Reviewer's report

Title: Effectiveness and cost-effectiveness of guided online treatment for patients with major depressive disorder on a waiting list for psychotherapy: study protocol of a randomized controlled trial

Version: 1 Date: 5 October 2013

Reviewer: Wai Tong Chien

Reviewer's report:

It is an interesting and important proposed research on the evaluation of online self help program for people with depression in the Netherlands. There are a few concerns to be considered for improvements of your protocol as follows:

Major Compulsory revisions:

1. Background: more elaborations needed on the worldwide scene on the waiting time of first consultation and treatments for depression and the reasons for the long waiting time; briefly introduce the rationale or important evidence on the effectiveness of internet based self help programme for depression and other major mental illnesses.

2. It is also important to introduce the development of online self help program with adequate evidence or theoretical support

3. Sample and study setting: Describe in more details of the total patient population and proportions of waiting time from 7 to 16 weeks in the two clinics, the similarities of services or policies between the two clinics, the triage of depression condition and suicide risks, and how to select those with less depressive clients for this study and how to determine in which level of depression to be included or excluded. In addition, in the last paragraph of intervention section, please explain how similar or standard the policy, protocol used, and practice in the two clinics under study.

4. As mentioned above, the details of the development of the intervention should be presented and how the existing program brought from other studies are appropriate or relevant to your study? Any modification or expert review needed before use?

5. It is important to clarify whether the main difference between treatment and control group is the guidance of the coach rather than the self help manual, as mentioned in the control condition section. If yes, the guidance or coaching will not be minimal as said in the last paragraph of the intervention section.

6. As there are variations of waiting period for clients under study, there should be consideration of such covariance in outcome analysis, as well as subgroup analysis on such differences, if any outcome found significant results.

7. In relation this data analysis, those demographic and clinical characteristics as well as the baseline scores of the outcome measures should be considered as
covariants for ANOVA test. Subgroup analyses in terms of different characteristics of interest should also be considered for those outcomes with significant results found.

8. Discussion: any comments on the long waiting time for initial treatment in the country or other parts of the world should be given. Also, any comments on the integration of the internet programme with standard care during the treatment process besides it is being used prior to treatment starting. Any thoughts about the continuation of the program during treatment process or follow up or as the boosters.

Minor essential revisions:
1. Tell use the reasons why the online is appropriate only before the standard treatments, but not in adjunct to and integrated into the treatment process; this is also interesting to know why the program would not use continuously within the 12 months follow up.

2. Not clear whether you will exclude all those with comorbidities of other mental illnesses.

3. Give reference to the 6-step approach used in the intervention.

4. What is meant by the coaches will provide minimal additional guidance within 3 days after receiving questions from the clients? Is there any guideline or protocol to guide their guidance or action to be done of consistency and integrity of the intervention used.

5. Any actions or precautions for high attrition rates or changes in policy or practices in the two clinics, e.g., the author mentioned that the waiting time period can be adjusted or changes suddenly.

6. Block randomisation in subject selection has been described, but not clear whether subject assignment intoe groups will be in blocks or not. Also, who is the assessor of the outcomes?

7. There will be differences in the method of questionnaire administration between baseline and post tests, one by phone and others by online completion. Why and how to ensure such differences in instrument administration?

8. The instrument used should be clearly described; the reliability and validity of them should be presented. It is not clear whether these tools are in Dutch or English. Will a psychiatrist or Anyone trained to administer the CIDI? Why are there two satisfaction tools and what are their differences in terms of outcomes or understanding about satisfaction with the interventions? Also, it is unclear how to rate or score the satisfaction with the internet scale (i.e., AOCSQ).

9. Sample size calculation section can be moved to the section after sample recruitment.

10. The limitations of the proposed study can be presented in a separate section
and the limitations on the inclusion of mild or less severe depression and limit control on the two clinic environment and practice and the therapists’ intervention after online program (not only when they intentionally reduce the number of treatment needed but on the other hand, they may increase the treatments when knowing that they are clients to be tested for the effect of online intervention) should be discussed clearly.

Discretionary revisions:
1. The content and format of the intervention can be summarised and clearly presented in a table.
2. As the clients selected for this study is not so severe in depressive condition, then justify why your consider follow up for 12 months. Any reference for your consideration?
3. As mentioned, the 20% attrition rate estimation should be too conservative if not other evidence to support such estimation. Please further elaborate.
4. In table 1, it appears that some measures will not assessed at follow ups (including HADS, ISI, CAGE and F2F at 6-month). Any reasons for these not being measured?

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I do not have any conflict of interest in terms of any of the issues mentioned in the above questions.