Author's response to reviews

Title: Computerised Therapy for Depression with Clinician vs. Assistant and Brief vs. Extended Phone Support: Protocol for a Factorial RCT

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Author's response to reviews: see over
The Editorial Team

Trials

Dear Editors,

Re: Computerised Therapy for Depression with Clinician vs. Assistant and Brief vs. Extended Phone Support: Protocol for a Factorial RCT, by Gega et al

Please accept our revised manuscript for the trial protocol above; changes in the manuscript are highlighted in grey. Also, please find our responses to your reviewer’s comments below. We confirm that this paper contains original work and has never been submitted for publication elsewhere. Patient recruitment was ongoing at the time of the manuscript’s submission to the journal and data collection will not be completed until September 2012.

We look forward to hearing your final decision.

Yours sincerely,

Dr. Lina Gega & Co-authors
AUTHORS’ RESPONSES TO REVIEWER’S REPORT:

Reviewer’s comment:
Overall, it is well-written and contains the necessary information. One area that should be clarified is the lost-to-follow-up/missing data. The authors indicate that the necessary sample size is 140, but because they expect about 30% attrition, they will randomize 200. There is a discussion of handling small amounts of missing items within individual scales (page 18), but not how the complete absence (or large absence) of data from as much as 30% of the participants will be handled. How will they conduct an intention-to-treat analysis with that much missing information?

Authors’ response:
The reviewer is correct in that we plan an intention-to-treat analysis only in the sense that in our primary analysis patients will be analysed in the groups to which they had been randomly assigned regardless of the actual treatment they received. We will only include non-missing data in our primary analysis. The baseline characteristics of patients with missing and non-missing data will be compared and this information will be used as a basis for multiple imputations in sensitivity analyses (Altman, 2009). To this end, we have added the following paragraph into the manuscript (p.18): “The primary analysis will include patients in the groups to which they had been randomly assigned regardless of the actual treatment they received. The primary analysis will include non-missing data only but the baseline characteristics of missing and non-missing values will be compared to assess the pattern of missing data. Further, as recommended by Altman, sensitivity analyses will be performed by employing multiple imputation techniques. Where a few items within a scale are missing for an individual participant we will impute using that person’s scale average.”

Reviewer’s comment:
Also, the authors say that the study will be complete in June, 2012. Is it indeed completed? If so, what is the status of a results publication?

Authors’ response:
Under the heading “Trial Status” in the manuscript (p.24) we have added the following statement: “Patient recruitment was ongoing at the time of the manuscript’s submission and it stopped in June 2012. Data collection will continue until September 2012”. The study’s main results will not be ready for submission to a peer-reviewed journal till November 2012.