Author's response to reviews

Title: Web-based guided self-help for employees with depressive symptoms (Happy@Work): design of a randomized controlled trial

Authors:

Anna S Geraedts (a.s.geraedts@vu.nl)
Annet M Kleiboer (a.m.kleiboer@vu.nl)
Noortje M Wiezer (noortje.wiezer@tno.nl)
Willem van Mechelen (w.vanmechelen@vumc.nl)
Pim Cuijpers (p.cuijpers@vu.nl)

Version: 4 Date: 28 November 2012

Author's response to reviews: see over
To: BMC Psychiatry

Date: 28 November 2012

Dear Editor,

In this letter we respond to the reviewers’ comments on the paper entitled ‘Web-based guided self-help for employees with depressive symptoms (Happy@Work): design of a randomized controlled trial’ (MS 1166300509677657).

We would like to thank you, the editor, for giving us the opportunity to revise and resubmit the manuscript and the reviewers for their valuable comments. Please find below a point-to-point description of the adjustments we have made to the manuscript and our responses to the reviewers comments. I hope we have answered all questions to your satisfaction.

Yours sincerely,

Anna Geraedts
PhD-student
Vrije University Amsterdam
Van der Boechorststraat 1, 1081 BT Amsterdam
The Netherlands
Phone: +31 20 5987451/ Fax: +31 20 5988758
Email: a.s.geraedts@vu.nl

Reviewer 1: Anette Kersting

Major compulsory revisions:
- As suggested by the reviewer, the background (page 3) now includes prevalence numbers of depression in the Dutch population.
- ‘€’ signs are now used consistently on page 3.
- The reviewer commented that we started several sentences with ‘The ..’ on page 7/8 and advised us to vary more to improve the readability of the text. We agree and have rewritten this section.

- More information about the guidance that participants receive during the intervention was requested. We have now explained in more detail what the guidance involves on page 7 and 8.

Minor essential revision:
- We have removed an extra space in citation 41.

Reviewer 2: Jordan Silberman

Major compulsory revisions:
- The reviewer recommended using multi-level techniques to account for non-independence in our data structure. We agree that non-independence may be an issue and we will use multi-level-analyses when needed, this was not clearly mentioned in the manuscript. Before we start analysing the data, we will calculate the intra-class correlation to determine if independence is an issue in our data. If so, we will use multi-level regression analyses. We have now mentioned this in the statistical analyses section.

- Next, the reviewer commented on the control group we use in our study (CAU). A related comments was made by reviewer 3 and we have addressed both comments together below (see minor essential revisions reviewer 3).

Minor essential revision:
- Reviewer 2 asked for a more detailed description of the methods proposed for testing the mediation. We have now included these in the statistical analysis section.

Discretionary revisions:
- It was noted that we use different recall windows at different assessments. This is true. However, we need these recall periods to make an accurate cost-effectiveness analyses via the per capita costs method, the standard method used in the Netherlands.

- The reviewer suggested the addition of a questionnaire measuring the number, frequency and severity of personal problems. This is a good suggestion that we considered when we
designed the trial. However, we did not want to burden the participants too much by using a very lengthy assessment and decided therefore not to include such a questionnaire.

- Finally, the reviewer included several hand-written suggestions and comments in the text. We checked these thoroughly and where appropriate made changes to the text.

Reviewer 3: Bo Netterstrøm

Minor essential revisions:
- The reviewer asked why absenteeism is an exclusion criteria. In the Netherlands, employees with depression who are also on sick leave receive standard treatment from the occupational health service (see the references in our manuscript). However, there is no standard treatment for employees with depressive symptoms that are not sick listed. Happy@Work is developed for this group of people and therefore we exclude people who are sick listed. Employees that are already receiving treatment from the occupational health service will also be excluded to prevent co-intervention because the guidance during Happy@Work is provided by employees from the occupational health service. Please note that we only exclude people who receive help from the occupational health service. We do not exclude people who already receive treatment from other health care providers; people are free to seek any help they want.
- Further, it is important to mention that we do not only include employees with mild symptoms of depression. To be eligible to take part in the study, a score of 16 or higher on the CES-D is required but there is no maximum score. Ample studies have shown that mental health can be beneficial for people with mild and more severe depressive symptoms [1]. We believe that we will recruit a heterogeneous study population of employees with mild to moderate symptoms of depression who have in common that they are not sick listed. When we notice that symptoms worsen during the study or that participants are suicidal, we will contact them and refer them to more specialized healthcare if needed.
- The reviewer mentioned that it was not clear when the CIDI interview will be assessed. This is now more clearly described in the ‘clinical interview’ part on page 11.
- Finally, the reviewer questioned our control group because we allow people to seek help. Reviewer 2 in contrast commented that we just control for the passage of time and advised us to modify the control group (e.g. placebo-control group). We will explain the rationale behind this decision. We have chosen to use a care-as-usual control group because of a
lack of standard treatment for our study population and we wanted to examine if our
treatment would add something to the regular care that people could seek. There is also an
ethical component related to this and that is that we are not allowed to refuse participants
to seek treatment. We believe that a care-as-usual control group is a better option than for
example a waiting-list control group, which has its own problems [2]. However, we do ask
for the type of (additional) treatment that participants received at each assessment so we
can control for treatment use in our analyses.

References:

get low-intensity treatments for depression? An individual patient data meta-analysis.
Submitted

selection and design of control conditions for randomized controlled trials of