Author's response to reviews

Title: Randomized controlled trial on cardiovascular risk management by practice nurses supported by self-monitoring in primary care

Authors:

Ans H Tiessen (a.h.tiessen@umcg.nl)
Andries J Smit (a.j.smit@umcg.nl)
Jan Broer (jan.broer@hvd.groningen.nl)
Klaas H Groenier (k.h.groenier@umcg.nl)
Klaas van der Meer (klaas.van.der.meer@umcg.nl)

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Author's response to reviews: see over
Dear Dr. Smith,

We want to thank you and thank the reviewers for looking at the paper "Randomized controlled trial on cardiovascular risk management by practice nurses supported by self-monitoring".

In this letter we will give a point-by-point response to the comments made by the reviewers. Changes in the revised manuscript are visible in Microsoft Word-Track Changes. We also provide a manuscript without Track Changes, with the desired lay-out and revised reference list.

Reviewer 1 (J. Noordman):

1. We changed the phrase (...) practice nurses relieved the workload of general practitioners into assist and clarified that the references are about international studies concerning the role of practice nurses on cardiovascular risk (see page 4).

2. The Dutch Prevention Consultation study was performed after the execution of the SPRING study and focuses on screening rather than on treatment of cardiovascular risk factors. In the discussion we added a reference to the recent introduction of the Dutch Prevention Consultation and related the importance of studies on treatment effect to the Prevention Consultation. We introduced the following sentence in the Discussion: 'Effective treatment and follow-up are increasingly necessary as improved screening strategies like the recently introduced Dutch Prevention Consultation and similar initiatives elsewhere, such as the NHS Health Checks, have been developed. [25, 26] Because of these screening initiatives, increasing numbers of individuals with an identified elevated cardiovascular risk are expected.' (page 13)

3. The text is adjusted: more explicit formulation of the research question. The current text is (page 5): The research question that the SPRING study (Self-monitoring and Prevention of Risk factors by Nurse practitioners in the region of Groningen) aimed to answer, was: is cardiovascular risk management according to the Dutch GP’s Guideline, [9] supported by self-monitoring, more effective than standard cardiovascular risk management according to the same guideline, both carried out by practice nurses in primary care? Also more explanation on the Anglo-Dutch-Scandinavian approach of integrated lifestyle and drug treatment is added (page 4-5)

4. We compared usual care to usual care supported by self-monitoring. To inform the participants from the intervention group about self-monitoring and use the results of the self-monitoring for feedback and motivation during the treatment, a more pro-active approach and motivational interviewing techniques were part of the intervention program only. This is explained more clearly now in the abstract (page 2), the research question (page 5) and the methods (page 8). As a consequence both elements (self-monitoring and the pro-active approach with motivational interviewing techniques) can’t be determined separately. This is mentioned in the limitations section of the discussion. We included in the Discussion, page 15, the following sentence: 'The intervention was an integrated combination of self-monitoring and a more pro-active and motivational interviewing-based approach. The two group design made it impossible to determine the separate influence of these specific aspects of the intervention.'
5. General practices could participate if a practice nurse was active in the practice. All practice nurses of the participating practices participated in the study, except for two practice nurses (not working in the same practice), that switched to other practices during the study. Per location, one or two participating practice nurses were working and some nurses worked at several locations. Practices were located in the northern part of the Netherlands, both at the city of Groningen and in smaller cities/villages. We assume that this makes the sample representative, but no additional analyses were performed. (This additional information is not added to the paper, to avoid going into too much detail)

6. The training was developed by the SPRING research team. For each subject, specific experts were invited (cardiologist, dietician, trainer from Dutch smoking-cessation organization “STIVORO”, scientist (M. de Greeff) who developed an exercise counseling method supported by pedometers, researcher from the SPRING team (AT), etcetera). Motivational interviewing techniques were trained by M. de Greeff and the trainer from STIVORO (by means of both theory and role playing). Additional information on motivational interviewing and minimal intervention strategy is added to the methods section. We did not discuss motivational interviewing in the background section, as the motivational interviewing was not the goal of this research, as explained at 4.

7. We added the Prevention Consultation to “Comparison with existing literature” (see also above under 2 the newly introduced sentence). Motivational interviewing is added to “Methods”. Due to probable contamination of research conditions in both groups, motivational interviewing might have influenced both study groups. The goal of this study was not to determine the effect of motivational interviewing.

8. Practice nurses is in fact the correct description, but the study was already registered at the Dutch Trial Register that way.

9. The sentence is adjusted. Page 7: ‘65 is the maximum age for this risk calculator and was used for all participants aged ≥ 65 years.’

10. The levels of education are explained in the footnote of the table. Page 27: ‘Level of education: 1 = no education or only primary education 2 = lower secondary education, 3 = higher secondary education, 4 = college or university’

11. The use of the English language has been reviewed and improved.

12. We regard figure 2 as illustrative, but if desired, this figure can be omitted.

13. We added this hypothesis to the background-section.

Reviewer 2 (L. Glynn):
We agree that a cluster design would have been optimal. We made the choice for the current design with randomization at patient level, and motivated this choice in the discussion as follows: ‘Randomization at patient level was chosen to diminish the influence of differences between practices c.q. practice nurses. Another advantage was that it made the study more efficient, since individuals were the unit of analysis and only a limited number of practices was required with this design. All practice nurses had followed the training and were very motivated. The fact that the time investment in de intervention group was much higher, made us expect that contamination of research conditions would be limited. However, some degree of contamination might be present and may have diminished the difference between both groups.’ The training (which was free of charge) was the greatest motivation for the practice nurses for participation. With a cluster design, we would have needed many more practices and it would have been harder to motivate practices/practice nurses. The disadvantages of this design are discussed more extensively in the limitations section now.

Some information on number of visits was already present in the results:
The mean number of visits was 2.6 (SD 1.5) for the control group and 4.9 (SD 2.2) for the intervention group (p<.001) and the median duration of each visit was 27 (P25 –P75:20-33) minutes/visit for the intervention group and 23 (P25 –P75:19-30) for the control group (p=.048).

If this information is not sufficient to your opinion, please let us know. We added a comment on the number of visits to the discussion.

We changed the title according to your suggestion.
Yours sincerely, on behalf of all authors,

Corresponding author:

Ans Tiessen, general practitioner
Department of General Practice, FA21
University Medical Centre Groningen
PO Box 196, 9700 AD Groningen, the Netherlands
Phone: ++31 50 3632991
Fax: ++31 50 3632964
Email: a.h.tiessen@umcg.nl