Author’s response to reviews

Title: A Mobile Phone-based Program to Promote Healthy Behaviors among Adults with Prediabetes: Study Protocol for a Pilot Randomized Controlled Trial

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Carmel Hughes
Associate Editor
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Queen’s University Belfast, UK

Dear Dr. Hughes:

We thank you and your team for your review of our manuscript titled, “A Mobile Phone-based Program to Promote Healthy Behaviors among Adults with Prediabetes: Study Protocol for a Pilot Randomized Controlled Trial” (PAFS-D-17-00024R1), which we are resubmitting as a protocol paper in Pilot and Feasibility Studies. Our responses to the reviewer’s comments are detailed below:
1. Thank you for the opportunity to look again at this paper. The authors have undertaken a lot of work and considerably strengthened the document.

We appreciate these comments.

2. Secondary outcome measures - have the authors considered time to recruit, since this is a hard to reach group?

We agree that our target population may be more difficult to engage than a general population of individuals with prediabetes, as our group has already declined to participate in a formal Diabetes Prevention Program. Therefore, we will calculate the intervention uptake rate to understand unique recruitment challenges and to estimate the number of potentially eligible individuals that would be required to achieve recruitment goals for a larger study. While we will consider the total time needed to recruit our pilot sample, we recognize that this measure may reflect additional factors such as low staffing and breaks in recruitment efforts, and therefore the absolute number of recruitment days may be less informative than the intervention uptake rate.

3. Have the authors considered interviewing the control arm to explore why they signed up (when not guaranteed to get the intervention) and how participation in the control affected compliance.

We agree that it would be interesting to understand why control group participants enrolled in this study. However, because this topic does not directly align with our specific aims and because we will run this pilot study on a limited budget, we will be unable to conduct these additional interviews. In future work we would certainly plan to include a robust evaluation of the control group.
4. Also, please say how interviews are undertaken (telephone, face to face) and how data are collected (recorded?)?

We apologize for this confusion. The interviews will be conducted by telephone and the interviews will be audio recorded. We have now added the following information:

“The acceptability of the intervention will be determined though semi-structured interviews conducted via telephone.” (Lines 199 to 200)

“Semi-structured interviews will be audio recorded and subsequently transcribed verbatim.” (Line 252)

5. Lines 212 onwards: Please confirm that the measures are self-reported.

We have revised this section to specify those items that will be measured by self-report:

“We will evaluate change in HbA1c; baseline HbA1c will be abstracted from the Electronic Medical Record and participants will be asked to have a follow-up HbA1c drawn after the 12-week intervention period. Additional exploratory outcomes will include change in the following self-reported measures: weight (kg) and/or BMI (kg/m2); change in overall level of motivation to prevent T2DM [34]; purpose in life [45] [46]; perceived competence to prevent type 2 diabetes [47]; social support [48]; eating behavior [49]; self-reported physical activity[50]; patient activation[51]; and willingness to participate in a Diabetes Prevention Program.”

6. Also, please clarify how data are down loaded from JOOL/fitbit.

We have added the following sentences to clarify this important point:
“Because the Fitbit devices interface with the JOOL Health platform, Fitbit data will be stored within the JOOL Health application. At the end for the study period, the JOOL Health team will provide our study team with a comma-separated values (CSV) file containing raw data from the JOOL app and Fitbit devices.” (Lines 226 to 229)

Sincerely,

Dina H. Griauzde MD, MSc