Author’s response to reviews

Title: Motives for (not) participating in a lifestyle intervention trial

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Author’s response to reviews: see over
Dear Iratxe Puebla

Please find enclosed the revised version of the manuscript "Motives for (not) participating in a lifestyle intervention trial". With the help of a native English-speaking colleague, the paper has been thoroughly copyedited. Many corrections have been made concerning language, grammar and punctuation. The content of the paper has also been revised according to the comments of the referees. In the following, we are giving a point-to-point account of how we have addressed the issues and comments raised by the referees.

REFEREE 1 (Nicola Mills):

Minor essential revisions:

Abstract:

1. The referee suggests that the final sentence of the method’s section in the abstract could be modified in order to give an indication of how the data of ‘motives and barriers that underlie study enrollment’ were collected.

Authors’ comment: The sentence has been modified according to the suggestion: “Furthermore, motives and barriers that underlie study participation were investigated by means of questionnaires.” (page 2, methods section, lines 6 and 7).

2. The referee points out that a sentence is needed with regard to methods of statistical analysis in the method section.

Authors’ comment: We agree, and added the following sentence: “Univariate and multivariate logistic regression was used to describe the relationship between explanatory variables and study participation.” (Methods section, lines 4 and 5).

Background:

3. The referee found an inconsistent sentence in which the word ‘non-participant’ had to be changed in ‘participants’.

Authors’ comment: We changed this accordingly (starts at last sentence of page 3).

Methods:

4. The referee notes that it is not mentioned in the manuscript why we chose to stop the patient inclusion at the cut-off point of 50 in each group.

Authors’ comment: We added the following sentence: “This cut-off point was chosen in order to achieve a representative, yet feasible sample in both groups.” (page 6, second paragraph, lines 2-4).

5. The referee points out that it would be useful to state the amount of non-participants that were initially contacted.

Authors’ comment: This was also a comment of referee 2. We have clarified this issue in the results section with an adjusted sentence: “All of the 65 non-participants who were contacted were reached by phone, and they all agreed to complete a questionnaire, but 15 (23%) of the non-participants did not return the questionnaire.” (page 9, lines 1 to 3).
6. The referee misses the criteria for selecting the non-participants to telephone, as it would seem that not all of the 729 patients were contacted.

**Authors' comment:** Indeed we did not contact every non-participant for this survey. We chose to ask every consecutive non-responder for participating in the survey, until we had 50 questionnaires returned; then we stopped. The following is added: “Consecutive participants and non-participants in the ALANT study were then invited to take part in our survey, the protocol of which was reviewed and approved by the Medical Ethics Committee of the VU Medical Center.” (page 5, lines 5 to 8) Then we added another paragraph on this: “The inclusion of participants and non-participants in this survey was stopped when 50 questionnaires had been filled in and returned by each group. This cut-off point was chosen in order to achieve a representative, yet feasible sample in both groups.” (page 6, second paragraph) and modified two sentences: “Successive non-participants in the ALANT study were asked by telephone to complete and return a questionnaire, and two gift vouchers were raffled among the non-participants who did so.” (page 6, third paragraph, lines 2–4), and “Successive participants in the ALANT study were asked to fill in the same questionnaire during their first measurement visit.” (same paragraph, lines 6 and 7).

7. The referee asks if the term ‘Packyears’ can be explained.

**Authors' comment:** We added the explanation: “{…} pack years (average number packs of 20 cigarettes per day smoked, multiplied by the number of years as a smoker), {…}.” (page 7, behavioral variables subsection, lines 2 and 3).

8. The referee notes that it is not clear how the various determinants assessed by Likert scales were decided upon.

**Authors' comment:** We changed the sentence: “A four-item Likert scale was used to assess the role of various determinants that were presumed by the investigators to influence the decision to participate or not {…}.” (page 8, motives and barriers subsection, lines 1 and 2).

Results:

9. The referee points out that it is not mentioned how the 50 participants are selected from the 148 participants to take part in the survey.

**Authors' comment:** This has been done in the same way as non-participants; in order of inclusion, until 50 has entered. This is noted under point 6 above.

Discussion:

10. The referee states that if there is any possibility that the selection of the patients for the survey could be a different group of patients due to the selection method, it should be stated in the discussion.

**Authors' comment:** Because of the recruitment method (described under point 6 and 9) we do not expect the selection to be different. Therefore we chose not to cover this in the discussions section.

Discretionary revisions:

Title:

1. The referee remarks that the title fails to express that the study additionally explores differences between trial participants and non-participants.
Authors’ comment: We agree. However, we have been thinking before about a title that conveys both study aims but that made the title too long.

Methods:
2. The referee notes that it might be useful to know why we did not use the BMI measured by the physician in stead of the self-reported BMI, because we mention in the discussion that a comparison showed an underestimation of the self reported BMI.
Authors’ comment: The measurements by the physician were only done in the intervention group, and were not taken from the database. Therefore we chose to use the self reported weight and height for both the participants and non-participants in order to be able to compare these values between the groups.

Figure 2:
3. The referee comments that it would be useful to the reader if we could indicate some numerical values to the terms ‘Large role’, ‘fairly large role’ and ‘small role’.
Authors’ comment: At first have inserted the mean values of the four item Likert options at each bar. Then we chose not to display these values because it could confuse the reader. For example: when a bar between ‘small role’ and ‘fairly large role’ has the value 2.83, it is not obvious how to interpret it.

REFEREE 2 (James LoGerfo):

Major revisions:

1. The referee notes that in most studies participants do not require a payment of the participants in order to get the intervention; and therefore the generalizability of this study-outcome might be less significant. The referee requires some comments about this level of cost and how it may compare to other studies.
Authors’ comment: We are aware of the quit unique disadvantage of the intervention. This study shows that the costs were a reason not to participate. We added the following to the discussion: “Fifthly, most studies do not require payment from patients for the intervention. Therefore, the results have to be interpreted with caution with regard to comparison with other studies, and generalizability of the results. Furthermore, because study participation implied possible costs, it is plausible that patients with a low socio-economic status were less likely to participate. Unfortunately, we were unable to evaluate the exact socio-economic influences, because data on type of job or level of income were not collected. Based on the data concerning level of education there is reason to believe that socio-economic class is of influence. This is reinforced by the identified effect of the variable ‘still working’.” (page 12, second paragraph, starts at the first line).

2. The referee notes that it would be important to know how the non-responders to the survey compared to the non-participants who responded to the survey, based on the eligibility database.
Authors’ comment: Regrettably, we did not collect information on age, disease burden etc. on these pertinent non-responders. But, as we point out in the discussion, since it is such a small group, the absence of these pertinent non-respondents is not likely to bias our profile of the typical non-participant.
3. The referee comments that information is missing about how the samples were drawn for this survey.  
**Authors’ comment:** This is addressed as described above (response to referee 1 under point 6 and 9).

4. The referee notes that some comment is required on the fact that the ALANT study had differential recruitment rates based on whether participants were invited by their physician vs from the databases. The non-participants should have been similarly stratified or at least analyzed to see if non-participants related to the 2 recruitment methods are similar.  
**Authors’ comment:** We have been hesitating to describe the recruitment methods separately. We did not choose to split up the description in recruitment rates for the cardiology ward and the vascular surgery ward, and we signal that a separate report of the recruitment by databases is confusing. Therefore we chose not to describe the 2 methods separately. We revised Figure 1, and hope that this will more clear to the readers.

5. The referee comments that there is no indication about how many people of the non-participants were non-contactable in order to get 65 to initially agree.  
**Authors’ comment:** We added more information about this aspect: “All of the 65 non-participants who were contacted were reached by phone, and they all agreed to complete a questionnaire, but 15 (23%) of the non-participants did not return the questionnaire.” (page 9, first sentence).

Minor revisions:

6. The referee suggests to use the term ‘not meeting recommended levels’ in stead of ‘sedentary lifestyle’, when writing about no-regular physical activity.  
**Authors’ comment:** We agree, and changed this accordingly in the text (page 5, second paragraph, first sentence; page 7, behavioral variables sub-section, last sentence; table 1). The term is defined in the last sentence of page 5: “The recommended level of physical activity was defined as moderate intensive exercise for at least half an hour, five times a week (i.e. brisk walking, cycling or other forms of brisk exercise).”

7. The referee notes that more comment is warranted about the lack of data concerning income level, which could have a relationship with the need to pay 150 Euros if participants are randomized to the intervention.  
**Authors’ comment:** We have now commented on this issue in more detail: “Therefore, the results have to be interpreted with caution with regard to comparison with other studies, and generalizability of the results. Furthermore, because study participation implied possible costs, it is plausible that patients with a low socio-economic status were less likely to participate. Unfortunately, we were unable to evaluate the exact socio-economic influences, because data on type of job or level of income were not collected. Based on the data concerning level of education there is reason to believe that socio-economic class is of influence. This is reinforced by the identified effect of the variable ‘still working’.” (page 12, first sentence).

8. The referee comments that Figure 1 is misleading because of the term responders rather than participants>
**Authors’ comment:** We agree. The figure title has been changed: “Figure 1 - Flow chart of patient recruitment in the ALANT Study and in the non-participant survey.”

Discretionary Revisions:

9. The referee states that a comment or two might be useful on the issue that based on the data about education level there is reason to believe that the concept of socio-economic class may be at play in the decision to participate or not to participate.

**Authors’ comment:** As we added information on the absence of data concerning income level in the discussion, we also added a comment on this issue, as is described under our comments on point 7.

10. The referee points out that there are some awkward grammatical constructions and suggests some additional editing.

**Authors’ comment:** We have revised the manuscript according to the many suggestions of a native English speaker, and regret that we have not done it on forehand.

**REFEREE 3** (Sirpa-Liisa Hovi):

Major Compulsory Revisions:

1. The referee notes that it should be described properly how many questionnaires were delivered and what the response rates were in each arm.

**Authors’ comment:** This was presented in the results section. We have added some details in order to make it completely clear to the reader: “All of the 65 non-participants who were contacted were reached by phone, and they all agreed to complete a questionnaire, but 15 (23%) of the non-participants did not return the questionnaire. All of the 50 participants who had been invited agreed to participate in this survey and completed the questionnaire.” (page 9, first sentence). Additionally, we added information about survey response in Figure 1.

2. The referee points out that Figure 1 is confusing because according to reference 12, 261 persons were recruited to the ALANT study, which cannot be found in the given flowchart.

**Authors’ comment:** The reference to the article of Sprangers et. al. (ref 12) was given in order to inform the reader that the intervention has been described before. The intervention in the article of Sprangers et. al. was part of a study with no control group, and only referred to in order to provide more information about the lifestyle program. We are now aware of the confusion and changed the sentence with the reference: “The program has already been described in more detail in an intervention study with no control group [12].” (page 4, second paragraph, second sentence).

2a. The referee asks how the given recruitment sources differ from each other, and if the different recruitment sources explain results, and also what the reason is of the separate description.

**Authors’ comment:** We acknowledge the confusing element of introducing these separate recruitment methods, and changed the Figure (as explained in our comment to referee 2, point 4).
2b The referee questions what responders are described in Figure 1; responders to the ALANT trial or responders to the survey.

Authors' comment: We hope that the revision of the Figure has clarified this.

Results section:

3. The referee correctly notes that the term ‘responders’ in table 1 is not corresponding with the text referring to the table, in which the term ‘participants’ is used.

Authors' comment: We have changed the title of table 1: “Table 1 - Characteristics of participants and non-participants in a multifactorial comprehensive lifestyle intervention trial for patients with CVD.”

4. The referee comments that ‘being unmarried’ is not opposite of ‘married or living together’, and notes that ‘single’ is rather the opposite, as used in the abstract.

Authors' comment: We agree, and changed the text accordingly. (page 9, third paragraph, last sentence; page 10, discussion section, first sentence).

Discussion section:

5. The referee states that the term ‘responder’ and ‘participant’ should be checked.

Authors' comment: The manuscript has been checked again, and corrected concerning the consistent use of this terminology.

6. The referee indicates that the sentence: “Non-participation under the non-participants was relatively low (23%)...” is unclear, and asks where the figure 23 comes from.

Authors' comment: We have changed the sentence: “(...) non-response under the non-participants was relatively low (23%) {...}.” (page 11, third paragraph, first sentence). The figure 23 has been explained in the results section of the paper: “(...) but 15 (23%) of the non-participants did not return the questionnaire.”

Discretionary Revisions:

7. The referee suggests to give a short description of the intervention, in order to offer more information for the assessment of the non-participation.

Authors' comment: We have now referred more clearly to a paper in which the intervention is thoroughly described: “The program has already been described in more detail in an intervention study with no control group [12].” (page 4, second paragraph, second sentence). We chose not to describe the full intervention in the paper to save space, and because it has been described before in the named reference.

Title:

8. The referee notes that it could be given in the title that the survey concerns participation in the CVD trial.

Authors' comment: We have considered adding CVD to the title, but prefer not to use abbreviations there.

Others:

9. The referee points out correctly that ref 12 (Sprangers et al.) is not about cost-effectiveness, as is suggested in the paper.
Authors' comment: The reference was meant to refer to more information on the lifestyle program that is used in the intervention. This has been made clearer (see also comment 7 above).

10. The referee informs us that ref 12 is not at all included in the PubMed, but is easily available on the journal’s web sites. Authors' comment: We have noticed the same, and do not know why that article is not registered in PubMed.

11. The referee states that the impact of used gifts in the data collection could have been discussed as well. Authors' comment: We decided to mention the use of raffling two gift vouchers among the non-participants that responded to the survey (page 6, method section, second sentence). We did not choose to discuss a possible effect of these gifts on our results in the discussion section, since giving or raffling small incentives is common practice to enlarge response.