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

Authors:

Suzanne H McKenzie (suzanne.mckenzie1@jcu.edu.au)
Upali W Jayasinghe (upali.jay@unsw.edu.au)
Mahnaz Fanaian (mahnaz@uow.edu.au)
Megan Passey (Megan.Passey@ucrh.edu.au)
Mark F Harris (m.f.harris@unsw.edu.au)

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Author's response to reviews: see over
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Dr Marienke van Middelkoop
Associate Editor
BMC Family Practice
BioMed Central
Floor 6, 236 Gray’s Inn Road
London
WC1X8HB
United Kingdom

Dear Dr van Middelkoop

Re: MS:4060730510787094

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 editor’s comments received on 19 November and for considering the revised manuscript for publication in BMC Family Practice.

The manuscript has been revised based on the editor’s comments and a point-by-point response (in italics) to your concerns follow.

Editors comment:

The authors will have to make the following changes:

- Please provide a flow-chart for the overall trial. In particular, possible differential flow between intervention and control practices should be clarified. It seems to me that in the intervention arm there was a selection of high risk patients performed at the index visit, as opposed to the control arm which included all patients identified from the practice register. Please discuss (discussion section) how this affects analyses.

  A flow chart has been included- see Figure 1: Participant recruitment, flow and follow-up.

  The discussion has been expanded to clarify that the various components of the intervention and the possible effects these may have had on psychological distress. Please see pages 15 and 16.

- Sample size calculation: please make clear, that this is a secondary analysis that does not refer to the main study objective and the main outcome(s)

  This has been clarified as follows:

  “A priori sample size calculation for the secondary analysis on the K10 score confirmed…” Please see page 9.
- Missing values, patients not available at 12 months: please state how exactly your software treated these patients. I assume they were deleted, but clarification is needed here.

*This has been clarified on page 10, Statistical analysis. The multilevel multivariable analysis was conducted for the sub group of participants who had complete K10 data at 12 months using list-wise deletion of missing values.*

- Main study objective: analyses regarding the main study question have been published elsewhere. They can also be found in table 2. Please summarize these findings in the 1st paragraph of the discussion section, because the analysis presented in this paper can only be judged in the context of the main results of the trial.

*The first paragraph of the discussion has been modified as follows:
“*This analysis of a secondary outcome from a cluster randomized controlled trial of a general practice based health check to identify vascular risk factors, with referral of at risk patients to a lifestyle modification program demonstrated that the intervention reduced the psychological distress of the participants. The only primary outcome associated with the intervention, using multi-level, multi-variable analysis on an intention to treat basis and adjusted for patient and practice characteristics, time and cluster effects, was an increase in self-reported physical activity [8]. There was also a small weight reduction (1.06 kg) only among those attending the group program [8]. However the reduction in psychological distress was not mediated by a change in the behavioural risk factors or BMI in the multi-mediator model. This finding is in contrast to other studies in which an increase in physical activity and weight loss has been shown to reduce symptoms of anxiety and depression [9].”*

Yours sincerely

*Suzanne McKenzie*

Associate Professor Suzanne McKenzie