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

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Reviewer: Sally Pears

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Given the relatively strong evidence that lifestyle behaviour 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 behaviour 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.

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 behavioural 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.

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:

4) The intervention description is vague. Try to summarize the intervention more succinctly – I would recommend listing the behaviour 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).

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’)
- Behavioural Determinants• Measures (e.g. all measures derived from the HAPA model)

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).

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.

9) The ‘data analysis’ section does not adequately describe how the data were collated and analysed. 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).

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

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

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 behaviour’ is too strong a claim given that there were very small, non-significant (and not always positive) changes in these measures.

*Minor Essential Revisions:
15) Use the term ‘Behavioural Determinants’ (which refers to the theorized mediators of behaviour change such as ‘perceived consequences’ and ‘intention’) rather than ‘Indicators of Change’ (which implies a measure that would indicate that a change in behaviour has occurred, e.g. VO2max could be called an ‘indicator of health behaviour 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.