Author's response to reviews

Title: Implementation of Internet-based preventive interventions for depression and anxiety: role of support? The design of a randomized controlled trial.

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Version: 3 Date: 6 May 2009

Author's response to reviews:

Revisions of the study protocol “Implementation of Internet-based preventive interventions for depression and anxiety: role of support? The design of a randomized controlled trial.” according to the points raised by the editorial board.

MS: 1624137634262112

We thank the editorial board for their careful comments.

Comment a:
In recruitment of participants, will only participants from the Netherlands be considered as the banner adverts will be placed in Dutch medical sites but also in Google. This is not very clear.

Reply:
The banner adverts in Dutch medical sites as well as in Google will be in Dutch. Participants from outside the Netherlands can apply for the study as well, however they have to have sufficient knowledge of the Dutch language to be able to participate in the study. We have added the following sentence to the Method section, paragraph ‘recruitment’ (page 6): “All advertisements are in Dutch”.

And in paragraph ‘inclusion and exclusion criteria’ page 5: “Participants who return the informed consent will be included in the study if they: 1) are 18 years or older…and 5) have sufficient knowledge of the Dutch language”.

Comment b:
One of the additional secondary outcomes is problem solving skills (page 8 under outcomes); however, under instruments no mention is made about how this will be assessed. It would be useful to see if participants did indeed improve problem solving ability and that correlated with reduction in anxiety and depression scores and that a non-specific effect of being enrolled in the study was not the reason
for improvement; as maintenance of treatment gains may be also affected.

Reply:
We have included the SPSI-R in the manuscript. The following paragraph is added to the revised manuscript:

“Problem solving skills
The 52-item Social Problem-Solving Inventory-Revised (SPSI-R; 51) is used for measuring problem solving skills. Three of the five scales ((Positive problem Orientation (PPO; five items), Negative Problem Orientation (NPO; 10 items), and Avoidance Style (AS; seven items) showed to be sensitive for change [52] and were therefore included in the study. Good internal consistency and test retest reliability are reported for all SPSI-R subscales within the manual [53].”

Comment c:
Would there be any interim stopping rules for participants (increasing suicidal ideation or worsening depression scores) or for the study (large numbers of drop-outs in one of the arms)?

Reply:
There will be no interim stopping rules for participants nor for the study.

With respect to the participants we like to stress that this study aims at people with mild to moderate symptoms of depression. We exclude participants before entering the program if they have severe symptoms of depression or have suicidal ideation. Furthermore, we have no reason to believe that depression will worsen due to this course. People are also free to seek additional help if they want to. In fact this is encouraged in case there are signs (in the e-mail contact) that there are any severe problems which go beyond the scope of the intervention (e.g. physical abuse).

We don’t have stopping rules for the study because the difference in drop-out rate is one of our primary endpoints of this study. Furthermore, even in case the drop-out is high in one of the arms, the intervention might still be beneficial to those who remain in the study. After all, it is unlikely that drop-out will be caused by ‘side effects’. It is more likely that drop-out is due to lack of time and motivation.