Reviewer's report

Title: Does treatment of subsyndromal depression improve depression- and diabetes-related outcomes? A randomised controlled comparison of psychoeducation, physical exercise and diabetes re-education

Version: 2
Date: 30 April 2015
Reviewer: Sarah Hetrick

Reviewer's report:

This is an excellent study and a very well written manuscript that was a pleasure to read. There are a few issues that need to be addressed to ensure that this manuscript is of the high standard required by Trials for publication.

Major compulsory revisions:

1. There is very limited description of what this “control group” received in terms of how many sessions (only in the discussion is it clear that it was only one session), the length of session(s), and I wasn’t clear exactly was being discussed in terms of ‘current laboratory findings” (was this research findings or findings of the investigations done on each individual?). Further description of this arm is required so that it is clear what the nature of this arm is.

2. Related, there is considerable inconsistency in describing this “control group”; at times the authors describe “three behavioural interventions” (pg 4), “three treatment arms” (pg 8 and in the discussion), but they also state that they use a “control group” (abstract), and a “minimal intervention” (pg 6). This needs to be addressed by the use of an accurate and consistent term throughout.

3. There are significant implications with regard to points 1 and 2 above in terms of how the results of the trial are understood i.e. if there is no difference between three intervention groups, one can implement any of the interventions tested that might best suit the population you are working with. However, if as I read it, there are no differences between the two intervention arms and a control group or minimal intervention, then one would question whether an intervention was justified and the conclusions of the study should not be as stated “that patients were responsive to treatment”. The second two paragraphs on page 13, therefore, go beyond the results of the study in that they suggest physical activity and psychoeducational treatment are effective. However, in fact compared with a ‘minimal intervention’ (a one off diabetes education session), they are no different. The discussion up to these last two paragraphs on page 13 is useful in suggesting that attention, concern and support with a focus on addressing diabetes-related problems (given they may underlie the depression symptoms) might be all that is required and this I think constitutes the main finding of the study. Therefore, the conclusion should be that this type of minimal intervention (which may also be described as enhanced TAU) might be sufficient. Authors
need to address this key issue of needing to ensure that the discussion and conclusions are adequately supported by the data.

4. The authors state that there are more detailed descriptions of the study methods in other publications, however, this paper should also be able to be read as a complete and whole description of the study and therefore include all of the basic details one would expect to see as per the CONSORT statement. The aspects most noticeably missing were descriptions of how allocation according to the randomisation sequence was concealed from the researchers (to avoid any manipulation of the randomization sequence according to knowledge of patient characteristics) and whether the outcome assessors were blinded. The (participant) Flow Chart should include a description of those who did not complete the intervention (drop outs and/or withdrawals) as well as (separately) the numbers who completed the assessment at each time point.

5. Authors should discuss the assumptions and limitations with regard to how they have dealt with missing assessment/outcome data and with reference to the now commonly accepted gold standard approaches such as multiple imputation e.g. Sterne, J. A., White, I. R., Carlin, J. B., Spratt, M., Royston, P., Kenward, M. G., Wood, A.M., Carpenter, J. R. (2009). Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls. The British Medical Journal, 338, b2393.

6. A section about the limitations of the study is required (which should address the risk of bias that may have been introduced by e.g. not having adequately concealed allocation and/or not have blinded outcome assessment, as well as the issue regarding missing outcome assessment data).

7. Authors should include a discussion of the clinical as well as research implications e.g. some interesting mechanisms are discussed but this requires further study (which are mentioned in the abstract but do not appear in the main text). A useful format for writing a discussion is provided in Docherty, M., & Smith, R. (1999). The case for structuring the discussion of scientific papers. BMJ, 318, 1224-1225.

8. Authors should also conform to the reporting standards of TIDieR (Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., ... & Michie, S. (2014). Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ: British Medical Journal, 348.). Again, the most noticeable aspects that weren’t described included the rationale/theory for the interventions/essential elements of the intervention were chosen; where the materials used (e.g. manuals) could be sourced from; details about the procedures e.g. how long did participants spend watching presentations vs engaging in activities or exercise, where were these done, what equipment was used; whether there was any tailoring e.g. for the exercise intervention was this gentle to start with and then increased in intensity; there is no description of how fidelity to the intervention was assessed or strategies to maintain fidelity and whether it was delivered as planned. Ensuring an adequate description of the intervention helps with implementing successful interventions in
every day clinical practice. In the case where interventions do not prove to be beneficial, understanding aspects of the intervention in this detail can provide some insight to why they may not have been effective.

9. Given the above points, the conclusions in the abstract require careful attention to ensure that the results are accurately reflected.

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

**Quality of written English:** Acceptable

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

**Declaration of competing interests:**

I declare that I have no competing interests