Reviewer’s report

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

Version: 0 Date: 16 Sep 2016

Reviewer: Marjolein Visser

Reviewer's report:

This study among 67 patients with depression examined the impact of dietary support provided by a dietitian to improve dietary quality, versus control, on depression severity as assessed by the MADRS score. RCTs in the field of nutrition and mood are desperately needed to extend the findings of previous observational studies. Therefore, the RCT could be of high importance to this field of research. However, some issues need to be clarified before the study design and results can be fully interpreted.

General comments:

Page 3, line 27: the comment that intervention studies are lacking is not completely true. There are a substantial number of RCTs investigating the role of nutrient supplements which could be mentioned. Secondly, there are some (but not many) RCTs focusing on dietary intake in general that should be acknowledged (Forsyth A et al. Psychiatric Research 2015, Sánchez-Villegas A et al. BMC Medicine 2013). It should also be acknowledged that both trials failed to show a statistically significant impact of a dietary intervention on the prevention/treatment of depression.

Page 5, line 1-2: potential study participants were screened to have a poor dietary quality using the DST tool. Please add what specific score cut-point was used to identify persons with a poor dietary quality. Most importantly, also state the relevance and validity of this tool for your sample. The tool was originally developed for and validated in a much older population (persons aged 73-94 y) and was developed to detect nutritional risk in older persons.

Page 6, line 5-31: It remains unclear what the content of the dietary intervention was. Please describe in detail what the ModiMedDiet consists of. Was it based on nutritional advice only or was it based on a prescribed, personalized diet that met specific food group targets (and if so, what were these specific targets)? What was the adherence to the ModiMedDiet diet (mentioning the diet was 'easy to follow' (line 24) is not sufficient) and attendance rate of dietary support sessions?
Page 8, line 19: Dietary quality was assessed using the ModiMedDiet score. Again, provide detailed information how this score was created. Also explain on what dietary intake data the score was based (the 7-day food diary, the Cancer Council of Victoria FFQ, or the diet history obtained by the dietitian at the first session)? Also explain why 3 different tools were used to assess dietary intake at baseline and which one was used to determine the (change in) dietary quality score and why.

Page 8, line 37: please add why only 67 persons in total were randomized while the power calculation indicated that 88 people per group were necessary. This means that the study is significantly underpowered and the observed effect could be a chance finding.

Page 11, line 1-2: At baseline the ModiMedDiet score was lower for the dietary group than the control group. Provide a table with the baseline actual dietary intake (energy, nutrients and relevant food groups) of the participants in both groups as well as the actual dietary intake at 12 weeks of follow-up.

Page 13, line 5: Please add the biomarker results to table 2. Was the change in biomarkers (especially LDL-cholesterol) different between the two intervention groups?

Page 13, line 5: In 12 weeks an improvement in dietary quality will result in a reduction of LDL-cholesterol, especially in persons with a poor dietary quality at baseline. However, the change in MADRS was not correlated with any of the changes in biomarkers. This could suggest that the impact of the dietary intervention on MADRS is mediated through other variables (e.g. inflammation markers as indicated by the authors in the discussion section). Alternatively, this could indicate that the dietary intervention was not successful in changing the actual dietary behavior and that the impact on MADRS is not due to a change in dietary intake perse but rather due to effects on e.g. structuring daily activities - meals, food preparation, food shopping etc.

Page 16, line 7: As 1) this is the first RCT showing a potential effect of dietary improvement on depression severity, 2) the results of the study cannot be fully interpreted at this point due a lack of information regarding the dietary intervention and the actual dietary intake, and 3) as the RCT was performed in a very specific subgroup of persons with depression (recruitment was very difficult as indicated in the discussion, and only those with a low dietary quality were selected) which reduces generalizability, please describe the potential implications of your study for clinical care much more careful.
Specific comments:

Page 3, line 22: please remove the remark 'and not apparently explained by reverse causality (e.g.). Observational research approaches can never exclude reverse causality.


Table 1: The ModiMedDiet score of the control group is 44.96 in table 1, but 44.9 in table 2. This seems not correct.

Table 2: Please also provide adjusted estimates.

Figure 2: The Y-axis should start at 0 (zero).

The other figure 2 (?): How was adherence to the ModiMedDiet assessed? Or is the figure showing quartiles of the 12-week change in ModiMedDiet score, which is something completely different?

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.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

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