Author’s response to reviews

Title: Lifestyle counselling as secondary prevention in patients with minor stroke and transient ischemic attack: Study protocol for a randomized controlled pilot study

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We have made the following revisions:

° The reviewer comments that formal statistical testing on primary and secondary outcome measures are generally not appropriate in a pilot study. We have therefore made the following changes to the Analysis plan section (pages 11-12; changes marked in red):

- “The primary endpoint (12 weeks study retention in the two randomization groups) will be reported as absolute numbers and proportions with 95% confidence intervals.”

- The secondary endpoint (arterial blood pressure) will be reported as an absolute number for each group and estimate of the between group difference with 95% confidence intervals

- Twelve months follow-up data will be reported as absolute numbers, absolute risk reduction, and risk ratio (with 95% confidence intervals) comparing the risks of a negative event (recurrent stroke, TIA, cardio-vascular incident, or death) in the two groups
The line: “A significance level of 5 percent will be considered statistically significant” has been deleted, as this only applies if formal testing is conducted.

Furthermore, the reviewer comments that no criteria are presented on the feasibility outcomes for what results would be considered acceptable to proceed to a full trial. We have therefore added this paragraph to the discussion (page 14):

“A key part of a pilot study is to evaluate the feasibility of conducting a full-sized trial in the future. A potential impediment for conducting a full-sized trial of this type might be a restricted number of willing participants. To assess whether a full-sized trial is feasible, we must therefore 1) assess how many participants can realistically be recruited within a reasonable time period, and 2) analyse available data on non-participants and low adherence to find potential strategies to reduce non-participation.”