Author's response to reviews

Title: Analysis of the psychological impact of a vascular risk factor intervention: results from a cluster randomized controlled trial in Australian general practice

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Author's response to reviews: see over
Dear Dr van Middelkoop

Re: MS:4060730510787094

New title: **Analysis of the psychological impact of a vascular risk factor intervention: results from a cluster randomized controlled trial in Australian general practice**

Thank you for the opportunity to address the comments provided by the two peer reviewers and for considering the revised manuscript for publication in BMC Family Practice.

The manuscript has been revised based on their comments and a point-by-point response *in italics* to their concerns follows.

**Reviewer: Winifred Paulis**
1. Is the question posed by the authors well defined?
   Clarification is necessary. I think the introduction, the Abstract and Title need significant rewriting. The research questions are secondary and with the present introduction I don’t see the need for answering these questions. Furthermore, I wonder if the design of the study is the correct one for answering these questions.

   *The introduction, abstract and title have been re-written to clarify and justify the research questions.*

2. Are the methods appropriate and well described?
   Methods of the trial are appropriate for the primary aims of the trial. I wonder if the data for the present study can be used to answer the questions in the present manuscript.
   One of the aims is “1. Assess the emotional impact on patients participating in a cluster randomized trial of vascular risk factor management in Australian general practice and;”
   This seems to me that you want to compare k-10 scores of people in the trial with comparable population not included in the trial.
   When reading the background I thought you wanted to measure the supposed negative impact of the health check and see if a lifestyle program can reverse the negative score. Then however, you need an extra measurement point directly after the health check.
   Was the baseline measurement before or after the health check?
   The control group gets the health check too right? So they have the supposed ‘negative’ impact too. Only the lifestyle intervention group improves on emotional distress. However, that was already known in literature, right? Or is this the real research question?
   Please explain the exact aim of the present analyses and how the methods of the trial help to answer...
these questions.
If the aim is to measure the effect of the intervention on emotional distress more information about the intervention would be useful.

The aim of the study was to measure the effect of the intervention on emotional (psychological) distress. This has been clarified in the introduction and methods. Additional details have been included in the methods to clarify the timing of the baseline measurement (before the health check) and provide more information about the intervention.

3. Are the data sound?

See above: Differences in emotional distress at twelve months between the groups is not answering the questions about emotional distress of one health check at t0. I think the analyses of k10 at baseline being associated with k10 at follow-up is not so useful. Besides, the authors first state that there are no baseline differences and later on the same page (page 12) note that they correct for baseline differences. Please explain.

“Adjusted for baseline differences” was included in error and has been removed. There were no significant differences in the measured variables at baseline between intervention and control groups.

Furthermore, the mediating effect of diet is only borderline significant. Did the authors correct for multiple testing?

We have reviewed the results and now consider that the mediating effect of diet is not significant. Multiple testing is not an issue as non-significant effects will not be significant after multiple testing.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

The tables are hard to interpret. Table 1 does not need the confidence intervals. Table 3 however, I think does need confidence intervals. I think a restructuring of Table 3 to the design of Table 4 for example would help to interpret the findings.

Confidence intervals have been removed from table 1. Table 3 now includes confidence intervals. It has also been simplified and is now in a similar format to table 4.

5. Are the discussion and conclusions well balanced and adequately supported by the data?

I think too much attention is given to the mediating effect of diet. The effect is non-significant and to me it is unclear if this can not be caused by chance due to multiple testing. It was not your aim to make a multilevel model and I feel the variance explained by the model is not that useful information.

Following a review of the results, we agree that the original manuscript did give too much attention to the mediating effect of diet change and have modified the manuscript accordingly. As we now consider that the mediating effect of diet change is not significant, multiple testing is not an issue as non-significant effects will not be significant after multiple testing.

The primary implication of adopting a cluster randomized design is that patients within any one cluster (such as a practice) are often more likely to respond in a similar manner and thus can no longer be assumed to act independently (outcomes of individuals within the same cluster or practice are likely to be correlated). Therefore we used cluster specific analytical methods. We included the variance explained by the model to show the strength of association between K10 and the independent variables.

Please focus the discussion on the main findings and how these relate to literature and what these findings implicate for practice.

The discussion has been revised.

6. Are limitations of the work clearly stated?

Limitations are stated

7. Do the authors clearly acknowledge any work upon which they are building, both published and
unpublished?
They refer to previously published articles. However only when reading the methods it became clear to me that this article presents secondary analyses.

The title, abstract and background have been revised to clarify the analysis of a secondary outcome. This analysis was planned in the original protocol so is not a secondary analysis of the trial data.

8. Do the title and abstract accurately convey what has been found?
Title and abstract should be rewritten

The title and abstract have been revised to clarify the aims and findings.

9. Is the writing acceptable?
English is ok. Clarification is needed. Clarify the exact purpose of these analyses and the meaning of the results found
Main points for clarification:
Title, Abstract and Background: it is unclear until the methods that these are secondary analyses of an already published trial. I feel that it is necessary to state that these are secondary analyses and report the aims of the trial as well as the aims of the secondary analyses separately.

The aims of the trial and the analysis of the secondary outcome have been stated in the background.

In the background and abstract “positive behaviour change” is addressed as the opposite of “disease risk awareness” I find this hard to follow. I think the background and the motivation for these secondary analyses should be clarified.

The background has been revised and clarified.

Minor: Page 16: ICC – number missing
We were unable to find the missing ICC however the manuscript has been carefully checked for all missing/ incorrect data.

Reviewer: Davorka Vrdoljak

The article is interesting for general practitioners, because lifestyle interventions aimed at cardiovascular risk factors is GP s everyday work worldwide. And yet, adherence is very low, especially in long term and CVD are still No 1 killer. So, the topic of the article is interesting, but according to my opinion some important revisions should be made:
• It is not very clearly stated how the participants were recruited: were they randomly taken from the e-base of those who attended GP practice in the preceding 12 months and then invited to come to practice for a health check up?
If so, were they invited by letter, e-mail, telephone? What was the response rate?
How many of the eligible responded? What were the main reasons for refusal? I strongly recommend drawing the flow-chart diagram (according to CONSORT statement for RCTs).

Additional details have been added to the manuscript to clarify that the participants were recruited by mail following random selection from practice records. The response rate (30.6%) was already provided (see first paragraph of the results). We did not collect reasons for refusal so are unable to report this data. This study is embedded within an already published cluster randomized controlled trial and the results are reporting the analysis of a secondary outcome. The RCT flow chart diagram was included in the publication of the results of the primary trial and the reference included.

• Why is the population aged>65 left out?
The majority of general practice patients aged over 64 years have already developed chronic disease so were not included. This has been added to the section about recruitment.
• What did the health check up consist of? Authors mentioned “assessing vascular risk”? They should describe in detail what that assessment included: BP measuring? SCORE chart? Framingham risk chart? Cholesterol levels? Something else?

The risk factors that were assessed include: blood pressure, lipids, fasting blood glucose, body mass index, waist circumference, smoking, nutrition, alcohol intake, and physical activity. Additional details about these have been added to the section describing the intervention.

• Blinding was not described: were participants blinded? Investigators, data collectors, statisticians?

This information had already been included in the section headed, “randomization”. A statistician who was not involved in the data collection used computer generated random numbers to randomly allocate practices to intervention and control groups, stratified by location. Data collection officers were blinded to the allocation of practices.
Patients were blinded to the practice allocation. This has been added to the section outlining the data collection.

• How did authors prevent information exchange between GPs from intervention and control group? How did they prevent each other from discussing what they were doing (contamination)?

The following statement has been added to the discussion: “Individual practices were randomized to intervention and control groups and it is unlikely that practitioners in the intervention group communicated with the control practices.”

• The main outcome measure of the study is based on self reporting which is a subjective and indirect measure and that important fact should be mentioned among the limitations of the study. Also, if each K10 form was not anonymous/coded but signed with the participants name, after 12 months the Hawthorne effect was still very probable. Meaning that knowing they have been watched, participants answered what investigators expected them to answer (that they changed their lifestyle to healthier one and did better).

The limitation of self-reported data had already been included in the limitations section within the discussion. An additional comment about the Hawthorne effect has been added as follows: “Self-reported data used in the study could have had significant response bias as the participants were aware that they were in a study. However this should have affected both intervention and control groups and not changed the findings of the study.”

• The subgroup analysis and assessment of the participants who most commonly gave answer „some of the time” and „all of the time” in K10 should be done and I strongly recommend it.

The number of participants who had a high K10 was very small and it is unlikely we can do any meaningful analysis. A sub-group analysis of this group is not related to our research question.

• Page 10 paragraph 1: “patients at level 1 clustered within GP at level 2”: write it more clearly, it is not understandable to the reader in this form.

This has been clarified as follows: “Patients (level 1) were clustered within general practices (level 2).”

• If bivariate analysis and multilevel analysis showed no difference in neither BMI, daily intake of fruit and vegetables, physical activity, smoking nor alcohol intake, is the marginally significant change in diet score according to mediation analysis a solid enough base to conclude that change in diet score mediated the reduction.
on distress? Please explain.

The results and conclusion has been reviewed and modified to clarify the findings. The change in K10 in the intervention group was not associated with change in any of the behavioural risk factors or BMI in the multiple-mediator model.

Yours sincerely

Suzanne McKenzie

Associate Professor Suzanne McKenzie