Reviewer's report

Title: Developing stepped care treatment for depression (STEPS): protocol for a mixed methods study involving a pilot randomised controlled trial and qualitative interviews

Version: 3 Date: 15 September 2014

Reviewer: Tine Nordgreen

Reviewer's report:

The proposed study has a high relevance as national guidelines increasingly recommend stepped care as a cost-effective way to deliver treatment for common mental disorders. However, little is known about the effects of such models. The protocol describes a two-arm randomized controlled pilot trial comparing the effects of CBT-based stepped care to high-intensity treatment. The stepped care consists of two steps: 1. guided self-help using written material and 5 short (maximum 30 minutes) telephone or face-to-face consultations and 2. manualized 8-20 session face-to-face consultations of maximum 16 weeks.

Patients will be recruited from one IAPT clinic.

Minor essential revisions:

In the Introduction

The uncertainties regarding the effects of stepped care are well documented in the introduction. This makes the need for this study clear. However, it would be helpful for the reader if you restructure your introduction. The main research questions may be introduced earlier and more clear in order to lead the reader through the introduction. It is also unclear whether you need to differentiate between your own work and the literature in general.

In the Methods/Design

Setting

The IAPT service selected is not described. As IAPT services differentiate regarding the proportion of patients being stepped up and not (0-50%) it would be interesting and relevant to know the “culture” for stepping up at the specific IAPT service. Please describe the setting in further detail.

Stepped care

The evidence for the guided self-help material is unclear as the references refer to computerized interventions. Please clarify.

It is not described how to proceed with patients who do not adhere to the first step of guided self-help. Will they be invited to step up or not? Please clarify

Quantitative analysis

In the text it is stated that data will be analyzed with an intention-to-treat
approach. In the Figure it is stated that only patients with available data at follow-up will be analyzed. Please clarify.

Discussion
Potential strengths and limitations in the design should be discussed.

Discretionary Revisions:
Setting
IAPT services differentiate regarding the proportion of patients being stepped up and not (0-50%). As this variability is acknowledged I wonder if it you may consider to recruit two IAPT clinics; one at each extreme on the stepping-up scale? This would inform a future large scale RCT and make the pilot study an even greater contribution to the existing knowledge-base.

Stepped care
Patients may decide that all guided self-help consultation may be face to face. To our clinical experience therapists’ preference may be as significant as patients’ preferences when it comes to preferring face-to-face contact during guided self-help and regarding stepping up or not. In this trial this is especially relevant to the two groups of patients were stepping up may be decided based on patients wishes. Information about the therapists’ wishes is to our experience also relevant.

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 declare that I have no competing interests