Reviewer's report

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

Version: 2 Date: 28 January 2010

Reviewer: Charlie Goldsmith

Reviewer's report:

1. Page 3 paragraph 2 line 3: Since “or” logically includes “and”, drop “and/”.

2. Page 4 paragraph 2 line1: They clearly do not have a population, so the word “population” should be replaced by “group”.

3. Page 4 paragraph 2 line 2: Insert “years” after “78”.

4. Page 4 paragraph 2 line 6: Make the “n” lower case, just like it is in the tables later on.

5. Page 5 paragraph 1 last line: Insert a space between “>” and “1500”.

6. Page 5 paragraph 2 line 4: Insert a space between “>” and “1500”.

7. Page 6 paragraph 2 last sentence: Details here on (n=55) who dropped out should be showing by the different groups and comparing those who are in the study with those who dropped out of the study on baseline characteristics to see if they look similar. All of this depends on similarity before the results reported in this paper are credible.

8. Page 7 paragraph 1 line 2: The analyses is only done on those who completed the informed consent questionnaire, so it is important that we know what characteristics are of those who completed these questions which groups they where in and compare them against people in those groups who did not complete the questionnaires. Otherwise the results are not credible.

9. Page 7 paragraph 1 line 4: Replace “parameters” by “variables”. A parameter is a characteristic of the distribution of a variable and not another name for the variable.

10. Page 7 paragraph 2 last sentence: Since the authors don’t report anything on the standardized grading they should downplay the reliability of anything that they are coding here. They did not do any reliability studies as they mention later in their paper.

11. Page 7 paragraph 3: This reviewer was not convinced that they used Ordinal Regression in their analyses. It looks like standard univariate analyses of variance followed up with multivariable analyses stepwise, but with backwards elimination. They should describe it. My comments here relate to that. In this
A multivariate analysis is one that analyses simultaneously two or more outcome variables regardless of the independent variables in the model. A multivariable model is the one that has a single outcome variable and two or more independent variables considered simultaneously. In this reviewer's opinion you are doing multivariable analyses not multivariate analyses.

12. Page 8 paragraph 2 line 1: Replace “ranged” by “varied”.

13. Page 8 paragraph 2 line 9: Drop “only” and spell out “4” and “%”. Only implies an unstated expectation.

14. Page 8 last paragraph line 4: Drop “only”.

15. Page 9 paragraph 2 line 4: Drop “only”.

16. Page 10 paragraph 2 line 4: Replace “population” by “group”.

17. Page 10 paragraph 2 line 1: Drop “in order” in front of “to” as the words are redundant in English.

18. Page 10 paragraph 2 line 10: Drop “perfectly”, since they do not show any data. This is a very hard task to obtain!

19. Page 10 paragraph 2 line 14: What does the “cf” refer to?

20. Page 10 last sentence: Since the authors have not shown any comparison between long term and short term research or in older versus younger research participants in this study they should not make this claim.

21. Page 11 paragraph 3 line 2: Drop “and/”.

22. Page 12 references in general these were well done, except I believe for the Lancelet and BMJ it would be helpful if you put the issue number, for example:

   • reference 1, volume 371 (9611)
   • reference 4, volume 367 (9519)
   • reference 6, volume 371 (9614)
   • reference 11, volume 362 (9400)
   • reference 13, volume 332 (7538)

When you go to find the paper in the computer searchers it is often helpful to have those issue numbers as well as the volume.

23. For reference #11 it looks like there is another “D” between the “N and G” for the second author “Chaves DNDG”.

paragraph on line 3: replace “multivariate” by “multivariable”; on line 4: put a space between “<“ and “0.1”; on line 5: replace “multivariate” by “multivariable” and drop “ordinal regression”; line 6: replace “multivariate” by “multivariable”; line 7: drop “ordinal” and in the last line: replace “multivariate” by “multivariable”.

A multivariate analysis is one that analyses simultaneously two or more outcome variables regardless of the independent variables in the model. A multivariable model is the one that has a single outcome variable and two or more independent variables considered simultaneously. In this reviewer’s opinion you are doing multivariable analyses not multivariate analyses.
24. Page 14 table title: Replace “parameters” by “variables”. For age make the first category “< 63”, the last category “> 70” and there needs to be a referent category with numerical codes for the understanding of the regression results. In tables 2 and 3 always need to be a referent category for these and how they coded with the response variables will be important to the choice of these regressions.

25. Page 15 table 2: This reviewer does not believe the authors used ordinal regression, but maybe they did. It is not explained well. I think that you should be reporting the step one with p values for all variables that are listed in the table 1. This was not done, because you are only reporting on 4 variables, and then once you get down to the last step it is okay to put the one that remained in this model along with the standard error. But presumably to answer it correctly was the referent category of 0 in the model. This notation needs to be explained better otherwise table 2 does not make sense. Similarly with table 3, it looks like the standard error should raised up one level for the participants view of the study.

26. Figure 1 looks like it is a complete CONSORT type statement for the main study with the 6 groups in it but not for the study that it is reporting on the success of the informed consent. So the authors now need to create a similar type of chart that shows the numbers that go into the informed consent reporting. This has numbers like 500, not 1300.

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

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.