

Response to Reviewers

Name of journal: World Journal of Diabetes

ESPS manuscript NO: 32000

Title: Impact on dietary intake of a self-directed, gender-tailored diabetes prevention program in men

Dear Associate Professor Lu Qi and Associate Professor Jingbo Zhao,

We would like to thank the reviewers for their constructive feedback. The suggested changes have greatly improved the quality of the manuscript.

The comments for each reviewer have been addressed below and the appropriate changes incorporated into the revised version of the manuscript. The supplementary materials requested by the journal have been uploaded and/or relevant changes made to the manuscript text. All revisions to the manuscript have been made using 'track changes'.

Sincerely,

Dr Megan Rollo, PhD

(on behalf of co-authors)

Reviewer's code: 00043561

Comments to Authors:

Thank you for inviting me to review the manuscript titled "Impact on dietary intake of a self-directed, gender-tailored diabetes prevention program in men". The authors reported a set of data from the so called their Pulse study. The major findings were published elsewhere recently. Now the authors submit data related dietary content changes measured specifically. The results are largely not novel, only male gender was included, the sample size is somewhat low, all confounders for eating behaviour (i.e., depression/anxiety, GIS disorders, medications) were not included, and "personally" recorded lists of consumed foods suggest limitations. However, this is overall a well conducted prospective study submitted upon invitation and can also be interesting to the readers.

AUTHORS' RESPONSE: The authors thank the review for their comments. The reviewer has not raised any issues that require changes in the manuscript or a response.

Reviewer's code: 00506294

COMMENTS TO AUTHORS

The article entitled: "Impact on dietary intake of a self-directed, gender-tailored diabetes prevention program in men" is an interesting study about the modifications of diet in gender-tailored type 2 diabetes mellitus following the Prevention Using LifeStyle Education (PULSE) program in men .The PULSE is a self-directed type 2 diabetes mellitus prevention program for men resulted in significant improvements in dietary intake, including a reduction in energy-dense, nutrient-poor foods and increased overall diet quality and variety within healthful food groups and fruit, non-meat protein and meat following the Australian Recommended Food Score scales. Portion sizes for potatoes, steak and casserole were significantly reduced in the intervention group versus the control group. Changes in the desired direction were observed for increased vegetable variety and decreased alcohol intake. The findings are important and the interest also of the study will be the efficacy of these modifications in the future of subjects prone to develop diabetes mellitus.

AUTHORS' RESPONSE: The authors thank the review for their comments. The reviewer has not raised any issues that require changes in the manuscript or a response.

Reviewer's code: 00506346

COMMENTS TO AUTHORS

None

AUTHORS' RESPONSE: Nil changes made to the manuscript.

Reviewer's code: 00506298

COMMENTS TO AUTHORS

The study by Rollo and colleagues aimed to evaluate the impact of an educational program (PULSE) during 6 months on changing eating habits in a sample of population in Australia. This is a randomised controlled trial. The study is very interesting from a clinical practice point of view, however, authors' should clarify some points before the study will publish in the WJD. 1. Why only males were studied? 2. Did you calculate the sample size of study subjects? How? 3. What are the main reason to lost of follow-up? 4. What mean "completer" and non-completer"

AUTHORS' RESPONSE:

1. The primary objective of the main study was to determine the efficacy of a self-directed, gender-tailored type 2 diabetes prevention program developed for men. The purpose of gender tailoring is to get better engagement of participants but by necessity it then is only appropriate for one gender. We targeted men because we had already found that men were more willing to participate in weight loss programs that were just for men. We have provided more information to support the rationale of the study.

Page 6: "Detailed information regarding the rationale, study design and methods are reported elsewhere ^[1, 2]. Briefly, emerging evidence supports the use of gender-tailored approaches, in particular to weight loss ^[3, 4]. Our previous research has found gender-tailored programs to be effective in producing weight loss in men ^[5-7]. However, T2DM prevention programs predominantly involve both men and women with results reported collectively ^[8]. Therefore, the PULSE program aimed to address this gap in the evidence through the evaluation of T2DM prevention program designed exclusively for men."

2. The current study is an analysis of secondary outcomes in relation to diet. A sample size calculation was performed for the primary outcome of change in weight (kg). To allow 20% loss to follow up, a minimum sample size of 97 was required at baseline. Full details on the calculation are provided in the protocol paper (Aguiar et al., Cont Clin Trials: 2014, 39(1):132-44). The target sample size of a minimum of 37 participants in each group was achieved (total 101 participants) enrolled in the study; n=53 PULSE intervention, 48 control) (see Aguiar, et al. Am J Prev Med. 2016;50(3):353-64).
3. The main reasons for lost to follow-up at 6 months were not being able to attend the assessment session (eg because they no longer lived close) or unable to be contacted (eg phone number no longer current); these reasons are reported in the primary outcomes paper (see Aguiar, et al. Am J Prev Med. 2016;50(3):353-64). Non-completers refers to those who were unable to

attend the assessment sessions, were unable to be contacted or did not complete all measures.

We have clarified this in the text Page 9: “(not able to attend the assessment sessions or were unable to be contacted)”.

4. ‘Completers’ refers to those participants. We have clarified this in the text: Page 9: “Between group differences in completers (those who did complete all 6-month follow-up measures) vs non-completers (those who did not complete all 6-month follow-up measures, including those lost to follow-up)....”

Page 10: “An additional two participants in the intervention group attended the follow-up session, but did not complete the AES at 6-months, leaving a total of 21 non-completers and 80 completers from the original 101 participants whom commenced the study.”