Reviewer’s report

Title: DECADE-pilot: Decision aid, action planning, and follow up support for patients to reduce the 10-year risk of cardiovascular diseases. A protocol of a randomized controlled pilot trial

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Reviewer: Audrey Rankin

Reviewer’s report:

REVIEW

"DECADE-pilot: Decision aid, action planning and follow up support for patients to reduce the 10-year risk of cardiovascular diseases. A protocol of a randomized controlled pilot trial"

(Manuscript ID: PAFS-D-16-00089)

Comments to authors:

The study protocol describes a randomized controlled pilot trial to reduce the 10-year risk of cardiovascular disease. The manuscript sets out details on the various elements of the new DECADE intervention versus the use of a cardiovascular risk calculator alone. Overall I thought that the paper was well laid out and the intervention of sound concept. I do however think that in a number of sections the structure of the sentences could be revisited to make the meaning clearer to the reader. Whilst I have commented below on a number of these sentences, I would strongly suggest that the paper be further proof read by a native English speaker. Additionally, I think that in a number of sections there is a lack of detail surrounding some of the material included (e.g. the information provided in the DECADE brochures and the Arriba calculator), more details should also be given as to how the intervention was developed. Nevertheless, I feel that these changes are minor and would recommend publication of the manuscript once the comments presented below have been addressed.

Abstract:

1. The authors state that patients with increased CVR have major difficulties implementing the necessary health behavior changes, examples of these could be included.

2. There be an "a" before cardiovascular risk calculation.

3. Would the word "usability" be better than "applicability"?

4. Change the sentence "It generates first data of the effects of…” to "It will generate initial data on the effects of…”.
5. Authors state that the intervention will show effect on "clinical outcomes" - these should be briefly stated here.

6. In the first use of CVD spell out "cardiovascular disease".

Background:

1. The introduction could benefit from the use of some statistics surrounding the risk factors for CVD (in Germany and worldwide), to make the problem clearer (e.g. X% of CVD are caused by Y).

2. There are various causes for hypertension, obesity diabetes etc. besides genetic and lifestyle factors - the wording of this section needs changed to make this clearer.

3. Line 7: The first use of cardiovascular risk should be abbreviated (CVR) and abbreviated on Line 9.

7. As with the abstract the authors state that patients with increased CVR have major difficulties implementing the necessary health behavior changes, examples of these could be included.

4. The author state that "there exists a lot of information material for patients about CVD" the authors should elaborate on what information is routinely provided to patients (i.e. information about risk factors, prevention, healthier lifestyles, smoking cessation etc.).

5. Provide some references after the sentence ending "for medical doctors in shared decision making".

6. Change the sentence "there exists a lot of information material… in shared decision making" to "There exists many different forms of information for patients about CVD including: some decision aids to reduce elevated CVR (give examples here); educational training for patients to enhance patient knowledge (give examples here); and, training for medical doctors in shred decision making."

7. Authors state that previous interventions showed no effect on "health behavior" or "clinical outcomes" - these should be briefly stated here.

8. Elaborate on the term "self-management" and "patients' activities".

9. Reword the following sentence to make it clearer "However, patients with e.g. diabetes feel themselves faced with (too) high expectations on general practitioner's (GP) side and absence of support [20]."

10. Add space between (GP) and side.
11. Add "s" after "process parameter"

12. The authors consider the results from a paper [21] in relation to diabetes. This paper however investigates diabetes and CHD, the authors should consider the results for CHD in comparison to their own intervention targeting CVD.

13. More detail is needed surrounding the intervention development process. Whilst the authors direct the reader to 3 sources of additional information, these are lacking in detail. The authors state that the intervention was developed together with experts from other institutions an out-patients - this should be elaborated on more.

14. Recent literature in the area of intervention design has been advanced by the publication of the MRCs guidelines surrounding intervention development, pilot and feasibility testing: 1. development, 2. Feasibility/piloting, 3. Evaluation and 4. Implementation. The authors could strengthen the intervention developed for this study by considering these guidelines.

15. Change sentence "to meet the requirement of a long-term" to "to meet the requirements of long-term support for patients…".

16. The authors state they will use the concept if HAPA, but no further information is provide as to what this is. HAPA and previous studies using this framework alongside CVD should be considered.

17. The authors state that patients using DECADE will have access to a link collection on our homepage. Will this be password protected so those in the Arriba group cannot see the information (i.e. to avoid contamination and bias).

18. What information will be provided on the website - specifics should be given as to the other organizations the patients will have access to.

Methods / Design:

Aims

1. In the aims, change the sentence "the pilot study is (3)" to "the pilot study (3) will generate the initial data on the…".

Design and setting

1. Clarify whether this is a randomized controlled pilot trial or cluster randomized controlled pilot trial (i.e. are patients or GP practices randomized"

2. To avoid contamination would a cluster randomized controlled pilot trial be more rigorous with regard to selection and performance bias?
3. Change sentence "each GP practice" to "each GP practice will seek to include 15".

4. More details is needed as to the selection of patients (i.e. based on at least one cardiovascular risk factor" - what risk factors will the GPs specifically use?

5. More details is needed surrounding the Arriba group and cardiovascular risk calculation - what are the parameters used in this assessment and is this a validated process?

6. Will training of the GPs be provided in using these tools?

Study population and recruitment procedure
1. Change "wait list" to "waiting list".

2. More details should be given for the inclusion/exclusion of the patients (i.e. age, gender, pre-existing disease states).

Randomization of the patients
1. More details needed on what the patients will be randomized based on (i.e. CVR score, age, gender etc.).

2. The authors state that the GPs and patients will not be blinded, what about the MAs?

Intervention
1. An example of the brochure would be useful as supplementary materials. It is hard to visualize what the patients will be given with limited written material.

2. Change sentence "after randomization, patients …" to "after randomization, patients allocated to the DCADE group will receive the DECADE brochures in addition to the …".

Data Assessment
1. Authors should consider also measuring adherence (morisky medication adherence scale)

2. More details are needed on the scales of the authors "own development" (satisfaction of goal attainment and satisfaction with consultation and support by the GP) - how have these scales been developed, how are they assessed and scored?

Qualitative data assessments
1. More details needed on the questions asked during the half-standardized interview. A basic topic guide could be placed as an appendix.

Study endpoints and analyses

1. As previous - would the word "usability" be better placed than "applicability"?

2. In line with MRC guidelines the authors could state that an aim is "to investigate whether refinement to the intervention content, mode of delivery and study parameters / procedures are required for future evaluations.

3. Change "valuation" to "evaluation".

4. The authors could also add rigor to the feasibility testing of the study by using the APEASE criteria (affordability, practicability, effectiveness/cost-effectiveness, acceptability, side-effects (and safety), and equity.)

Sample size calculation

1. Number of drop-outs should at least be determined from similar studies in terms of methods, study population and outcomes etc.

Discussion:

1. Authors may wish to state that the information received from the feasibility study will be used to make refinements in the definitive trial.

Authors' contribution

1. Dada should be data.

2. Trail should be trial.

Figure 1

1. Enrolled should be enrolled.

2. 2nd box - patienten should be patients.

General comments
1. The use of a hyphen in the following words should be standardized throughout the manuscript (i.e. follow-up OR follow up): follow-up, half-standardized, DECADE-pilot.

2. The authors should standardize the use of analyze or analyse throughout.

Level of interest
Please indicate how interesting you found the manuscript:

An article of importance in its field

Quality of written English
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