Reviewer's report

Title: Improving medication adherence in stroke patients through Short Text Messages (SMS4Stroke)-study protocol for a randomized, controlled trial

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Reviewer: Paul Dorian

Reviewer's report:

The authors have planned a very carefully done study of a strategy to improve medication adherence following stroke, using text messaging. The problem is important, the idea is inventive, and the methods are original.

There are a number of issues which the authors should address to achieve the maximum impact from the study, as well as the publication of the methodologies. First, the authors have presumably considered but should detail in the manuscript, the strategies for SMS messages as a function of the number of medications and number of times patients take medications. If a patient, for example, is receiving all of a BID anticoagulant and once a day or BID beta blocker, ACE inhibitor or ARB, aspirin or other antiplatelet drug, statin, calcium channel blocker, as well as other non-cardiovascular therapies, will there be a separate and individual SMS message for every single drug at every time of day when indicated? Will the SMS messages contain all of the drugs that are to be taken for example in the morning (presumably several drugs per message for some messages, and other drugs and fewer drugs per message for other messages?)

Will the message contain the name and dose of the individual drug? Or will it be a generic message: please remember to take your medication(s)? Exactly when will the messages be sent? ie: for the morning dose, early upon arising, later in the morning, mid-morning etc? is the precise time of day when the message to be sent specified per protocol or individualized for each patient? For medications taken at bedtime, will the message come after the patients are in bed and potentially asleep, or at some other time?

Do the authors have any information on whether the participants may find the potentially high frequency of messages intrusive, and choose to disable them? Is disabling the messages an option for the participants?

Will the reinforcing messages regarding the nature of the condition and the need to take medication be the same from day to day? Will they change during the duration of the study?

How, specifically, do the authors plan to deal with medication changes? Will they depend on the patient volunteeringness?

I have major concerns, as the authors mention and acknowledge, about the
accuracy of the measurement of the primary endpoint ie: adherence. The availability heuristic suggest that even if patients wish to be “honest” in their responses, they may not remember or accurately remember the actual number of missed doses or frequency of adherence/non-adherence. In addition, since patients know that they are being “tested” for adherence, and the intervention obviously cannot be blinded, there is a high risk in my opinion that patients will answer in the affirmative to adherence questions even if they are not entirely adherent, or if they cannot remember. At a minimum, a validation sub-study must be done to verify the adherence reporting, for example using pill counts or some other measure.

The statistical description can be shortened substantially. The primary outcome should, in my opinion, be simply rephrased as “the difference between overall adheres in the first two months of therapy between the control and intervention groups”. Since prior to the study, the patients may be less aware of or keeping track of their adherence, I am not sure how much the “delta MMAS score” will be useful.

The section of on participant timeline could be very substantially shortened or placed in an appendix.

As a minor point, the section on pilot studies is in the present tense, and some of the other sections are in the past or future tense. Presumably if the study has not been performed yet, all statements everywhere in the manuscript should be in the future tense (unless some of the pilot testing is already complete).

Presumably important covariates in the usefulness of the adherence program will be patient age, the severity of their stroke, and the number of medications they are required to take. At a minimum, it may be useful to stratify the randomization by “able to take medications independently”, and or by “number of pills required daily” (divided into two arbitrary groups) to ensure a balance in these potential confounders.

Level of interest: An article of limited interest

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