Reviewer's report

Title: A randomized, controlled trial of dietary improvement for adults with major depression (the 'SMILES' trial)

Version: 0 Date: 13 Oct 2016

Reviewer: Mark Weaver

Reviewer's report:

This is a manuscript describing the results of a randomized trial to evaluate a dietary intervention for depressions symptoms.

There are several aspects of the study design that appear to allow for possible threats to the internal validity of the trial. First, the method of allocation concealment is inadequately described. It's indicated on page 8, line 54, that "the randomization allocation was managed by the trial dietitians or 'befrienders' in order to maintain blinding." However it's unclear what this means, the method of allocation concealment should be clearly described; that is, what methods were implemented to prevent foreknowledge or guessing of upcoming treatment assignments by either prospective participants or others involved in interacting with those prospective participants prior to randomization? If no such methods were used, the manuscript should clearly say so. Furthermore, it's indicated that a 2x2 randomized block design was used, but in an unblinded (or partially blinded) trial a block size of 4 is insufficient to support allocation concealment - this should be noted as a limitation of the trial. Finally, the clear and substantial differences in follow-up causes major validity concerns, and neither the complete-case nor the BOCF analyses address these concerns; since MADRS tended to decrease, on average, in both groups, these analyses would tend to bias the results away from the null. A more convincing sensitivity analysis would be a best/worst case analysis in which all intervention participants who dropped out would be assumed to have no change (i.e., worst case) but the control dropouts would be assumed to have substantial positive change.

A few comments on the analyses:

1) A confidence interval should really be included for the estimated NNT, particularly since this value is based on a very limited number of events (10 and 2 in the intervention and control groups, respectively). The point estimate carries no useful information by itself.

2) Page 9 lines 50-52 and Table 1 - it is generally inappropriate to conduct statistical tests for balance of baseline characteristics in a randomized trial (see, e.g., Senn, Stat. in Med 1994, pp 1715-1726, or the CONSORT Explanation and Elaboration document item 15).
Contrary to the statement in the manuscript on page 9, line 47, these comparisons are not in accordance with ICH E9. These p-values should be removed.

3) It's correctly noted (line 14, page 10) that mixed models allow for inclusion of all available participant data. However, it's unclear from Table 2 and Figure 1 that this was actually done. Were available data for participants who dropped out included in the model or not?

4) It's unclear what the statement that "non-parametric statistics were used when assumptions for parametric methods were violated" (line 26, page 10) refers to. When were the parametric models used and when were non-parametric method used, and what criteria were used to decide?

5) In Table 1, again, please exclude the p-values.

6) In Table 2, the within-group, within-time standard errors should be removed. Standard errors are inferential statistics and within-group inferential statistics are not supported by randomization.

7) Figure 2: a bar chart is a poor means for summarizing the results, plus the results are redundant with Table 2, suggest removing. Furthermore, it's unclear what the error bars in this figure represent but, as noted above, it's generally unnecessary to present within-group inferential statistics in a randomized trial.

Are the methods appropriate and well described?  
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?  
If not, please specify which controls are required in your comments to the authors.

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