Reviewer’s report

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

Version: 0 Date: 23 Jan 2020

Reviewer: Claire Chan

Reviewer's report:

Editor assessment and comment

Thank you for submitting your article entitled "Lifestyle counselling as secondary prevention in patients with minor stroke and transient ischemic attack: Study protocol for a randomized controlled feasibility study". Please find below some suggestions to help improve the reporting of your protocol.


Abstract:

One of your objectives is to describe the participants experience of life after a stroke. Please can you explain the purpose of this objective. Is it to refine the intervention?

In the discussion you say that "The study will provide evidence of the feasibility and effect of early initiated counselling". Please change to "potential effect".

Background:

You have given a rationale for the future definitive trial, but please include more on the reasons for conducting a randomised pilot trial. Before listing your objectives, please state what the areas of uncertainty are that you want to assess feasibility for, and why are you uncertain about these things.

Randomisation and group allocation:

Please report the method of randomisation e.g. Simple? Stratified? And list any factors for stratification. To reduce predictability of a random sequence, do not include details of any
planned restriction (eg, blocking). Who will generate the allocation sequence? Who will enrol participants? Who will assign participants to interventions?

Outcome measures:

You state that the secondary outcome measure will be arterial blood pressure. Please correct table 1 to match this, as it is listed as the primary outcome measure in table 1. Please ensure that table 1 matches your main text.

Under 'Long term outcome' you state that this will be analysed as a compound binominal outcome measure. Do you mean binomial? And analysis methods should be moved to the analysis section of your manuscript.

Analysis:

You state that baseline comparisons of demographic and clinical characteristics will be performed using Student's independent sample t-test for continuous variables and Fisher's exact-test/chi-squared test for categorical variables. This is not appropriate for a randomised trial. See this paper for explanation of why: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4310023/

Please describe how you will present your results. In pilot studies, it is not appropriate to present p-values - it is advised to present confidence intervals instead. You should reiterate that you are only looking at potential effectiveness, and the study is not powered to make any definitive conclusion.

Discussion:

The discussion currently reads somewhat as though this is a main trial rather than a pilot trial. Please amend with better focus on the pilot trial - i.e. limitations specific to the pilot trial design, generalisability (applicability) of pilot trial methods and findings to the future definitive trial and other studies, implications for progression from pilot to future definitive trial.

Ethical considerations:

You state that the use of a control group as a comparison is necessary if we wish to find evidence of the hypothesized effect of the treatment. Please change to "potential hypothesized effect".

Other:

Progression criteria:
Do you have any prespecified criteria to judge whether, or how, to proceed with the future definitive trial?

Sample size:

Please provide a rationale for the numbers you will recruit in the pilot trial. Do you have any strategies for achieving adequate participant enrolment to reach target sample size?

Harms:

Please report any plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of pilot trial interventions or pilot trial conduct.

Trial status:

You state that recruitment began in October 2018 and is expected to be complete in May 2019. Please update this as we are beyond May 2019.

Items from the WHO trial registration dataset, and protocol date and version: You tick in the SPIRIT checklist that you have reported this on page 3 but I can't see it. See the explanation and elaboration SPIRIT paper for an example of how it should be reported.

Funding: Please be explicit about whether the funding is for the pilot study or main trial or both. Moreover, please state the role of the funder in the study, even if no role.

Project organisation: what is the role and responsibility of the UCSF steering committee in your pilot trial, and/or any other individuals or groups overseeing the pilot trial?

Level of interest

Please indicate how interesting you found the manuscript:

An article of importance in its field

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?

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5. Do you have any other financial competing interests?

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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.

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No