Author’s response to reviews

Title: Effects of the Proactive Interdisciplinary Self-Management (PRISMA) program on self-reported and clinical outcomes in type 2 diabetes: A pragmatic randomized controlled trial

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Author’s response to reviews:

Dear Ciarán Martin Fitzpatrick,

Thank you for peer-reviewing our manuscript entitled "Effects of the Proactive Interdisciplinary Self-Management (PRISMA) program on self-reported and clinical outcomes in type 2 diabetes: A pragmatic randomized controlled trial" (BEND-D-19-00371)" and considering it for publication in BMC Endocrine Disorders.

Please find attached our revised manuscript with changes highlighted. A point-by-point reply to the peer reviewers’ comments and additional changes we have made can be found on the following pages. We trust we completed the necessary revisions to your satisfaction.

We look forward to your response.

Sincerely yours,
on behalf of all co-authors,
Esther du Pon

Reply to the reviewers’ reports

Yoshifumi Saisho (Reviewer 1)

Please add the legend for figure 5.

Thank you for reviewing. This manuscript does not include a Figure 5. Figure 1, Table 1 and Table 2 are provided with a legend (page 20).

Nancy Schoenberg (Reviewer 2)

This manuscript presents outcome data on a randomized trial of a diabetes self-management program, PRISMA, which did not change the intended self-reported outcomes. The paper is a refreshingly honest and straightforward paper with a story that needs to be told.

There are a number of strengths of the research, including the program being based in previously implemented protocols; sufficiently long timeframes to allow for a robust examination of the outcomes; an unusually sex/gender inclusive sample (usually far fewer men participate); use of the CONSORT checklist; and a very thoughtful discussion section.

Thank you for reviewing our manuscript and for the compliments on our work.

There are several limitations, which are acknowledged by the authors including a lack of reporting of the clinical outcomes due to missing data; possible selection bias; and questions about fidelity. The most concerning issue is presented as #6 below.
To improve the manuscript, the authors should address several concerns or questions:

1. Most behavioral research suggests that interventions are more successful if they have a larger dose. It would be helpful if the authors justify why they considered two group sessions sufficient to possibly change these complex behaviors of T2DM.

The question above is also discussed in the article. PRISMA is an intervention existing of 2 sessions, changing that dose was not possible. According to the literature, the two group sessions of PRISMA appeared to improve self-management behavior in terms of dietary behaviors, foot care, action planning, and medication adherence [1,2] (page 3, line 76-79). During the two group sessions, a learning process was expected to be initiated that helps patients to (continue to) work on promoting and monitoring their health. The trainers encouraged the patients to discuss their individual action plans with their health care provider during their next consultation and bring up the topics important to them. The two PRISMA meetings should therefore be seen as a starting point to motivate/activate patients, with behavior change as the final objective. We added this in the text (page 5, line 111-114).

2. What is meant by “the trainers strictly adhered to the PRISMA protocol”? What steps were taken to ensure fidelity? To ensure intervention fidelity, the trainers followed a standardized training program. Besides, during the training, every topic of PRISMA had to be registered in, including time and depth of discussion. The trainers were asked to indicate any deviations from the protocol after the training. We have no indications that they deviated from the protocol. Two trainings were attended personally by the researcher. In an ideal situation, the researcher would personally attend or record all training sessions in order to check intervention fidelity, however, this was not possibly due to time constraints. We added this point to the discussion (page 10, line 251-253).

3. The enrollment rate (<14%) seems modest. Can the authors explain why this rate was so low or if this rate is similar to other clinically-oriented recruitment enrollment? In spite of the expected positive effects, in other studies about 30–50% of the eligible patients do not participate in diabetes education [3,4]. In our study this rate was even higher. Despite our efforts to enthuse patients about the PRISMA program, only a small number of the approached patients participated. However, this lack of interest is not an exception in diabetes care. In previous research, more than 80% of the patients preferred to receive diabetes education during their regular diabetes check-ups and only 3% preferred a special diabetes course [5].
4. It would be helpful in Table 2 to include information on the potential range and direction for scoring so that the reader has a sense of where the sample falls. This range and the population norms should also be described in the findings so that the reader can assess the authors’ conclusion that the relatively high starting point at baseline may have produced a ceiling effect that could not support a significant change in outcomes.

We now included the potential range and direction for scoring (Table 2, page 16).

5. The authors indicate that recruiting from a clinical sample is advantageous but do not address the limitations of such recruitment (a sample that may exclude those in greatest need of self-management—i.e., those people who actually don’t go to the doctor’s). This potential limitation should be explained or addressed. We agree and now explained this issue (page 9, line 236-237).

6. What is meant by the statement on page 11, line 251: “Fifth, because of organizational reasons, the patients completed the baseline questionnaire at the end of the intervention rather than at the start.”? This seems highly problematic and inconsistent with RCTs and may be a fatal flaw for the paper. We understand your concerns. All patients indeed completed the baseline questionnaire at the end of the intervention. However, the intervention consisted of more than two group meetings: the two PRISMA meetings should be seen as a starting point to motivate/activate patients, with behavior change as the final objective. Therefore, strictly speaking, the questionnaires were not completed at the end of the intervention but halfway through. In an attempt to explain this, we changed several aspects in the text about the description of the intervention (page 5, line 111-114) and the baseline outcomes, e.g. we did not use the term “baseline measurement”, and changed “at the end of the intervention” to “at the end of the two PRISMA meetings” (page 5, line 121-122; page 10, line 261-263).

Antonio Nenna (Reviewer 3)

Even if daunted by missing values, clinical outcomes should be reported. theoretically, the importance of methodology should be stronger than any significant P value. also, the lack of clinical outcomes is discussed. Thank you for reviewing our manuscript. We decided now showing the clinical outcomes due to the large jnumber of missing values. However, we now presented the clinical outcomes in an appendix (page 8, line 195-196; page 20).
Quantitative tests for comparison of data in Table 2 should be provided (P values). The P-values are added now in Table 2 (page 16).

A longitudinal analysis for repeated-measures could be performed (0-6-12 months) and would be extremely useful to monitor temporal trends. In case of repeated measures, longitudinal analysis might produce significant results that cannot be evaluated in simple analysis of paired data. We used predefined methods and analysis. We were mainly interested in health outcomes at 6 month, after that period the control group received the intervention as well, but that was actually outside our primary scope. We followed the methods described in our study protocol [6].

Scales (e.g. WHO-5) are generally considered as ordinal variables rather than continuous, please verify this issue and correct Table 2 accordingly. We described the outcomes according to generally used methods, as reported elsewhere [7-9].

English language should be revised by a native speaker to improve fluency. The paper was already revised by a native speaker, experienced in research in health care.

Literature


