Author’s response to reviews

Title: Implementation Findings from a Hybrid III Implementation-Effectiveness Trial of the Diabetes Prevention Program (DPP) in the Veterans Health Administration (VHA)

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Author’s response to reviews:

Thank you for the opportunity to revise this manuscript for review. We have made significant edits and we feel the revised version is much stronger. Because we added a lot of extra text in the introduction and discussion sections, we cut text as well so we met word limits, which will explain the extent of edits in these sections.
Point-by-point responses to reviewers' comments (line numbers refer to track-changes version with in-line edits):

Reviewer #1:

There is nothing new in your paper. The problems you uncovered are well-known and so are many of the solutions.

A more thorough review of the international literature would have resulted in a different slant on what you reported. In Europe and Australia small implementation trials had been conducted before CDC/YMCA started. In line 163 it would have made sense to refer to a European Union-funded project which led to evidence-based guidelines for diabetes prevention projects. (Paulweber et al Horm Met Res 2010.) Much international experience was summarised in: Schwarz P et al. Diabetes Prevention in Practice. 2010. Tumaini Institute, Dresden, Germany. Finland has a national diabetes prevention program which it reported in 2007 (Saaristo International Journal of Circumpolar Health) Australia reported its national program in 2014. (Dunbar. Diabetes Care.)

In response to line 344 onwards, from the international literature you would see that it is possible to embed diabetes prevention within primary care settings (family physicians in Finland) or alternatively provide a service to which family physicians are happy to refer. E.g. Life! In Australia.

• Thank you for pointing us to this literature. We have expanded the introduction and discussion to include many of these citations. Inclusion of international studies (beyond just the reviews already cited) strengthened the paper by providing greater context for results from this demonstration.

• The Background and Discussion sections were extensively expanded to include more of the international literature including use of screening instruments.

The Consolidated Framework for Implementation Research, a self-reference to the first author, is unnecessary. Simple English is better suited to the task.

• We cited CFIR to promote use of consistent language and concepts across diverse studies in a well-established framework to enable integration of new knowledge into a common knowledge-base. We also use the RE-AIM framework to guide the evaluation.

• See lines 401-404, 687-688
Throughout this rather wordy paper you refer to your previous papers which means there is very little in this paper.

• The focus of this paper is to report implementation findings from a hybrid trial, which complements the protocol paper and clinical outcomes paper that were reported elsewhere. Together, these papers provide necessary context for the current findings.

What you say in lines 176 to 178 (with another self-reference) doesn't fit with general experience internationally. It is difficult to recruit people to diabetes prevention interventions but many solutions have been described.

• We have added additional references and now reference published toolkits such as IMAGE toolkit by Lindstrom et al.

• See lines 601-609

You don't seem to have tested realistic recruitment processes nor do you seem to have assessed 'Reach' in terms of the proportion of VA patients at high risk of diabetes. Why use expensive point of care tests when large numbers of people can be screened at low cost using FINDRISC, AusDRISK or similar short questionnaires but you don't mention them.

• Thank you for highlighting these risk assessment alternatives. We have added these references to the introduction and discussion sections to help place our more intensive screening process in context. Some studies using these risk assessments did confirm diagnoses with clinical tests of fasting plasma glucose and/or glucose tolerance (e.g., Laatikainen, et al. "Prevention of type 2 diabetes by lifestyle intervention in an Australian primary health care setting: Greater Green Triangle (GGT) Diabetes Prevention Project." BMC public health 7, no. 1 (2007): 249).

• See especially lines 229-250, 650-652

The reason to prevent type 2 diabetes is because it is a risk factor for cardiovascular disease which is what actually kills people yet I see no mention of blood pressure or cholesterol as outcomes.

• Blood pressure and cholesterol assessments were outside the scope of this study. We note this as a limitation in the revised discussion.

• See lines 725-726
In line 387, you list barriers which many participants overcome and therefore they shouldn't be taken at face value. It rather suggests that goalsetting may have been happening without prior problem-solving with participants.

- This is a possibility but assessment of this was outside the scope of this study.

Providing costs is interesting but meaningless unless they are part of a health economic evaluation demonstrating the cost consequences of usual care.

- We have added this limitation to the discussion section.
- See lines 733-734

Reviewer #2:

This is a comprehensive assessment of the implementation of the DPP in 3 Veterans (VHA) sites, using a variety of forms of data collection in a hybrid intervention-effectiveness trial.

There are some useful insights in this important clinical and policy area and the paper makes a suitable contribution to the literature.

The paper begins with a review of two major studies in this area, highlighting variation in delivery and exploring drivers of DPP delivery. A core finding is that 'reach' is identified as an important driver of performance.

The hybrid effectiveness-implementation design might be described briefly. Although familiar to many readers, this paper may attract those outside the implementation science field, so some context would be useful.

- The reviewer’s point is well taken and we have added a sentence about the Hybrid Type III design used in this study under the Methods/Study Design section.
- See line 305-310

The use of the hybrid design has advantages and disadvantages and I would be interested in the views of the authors as to the latter when the focus is on the process of implementation. The title of the paper might need changing to reflect that fact that the analysis is focussed on comparison
of the DPP in the context of a trial, and an existing weight loss intervention, rather than a context lacking any existing services of this type. That would seem important to interpretation.

• Based on your suggestion, we have changed the title to better place these findings within context of a comparative effectiveness trial.

I was also interested in the degree to which it was possible to distinguish issues related to the implementation of the DPP, and those which related to the issues related to taking part in a trial - for example, barriers to recruitment that led to low levels of recruitment? The authors found that many patients did not meet the pre-diabetes criteria, but was the confirmation of prediabetes only required in the trial, or is that part of routine DPP delivery? Are these analytic distinctions easy to make?

• Our protocol paper (see especially Table 3) details the distinction between research and “quality improvement” components of this study, and we also note that confirmation of prediabetes is not a standard VA practice and was only conducted due to this trial.

• We have noted that a strength of this study was that all screening and outcome assessments were done as part of a quality improvement initiative and relied on measures obtainable through clinical processes. No additional patient assessments were necessary for the “research” aspects of this study. However, interviews and fidelity assessments were partially supported with research funds.

• Note that the recruiting process was a part of operational clinical processes for an already-existing weight management program.

• See lines 723-733

I struggled a little with the interpretation of the fidelity differences. Is it something inherent in DPP that makes it easier to deliver in a way that leads to high ratings? Or does it relate to more pragmatic differences (such as the training for the DPP being more recent)? I was not clear what that meant for implementation.
• We have added a sentence in the discussion that highlights the possibility that more recent and structured DPP training may have contributed to higher fidelity scores.

• See lines 578-580

Table 3 is useful and the advice seems sensible, although there was no attempt to provide any indicator of importance or weighting. The advice also seemed to focus quite a lot on 'targeted information' to various groups and I was not clear on the evidence that these were effective strategies to overcome some of these barriers. For example, is there evidence that such information can overcome some of the inertia among clinicians - which seems to be related to their experience of the effects of these interventions in routine populations? Could some of this advice be extended in depth and specificity? What sort of process meets the criteria discussed under Reach? What are the likely cost implications?

• These strategies were developed based on observations at the three study sites. We have clarified that these recommendations are hypotheses of what might work but that need to be tested in a larger trial.

• See lines 524-528

I do not understand the comment made about weight loss being significant for DPP clients, but not significantly different between arms. Does the first statement relate to significant change over time within one arm? I am slightly wary of that being used as an indicator of something relevant, as it is not really legitimate in the context of a trial.

• Thank you for pointing this out. As suggested, we deleted the observation about significant weight loss within arms.

• See line 214

Minor issues

A short definition of the RE AIM dimensions on page 11 might be useful.

• We have reworded this section to provide more description for each dimension

• See lines 224-230
On page 19, was the positive quote about experience in DPP unmatched by similar comments for MOVE?

- We have clarified that in our staff interviews, we focused on DPP and not on MOVE!. However, this general perception was reinforced through patient satisfaction measures and via interviews with MOVE! and DPP participant, the latter of which are not included in this paper.
- See lines 406-407