Author’s response to reviews

Title: The effectiveness of a primary care nursing-led dietary intervention for prediabetes: a mixed methods pilot study

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Dear Susan,

Thank you for providing us with the opportunity to revise our manuscript "The effectiveness of a primary care nursing-led dietary intervention for prediabetes: a mixed methods pilot study"
(FAMP-D-17-00184), in response to the points raised by the reviewers. We thank the reviewers for their overall positive comments about the importance and challenges of our study. The points raised were helpful, and we believe our revision has improved our manuscript. All changes to the manuscript have been made using track changes. Please note that we also corrected any grammatical and typographical errors that we noted, for example, we identified that one reference had been listed twice.

The following details our point-by-point responses to the points raised by the reviewers.

Editor Comments:

• You do state this is a non-randomised pilot study but the nature of the design and the fact that it was underpowered based on your own sample size calculation (which had a very ambitious clinical target regarding weight loss), means that it is not appropriate to conclude that the intervention was effective in the abstract or conclusions.

We agree with this comment and have amended the abstract and conclusions accordingly. The concluding sentence of the abstract, “Study findings confirm the feasibility, acceptability and effectiveness of primary care nurses providing structured dietary advice to patients with prediabetes in busy general practice settings.” has been amended to read “Study findings confirm the feasibility and acceptability of primary care nurses providing structured dietary advice to patients with prediabetes in busy general practice settings.”

• It would be more appropriate to discuss potential effectiveness and mention the need for a definitive RCT before consideration of implementation

We agree and have amended the text accordingly. We have modified text in the discussion and now conclude the discussion with the following statement, “Increased intensity of the intervention may be necessary to achieve greater weight loss, and definitive randomised controlled trials are required to assess intervention effectiveness.”

Reviewer reports:

Marie Barais (Reviewer 1):

We thank Marie for recognising that our ‘topic is relevant and focuses on real life settings, and that the ‘introduction is well written.’ Our response to the specific comments are:
• The authors should describe in more details the way other studies did not set in real life.

We have amended the last sentence of the 2nd paragraph of the introduction to more clearly explain the reasons, which is primarily few such studies have been reported. The relevant part of the sentence now reads, “…similar results have not been demonstrated in ‘real-world’ general practice settings [10], partly because few studies have examined the translation of diabetes prevention clinical trial evidence into this primary care setting [11].”

• The articulation between the six components of the multilevel package should be resumed in a scheme.

We did not clearly understand this comment, specifically we were unsure what was meant by ‘a scheme’. We wondered if it meant that the six components of the package were listed in a diagram or box? We have not done so, but would be happy to include a summary box, if deemed important to do so.

• The authors should distinguish the differences between the study and the feasibility evaluation. The feasibility study in itself was qualitative and not quantitative, wasn't it? I was puzzled by the mixed method study in the title.

While we did not clearly understand this comment, as stated in our manuscript the study is mixed method in design comprising both a quantitative component and a qualitative component. The process evaluation (qualitative) was part of the original study design and is an integral part of the study, rather than a separate study run in parallel to the intervention. Accordingly we have not altered the text.

• The usual care should be more detailed.

A brief description of usual care and an additional reference is now included (page 10, lines 56-60 and page 11, lines 1-13).

• What implies a green prescription?

A ‘green prescription’ is now described and an additional reference is now included (page 11, lines 9-13).
The discussion section should begin with a summary of the main results.

We have re-ordered the first two paragraphs of the discussion, so that a summary of the main results now appears at the beginning of the discussion.

As the control group did not have the same number of visits, how to be sure that the differences between the two groups are due to the intervention and not to frequent patient centered care visits in the intervention group? Why not including the same number of visits with different nurses on another topic for the patients of the control arm? If significant differences between the two groups are found at the end of the major study, I would ask the same questions: was it because the intervention led by the nurses achieved its goal or because the intervention group patients were involved in a centred and dynamic care through multiple visits whereas the patients in the control group did not have this kind of care? This aspect of the person-centred approach is not enough developed in the discussion.

Part of our intervention package was more frequent nurse visits to reinforce healthy lifestyle messages, to provide further lifestyle education and to provide general support. Intensity of lifestyle interventions is a critical component of lifestyle interventions. The difference between standard care (with fewer health professional visits) and intensive care (with a greater number of health professional visits) in terms of weight loss and diabetes risk reduction is clearly documented in the well-known Diabetes Prevention Programme (DPP) and Diabetes Prevention Study. The intensity of visits underpinned the results from both these well-known and well-conducted trials. In the DPP the standard (control) lifestyle group were encouraged to follow the Food Pyramid guidelines and to consume a healthy diet; to lose 5–10% of their initial weight through a combination of diet and exercise; to increase their activity gradually with a goal of at least 30 minutes of an activity such as walking 5 days each week; and to avoid excessive alcohol intake. All participants who smoked were encouraged to stop. These recommendations were reviewed annually with all participants. In the intervention group, visits were frequent (no less than monthly) to provide support for behaviour change. Because of this, and the fact that our intervention was a package and the study was not designed to disentangle the individual components of the package, we have not amended the text of our paper on this point.

Mark Harris, MBBS FRACGP MD (Reviewer 2): This is an interesting mixed method pilot study lifestyle intervention delivered by practice nurses for people with pre-diabetes in New Zealand primary care.
There are a number of problems with the trial which need to be more fully discussed and the conclusions adjusted accordingly:-

1. The design was not randomised - with control practices from a neighbouring provincial city.

This is stated in the text and we have not amended the methods, but have revised the discussion to better reflect our study design.

2. The trial was registered in August 2015 well after the conclusion of patient recruitment in April 2015.

We acknowledged this and provided an explanation in our covering letter accompanying the original submission.

3. The study was powered to show an 4kg weight loss equivalent to 5% of weight - a minimal clinically significant loss at 6 months. However only a mean 1.3kg weight loss was demonstrated with non significant changes in Hb1c.

The sample size was, as noted by the reviewer, determined by assuming a minimum clinically important difference of 4kg, a value larger than the weight loss observed (a 2.2 kg difference unadjusted, 1.3 kg after adjustment). We have discussed that a more intensive intervention may be required to produce a greater weight loss over a 6 month period. While the observed weight loss was lower than our initial threshold for clinical significance (one half or a third of the magnitude depending on adjustment), any weight loss or avoidance of further weight gain is likely to be beneficial to our patients. We are exploring this outcome further in a separate manuscript under preparation that will present a cost-effectiveness analysis. The addition to the discussion reads (page 22, lines 47-60 and page 23, lines 1-5), “The less than expected mean weight loss and insignificant change in HbA1c may reflect insufficient intensity of the intervention as both nurses and patients recommended additional sessions or monthly phone check-ins, particularly between months 3 and 6 of the intervention. This is a highly likely explanation considering that during the first 6 months of the DPP lifestyle intervention, case managers met with individual participants at least 16 times during the first 24 weeks of the study,[33] compared with only 4 appointments during our 6 month intervention. However, although mean weight loss was relatively small in our study, it is clinically meaningful, as in the DPP for each kilogram of weight loss, the risk of progressing to diabetes was reduced by 16%.[34]”

We have also now included the proportion of participants in each group who achieved a 5% weight loss (page 13, lines 7-13; page 15, lines 49-54)
4. In table 3 it is unclear what statistical test was performed to compare change in intervention and controls.

We have now reproduced some of the statistical methods as a note Table 3 to make this clear. The note reads, “Statistical comparisons are from linear regression models, except for GGT where a quantile regression model was used to model medians, adjusting for baseline values, sex, alcohol consumption, family history of T2DM, and ethnicity and adjusting standard errors for clustering within practices.”

5. The retention rate of 79% was reasonable. Further there was evidence provided that the practice nurses attended the training. However there is insufficient information about how the fidelity of the intervention as delivered by the practice nurses was monitored. How did the support dietician confirm that this was delivered as per protocol.

We appreciate the acknowledgement of the reasonably good retention rate. More information has been added about the role of the dietitian and the liaison nurse and how this information was ascertained for the process evaluation (page 8, lines 52-56; page 16, lines 14-20, 26-30).

6. The qualitative findings were all positive except for a comment about group participation. Was there any variance in responses of patients or nurses? Was there any difference based on their relative success in weight loss.

This reviewer appears to have missed that we also mentioned three other challenges, all of which were identified by both key informants and patients: 1) not enough time for initial visit; 2) too long a gap between 3rd and 4th appointment and 3) difficulties working with limited food budgets. We have made changes to ensure this is clearer for the reader (page 20, lines 36-51). There was no variance in the responses of nurse and patients (except about information flow between practice nurses and group educators) and no variance amongst patients according to their health outcomes. These points have also been added (page 21, lines 6-9).

Yours sincerely

Dr Kirsten Coppell

Senior Research Fellow