Reviewer’s report

Title: A virtual clinic for the management of diabetes-type 1: Study protocol for a randomised wait-list controlled clinical trial.

Version: 0 Date: 08 May 2020

Reviewer's report:

This manuscript describes the protocol for a randomized wait-list controlled clinical trial to evaluate the effect of a virtual diabetes clinic on glycemic control, treatment satisfaction, quality of life, and patient care experience in young adults (ages 18-25) with type 1 diabetes. Strengths of the manuscript include outlining a feasible RCT study design and addressing a gap in the literature surrounding the assessment of patient-centered virtual diabetes care, especially for young adult patients. Although an important and relevant topic, more detailed information is needed in the current manuscript. Following are points of consideration:

Background:

* The authors describe how young adults are particularly vulnerable to suboptimal glycemic control, but don't include any specific examples or speculate why this might be. The paper would benefit from discussion of some of the major developmental milestones and challenges that young adults face as they relate to glycemic outcomes.
* It would be helpful to the reader to provide more concrete examples and citations of why virtual diabetes clinics would be useful in supporting diabetes management in the last paragraph of the background section.
* The authors state that “…the technological developments in diabetes care have placed higher demands on education and support,” which contradicts the overall argument that virtual diabetes care (a technological development) can help to improve management. Please clarify this on page 3.

Method/Design:

* Please include rationale for exclusion criteria of severe depression, eating disorders, serious mental illness, alcohol/drug abuse, or severe diabetes complications- several of which are not uncommon in this young adult population with T1D. Please also describe how these will be assessed in order to exclude.
* It would be helpful to include whether or not duration of diagnosis will be used as inclusion criteria. The authors should consider excluding participants with duration less than 1 year- honeymoon is often continued through one year and patients are still adjusting through the one year period.
* The author states that "hospital staff in the clinic (doctors and nurses) will be responsible for the inclusion, randomization and the interviews," but concerns about experimenter bias should be raised, as these staff are also providing direct care for the patient.
* As these participants will still be receiving their "usual diabetes care," what role does the smartphone application play? Please provide more information about how this app is used as
a supplementary tool (e.g. does it include information about nutrition, exercise, etc.) to usual diabetes care.
* Please report use of diabetes technology including meter use, insulin pumps, and CGMs. Further, differences in technology may impact participants' ability to interact with the application and should be included in analyses. Will patients who are not using CGM be excluded from participating?
* Please provide information on race and ethnicity in addition to the report of Swedish nationality. Relative lack of heterogeneity should also be included as a study limitation.
* It is unclear why insulin requirements/dosages will be used as an indicator of glycemic control, please provide more information and/or citations.
* A more appropriate title for "Clinical Outcome Measures" may be "Clinical Variables," as not all that are listed here are "outcomes" (e.g. diabetes duration is not an outcome).
* Under Psychometric Measures, we suggest "health and quality of life" be replaced with the measure name "Check Your Health"
* It would be helpful to know how the surveys are administered (e.g. in-person or online).
* The qualitative interview may be a good opportunity to ask about specific aspects of the app that were helpful/not helpful to the participant, in addition to the more broader perceptions about virtual care.

Discussion:
* Please discuss potential limitations and risk of study.

Miscellaneous:
* Authors should carefully review paper for typos and awkward wording (e.g. page 3, sentence beginning with "To achieve optimal self-management..."); page 5 line 16 "collect data t"; page 6 lines 15-16 "continuos glucos").

**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:

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

Nothing to disclose.

Reviewer Publication Consent. I agree for my report to be made available under an Open Access Creative Commons CC-BY License (http://creativecommons.org/licenses/by/4.0) if this manuscript is accepted for publication. Any comments that I do not wish to be included in the published report have been included as confidential comments to the editor, which will not be published. If you are not happy for us to publish this report, please contact the editorial office before completing the review. If you wish, you can include your name in your published report. Please note you must decide whether to include your name at the start of the process and confirm this decision whenever prompted. If you change your decision later, we will not be able to publish your name.
I agree to the terms of the CC-BY 4.0 license; please do not publish my name with my report. (default)