Author's response to reviews

Title: Factors influencing participation in a vascular disease prevention lifestyle program among participants in a cluster randomized trial

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Author's response to reviews: see over
Response to Reviewers

Title: Factors influencing participation in a vascular disease prevention lifestyle

We thank the reviewers for their helpful comments

Authors response shown in bold italics

Reviewer 1: Elizabeth Venditti

Minor Essential Revisions

1. Page 2 -Abstract. Results. The authors should give the N of referred patients to LMP (197) in the abstract otherwise the reader may erroneously look at the methods section above (as I did) and try and extrapolate this from the cluster randomization (e.g. 16 X 160).

This has been added to the results section of the abstract (page 2, line 112)

2. Page 4-Introduction. Paragraph 3. The authors present their rationale for the need to focus on dose and reach as the field moves from efficacy to translation/dissemination studies in diabetes prevention and cardiovascular risk reduction. This is indeed an important data gap to examine in order to advance the field. However the references given in the third paragraph (6,8,12) do not do a good job of supporting the statement that "low overall participation rates are often reported" (e.g. rates of lifestyle participation in the initial year of DPP are not reported at all in the reference given --Knowler et al, 2002; they are reported in Wing et al, 2004 as very high (95%). I think that with some additional literature review and data reporting the authors could make a better argument (e.g. research on clinical trials focuses on treatment efficacy and attendance rates tend to be higher......but in the real world the attendance is more variable and it is not always clear how to best engage individuals in intensive interventions). More to the point, the authors could also then report on the actual attendance or completion rates in the translation/dissemination studies they have already cited (14-20). They could then note that there is a wider range of engagement (e.g. 50-80%) and that is important to try and better understand the predictors of such engagement through quantitative and qualitative analysis.

The authors have amended paragraph 3 and 4 to reflect the reviewers suggestions. It is important to distinguish between recruitment rates (which are often low in large efficacy trials, resulting in significant selection bias) and intervention completion rates (which tend to be high in efficacy studies and lower in implementation trials). This has now been clarified in paragraphs 3 and 4 of the introduction (page 4 and 5)

3. Results/Discussion. While several of the findings are not particularly novel, the authors present a wide range of mixed methods data (about both practice characteristics and individual participant characteristics) that may be useful to
those in the lifestyle dissemination field. I think the discussion section could be more concise and stronger in the following ways:
a. In the intro paragraph of the discussion the authors states that "patients who were older, did not work and had higher levels of psychological distress were significantly more likely to attend". In the second paragraph however, it is stated that "age was not a significant independent predictor" in the quantitative analysis. The table does show that the cutpoints shown are not significant. Might age have been significant is examined as a continuous variable? These seem not to be the best cutpoints (in several other studies is seems it is the over 60 category is most predictive). In this study the mean age is 58 so it may have made more sense to compare those above and below the mean.

There were different recruitment criteria for the 40-54 year age group than the 55-64 year age group. The 40-54 year age group had to have one CVD risk factor (eg hypertension and or dyslipidaemia). The 55-64 year age group did not have to have a CVD risk factor as thet were already considered high risk because of their age (as per the text in the paper line 153-154, p 6). Due to the different recruitment criteria it is not appropriate to treat age as a continuous variable in the analysis and Table 1 categories are appropriate.

b. Paragraph 3 --and the hypothesized association with neurotic personality seems quite speculative (it kind of stuck out to me, in an otherwise straightforward, data driven report). Personality traits were not measured in this study --just psychological distress---and there isn't any signal from the qualitative analysis regarding neuroticism. I think the authors are on stronger footing emphasizing the social support/group facilitation factors and how that may be related to attendance, particularly among distressed individuals. There is also a stronger medical literature supporting this association. My recommendation would be to then just leave it at the final sentence "Further research is warranted to explore the associations between psych distress and use of preventive health services---including the characteristics of the practices".

We agree with the reviewers suggestion and have amended this paragraph to reflect this
Reviewer: 2 Jeroen Lakerveld
Reviewer's report:
The authors provide a well written paper on factors associated with (non)attendance to a lifestyle intervention, and solid statistical methods were used. Although outcomes are potentially relevant for future interventions (e.g. to tailor recruitment strategies and intervention approaches), I am not convinced that the methodology used is – in its current form- adding much value. My main concern is that factors associated with (non)attendance is assessed in a selection of individuals that already responded to initial invitation, were eligible, attended the health check and agreed to be referred to receiving the Lifestyle programme. The identified factors were therefore probably very specific to those who were really far in this specific selection process, which makes it hard to generalise results. There were 3,128 patients invited, and only 125 participated. This means that the reach was low (less than 4%). This is not uncommon with this type of recruiting methods, and it would therefore be relevant to know who these non-responders and non-attendees are, in what aspects they differ from attendees, and why they did not respond/attend. The introduction section shows that the authors are acknowledging the need to evaluate this (paragraph 3).

The focus of the paper was to examine factors influencing attendance rates at a lifestyle modification program amongst those eligible to participate ie patients from intervention practices who attended the health check and were referred to the lifestyle program by their GP. The authors agree that it is also important to understand factors influencing initial enrolment in the study but this is a different research question and not the focus of this paper. As with most studies, ethics requirements only allow information to be collected on participants who consent to take part in a study. Therefore no information was able to be collected on those invited from the GP records who declined to take part in the study. The authors have added a paragraph into the discussion (page 18 ) to acknowledge the important point raised by this reviewer. Factors associated with referral have been examined in another paper –


1.) The difference between the non-attendees and the low-attendees is, as I see it, larger then the difference between the low- and high attendees. I
recommend to merge the latter two (attender), and analyse the non-attendees as a separate group (non attender). I realise that this may change the results.

The authors disagree. Low attenders by definition attended less than half of all sessions. Evidence suggests that a dose response relationship exists between attendance rates and changes in lifestyle and physiological risk factors [1, 2]. For this reason, the authors feel that conceptually it makes more sense to combine low and non attenders. Nevertheless, we conducted the supplementary analyses with two suggested groups (attenders vs. non-attenders) in relation to employment and psychological distress (K10). The results are consistent with those of the paper. Compared to non-attenders, attenders (high or low) were more likely to be not working (24% vs. 39%, P = 0.032) and have high distress (25% vs. 45%, P = 0.008).

2.) Introduction (page 4): Please check refs 3-9, as they do not prove the effectiveness of lifestyle interventions (they rather suggest the contrary, or evaluate the efficacy or secondary prevention). It is well known that lifestyle interventions are efficacious. However, so far, rct’s evaluating the effectiveness of programmes that target lifestyle behaviours to prevent diabetes or cardiovascular diseases in primary health care settings have shown mixed effects, and if effective, the effects were small and unsustainable.

The first sentence of second paragraph of the introduction (page 4) has been amended.

3.) 30 practices invited 160 individuals each (described in the Methods), counting up to n= 4,800. Please explain why only 3,128 individuals were invited (Figure 1).

Some practices had less than 160 eligible patients, the text has been modified to “up to 160 patients per practice” (line 156, page 6 and the abstract).

[Minor]

4.) The stages of change model has long since been abandoned as a useful framework to categorise individuals (mainly because they tend to shift between stages in a relatively short term). This could be added in the discussion section as reason for not finding any association with the readiness to change.

This has been acknowledged in the discussion (page 17, third paragraph)

5.) The factors found could be discussed in the light of other study results (e.g. by Lakerveld et al. 2008), as they differ mainly with regard to those who are employed or not.
This Comparison of key findings with other studies has been made throughout the discussion. Specific reference to Lakerveld et al 2008 has been added into the discussion, page 16, paragraph 1.

6.) Please use the term patients or participants, not both.

The term participants has now been used throughout

7.) Last sentence of page 17 is not a proper reflection of the results of the current study and should be omitted.

This sentence has been amended to be a general statement of the importance of undertaking qualitative interviews with non attending individuals to better understand factors influencing individual engagement with lifestyle intervention programs (line 470-474, page 19)

8.) Please also add a box to Figure 1 with number and reasons of those who attended the health check but were not referred.

Only high risk patients (as defined in the methods – page 7, line 165-169) attending the health check were eligible to be referred to the lifestyle program. Information was not collected on the reasons why patients were not referred to the program but it is assumed that they were either not eligible or declined to take part. Figure 1 has been amended to show the number and % of those eligible to participate in the lifestyle program.

References
