Reviewer's report

Title: Mobile Phone Intervention for Increasing Adherence to Treatment for Type 2 Diabetes in an Urban Area of Bangladesh: Protocol for a Randomized Controlled Trial

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Reviewer: Marcia Vervloet

Reviewer's report:

This is a protocol for an interesting study, which can provide useful answers in the issue of improving adherence and control in diabetes patients in Bangladesh. A large amount of very interesting data are collected. The minimization of risk of bias is very well described in all sections. However, I do have some comments that need clarification.

Minor Essential Revisions

1. Only two hypotheses are given (for two of four objectives of the study). Maybe the authors want to think about providing hypotheses for the other two objectives as well?

2. I would like to suggest to provide more details on the methods in the abstract, e.g. on the randomization methods, measurements and in/exclusion criteria. The background can be shortened to gain space.

3. The randomization described in the discussion (p.16) is slightly different from what is described in the methods (p.6). In the discussion, income is also mentioned as variable. And a typo: sex and gender are synonyms.

4. Please clarify the abbreviation icddr,b in the data analysis section (first sentence, p.11).

Major Compulsory Revisions

5. The background needs more literature references as now statements are made without evidence. One example is the second sentence of the Background “More than 80% of diabetes related deaths occur in developing countries”. The authors may also want to find a more recent and fitting reference for the burden non-adherence rates pose on health systems (now a paper published in 1980(!), ref 3).

6. Do the authors base their power calculation on the literature? A reduction of 1% (control group) and 1,5% (intervention group) in HbA1c level with an SD of 1 is assumed. On what are these assumptions based?

7. The first exclusion criterion is uncontrolled diabetes. What exactly do the authors define as ‘uncontrolled’ diabetes? And do the authors only wish to include patients who already have their diabetes under control, i.e. have a near optimal HbA1c level? In that case, the intervention is not aimed at the right
patients, that is patients who need support in controlling their diabetes? The authors need to further clarify this criterion.

8. It remains unclear what the content of the SMS can be. A total of 90 different messages were developed, with medication reminders, diabetes education, diabetes complications, diet and physical activity as topics. Maybe the authors can provide some examples. In addition, it is unclear whether patients receive all possible messages, or whether the messages will be tailored to the needs of the patients. E.g. patients forgetting to take their medication receive reminders, whereas patients not being forgetful do not receive reminders? In other words, will the SMS be send completely randomly to each patient?

9. Please provide more details about outcome variables: medical history, family history and medication history - are these extracted from medical files or self-reported by patients?

10. The authors may need to correct for baseline HbA1c level in their analyses of the effect of the intervention, as this can have an influence on the measured effect. When baseline HbA1c level is already near optimal in patients in the intervention group, there is little room for improvement, concealing the effect of the intervention.

11. In the discussion (as well as the background) it is stated that “lack of awareness and education about diabetes, its complications and optimal way to treatment” is one of the most significant barriers to effective treatment. And the second objective of the study is “Test the use of mobile phone SMS for … building awareness about diabetes and its complications”. However, awareness and education about diabetes are not described as outcome measures: the primary outcome is change in HbA1c level, secondary outcomes are adherence, QoL and clinic attendance. When the awareness and knowledge of diabetes are such important factors, the influence of these factors on treatment adherence and treatment effect are not well investigated in this study? Or the path to effective treatment (the mechanism that the authors investigate) needs more clarification (or better explained in background and discussion): increasing awareness/knowledge leads to increased adherence, which leads to better glycemic control.

12. In the discussion, the health literacy issue is not being well addressed, as patients may be able to read the message, but whether they also understand the message goes further than the ability to read.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests