Author’s response to reviews

Title: Pilot randomized controlled trial of a complex intervention for diabetes self-management supported by volunteers, technology, and interprofessional primary health care teams

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Note: Location stated is page number based on tracked changes version of the document

REVIEWER 1

Comment: One omission was that Figure 1 was not included in the document

Response: From what we understand, figures are supposed to be uploaded into the system separately. It may have been missed, so we are ensuring to upload it now.

Location: Uploaded into online submission system
Comment: The areas in which the paper was weakest was in relation to it being a pilot study, and it was not clear that the study had always been planned as a pilot study (as opposed to a study for which recruitment was challenging and therefore resulted in small numbers of cases).

Response: See our revisions in the sections below, which we believe address these issues.

Location: N/A

Comment: In terms of the quality of the paper as a report of a pilot study, the following need to be noted: * The objectives of the pilot need to be described much earlier in the paper, e.g. in the background. These don't appear until page 13, line 50-51.

Response: The pilot objectives are now included in the Background

Location: Background, pg. 7-8

Comment: * As well as the objectives stated, as a pilot study additional objectives could usefully be considered, e.g. acceptability of the intervention and completion rates (of the intervention not just outcome measures; acceptability of randomisation; time required to undertake a full trial (based on recruitment and power); piloting bespoke data collection methods; any risks or safety issues arising from the pilot.

Response: Further pilot objectives (process measures) were already included in Table 2, but we realize this may have not been clear by reading the text alone. They are now fully listed in the text (pg. 13-14). In reference to your suggested objectives, see below.

Acceptability of intervention: We did not directly collect acceptability, but we did collect qualitative data on the benefits and areas for improvement of the program. We have added this explicitly as an outcome in the abstract, outcome list (pg. 13-14) and Table 2. We have also changed “Perceived program impacts and outcomes” in the qualitative results section (pg. 24-25) to “Benefits and areas for improvement” and added further content to reflect this change.

Completion rates of the intervention: Already included as an objective and described in results; now explicitly stated (pg. 13-14).

Acceptability of randomization: We have added appropriateness of randomization process as a pilot outcome. See list of outcomes (pg. 13-14), Table 2, and Results – Process Measures (pg. 18)

Time required to undertake a full trial: We have added this into the Discussion rather than as an objective (Discussion – Implications for Research and Practice, pg. 27)
Piloting bespoke data collection methods: The primary data collection method, i.e., the Healthy Lifestyle App, was piloted earlier with results presented in another paper. A sentence stating this was added to Methods - Process Measures, pg. 14.

Any risks or safety issues arising from the pilot: Risks/drawbacks were already discussed in the qualitative, but now we have added it as a specific (qualitative) outcome and highlighted this change with a sub-heading. (See Results – Qualitative Interview Data: Results or safety issues, pg. 24; also mentioned in outcome list (pg. 13-14) in Methods and in Table 2.

Location: See individual notes on each suggested outcome above.

Comment: * The study reports p values, but it is not clear that the study is powered to identify a difference, and indeed, estimating sample size needed for this is part of the purpose of the study: confidence intervals would be more appropriate.

Response: We have removed references to p-value and significance.

Location: Results – Assessment of Trial Outcomes, pg. 20; Table 5; anywhere else significance was mentioned

Comment: In terms of the discussion of the results: This would ideally start with the extent to which the objectives of the pilot (as discussed above) have been addressed.

Response: The pilot outcomes as above that were added and were missing from the discussion have been integrated into the discussion.

Location: Discussion, pg. 26

Comment: * One challenge with multi-faceted interventions is that they can be difficult to implement in a standardised way. It would be useful to cover this point in the discussion, particularly in terms of whether the intervention is scalable - would it be possible to implement consistently across a wider group of patients and using a larger number of volunteers?

Response: We have added this concept to the Discussion

Location: Discussion - Implications for Research and Practice, pg. 30
Comment: * Retention rates: although 35 people completed overall (out of 49), only 15/26 of the intervention group completed - this should be noted in the discussion, which only refers to the overall retention.

Response: This concept has been added to the Discussion

Location: Discussion, pg. 26

Comment: * Recruitment challenge: this could usefully be discussed further, to tease out the reasons for this, e.g. is this to do with lack of relevance of the intervention to the study population, or concerns over randomisation/taking part in research? Were there differences between the physicians involved and what might be done to improve recruitment in a full trial?

Response: We have added detail in understanding recruitment challenges – the general disinterest is more difficult to parse out, but we described the main reasons for decline in more detail as well as describing some potential reasons for this (e.g., it’s took place in highly resourced interprofessional clinics), and ways this would improve in the future (e.g., internet access becoming more widely available). Physicians were not heavily involved in recruitment – nor were their differences evaluated – so we only briefly touched on their input here.

Location: Discussion, pg. 26-27

REVIEWER 2

Comment: A. I think the main weakness of this paper remains in the rigor of the qualitative analyses as they are described and presented currently. The paper would benefit from some additional changes to fit in with the requirements of reporting a qualitative study. A consolidated criteria for reporting qualitative research (COREQ) checklist could be used.

Response: We have completed the COREQ checklist.

Location: Additional File 2 (and added sections to the text based on COREQ)

Comment: Specifically, 1. a. The coding approach could benefit from more rigor. Please expatiate on thematic data coding. Specific type of thematic analysis conducted is missing. You might want to consider describing the phases (including a framework) as noted by Braun and Clarke (2006)...Referenced 37 in the manuscript.

Response: Details of Braun & Clarke (2006)’s phases for thematic analysis have been described.
Comment: b. It might be helpful to report the rate of agreement between the two coders.
Response: Unfortunately, we did not collect the agreement rate between coders

Comment: c. Please include what qualitative experience the coders had, and other efforts to promote rigor of the analyses (e.g. other members check).
Response: Coders’ experience added to the Interviews section (same team members were interviewing and coding) as part of COREQ. Further detail around rigour added to that section and to the Data Analysis section (following Braun & Clarke’s phases, as per above)

Comment: 2. There was no explanation about how the 12 respondents who participated in the interview were selected. There is also need to explain how data saturation was achieved.
Response: All intervention participants were invited at their 4-month mark. This has been added. We have described data saturation.

Comment: 3. Duration of interview was not mentioned.
Response: Duration added

Comment: 4. Please note other points that is included in the COREQ checklist and ensure they are reported in the paper, as the checklist is not supposed to replace what is reported in the paper.

Response: Missing points from COREQ are now reported in the paper.

Location: Additional File 2; changes made throughout paper based on criteria

Comment: B. 1. I observed in Table 3 which listed the participant characteristics, that some participant Language was not English. This raised the question of, in what language was the questionnaire administered to this non-English cohort? How did they communicate with volunteers? Were they part of the interviewees?

Response: This was a missing word that added confusion – it should say “First language”. All interviews and surveys completed with volunteers were completed in English. This has been fixed.

Location: Table 3, pg. 18

Comment: 2. In one sentence, please state the discipline or professional background of the volunteers

Response: One sentence on volunteer background has been added.

Note: Another manuscript describing an evaluation of the volunteer program has also been completed and submitted elsewhere.

Location: Results – Process Measures, pg. 19

Comment: 3. In the introduction, please add a theoretical definition of what self-management is. It is actually missing.

Response: A definition has been added to the first paragraph

Location: Background, pg. 5

Comment: 4. Under the study design session; "The controlled group received usual care, followed by elements of the intervention that were feasible to include after the intervention period..". The aforementioned statement in quote is not clear. Please make more explicit.
Response: Added a reference to look at the Control Group section, and added specific detail of what the control group received to that section.

Location: Methods – Control Group, pg. 13

Comment: 5. Please ensure the full meaning of all abbreviations are provided before subsequent use. Particularly "EMR" used under setting, "RAPA Aerobic score" used under the session 'Assessment of trial outcomes'

Response: EMR and RAPA are now defined at their first mention in the text.

Location: EMR: pg. 9
RAPA: pg. 14

Comment: 6. Please move the paragraph under Table 1. i.e. lines 42-53 on page 11 to page 10 after line 42. This will provide the reader an immediate access to what the "Huddle team" entails.

Response: Paragraph has been moved.

Location: Pg. 11

Comment: 7. Line 26, page 14 should read, except HbA1c and not excepting HbA1c.

Response: Fixed

Location: Pg. 16