Author's response to reviews

Title: Implementation of personalized self-management support using the Self Management Screening questionnaire SeMaS; a study protocol for a cluster randomized trial

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Subject: revised manuscript

Dear Editor-in-chief,

We would like to thank the reviewer for the comments and thank you for the opportunity to revise our manuscript. We feel encouraged by the general comments and we are sure that these helped to improve our manuscript. Below, we will describe the revisions we made based on this review.

1. For me, the concept of personalization is unclear as stated. The authors must give a clear definition of it and describe more clearly how self-management support can be personalized.
   
   We have elaborated on the concept of personalization in the Introduction. For comprehensiveness, we provide the adjusted section below.
   
   Personalization is defined as adjusting the self-management support to the individual characteristics of the patient. For example, in the case of low self-efficacy, the practice nurse and patient make an individual care plan with small steps in goal setting to enhance the self-efficacy of the patient.

2. More details are also needed about the development of the SeMaS questionnaire: which kinds of health professionals were involved? Are the relevant aspects of self-management included in the SeMaS are those identified by professionals and patients? How the categories of self-management capability were determined? Are these categories can be determined for every aspect of self-management or the category of a participant only represents an overall unspecific score? For example, can a participant be considered capable of self-management for one aspect and present major barriers for another?
   
   We provided more detail about the development of the SeMaS questionnaire in the Methods section, subheading Self Management Screening tool: SeMaS. Note that we are preparing a separate publication on this topic, because it is too extensive to include all details in this protocol. Nevertheless, we provided more information on the health care professionals involved, and how the relevant aspects of self-management were selected based on literature and the focus groups. Also, we explained the categories for self-management capability further in the Methods section, subheading Self Management Screening tool: SeMaS.

   For comprehensiveness, we also provide the adjusted sections here:
   
   For the development of SeMaS, we performed a broad, systematic literature search to identify reported aspects that are associated with successful or unsuccessful self-management. Second, we held focus groups with professionals from primary care (general practitioners, psychologist, dietitian, physiotherapist, pharmacist) and patients to identify the most important aspects that would determine the chance of successful self-management, based on their experience and the literature search. The final selection of aspects was made in the stakeholders group, combining the findings of the literature study and focus groups. The aspects were selected if they were mentioned in the focus group, found in the literature, and an instrument was available. Third, we developed a prototype of the SeMaS and tested it in 24 consults for applicability and readability, resulting in minor adjustments. Fourth, we validated the SeMaS in a test with 200 patients.

   Screening with SeMaS results in a personal profile on these aspects that are important for self management, divided in three categories per aspect: 1) capable of (more) self management, 2) capable of self management with minor barriers, and 3) major barrier(s) for (more) self management at this time. These categories were
based on the scoring categories of the original instruments, and face validity. SeMaS will support the creation of individual care plans, make it possible to influence barriers for self management, and support the referral to and participation in self management activities. The profile will provide an overview which aspects need special attention when undertaking self-management activities.

3. For the intervention, authors need to be more precise about the content of tailored advice to enhance self-management depending on the results of the SeMaS questionnaire. It would be very interesting that they explain the kind of advice that the practice nurse can give in each self-management aspect of the SeMaS. What are the theoretical foundations of these advices?

We elaborated on the tailored advice in the Methods section, subheading Self-management support. We found it too extensive to describe all advices for all aspects in this article, and therefore we present some examples. However, the manual is available for review upon request. For comprehensiveness, the adjusted section is provided here:

For each factor, the manual provides advice to help support the patient in case of a barrier. For example, when a patient experiences low social support, the practice nurse and the patient search for additional social support, or find ways to cope with this low support. For a patient with low self efficacy, the advice is to set a goal with the patient with a high chance of success, to foster the self efficacy. When patients show major barriers for self-management, the manual gives instruction and support for the practice nurse to work on this barrier before starting with self-management activities.

When no barrier is present, the practice nurse is advised to create an individual care plan with the patient, and refer to the self-management interventions if applicable. Also, the manual contains a card with the possible self-management interventions, categorized by the skills that are asked in the SeMaS questionnaire (computer, group, self care). The manual was developed by the research team and reviewed by the stakeholders group. The advices were based on the method of “actual practice and maintenance”, which is used in the care group.

4. A logic model of intervention would ease understanding.

We attached a logic model (Figure 1) as a separate file with the original manuscript. We expect this logic model will clarify the study presented.

5. How the SeMaS can support the self-management intervention in the creation of an individual care plan, in influencing barriers and foster referral and participation in self-management activities? What will be the advice in the case of patient presenting majors barriers for self-management?

We adjusted the manuscript, and further elaborated on these issues in the Methods section (see also question 3). Practice nurses all received a manual as a practical tool. This will help them to find solutions to overcome the barriers or to adjust the individual care plan in such a way that the barrier is taken into account.

6. For the outcomes, how the review of the medical records for data analysis will be done and by whom?

Medical record data extraction will be performed by the data management agency of the care group. They can provide anonymous data of the participating patients from the research period. The research team will perform medical record data analysis. We added this information in the Methods section, subheading Patients.

7. Authors need to give more details about the content of the evaluation questionnaire they plan to use. What is the content of this questionnaire, how it was developed, and how participants will fill it?
We elaborated on this issue in Outcomes section. We also provide the adjusted section below.

To evaluate whether the SeMaS was discussed, and which actions were undertaken with the patient, an evaluation questionnaire was newly developed. Patients will be asked whether the SeMaS profile was discussed and which of the psychosocial aspects from SeMaS were covered during the consult. The current self-management activities, and whether the patient received information, advice or a referral to interventions for lifestyle or self care will also be covered in the questionnaire. The participating patients will receive the questionnaire one week after the consultation.

8. How will be assessed or measured social support and chronic conditions, considered as covariates?
   The social support is measured in the SeMaS questionnaire based on the short scale of social support, and the chronic conditions will be assessed from the medical record data. We added this information in the Analysis section.

9. About sample size calculation and statistical analysis, I recommend first that authors make adjustments to these sections and after, that their new version will be seen by an expert statistician. The first adjustment to be made is that the authors need to be more specific about ways by which they consider the particular methodological challenges of cluster randomization. As it is explained in the submitted protocol, the sample size calculation does not seem to consider the effect of cluster on the power of the study.
   We explained why we chose for cluster randomization in the first part of the Methods section. We also provide this section below.
   Also, the sample size calculation does consider the effect of cluster on the power by using the estimated intraclass correlation in the calculation of the sample size. We adjusted this in the Methods section, subheading Sample size, and provide the adjusted section below.
   Since practice nurses were trained in the SeMaS method, the intervention was implemented at general practice level instead of patient level. Another problem in this study was the risk of contamination when control patients would be exposed to elements of the intervention. Therefore, randomizing all patients within a general practice (=cluster) to either the intervention or the control was the most logical choice.
   For the power calculations, we assume an intraclass correlation coefficient (ICC) of 0.05 based on the article of Campbell et al. This article states that an ICC of 0-0.5 is normal for outcomes in primary care research. To reach a power of 80% and alpha of 0.05, and considering ICC 0.05, at least 25 patients per practice are needed when using 15 practices.

10. Second, the analysis plan does not explain how the effect of cluster will be calculated.
   We used the reference of Campbell et al. (2000) to estimate the intraclass correlation (ICC) for this study. In the article of Campbell et al. (2000) they state that an ICC of 0-0.5 is normal for outcomes in primary care research. We added the reference and this explanation to the Sample size section.
   The effect of cluster will be determined by performing a multilevel regression analysis without explaining variables. With this analysis, we can determine the variance on the different levels. Subsequently, we can determine the intraclass correlation of this study: ICC= cluster variance/(cluster variance + patients variance)

11. Thirdly, authors need to specify how they will determine that a patient present a positive behavior change in his lifestyle.
   We have adjusted the manuscript to state this more clearly. See the Outcomes section.
The secondary outcomes are defined as:
- RAPA: difference in the average score between control and intervention at T0 and T1.
- REAP-S: difference in the average score between control and intervention at T0 and T1.
- smoking: difference in the number of smoking patients between control and intervention at T0 and T1.

12. Fourth, regression analysis is not suitable to examine difference in scores between subgroups on the two measurement times.
   In the manuscript, we stated more clearly that we will perform a multilevel covariance analysis in the Analysis section.

13. Last, the authors are unclear about why they want to examine the test-retest reliability of the SeMaS. Also, the way they propose to do it, by administering the SeMaS at a subsample of 50 participants of the control group two weeks after returning the first questionnaire, can influence the result for these participants. Can they consider measuring test-retest reliability only at six-month at the end of the observation period? This analysis can also be not described in the protocol because it is not the focus of the study.
   We agree with the reviewer and we deleted this potentially confusing issue.

14. How the authors plan to do analysis for the triangulation of the data?
   We elaborated on this issue in the Outcomes section, and provide the adjusted section below.
   Per dimension we will assess whether this was a barrier in the profile, and whether it is mentioned in the medical record and the evaluative questionnaire. If so, this will be scored as ‘proof of attention’. We will assess the percentage of patients with a barrier and proof of attention for that dimension/barrier.

Discretionary Revisions

15. A graphic representation of the design and timeline data collection can help the understanding.
   A graphic representation of the design and timeline is attached as a separate figure (Figure 2).

We hope these adjustments are satisfactory for answering all the reviewer’s concerns, and for publication of the manuscript. We will be happy to answer any remaining questions.

Yours sincerely,

Nathalie Eikelenboom