Author's response to reviews

Title: DiAlert: a prevention program for overweight first degree relatives of type 2 diabetes patients: Results of a pilot study to test feasibility and acceptability

Authors:

Wieke H Heideman (w.heideman@vumc.nl)
Maartje de Wit (m.dewit@vumc.nl)
Barend JC Middelkoop (B.Middelkoop@lumc.nl)
Vera Nierkens (v.nierkens@amc.uva.nl)
Karien Stronks (k.stronks@amc.uva.nl)
Frank J Snoek (fj.Snoek@vumc.nl)

Version: 2 Date: 6 August 2012

Author's response to reviews: see over
Dear Editors,

We thank the two reviewers for their effort and time in reviewing our paper and for acknowledging the interest of our paper, entitled "DiAlert: a prevention program for overweight first degree relatives of type 2 diabetes patients: Results of a pilot study to test feasibility and acceptability". Below, we respond to the concerns of the reviewers. Primarily based on these comments, we carefully revised our paper to make it more constructive and clear.

We marked changes in the revised text with track changes. We also included a clean version of the manuscript.

We hope that after our revision, you find our work of sufficient quality to merit publication in Trials.

Yours sincerely,

Wieke Heideman
Reviewer’s report

Title: DiAlert: a prevention program for overweight first degree relatives of type 2 diabetes patients: Results of a pilot study to test feasibility and acceptability

Version: 1 Date: 19 June 2012

Reviewer: Sally Pears

Reviewer’s report:

Reviewer’s Report

Given the relatively strong evidence that lifestyle behavior change can significantly decrease the risk of developing type 2 diabetes, there is a clear need for effective interventions. However, given the limited resources available in primary care, it is also essential that any interventions delivered in this setting are not only effective but are also feasible (in terms of necessary resources such as time, training, cost etc.) and are acceptable to both the intervention recipients and deliverers. Consequently, the research under review (which aims to test the feasibility and acceptability of a reduced-intensity, preventative intervention aimed to promote lifestyle behavior change in first-degree relatives of T2DM patients) addresses an important question.

However, although the title and abstract of the paper clearly present this research question, the rest of the paper (particularly the Methods and Results sections) is disordered and does not appear to address this question directly or coherently.

We thank the reviewer for acknowledging the relevance of our paper. Below, we respond to the specific comments.

I would recommend the following revisions:

Major Compulsory Revisions

Introduction

The introduction needs to more clearly outline the goals of the paper / pilot study:

1) Briefly describe the DiAlert intervention (referring to previous methodology papers where necessary / possible).

2) Slightly elaborate on the description of the HAPA model and how it’s main behavioral determinants (risk perception, self efficacy, outcome expectancies, intentions and action planning) are related to the DiAlert intervention (a diagram of the model / intervention relationship would be useful here). Mention here that the pilot trial will also seek to examine whether the intervention has any effect on these determinants (as this is what is reported in the results section along with feasibility and acceptability).
3) Explain the importance of measuring Fidelity, Feasibility and Acceptability, giving examples of each that are specific for the DiAlert intervention (e.g. Fidelity: whether all educational modules are delivered as intended; whether group sessions are delivered in an ‘empowering’ manner/environment etc.; Feasibility: whether group sessions can be delivered within 150 minutes; whether recruitment strategies are effective; Acceptability: whether participants find the DiAlert intervention useful; whether the DiAlert intervention increases worry). Note: ALL components of Fidelity, Feasibility and Acceptability should be reported in the Methods and/or Results section, but it is important in the introduction to define these terms and give examples of the kinds of measures that are important for assessing the Feasibility, Fidelity and Acceptability of the DiAlert intervention, and also to highlight how this information can/will be used to modify the DiAlert intervention (if necessary) for the RCT.

Re comments Introduction: We thank the reviewer for the suggested revisions, we adopted the advice to reorder the introduction section, describing the HAPA framework briefly and the objectives of the study with focus on fidelity, feasibility and acceptability together with determinants of behavior change. In the introduction section we describe the main objectives of the paper.

Methods

Again, this section is very disordered and replication of the study would not be possible based on this description. The reporting of data collection in particular could be a lot clearer:

Re comment Methods: We understand the reviewer’s concern regarding the structure of the methods section. We made the effort to report data collection more clearly following the suggested headings.

4) The intervention description is vague. Try to summarize the intervention more succinctly – I would recommend listing the behavior change strategies used without going into too much detail (especially as there is a reference to a more detailed description of the intervention reported elsewhere).

Re: We included a figure of the HAPA framework applied for the DiAlert intervention, to explain the intervention and strategies used more clearly. In the text the intervention is now described in line with the determinants of HAPA.

5) Keep the description of the intervention separate from the description of measures – currently the ‘Process of intervention delivery’ is a hard-to-read mix of a description of the intervention and a description of fidelity assessment.

6) Report all measures in each ‘category’ of measurement, I suggest the following headings:

- Participant Characteristics (e.g. age, BMI, socio-demographic variables etc.)
- Fidelity Measures (e.g. all topics listed in the manual are discussed)
- Feasibility Measures (e.g. checklist of duration of modules, recruitment etc.)
- Acceptability Measures (e.g. patient ratings of ‘appreciation’)
- Behavioral Determinants Measures (e.g. all measures derived from the HAPA model)

Re comment 5&6: We adopted the suggested headings to describe the methods of our pilot. We think the description of the methods is more clear now.

7) List or tabulate all measures in each category, including:

- HOW they were measured (e.g. by questionnaire or by observation etc.);

- WHEN they were measured (e.g. at baseline and follow-up; at the end of the second session etc.); and

- BY WHOM (e.g. questionnaire completed by the participant; observation by trained researchers etc.).

Note: The ‘Indicators of Change’* measures are listed in Table 2 (along with associated baseline and follow-up values), but it is very unclear what the individual measures of Feasibility and Acceptability are, and when they were
measured. A table or list of all measures and their relevant attributes is necessary for clarity and for enabling replication. Furthermore, a list or table of measures could replace a lot of the confusing and disordered text that is currently present in both the Methods and Results sections. A list of Feasibility and Acceptability measures could be combined with results, as in Table 2 (which shows what ‘Indicators of Change’ were measured, when they were measured, and what values were obtained at the different measurement times).

Re comment 7: We summarized measures and results in two separate tables (2A and 2B) for the determinants of behavior change and for Fidelity, Feasibility and Acceptability measures including the measures, how it was measured, when and by whom.

8) For all measures, state whether the measure has been used before, whether it has been adapted, and whether validity and reliability of the measure have been determined (either previously or in the current study). It is not necessary that all measures have been shown to be valid or reliable, especially when assessing fidelity, feasibility and acceptability of an intervention (where measures are often very intervention-specific, e.g. a checklist for educational modules). However, the origin, previous use and/or development of all measures should at least be reported, so that the reader can form an opinion on the probable validity and reliability of the measure. For example, in the current paper:

- ‘Duration of the modules’ is reported as a measure of fidelity but it is unclear how this was measured (whether it was timed accurately with a stop-watch or roughly estimated by the ‘observers’).

- ‘Indicators of Change’ measures are reported to be ‘derived from the HAPA-framework’ but it is unclear whether they were derived specifically for this study or whether they have been identified and measured elsewhere. The origin of the individual questions used to assess these measures is also equally unclear.

Re comment 8: We added references for all measures that were derived from existing measures in the text and tables 2A&B. When measures were self-constructed it is now reported in the text.

Timing of duration of the modules is now described as: “Length of the modules was timed with a stopwatch by the observers and recorded on the checklist. Furthermore we examined whether all information could be delivered in two sessions of 150 minutes”

9) The ‘data analysis’ section does not adequately describe how the data were collated and analyzed. This section should be amended according to the suggestions above (e.g. by reporting how each variable is measured /
determined and what statistical analyses were performed. Again, where possible this information can be recorded as a footnote to a methods/results table to save on text).

Re comment 9: In the revised manuscript with headings for each topic of interest (fidelity, feasibility, acceptability and determinants of behavior change) we described data collection.

Results

10) The methods and results are inadequately reported so it’s not possible to assess whether the data are sound and well-controlled.

Re comment 10: We think that the revised manuscript with corresponding headings in methods and results is now more clear.

11) See comments 6 / 7 (above) about adding a table of measures (one for each measurement category: Fidelity, Feasibility, Acceptability and Behavioral Determinants).

Re comment 10&11: We described the results section along the suggested headings. In addition, results of all measurement categories are summarized in tables 2A and 2B.

Discussion

12) Again the discussion is somewhat disordered. I would suggest re-writing with a clearer structure.

13) Overall the discussion should focus more on Fidelity, Feasibility and Acceptability and what impact the findings of this study will have on the delivery of the RCT (rather than changes in ‘Indicators of Change’).

14) Some claims are worded in such a way that they are not supported by the data. For example, the statement ‘first findings indicate positive changes in self-efficacy, outcome expectancies and intention to change lifestyle behavior’ is too strong a claim given that there were very small, non-significant (and not always positive) changes in these measures.

Re comment 12-14: We agree with the reviewer that the main focus of our study was assessment of fidelity, feasibility and acceptability of our intervention. Therefore we reconsidered our statements in the discussion.

*Minor Essential Revisions:

15) Use the term ‘Behavioral Determinants’ (which refers to the theorized mediators of behavior change such as ‘perceived consequences’ and ‘intention’) rather than ‘Indicators of Change’ (which implies a measure that
would indicate that a change in behavior has occurred, e.g. VO2max could be called an ‘indicator of health behavior change’ as an increase in this measure would indicate a change in physical activity).

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: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.
Reviewer's report

Title: DiAlert: a prevention program for overweight first degree relatives of type 2 diabetes patients: Results of a pilot study to test feasibility and acceptability

Version: 1 Date: 17 June 2012

Reviewer: Masakazu Nishigaki

Reviewer's report:

This manuscript reports the results of pilot study of DiAlert, randomized controlled trials investigating the effect of preventive intervention for first degree relatives of type 2 diabetes patients, of which protocol had already been published elsewhere.

I fully agree that the DiAlert involves timely, important issues in public health genomics area. However, I wonder this article has outstanding importance itself.

We thank the reviewer for the thoughtful comments, which we address below.

Major Compulsory Revisions

1. Manuscript re-construction; methods, results and discussion section. Manuscript body other than introduction section was written in complicated manner. The objective of this study is to determine 1) feasibility and 2) possible impact of Intervention in DiAlert study. However, descriptions about each element were scattered and some of them were duplicated. Especially, these drawbacks are frequently found in methods section. For example, "views", "appreciation", and "acceptability" appeared in "indicators of change" section. Another example, descriptions in the first paragraph of methods section appear repeatedly. Author should avoid duplication and reorder the elements of each section in adequate sequence, concordant with objectives of this study. The manuscript will be more comprehensive if authors assemble the descriptions with adequate sub-heading, for example:

1 Feasibility (and validity?) of intervention
1-0 intervention description
1-1 recruitment
1-2 fidelity
1-3 appreciations
1-4 acceptability
2 possible impact of intervention
2-1 cognitive change
2-2 behavioral change
Following those subheading, how and when the researchers assessed the feasibility/impact in corresponding variable. I also recommend authors to draw scheme about data collection schedule. Similarly, Results and Discussion section should be reconstructed.

Re comment 1: In line with comments of the reviewer above, we adopted a new headings to describe the methods of the pilot study more comprehensively. We constructed two different tables 2A: for fidelity, feasibility and acceptability assessment and 2B: for determinant of behavioral change, both tables include information on data collection and measures.

2. It is unclear why participants were divided into two groups. Please describe the rationale of this point. If researchers planned to determine adequate group size, participants should be divided into three or more groups in different group size (small, medium, large). However, size of current two group is almost same.

Re comment 2: We now mentioned in the text (methods- paragraph “description of the intervention”) that the number of participants per group was derived from the PRISMA program. “Following the format of PRISMA a group size of 8 to 10 participants was considered to be ideal with ample opportunity for participants to interact with the trainer and the other group members.” In this study we aimed to confirm the number of participants per group.

3. The term "group comparison" in data analysis section is misleading. Actual analysis conducted by authors is pre-post comparison in one-sample setting.

Re comment 3: We thank the reviewer for this comment, we changed this in the analysis section.

4. Initial eligible criteria has been modified due actual result of recruitment. Authors should clarify whether the modification affect the validity of intervention.

Re comment 4: This pilot study attracted both younger and older relatives. The results of the pilot study showed that the intervention was valid in these participants as well. We therefore choose to change the inclusion criteria for the main RCT to match our age range in the RCT with this pilot study.

We revised the text in the discussion section into: “Another issue in relation to recruitment was that although the DiAlert-study was initially aimed at relatives 29 to 55 years of age, younger and older people showed interest and were enrolled. Therefore the inclusion criteria for the upcoming RCT will be changed into 25-65 years to certify validity of the intervention.”

5. Sample set in this study includes four normal weight subject. As authors has already mentioned in the manuscript, it is no matter in assessing feasibility of intervention process. However, analysis about impact of intervention would be biased (may be underestimated) by those ineligible subject. It would be valid to exclude them from analysis about intervention impact.

Re comment 5: We agree with the reviewer that analysis of determinants of behavior change could be biased by normal weight participants. We excluded these subjects from analysis of the determinants. Stating: “Post intervention analyses of the determinants of behavior change were performed for the
overweight participants only (N=16)” in the results section paragraph: determinants of behavioral change. See table 2B

6. It would be more comprehensive if the results relating feasibility are shown in table format.

Re comment 6: Results examination of fidelity, feasibility and acceptability are now shown in a table 2A, we think that the results of this analysis became more comprehensively.

7. Authors regard the neutral score of 3.0 for manual acceptance as "reasonable". Generally, the neutral response means that about half of participants didn't accept the clarity of manuals. Therefore I think authors should make effort to brush up the manuals. Please show the rationale why authors decided not to modify the manual.

Re comment 7: Unfortunately we made a mistake when describing the results of assessment of the manuals. We assessed the manual in the questionnaire at follow-up using a 4-point likert scale (scale 1=totally disagree to 4=totally agree). We changed this in the manuscript. We apologize for this error.

8. In discussion section, authors should emphasize interpretations about feasibility assessment. The most part of the discussion is occupied by the descriptions relating intervention impact. Subsequently, those issues should be discussed in main RCT.

Re comment 8: We revised our statements in the discussion session.

Minor Essential Revisions

1. It is difficult for readers to apprehend how researchers assessed the fidelity. It would be helpful for readers if the checklist is disclosed as table or appendix.

Re comment 1: We thank the reviewer for this suggestion, we added an example of the checklist the observers used in the sessions (see figure 1).

2. Authors mentioned the necessity of strategic recruitment in order to obtain diversified population while recruitment methods in DiAlert main study is almost same as those in this pilot study. This point is not problematic in this study by itself. However, I'm afraid that it would be a drawback in sincerity of study design process, if this manuscript was published as formal pilot study of DiAlert.

We revised our statements in the discussion section into: “However, in this pilot mainly women were reached, therefore in the RCT we should take into account possible strategies to include both males and females and from a broad range of socioeconomic classes. In the randomized controlled trial we will apply a mixed recruitment strategy, involving General Practitioners and diabetes specialists together with use of media and brochures to recruit participants with a positive FH of T2DM directly. As result of a direct
recruitment approach (through GP’s) we may expect participants with lower perception of risk, less positive outcome expectancies and lower self-efficacy for lifestyle changes.”

Discretionary Revisions

Why don't authors include description about the cultural adaptation for Turkish population in this manuscript?

The aim of this study was to test the intervention before perform a RCT in the Dutch population. The adaptations and development of the Turkish version of DiAlert has its own research objectives and outcomes which will be described separately. However we included brief information about development and pre-tests of the Turkish version of DiAlert in the discussion: “We plan to deliver a cultural sensitive version of the DiAlert intervention to relatives of Turkish origin living in the Netherlands. The intervention will be pretested in this target group before we conduct the RCT in this group.”

Masakazu Nishigaki
Level of interest: An article of limited interest
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests