Reviewer’s report

Title: Effectiveness of diabetes self-management education via a smartphone application in insulin treated type 2 diabetes patients. Design of a randomised controlled trial ('TRIGGER study').

Version: 0 Date: 12 Jun 2018

Reviewer: Elaine Lum

Reviewer’s report:

Thank you for the opportunity to review this research protocol. Congratulations to the authors/research team for putting together an interesting and useful study investigating the effectiveness of text messages to trigger desirable health behaviours via a smartphone app focussed on providing patient education in nutrition, physical activity, avoiding hypoglycaemia and variability in blood glucose. Some comments below for the authors' consideration:

1. Background section: Line 98-99 requires a reference (sentence ending with "... but apps facilitating these features are associated with higher costs").

2. Background section: Line 102 (and the corresponding paragraph): A new paper has just been published which the authors may wish to include. Byambasuren O, Sanders S, Beller E, Glasziou P. Prescribable mHealth apps identified from an overview of systematic reviews. nPJ Digital Medicine 1, Article number:12 (2018). Available from: https://www.nature.com/articles/s41746-018-0021-9

3. Methods section: Line 265-268. May be useful to survey patients in both the intervention and control arms at baseline (T0) and at the conclusion of the study (T6) regarding their use of other health apps relevant to this study (e.g. physical activity apps, diet/nutrition apps, weight management apps, blood glucose monitoring apps, etc).

4. Methods section: Line 293-294. For comparison of the intervention sub-groups at T9 between those who continued using the app and those who did not, why not include also the co-primary outcome of the proportion of patients achieving desired HbA1c without hypoglycaemia, and the number of hypoglycaemic episodes, as you would have collected this data anyway (patient diaries up to T9 was mentioned in Line 311). This would give us some interesting insights as to the sustainability of the intervention effect in regards to avoiding hypoglycaemia.

5. Cost-effectiveness analysis: I note that the cost-effectiveness analysis will only be carried out if the intervention is successful in delivering desired outcomes. Is it possible to also include ICER? The CEAC will only present the probability that the intervention is cost-effective.

6. Table 1 has 2 inconsistencies. Intervention row - Patients choose 3-4 topics, including hypoglycaemia; but in the manuscript this was stated as 2-3 topics, including hypoglycaemia.
Key secondary outcomes row - body weight is mentioned explicitly here, but not explicitly mentioned in the manuscript (implied via BMI only).

Looking forward to your findings!

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Yes

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Unable to assess

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

**Quality of written English**
Please indicate the quality of language in the manuscript:

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