Author’s response to reviews

Title: Telephone-Based Motivational Interviewing versus Usual Care in Primary Care to Increase Physical Activity: A Randomized Pilot Study

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Author’s response to reviews:

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Gillian Lancaster and Lehana Thabane
Editors in Chief
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Dear Sir/Madam,

We are submitting the above-referenced revised manuscript for possible publication in the Pilot and Feasibility Studies. We appreciate the favorable review of the manuscript and the carefully constructed comments by the reviewers. The revised manuscript shows highlights of the changes made highlighted in yellow. The research represents the results of a pilot study conducted for the sole purpose of establishing feasibility for a future fully powered randomized trial. The work has not been previously published and there is no overlapping information in the manuscript with previously published work. The work will not be submitted for publication elsewhere while under consideration at the Pilot and Feasibility Studies. The study was supported by the National Institutes of Health, R01 DK10090. NIH, nor any of the authors, have any real or perceived conflicts of interest with this research.

All authors take responsibility for the integrity of the work from inception to conclusion. Each of the authors has participated sufficiently in the work to take public responsibility for appropriate portions of the content; all of them have made substantial contributions to all aspects of the research and writing process, and have given final approval of the version to be submitted for review to the Pilot and Feasibility Studies.

Reviewer reports:

Reviewer #1: This is a well conceived study, well conducted and well described study. The intervention has a strong theoretical basis. The quantitative outcome measures have face validity and reliability.

There needs to be a short section on limitations

Responses: We added a paragraph on limitations.
- one is that there is little information on how clinics were selected. It sounds like a convenience sample of interested clinics and participating clinics and clinicians may be atypical of the broader group. If so this would be likely to have an impact on generalizability of the intervention.

Response: This is included in the limitations.

- second the number of participants interviewed was very small (four) and there is no information on how the data was analyzed so it is difficult to draw conclusions from this data.

Response: We included this as a limitation and provide more detail on how the interviews were analyzed.

- the methods of identifying participants changed over the course of the study and the two groups may have responded differently to the intervention.

Response: This was a pilot study, of which one of the aims was to pilot how to identify and recruit potential participants. By changing the recruitment methods we learned the best way to recruit, and thus, this was a learning opportunity and outcome of the pilot. We cannot think of one reason why there would be a differential response to the intervention based on our methods. In both instances, participants were called to determine if they would be interested in participating in the intervention. The only difference was that in the first case, the primary care provider cleared them for exercise prior to our initial contact (without the participant’s knowledge), the second was that we reached out to the provider to determine if a participant could be cleared.

- there is no data on the socioeconomic status of participants though this could be important for reaching those most in need of the intervention.

Response: We added educational attainment to Table 2 and report the results in the results section.
Reviewer #2: This is an interesting and concise manuscript, however in places it is lacking in sufficient detail. In order to improve this, I have some suggested minor revisions as follows:

The abstract does not contain details of the participants eligible for the trial, all I can ascertain from the abstract is that participants were diabetic or prediabetic, and this is an inference from what is written in the background section of the abstract. According to the CONSORT guidance for reporting pilot and feasibility studies, the abstract should specify eligibility criteria (i.e. that participants needed to be physical inactive and aged between 18 and 74 years). The abstract also does not specify the randomization procedure, blinding, or numbers analyzed (which is required by the CONSORT guidance).

Response: The abstract was revised and now meets the CONSORT guidelines.

The background section should introduce that the intervention involves telephone MI and briefly highlight the current knowledge about the potential efficacy/effectiveness of the use of this approach in i) physical activity interventions, ii) primary care settings, and iii) with diabetic populations.

Response: A sentence in the introduction section was added.

On lines 165-166 the authors note that 'methods to remind providers to clear patients were identified and tools were created' - it would be helpful if these were described in the text and reflected on explicitly in the results/discussion as to their utility (i.e. what did the interview data suggest was useful or not about these reminders/tools), as this might be an important learning for other studies based in the primary care setting.

Response: We added more information in the methods and results sections. Suggestions from the interview results are included in a paragraph in the discussion section (page 22).

The measure of 'physical activity self-regulation' described sounds like the 'Behavioral Regulations in Exercise Questionnaire' (http://pages.bangor.ac.uk/~pes004/exercise_motivation/breq/breq.htm) based on the description and associated citations. If this is the case, please specify this in the text and report which version of the questionnaire was used. The internal consistency for this scale should also be reported, in keeping with the description of the other measures.

Response: We used the Exercise Self-Regulation Questionnaire scale by Deci and Ryan. The reference we originally included referred to the instrument but was not the actual instrument. The reference has been replaced.
The methods section does not outline how the psychosocial measures were collected at baseline and follow-up, I assume this was a postal questionnaire (perhaps mailed with the accelerometer?), but this is not specified.

Response: Accelerometers and questionnaires were sent by mail to participants. This is now clearly stated in the methods section.

CONSORT guidelines for pilot studies specify the inclusion of a rational for the sample size used, this is not mentioned in the manuscript, other than in the abstract where the target sample size is specified but no rationale given. The manuscript is also lacking in detail required by CONSORT guidelines with regards detail of randomization (sequence generation, allocation concealment, implementation and blinding). Was randomization conducted before or after baseline data was collected? This is not clear from the text or the flow chart.

Response: Participants were randomized into intervention vs usual care using a block randomization using blocks of 8, 10 and 12, stratified by sex. Randomization was conducted after baseline assessment. Study staff conducting mailings and data entry were blinded to treatment assignment. All elements of the CONSORT guidelines are now stated in the manuscript.

In the description of the intervention, a link should be drawn between the conceptual model of SDT and the use of MI for this purpose, highlighting the overlaps between the aims of MI and the description of how autonomous self-regulation can be promoted. See the following papers for appropriate citations to underpin this link:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3310779/

Response: We made the link between SDT and MI that the reviewer suggested and also added a paragraph describing MI.

Also, in the description of the intervention, the role and background of the interventionist should be described - was it a member of the research team or was it a health care practitioner? Where
were they based and what was their existing training and knowledge with regards diabetes and physical activity? This is important for future replications of this approach.

Response: We added more text on pages 13/14 to describe the interventionist’s background and how study staff supporting intervention delivery.

The description of the qualitative assessment does not specify how many physicians/clinic staff were interviewed, and whether or not all participants were interviewed or a subsample. This information is included in the results but there could be some detail in this section with regards how interview participants were recruited/selected. This section also comes a little bit out of the blue as the use of qualitative interviews is not detailed in the study design section or in the abstract (except for in the results section of the abstract).

Response: We added a sentence in the Study Design paragraph about the interviews. We also added information in the Qualitative Assessment section of the methods about how the participants for the interviews were selected.

The discussion section does not include a limitations section. One limitation that I feel is important to include here is that there was no measure of the fidelity of the telephone MI. An important component of much MI intervention research is the assessment of whether the delivery of MI is consistent with the key principles of MI and also that it does not feature any MI-inconsistent aspects (there are several validated assessment tools for conducting such an assessment). This is important because a lot of previous research has shown that short MI training (e.g. 2-days) without appropriate follow-on supervision is not necessarily sufficient to result in efficacious MI practice. Without a fidelity assessment no conclusion can be made about the active ingredients of this intervention (i.e. if the calls were not MI-consistent then there may be something else going on that was involved in the improvements observed, e.g. telephone counselling alone may be sufficient to bring about these improvements with or without MI). Any future effectiveness trial of this intervention should ensure that a proportion of the telephone calls are recorded and an independent fidelity assessment is conducted.

Response: We now include a limitations section and include lack of MI fidelity assessment as a study limitation.

There are also some typos that need correcting, as follows:

Line 72 (in abstract conclusion) - remove comma after the word support Lines 103-104 - remove repeated 'are needed'
We look forward to learning the outcome of this submission.

Sincerely,

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