Author's response to reviews

Title: Short-term, intensive psychodynamic group therapy versus cognitive-behavioral group therapy in day treatment of anxiety disorders and comorbid depressive or personality disorders: study protocol for a randomized controlled trial.

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Prof. Altman
Editor, *Trials*
University of Oxford, UK

Dear Editor and Reviewer,

we are pleased to resubmit for publication the revised version of our paper “Short-term, intensive psychodynamic group therapy versus cognitive-behavioral group therapy in day treatment of anxiety disorders and comorbid depressive or personality disorders: study protocol for a randomized controlled trial.” We appreciated the constructive criticisms of the Editor and the Reviewers. We have addressed each of their concerns as outlined below.

**Editor comments:**

1. Please ensure the title conforms to journal style for study protocol articles. The title should follow the format “________: study protocol for a randomized controlled trial.” Please note that the title in the submission system should match that of your manuscript.

   *We modified the title according to the journal style: Short-term, intensive psychodynamic group therapy versus cognitive-behavioral group therapy in day treatment of severe anxiety disorders and comorbid depressive or personality disorders: study protocol for a randomized controlled trial.*

2. Please include the date your study was registered with your trial registration number at the end of the Abstract.
3. Please include a more detailed statement in your Methods section explaining that you obtained informed consent from each participant.

We added the following information: Participation is voluntary. Informed consent is given in writing and with personal signatures. Participants may withdraw their informed consent at any time, without any consequences for their treatment. Randomization will take place after informed consent is obtained.

4. Please include the reference number for your ethical approval.

We added this information.

5. Please mention each author individually in your Authors’ Contributions section. We suggest the following kind of format (please use initials to refer to each author’s contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

We modified this paragraph.

Reviewer comments:

1. The authors need to explain (and include these n’s in their Consort Flow Chart) how many patients will be in each condition (psychodynamic, CBT, wait-list).

We included the numbers in the flow chart.
2. The authors need to explain what constitutes “usual care” in this day-treatment service. Are any other groups or individual treatments offered in the 90-minute slots that are filled with either CBT or PDT in this trial?

There are no other groups or individual treatments offered in the 90-minute slots that are filled with either CBT or PDT in this trial. We attempted to clarify this in the following fashion: Psychodynamic and cognitive-behavioral group psychotherapy has been delivered at the Wola Center since 2011. This method was developed by the current team during last ten years in other clinical setting.

3. Further clarification is needed with regards to the wait-list group. Are they being delayed access to “all” day-treatment care or only to participation in the CBT or PDT groups. While they are waiting for day-treatment care, are they carrying on in treatment in another clinic? Could they be offered another treatment by another clinic while they are on the wait-list for the day treatment program? Please explain what happens to patients in the wait-list group at the end of 12 weeks, i.e. what treatments are they offered?

We clarified this with this additional information: Patients from the wait-list will continue pharmacological treatment and will take part in supportive consultations monthly. Crisis intervention will be offered when needed. In accordance with the informed consent they will not carry on in treatment in another clinic while waiting for day-treatment care. After the waiting period they will be randomized into two intervention groups.

4. When patients in the CBT or PDT groups are finished with their 12 weeks of group therapy as in the day treatment unit, what happens to them? Are they discharged to some other unit? Do they carry on at the day-treatment unit but in “usual care”? What happens if they are not improved? Do they carry on in the groups? Are they asked not to engage in any other treatments during the follow-up period?

We added the following information: As stated in the informed consent patients will be encouraged not to begin any other therapy in the 3 months period after the treatment. In cases of acute deterioration crisis intervention will be offered. Further treatment choices of the patents will not be controlled.

5. As the patients in the wait-list group are “released” from the study at the end of 12 weeks, the comparison between the active treatments (CBT and PDT) and this control group
must be at 12 weeks. This needs to be specified in the manuscript – or if I am incorrect this needs clarification.

We added the following information: Patients in the wait-list group will have one additional assessment at the end of the 12-week waiting.

6. In the statistical analyses section you say that you will use repeated measures ANOVA and multiple regression to analyze outcome. First, it is important to specify which of these statistical approaches is used for which specific primary outcome measures, or more importantly which is the statistical procedure for the “headline” outcome assessment, and again what is the final end-point for assessing outcome, i.e. post-treatment or follow-up. You list as one of your primary outcome measures the Mini-5. Neither regression nor repeated measures are particularly suited to analyzing dichotomous outcomes (i.e. above/below diagnostic threshold). How would this be analyzed?

We specified which statistical methods will be used for which outcome measures and what are the assessment points.

7. I believe your sample size calculation is based on your using repeated measure ANOVA (RM-ANOVA) for the main outcome analyses, a comparison between CBT vs WL and separately PDT vs WL. It is an acceptable choice but I think it was chosen to lower your overall sample size needs and represents a significant threat to your having sufficient power to do all of the primary and secondary analyses you plan. That warrants comment, if not in the manuscript then as part of the response to this review. Nevertheless, this RM-ANOVA model is under-specified in the statistical analyses and sample size calculation paragraphs. Please specify how many measurement points you are using (I assume pre- and post-treatment) and whether your primary planned comparison is the interaction between the Time (pre-to-post change on anxiety) Group variables (CBT vs WL; PDT vs WL) or if it is the main effect for Group. I believe it should be the former. Thus you need to be clearer about the model you used in G-Power and the parameters you entered beyond Cohen’s $d = 0.35$, one-side alpha $= .05$, and power $= .80$ (i.e., number of assessment points, correlation between the primary outcome measure(s) assessed at pre and post-treatment and whether you specifically powered for the interaction or main effects).
We added this information. We specified 3 measurement points: pre- post and follow up. We also specified our primary planned comparison. We clarified the model used in G-Power.

8. Related to the above paragraphs, the assumptions about the effect size difference between active treatment and wait-list, and between the active treatments requires further justification. The authors have the choice to add the additional information into the introduction or to include it in the statistical analysis or sample size calculations – but they need to specify the controlled and/or uncontrolled effect sizes for group PDT and group CBT for anxiety (and personality disorders) from previous studies, citing these studies. For example they should report the relevant controlled effect sizes from Arnevik et al 2009 which tests the group psychodynamic therapy similar (?) to what is used here. They should also report the range of controlled or uncontrolled effect sizes for group psychodynamic therapy for anxiety and personality disorders from other studies, whether delivered in a day-patient setting or not. They should report the range of effect sizes for day treatment reported in the Cochrane Review. The same should be done for group, trans-diagnostic CBT for anxiety disorders and personality disorders. I am not requesting an exhaustive review here but the assumptions the authors use regarding differences between the two groups are not clarified or substantiated and 1-2 paragraphs would address this issue.

We added effect sizes from other studies and calculated sample size based on this data.

9. Related to above paragraph, I think the authors need to consider some re-working of the introductory paragraph. It is extremely hard to reach a conclusion based on this review that one would expect either PDT or CBT in group format delivered in a day-treatment setting to be superior to no-treatment – or that the difference between these two groups would be in the order of \( d = 0.25 \). Why was this trial not powered as an equivalence trial? Furthermore, while the day-treatment center aspect of this trial is “unique” it seems strange to focus the review only on studies comparing “psychotherapy” delivered in day-treatment settings - where the treatment is almost always ‘eclectic’ or ‘unspecified’ – rather than an additional paragraph or two on the efficacy of group PDT and group, trans-diagnostic CBT for anxiety and personality disorders. Why should the efficacy of either of these two protocolized, theory-driven and evidence-based treatments be diminished (and not enhanced) when delivered intensively over 12 weeks in a day-treatment center relative to their efficacy when delivered in outpatient or inpatient settings? It seems to me
that you are undertaking a phase 1 trial of group PDT vs WL and group CBT for anxiety – both delivered intensively. The appropriate background literature also includes the effect sizes for these two treatment approaches when delivered in a range of different settings. Alternatively, you need to provide some literature stating that patients in day-treatment centers are somehow fundamentally different from those recruited for previous trials of PDT or CBT for anxiety.

We have rewritten the introduction and have explained more precisely that the populations of patients treated is specific – with severe psychopathology and that mode of treatment is also very specific – it is based on two 90-minute session each of CBT or PD a day in closed groups, for 12 weeks, in morning hours. This therapy setting requires 3 month of seek leave. We think that it is somewhat monotherapeutic than eclectic. However, unspecific group psychotherapy factors have some impact on the final results of both therapies.

We are really planning a phase 1 trial of group PDT vs WL and group CBT vs WL. However, if it is documented for both types of psychotherapy, we are going to compare results of them. The basic goal is related with reality of Polish Health Care System, where similar, but not so precisely described PD and CBT therapies are widely applied.

The comparison of the efficacy of the intensive psychotherapy in daily unit setting with psychotherapy in outpatient or impatient setting it is reasonably next stage of research. However, the documentation of the effectiveness of the psychotherapy in daily unit setting seems to be justified first step.

We appreciate all above comments. Thank you for your time and consideration.

Sincerely,

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