Author's response to reviews

Title: Prevention of Type 2 Diabetes by lifestyle intervention in an Australian primary health care setting: Greater Green Triangle (GGT) Diabetes Prevention Project

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Author's response to reviews: see over
Dear Editor,

Thank you for the opportunity to resubmit our revised manuscript entitled ‘Prevention of Type 2 Diabetes by lifestyle intervention in an Australian primary health care setting: Greater Green Triangle (GGT) Diabetes Prevention Project’.

On behalf of my fellow authors I would like to thank the reviewers for their valuable comments. We believe that we have fully addressed these comments in tracked changes. In particular we have addressed the comment made by both reviewers about the absence of the control group. We make the distinction between a randomised controlled trial, which in its nature is too costly to implement in a health service setting, and “real world” implementation trials.

In the following we reply to the comments point by point. Please, find also attached the revised manuscript. We hope that our manuscript is now acceptable for publication.

We look forward to your response.

Yours sincerely,

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Review 1

General Comments

- Although the authors are cautious in interpreting the results I think that it may be premature to suggest that the effects are similar to previous studies because this study lacks a control group. The consequence of not having a control group should be discussed in the discussion section, because there is a large risk that the results are not the consequence of the program itself but of being involved in a research setting. In a previous intervention study carried out in the primary care setting this effect was clearly demonstrated (EM van Sluijs et al, 2005)

In order to be more cautious, the authors have omitted the text “with effects similar to those observed in clinical trials” and have replaced it with the text “with reductions in risk factors approaching those observed in clinical trials”. (Page 2, Line 56-57)

The authors have addressed these comments further throughout the manuscript in tracked changes. We have explained why it is inappropriate and unethical to do a randomised controlled trial. The costs incurred in clinical trials far exceed what health services could fund and it would be unethical to withhold treatment in any control group.

The authors have described the history of the progression from the Diabetes Prevention Study [1], to the GOAL implementation trial recently published in Diabetes Care [2]. The GOAL implementation trial is the sister programme of our study.

In short, both the GOAL intervention study [2] and the Greater Green Triangle Diabetes Prevention Project have been implemented in “real world” health service circumstances.

- The authors describe the costs of the intervention. I would suggest to differentiate between the various costs, so the reader gets more insight into it. In the discussion the authors compare cost per lifestyle and drug intervention and conclude that lifestyle interventions can be carried out at reasonable costs, suggesting that it may be more worthwhile to invest in lifestyle interventions. However to really compare costs, it should be compared with the (long term) effects. Since we should be careful in interpreting the effects of this study I believe the authors should also be careful in comparing the costs.

The authors have decided to omit the text related to the cost of the intervention throughout the manuscript. A subsequent paper outlining the costs of the intervention is currently underway and will differentiate between the various costs of the programme.

- The authors do refer to previous papers in which the program is described, but I would prefer to have more information in the paper (content of program, intensity etc.), because only in the discussion section it became clear that the intensity of the program was highest in the first 3 months.

As suggested, a more detailed description of the program has been included in the text, particularly relating to content and intensity of the program.
The following sentences have been added:
(Page 5, lines 124-125)
“The first five sessions occurred within the first three months, with two week intervals between sessions. The last session took place at eight months.”

(Page 5, lines 129-130)
“Session content for diet and physical activity was based on Dietary Guidelines for Australian Adults and National Physical Activity Guidelines for Adults”

• Furthermore, I believe the English language can be improved.

The English language has been improved throughout the entire document. Please refer to tracked changes.

Reviewer 2

General Comments

• The study was an observational intervention study without control group. Thus, the effectiveness of the intervention cannot be evaluated. It can only be suggested that observations are effects of the intervention. The aim of the study as well as the conclusion might better be “assessing the course of study subjects with respect to the investigated variables during intervention”. This point could also be discussed in the discussion section.

Please refer to previous text re: absence of a control group and effectiveness comments. The authors have addressed these comments further throughout the manuscript in tracked changes and referred to the GOAL implementation study [2].

• Is the Diabetes Risk Score appropriate in the study population (which is different from the population in which the Score was evaluated)? Only about one third of tested subjects had impaired glucose metabolism? The Diabetes Prevention Trial was performed in subjects with impaired glucose tolerance and/or fasting glucose. This point could be provided in the discussion section.

The Diabetes Risk Score [3] was developed from population based epidemiological studies. This risk screening tool was not utilised in the Diabetes Prevention Study [1], but was utilised in the GOAL intervention study [2] for identification of participants with an elevated risk of developing type 2 diabetes. In the GOAL programme, 30% of men and 21% of women were found to have impaired glucose levels at baseline. This is comparable with the findings in the present study, suggesting that this tool is appropriate for use in both populations. This is the first time the Diabetes Risk Score has been used in an Australian setting.

The following sentence was added to the text (Page 4, Lines 109-111):
“The Diabetes Risk Score tool, developed from population based epidemiological studies, was used to identify patients at high risk of developing type 2 diabetes.”
Specific Comments

- **Abstract - Introduction and Conclusions: effectiveness – see above**

  *The word “Effective” has been removed from the aim. (Page 2, Line 37)*

  *In order to be more cautious, the authors have omitted the text “with effects similar to those observed in clinical trials” and have replaced it with the text “with reductions in risk factors approaching those observed in clinical trials”. (Page 2, Line 56-57)*

- **Background - Aim of the study: (effectiveness)**

  *The word “Effective” has been removed from the aim. (Page 4, Line 93)*

- **Methods - Were the 1,500 approached people all patients in the included general practitioners’ practices or a selection? If a selection – which were the criteria to ask patients for participation (more than the described exclusion criteria)?**

  *The following sentence was added to the text. (Page 4, Lines 108-109)*

  > “Participants were patients presenting at local General Practices and were screened opportunistically by study nurses in reception and waiting areas.”

  *The 1500 people approached for screening were all patients presenting to the included general practitioners’ practices. All adults were approached equally, with no selection criteria implemented.*

- **Methods - How were the intervention costs assessed?**

  *The authors have decided to omit the text related to the cost of the intervention throughout the manuscript text. A subsequent paper outlining the costs of the intervention is currently underway.*

- **Methods - Fasting glucose – how defined? Was a quality control performed (e.g. asking people if they indeed had fastened during 8 hours)?**

  *The following sentence was added to the start of the paragraph (Page 6, lines 130-134):*

  > ‘All participants were required to fast overnight prior to each clinical test for a minimum of eight hours. A quality control was performed before each clinical test by asking participants the duration of their fasting period. Fasting hours ranged between 9-17 hours.’
References

