Author's response to reviews

Title: Is informed consent related to success in exercise and diet intervention as evaluated at 12 months? DR's EXTRA study

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Author's response to reviews: see over
Dear Dr Norton,

Thank you for the reviewers’ encouraging and valuable comments and suggestions concerning our manuscript entitled “Is informed consent related to success in exercise and diet intervention as evaluated at 12 months? DR’s EXTRA study’ (Ms. 1704541388281585). We have taken into account all of their comments and suggestions. These changes have improved our report. A point-by-point response to the points raised is appended to this cover letter.

Please note the changes in our address and e-mail due to the merging of our university with another. The new name is University of Eastern Finland. These changes have been updated on the journal page.

We hope that these improvements permit you to accept this manuscript to be published in ‘BMC Medical Ethics’.

Yours sincerely,

Helena Länsimies-Antikainen
Anna-Maija Pietilä
Tomi Laitinen
Vesa Kiviniemi
Rainer Rauramaa
POINT-BY-POINT REPLY (Ms. 1704541388281585)

Response to reviewer B. Palmer’s comment:
The exploratory/hypothesis generating intent of the study has been added in the Abstract (page 2, lines 12-16) and Conclusion (page 12, paragraph 2, lines 1-4) paragraphs.

Response to reviewer C. Goldsmith's comments:
1. The comment has been taken into account as the reviewer kindly suggested (page 4, paragraph 2, line 3).
2. The comment has been taken into account as the reviewer kindly suggested (page 5, paragraph 2, line 1).
3. The comment has been taken into account as the reviewer kindly suggested (page 5, paragraph 2, line 2).
4. The comment has been taken into account as the reviewer kindly suggested (page 5, paragraph 2, line 6).
5. The comment has been taken into account as the reviewer kindly suggested (page 6, paragraph 1, last line).
6. The comment has been taken into account as the reviewer kindly suggested (page 6, paragraph 2, line 5).
7. The mentioned sentence has been deleted (page 7, paragraph 2). The dropout details have now been specified for those participants who included in the data analysis of this paper (page 8, paragraph 2 and Figure 2). In addition, comparison between participants who are in the study with those who dropped out of the study has been done. This comparison (cross-tabulations and Fisher’s Exact Test) did not reveal any statistically significant difference between baseline characteristics (background variables or intervention group).
8. Comparison between the participants who completed the informed consent questionnaire and those who did not has been done (page 8, paragraph 2 and Figure 2). This comparison (cross-tabulations and Fisher’s Exact Test) did not reveal any statistically significant difference between characteristics (background variables or
9. The comment has been taken into account as the reviewer kindly suggested (page 8, paragraph 1, line 3).

10. The text has been modified so that the statement of standardized grading has been changed as follows: The bookkeeping was scored by jointly beforehand designed grading (page 8, paragraph 3, lines 6-7).

11. All the comments have been taken into account as the reviewer kindly suggested (page 9, paragraph 1, lines 1, 2, 4, 6). However, we want emphasize that we used Ordinal Regression in our analyses.

12. The comment has been taken into account as the reviewer kindly suggested (page 9, paragraph 3, line 1).

13. The comments have been taken into account as the reviewer kindly suggested (page 10, paragraph 1, line 1).

14. The comment has been taken into account as the reviewer kindly suggested (page 10, paragraph 2, line 4).

15. The comment has been taken into account as the reviewer kindly suggested (page 10, paragraph 3, line 4).

16. The comment has been taken into account as the reviewer kindly suggested (page 11, paragraph 3, line 3).

17. The comment has been taken into account as the reviewer kindly suggested (page 11, paragraph 3, line 1).

18. The comment has been taken into account as the reviewer kindly suggested (page 11, paragraph 3, line 10).

19. Redundant "cf" has been taken away (page 12, first line).

20. The last sentence has been taken away (page 12, paragraph 1).

21. The comment has been taken into account as the reviewer kindly suggested (page 12, paragraph 4, line 2).

22. The comment has been taken into account as the reviewer kindly suggested (references 1, 4, 6, 12, 13 at page 13).

23. The correction in author's name has been done (reference 11).
24. The comments have been taken into account as the reviewer kindly suggested. In addition, numerical codes and referent categories has been added (Table 1).

25. We have made an additional datafile where all the results of univariate analyses are presented in detail (Additional file 1). We hope that this file helps in interpreting the original Table 2 and Table 3. If needed, it can be linked into the final text.

26. Figure 1 has been changed so that this figure presents the DR's EXTRA study design up to the randomization. Figure 2 has been created. This figure presents in detail the participants included in this report.

Quality of written English:

Ewen MacDonald, Pharm.D., (native English-speaking) has revised the language of this revision.

Statistical review:

Statistician Vesa Kiviniemi, PhLic, is one of the authors and he has revised the statistical methods and data analysis of this revision.