Author's response to reviews

Title: Medication Coaching Program for Stroke Patients: A Pilot Study

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Author's response to reviews: see over
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Dr. Vasilios Athyros

Editor, BMC Public Health

Re: 1600843416725036 - Medication Coaching Program for Patients with Minor Stroke or TIA: A Pilot Study

Dear Dr. Athyros,

On behalf of my coauthors, I would like to thank you and the reviewers for the expert comments and reviews of our manuscript. We have responded to the individual concerns and provided point-by-point responses below. All of the edits are highlighted yellow in this revised manuscript. We believe the manuscript is now much improved, and hope that you and the reviewers consider it for publication.

Sincerely,

Cheryl Bushnell, MD, MHS on behalf of the co-authors

Editorial Comment:

1. Please include the context info of your study within the Background section of the Abstract.

Abstract is revised to include context.

We also updated reference 1 to include the latest Heart and Stroke Statistics Update from 2012, rather than 2011.

Reviewer 1

1. The two outcomes include refinement of the intervention and participant evaluation. The first primary outcome relates to development of the methods and should have preceded the study rather than be part of the outcome.

   This is a good point. Please allow us to provide clarification. The purpose of the pilot study was to assess the feasibility and refine the intervention prior to implementation as standard of care for all hospital patients, i.e. outside the research setting. The methods that we developed prior to the study start were the inclusion criteria, the basic medication coaching script, the timing of the call, and the triage between the coach and the pharmacist and nurse. The coaching script was the only portion of the methods that was revised after the first five participants (as described on pages 5 and 6) and then it was set for the remainder of the participants after receiving feedback. The remainder of the methods was constant throughout the study. The feasibility is the actual primary outcome, thus we have clarified this
in the paragraph describing the objectives (page 4, 3rd paragraph) and the methods (page 8, 3rd paragraph).

2. By my reading this was planned to be a study of 30 patients; the first 20 were offered the coaching intervention and the last 10 were the controls. Is my understanding correct?

   Yes, this is correct. To clarify the screening process, all consecutive potential patients meeting the inclusion criteria were approached regarding participation (page 5, 2nd paragraph).

3. The primary outcome changed throughout the study.

   We apologize for the confusion regarding the outcomes, and have clarified this in the abstract, background, and methods.

4. The discussion is more a literature review than a discussion of the results of this tiny study and the conclusion merely states clearly the hope of the investigators in the use of telephone coaching for the worthwhile purposes of this study.

   We do intend to test the intervention in larger studies, and we have added the reference to feasibility in the conclusions (page 15, 2nd paragraph).

5. The authors do not adequately state the limitations nor appreciate that this tiny non-randomized study was too small to reach any conclusions especially whilst the methods of evaluation were changing during the course of the study.

   We have added additional language to the limitations section to include acknowledgement of this non-randomized design. However, I would like to clarify, as stated earlier, that the methods of evaluation were not changing throughout the study. The first 5 participants in the intervention arm provided feedback on the coaching script, which was then slightly modified, but the rest of the participants received the same script. This was planned from the start and demonstrated the patient-centered input to our coaching intervention.

6. The authors should acknowledge the growing international literature on the use of telephone coaching in patient care which could augment the literature survey of the investigators.

   We appreciate this feedback and have added an important international citation, specifically the ongoing randomized trial of coaching for stroke patients in Scotland (ref 26).

Reviewer 2

1. Did the patients have aphasia?

   For patients with communication deficits such as aphasia who were unable to speak directly with the coach, a proxy/caregiver provided consent. Only two participants had aphasia reflected in the NIHSS at admission, and the aphasia resolved prior to discharge for both.
2. Was there an attempt to classify stroke etiology by TOAST criteria?

   No, the focus was on patients with medication changes from admission to discharge and those going home. Plus, patients with hemorrhagic stroke were included (albeit only 1 was enrolled).

3. Were all patients English-speaking?

   Yes, all of the patients approached for the study were English-speaking, and represents our usual population. Future studies will be needed to adapt the intervention to non-English speaking stroke patients.

4. Did the telephone coaching always occur with only the patient or were family members involved in these conversations?

   The coaching was conducted with the patient for all of the calls, and with both the patient and her proxy on one call because the patient requested it.

5. The young age of the patients should be mentioned as a limitation.

   We have added this to the limitation paragraph on page 15, 2nd paragraph).

6. Including stroke and TIA is likely to introduce a bias.

   This is true to an extent, but the secondary prevention guideline recommendations are the same for TIA as for stroke, thus these patients are another group likely to gain from secondary prevention coaching (see page 15, 2nd paragraph).

7. The NIHSS is low in this study, so the results cannot be generalized to all stroke patients, and they should be characterized as non-disabling stroke.

   We have added this language to the discussion (page 15, 2nd paragraph), and agree that it represents a subgroup of all stroke patients. Also, per reviewer 3, the title now reflects this clarification.

8. Coumadin use will also bias the results, since patients on anticoagulants are likely to have closer follow-up.

   Yes, this is true for most patients on anticoagulants, but we had only 5 patients on coumadin in this pilot study.

9. Discuss the use of a non-disabled population of patients discharged home is a plus since these patients may have high gain from coaching for secondary prevention.

   Yes, this is a great point. See page 15, 2nd paragraph.

10. Cost-effectiveness is a variable to assess in future, larger studies.

    Thank you. We have added this statement to the conclusions (page 15).
Reviewer 3

1. Make clear in the title and throughout the text that the patients had minor stroke and or TIA.

   We fully agree, and have revised the title accordingly. This was also pointed out by Reviewer 2, so we have added this to the limitation discussion.

2. Data on NIHSS and mRS on discharge would be useful. Any associations between parameters of stroke severity and functional independence should also be mentioned in the discussion.

   We were not able to obtain severity or functional status at discharge, and this was not done routinely as standard of care. Since the emphasis was on the comparison between control and intervention groups, we did not compare baseline severity with functional status since this is a well-established association.

3. P values should be provided for comparisons in Table 2.

   Because there were only 5 patients who were asked to evaluate the intervention, we were unable to perform statistical comparisons.