PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Primary prevention of stroke: engaging everyday activities promoting health – a randomised controlled pilot trial protocol
AUTHORS	Patomella, Ann-Helen; Guidetti, Susanne; Mälstam, Emelie; Eriksson, Christina; Bergström, Aileen; Åkesson, Elisabet; Kottorp, Anders; Asaba, Eric

VERSION 1 – REVIEW

REVIEWER	Valery Feigin Auckland University of Technology
REVIEW RETURNED	21-Jun-2019

GENERAL COMMENTS	This seems to be an important study but I think there are several issues to be addressed before the manuscript can be considered for publication. Major concerns: 1. Although it is a pilot trial, there should be some justifications provided as to why only 8-10 participants will be selected from each PHCs. I wonder whether this sample size would provide sufficient diversity of the study population by age, sex, SES, rurality? 2. I do not think that 10-week programme is sufficient to expect changes in health behaviour. Most lifestyle modification programmes have 6+ months duration. 3. As far as I know the Stroke Risk Score card was not validated. When I looked at the card, some criteria used there are confusing. For example, high risk group is defined as a score of 3+, caution risk group – as 4-6, low risk group – as 6-8?! In what units the physical activity was measured? Is it possible that physical activity is zero? Etc. Why would not the authors used easy to use truly validated measures of stroke risk, such as Stroke Riskometer, which also does not require any lab tests? Minor concerns: 1. In the Introduction, it would be reasonable to specify to what populations/regions 76,000 Euroes refer to. 2. Page 7: In one place you state 8-10 per 4 PHCs (total ranges from 32 to 40), but in the paragraph beneath it you state 60 participants. 3. How you are going to deal with possible contamination between the groups? 4. Page 12, drop-out will be removed from analysis. This is not the approach used in ITT analysis claimed to be used in the trial.

REVIEWER	Seana Gall University of Tasmania
REVIEW RETURNED	24-Jun-2019

GENERAL COMMENTS	This manuscript presents a protocol for an intervention for the primary prevention of stroke using 'engaging everyday activities'. The intervention builds on previous work by the investigators and includes consumer input. I only have a few comments and suggestions: 1. I had not heard of 'engaging everyday activities' before and I imagine the reader won't either. Can you give some examples earlier on of what these might be and how you might adapt them to include healthier behaviours? Did your pilot with people that had a TIA give insights into successful examples of these? 2. You mention that 'motivation' for lifestyle change is an inclusion criterion. How is this measured?

VERSION 1 – AUTHOR RESPONSE

Comments from Reviewer 1	Action and response
Justify why only 8-10 participants will be selected for each PHCs. Will the sample provides sufficient diversity of the study population by age, sex, SES, rurality?	In the Discussion on Pg 13 we have added a couple of sentences discussion this risk.
I do not think 10 weeks will be sufficient to expect changes in health behaviors, most lifestyle modification programs have 6 months+	A 6 month program would not be possible (feasible not affordable) for primary healthcare in the Swedish context. Therefore we have designed the program to provide the participants with self-management skills/strategies. This information has been added to the text on page 8 and 9.
As far as I know the Stroke Risk Score card was not validated. When I looked at the card, some criteria used there are confusing. For example, high risk group is defined as a score of 3+, caution risk group – as 4-6, low risk group – as 6-8?! In what units the physical activity was measured? Is it possible that physical activity is zero? Etc. Why would not the authors used easy to use truly validated measures of stroke risk, such as Stroke Riskometer, which also does not require any lab tests?	We have not been aware of the stroke Riskometer until now, and really appreciate the information, unfortunately the test is only available in English. We have used the stroke risk score card as it is easy to administer for non-English speaking participants. A short motivation for the language factor has been added on pg 11. One of the other outcomes measures is the Swedish Lifestyle habits survey that includes questions in four domains: physical activity, alcohol consumption, tobacco use and dietary intake. In that survey physical activity is registered in relation to time/week in exercise and moderate intense physical activity (same questions as in the stroke riskometer).
Minor concerns: 1. In the Introduction, it would be reasonable to specify to what populations/regions 76,000 Euroes refer to. 2. Page 7: In one place you state 8-10 per 4 PHCs (total ranges from 32 to 40), but in the paragraph beneath it you state 60 participants. 3. How you are going to deal with possible contamination between the groups? 4. Page 12, drop-out will be removed from analysis. This is not the approach used in ITT analysis claimed to be used in the trial.	1. The text related to DALYs has been revised and the figures are related to Sweden (has been added). See page 5. 2. As there are 30 participant that will be randomized to intervention group 4 PHCS will be sufficient, this was not clear and have now been added to pg 7 under Sample size and power considerations 3. The risk for contamination is low as the controls are not offered care from occupational therapist and the service in the program is new to the PHCs. There is a low risk for

	contamination as the care providers have been instructed to not deliver the program to other patients during this period of time (has been added on page 9). 4. This sentence was a mistake on our part and has been removed. Thank you for noticing, and drop outs will be included in analysis.
Comments from reviewer 2:	
I had not heard of 'engaging everyday activities' before and I imagine the reader won't either. Can you give some examples earlier on of what these might be and how you might adapt them to include healthier behaviours? Did your pilot with people that had a TIA give insights into successful examples of these?	On page 6 the concept has been further defined and examples added. Examples from the TIA study on EEA have been added on pg 13.
You mention that 'motivation' for lifestyle change is an inclusion criterion. How is this measured?	Motivation for change is asked about and participant ready to take part in the lifestyle program are included. This has been clarified at page 7 under Participants: Eligibility criteria.

VERSION 2 – REVIEW

REVIEWER	Valery Feigin Auckland University of Technology, New Zealand
REVIEW RETURNED	07-Aug-2019

GENERAL COMMENTS	This is an important research aimed at reducing stroke risk via lifestyle modification. However, I have several suggestions. Major concern The authors plan to use Stroke Risk Score card for both selection of the patients and as the outcome measure, but they provide no evidence that this card has been properly validated. It is also unclear what risk score will be considered as a high risk. Minor concerns 1. The stated economic impact of stroke in Sweden is 76,000 euros. I believe it is per person? 2. How the authors are going to deal with likely contamination issue? 3. It should be clarified how outcome measures will be administered. It is shown that self-reported information about lifestyle factors is often not accurate enough 4. It is possible that differences in outcomes between the two groups may be caused by time spent with the interventionists. Did the authors consider attention-control group? 5. It is not clear how and whom and where the intervention will be conducted.

VERSION 2 – AUTHOR RESPONSE

Major concern

The authors plan to use Stroke Risk Score card for both selection of the patients and as the outcome measure, but they provide no evidence that this card has been properly validated. It is also unclear what risk score will be considered as a high risk.

The reviewer is correct that there is limited evidence for the validity of the Stroke Risk Scorecard (SRSc), we have therefore decided that the SRSc should only be used in the screening process and selection of participants. Cut-off for the screening (to be eligible for the study has been clarified on page 8). We can also see that there is a need to translate and validate a Swedish version of for example the stroke riskometer in order to have a valid measure and outcome on stroke risk (this has been added to the Discussion part of the manuscript page 13).

Minor concerns

1. The stated economic impact of stroke in Sweden is 76,000 euros. I believe it is per person? Yes, we have added this in the statement on page 3.

2. How the authors are going to deal with likely contamination issue? Participants to the study are recruited via newspaper advertisement in a large city. The risk for contamination in this context are assessed to be minimal if any. The interventionists are not in contact with controls.

3. It should be clarified how outcome measures will be administered. It is shown that self-reported information about lifestyle factors is often not accurate enough Thank you for emphasizing the risk for bias using self-reports, we have acknowledged the risk in the Discussion, page 13-14.

4. It is possible that differences in outcomes between the two groups may be caused by time spent with the interventionists. Did the authors consider attention-control group? The study design does not include an attention-control group and the dosage of attention from interventionist is higher for the intervention group, although both groups do receive an analysis of stroke risks and goal-setting at baseline, see page 14.

5. It is not clear how and whom and where the intervention will be conducted. Needs to be explained

Please see page 9, we have clarified how, whom and where the intervention will be conducted.