention was evaluated as having added value compared to standard care. Recipients appreciated the open holistic focus. Specific elements of the intervention that were appreciated as helpful for patients were: open assessment of recipients’ holistic needs, holistic approach, tailoring of advice, patient activation, building confidence and motivation, goal setting, solution focused, shared-decision making, and working on a relationship of trust between the patient and professional. We describe this in the conclusion (page 26).

Response to the reviewers

Reviewer 1

Comment 1.1: In this paper authors tried to evaluate a new self-management support intervention for kidney transplant patients. The paper is not well written, the results are described in a confounding way, with a lot of useless details and without clearness.

Response 1.1: It would have been helpful if the reviewer had specified which details (on which pages) he/she found superfluous. We tried to clarify our paper by removing some details in our method, result and discussion section. We also have reduced the detailed description of the intervention on page 8 & 9 as the paper on the development of the intervention is now in press. A native English speaking author has thoroughly reviewed the manuscript to improve language use and phrasing.

Comment 1.2: The number of evaluated patients. Only 15 patients completed the TAM questionnaire. This is not a sufficient sample size for this kind of study.

Response 1.2: We agree that this low number is insufficient, when the primary aim is quantitative analyses. Our study was developed as a pilot study. This primary aim of the pilot study was to gain insight into the feasibility and acceptability of a nurse-led self-management intervention. Gaining insight in the preliminary effects was a secondary goal, including a preliminary exploration of which measures are appropriate to be included in a future follow-on study using an RCT design. When performing pilot studies, a small sample size is not unusual [1, 2]. Despite repeated effort, there were a number of participants who did not return the TAM and other questionnaires. In this pilot study we concluded that the intervention was useful for professionals and patients. Further research should focus on the actual effects of this nurse-led self-management intervention. We will perform a larger trial with a powered sample size in the near future.

To clarify that this was a pilot study, this was added to the title (page 1), abstract (page 4), and research design (page 7). Moreover, to emphasize the primary focus in this initial study on feasibility we have removed ‘and preliminary results’ from the title.
Comment 1.3: The study did not take into account the differences in pharmacological therapy nor between patients in the intervention groups, nor between patients in the control group. This factor is very important because can affect analyzed parameters as patient activation, building confidence and motivation, goal setting.

Response 1.3: We did not include this as all patients were being treated according to a standard protocol in the same treatment center. Most newly transplanted patients start on a standard preparation of tacrolimus, MMF, and prednisone for 4-6 months. We agree that in any future multi-center study, any differences in pharmacological treatment between experimental and control groups should be taken into account. We have added this to the discussion on page 26.

Comment 1.4: Results of the study showed that no significant differences were present in recipients' self-management knowledge nor within the intervention group (T0 vs T1) nor between the intervention and control group (T1 vs C). Moreover, no significant differences in quality of life between the intervention and control group were found. The further results that authors report in the study appear obvious. How can authors conclude that the nurse-led self-management support intervention we evaluated was found to be feasible and acceptable by professionals?

Response 1.4: In our pilot study, no significant differences in recipients’ self-management knowledge and quality of life were detected. Still, there was a significant difference between the evaluation of the quality of nursing care within the intervention group. There was a significant increase within the intervention group in the extent to which important areas were addressed by the healthcare professional. Also, the qualitative results indicated that our interventions was feasible and acceptable for both professionals and patients because of the appreciation of the content and process. The fact that both patients and professionals alike were positive supports this conclusion. To establish differences between the intervention and control group, a bigger sample size is needed. We feel that the results of this pilot-study warrant further research into the effectiveness of this intervention.

Reviewer 2:

Comment 2.1: Hi overall the manuscript is suitable for publication in this journal please describe the method of selection.

Response 2.1: We thank the reviewer for this compliment. We used a full sampling approach to select kidney transplant recipients and nurse practitioners. We have described this in the ‘sample and participants’ paragraph (page 7 & 8).

Comment 2.2: The 2nd point :the pages is more than expected for reading by anyone can you concise the manuscript.
Response 2.2: We tried to shorten the manuscript by removing some details in our result section.

Reviewer 3:

Comment 2.1: Thank you for submitting this interesting manuscript. Given the overall burden of end stage renal disease, an analysis of self-management intervention in kidney transplant recipients is important and relevant to improving quality of life.

Janet Maria and colleagues conducted this controlled baseline-follow-up mixed-methods trial to support the effectiveness of holistic nurse-led self-management intervention developed using the Intervention Mapping approach after kidney transplantation in addition to traditional care.

The study included 27 participants in intervention group and 33 participants in control group.

I believe the study was appropriately conducted and the results and conclusions are generally correct and appropriate.

A minor point:

Please correct the p-value for psychological well-being; it is 0.00 in the manuscript, page 19, line 1.

Response 2.1: We thank the reviewer for his/her compliments. We corrected the p-value for psychological well-being.

REFERENCES
