Reviewer's report

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 clinical trial

Version: 1 Date: 5 May 2015

Reviewer: Sean Perrin

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Major Compulsory Revisions

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).

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?

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?

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?

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.

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?

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).

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.

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.

Minor Compulsory Revisions - None.
Discretionary Revisions - None.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I have no competing interests whatsoever.