Author’s response to reviews

Title: Behavioural Lifestyle Intervention Study (BLIS) in patients with type 2 diabetes in the United Arab Emirates: A randomized controlled trial

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Author’s response to reviews:

Dear Editor-in-chief and peer-reviewers,

Thank you for your valuable comments on our manuscript and for re-considering it for publication. We have taken all your comments into consideration and amended the manuscript accordingly. Please find below our detailed reply to your comments.

Reviewer 1 comments

Comment 1: The abstract should be better shortened and reorganized.

Authors’ reply: We acknowledge that the abstract is quite lengthy. We have tried to reduce the background. However, we find it a little difficult to reduce the length of the other sections because we believe it may dilute our message.

Comment 2: The behavior lifestyles intervention is on the Arab diabetes, but at methods stage, it is not quite clear to the reviewer. And we can’t known about the interventions have cultural differences between Westen and Asian populations

Authors’ reply: Acknowledged. The difference between our lifestyle intervention and ones targeting western population has been elaborated on in the method section. Kindly refer to line 143-149.

Comment 3: Table 1 and table 2 should be merged
Authors’ reply: We respect your viewpoint and we do understand why both tables should be merged. However, we have kept them separated due to the length of the table when merged. Also, variables like age, gender and duration of diabetes can’t be merged because they are baseline data only.

Reviewer 2 comments

Comment 1: P6, Settings and Participants: Please provide more information on how patients were identified as potential participants in the study. How or when were patients referred to the clinic? What types of patients attend this clinic (newly diagnosed, physician referred, patients identified by PCP as needing managed care, etc.) What efforts were taken to recruit patients? Were patients informed of the study when they arrived at the clinic for their first visit? Who contacted patients about potential eligibility? Were flyers, letters, mailings, direct PCP referrals, etc. used.

Authors reply: P6 was amended. Kindly refer to line 117-123.

Comment 2: P9, Outcome measures: Please provide more information on the questions used to assess physical activity. What intensity of exercise was collected? Was a standard question used? How valid and reliable was this measure? Physical exercise was self-reported as part of the initial assessment done by the dietitian.

Authors’ reply: Sentence amended. Kindly refer to line 194-197 and line 199.

Comment 3: P10, Statistical analysis: The sample size recruited (n=35) was less than that needed (n=50) based on power calculations for the primary outcome. Please address this issue in the discussion and include information on efforts taken to recruit and retain the target sample size of 50. If information on recruitment barriers was collected, this should be included in the manuscript as it will provide important process information for future translation efforts.

Authors’ reply: Study limitations in the discussion section was amended as suggested. Kindly refer to line 360-364.

Comment 4: P11, L226: There were significant differences in weight and blood pressure between the intervention and control groups. This indicates that the randomization method selected may not have been effective. This should be addressed particularly when presenting the corresponding results for weight loss and blood pressure. Was physical activity similar between randomized arms? This information is missing from Table 1 and should be provided since it is a secondary outcome.

Authors’ reply: The results section was amended as suggested. Kindly refer to line 224-227 for the weight and blood pressure results. In regards to physical activity, both the intervention group
and control group were significantly different at baseline. Sentence amended. Kindly refer to P11, line 259 and also to Table 3. We have also slightly changed the sentence reporting physical activity. Kindly refer to line 268-271.

Comment 5: P11, L241-242: The authors reported no significant changes in weight during the intervention. More information on adherence to the intervention (number of sessions completed) and adherence to calorie goals would be helpful in speculating why a change in weight was not observed. Also, it needs to be addressed that the baseline weight between the intervention and control groups was borderline significant (p=0.06), with nearly a 10 kg difference between intervention and controls.

Authors’ reply: The difference in the baseline weight was added in the result section. Kindly refer to line 226. Unfortunately we have no data on adherence to intervention (i.e. number of sessions completed by subjects) after the first consultation. Hence, we are unable to study whether poor adherence to calorie recommendation could be the reason for ineffective weight loss.

Comment 6: P2, L44: Remove "all of"; since you haven't explicitly stated the other outcomes that will be assessed, it is cleaner and clearer to make a direct statement

Authors’ reply: Sentence amended as suggested by reviewer to “they were measured”. Refer to line 43

Comment 7: P2, L45: Please define measures that are collected and evaluated at 1 year follow-up

Authors’ reply: Amended as suggested by the reviewer to “All of the patients were then followed up at 1 year on all outcome measures”. Refer to line 45.

Comment 8: P3, Results: Either present mean change at both 6 and 12 months or present mean values at baseline, 6, and 12 months to make the results consistent across time points

Authors’ reply: Amended. All values were presented as mean change. Refer to line 52.

Comment 9: P3, L65-66: Focus less on global rates and more on prevalence of type 2 diabetes in UAE to give the readers a better idea of the potential impact of your intervention

Authors’ reply: Background amended. Refer to line 60-65.

Comment 10: P4, L79: add comma after "problem solving" since statement "which help patients...." in L80 pertains to "stimulus control" only.

Authors’ reply: Amended as suggested by the reviewer. Refer to line 75

Comment 11: P5, L93: behavioural lifestyle interventions for "patients with" type 2 diabetes

Authors’ reply: Amended. Refer to line 88.
Comment 12: P5, L94: Do the authors mean to say that only a few trials have been conducted that measure glycaemic control as the primary outcome? Later in the discussion the authors mention other translation trials that report weight loss as a result of behavioural interventions for patients with type 2 diabetes. Please be clear and concise about the literature being referenced.

Authors’ reply: We meant that most of the translational trials were done in patients at risk of type 2 diabetes and few were in patients diagnosed with diabetes. We agree with the reviewer that the discussion on weight loss may not have been clear. Hence, we have re-written the paragraph on weight loss in the discussion section. Kindly refer to line 323-329.

Comment 13: P5, L98: Replace "all" with "these 3 trials". The term "all" is too broad and sweeping of a statement and indicates that authors have reviewed all relevant literature.

Authors’ reply: Sentence amended. Refer to line 94.

Comment 14: P5, L104: Consider replacing "ran" with "offered" or "conducted"

Authors’ reply: Amended to “We conducted the program”. Refer to line 100.

Comment 15: P7, L138: 17% attrition is redundant of the 83% who completed the trial

Authors’ reply: Attrition rate was deleted. Refer to line 132.

Comment 16: P7, L155: change "achieving" to "achieve"

Authors’ reply: Amended. Refer to line 154.

Comment 17: P9, L199: Change "all of the patients" to "study participants"

Authors’ reply: Amended. Refer to line 200.

Comment 18: P9, L200: Change last sentence to "all of the enrolled participants were invited to attend a follow-up visit at 1 year". As demonstrated in Figure 1, not all of the patients at the clinic attended a visit at 1 year. The original sentence is misleading

Authors’ reply: Amended as suggested by reviewer to “all of the enrolled participants were invited to attend a follow-up visit at 1 year”. Refer to line 202.

Comment 19: P11, L233: At what time point?

Authors’ reply: At 3 months. Sentence Amended. Refer to line 234.

Comment 20: P11, L236: Please clarify to the reader that the comparison being made is between those with a diabetes duration more than and less than 5 years
Authors’ reply: The sentence amended to “The reduction in HbA1c levels remained larger at 6 months between those with a diabetes duration more than and less than 5 years, although the difference was not statistically significant (-1.77±0.43 vs. -0.43±1.09)”. Refer to line 236

Comment 21: P12, L256: Please list other sources of carbohydrates evaluated; this will give the reader a better idea of what sources are included in the “total carbohydrate” metric

Authors’ reply: Carbohydrates sources listed. Sentence amended to “At baseline, the intervention and control groups did not differ with respect to the intake of carbohydrates from all sources i.e. cereals, fruits, dairy products, vegetables, legumes and other carbohydrates like sweets. Refer to line 257.

Comment 22: P12, L257: Carbohydrate intake from dairy also reduced as per Table 3

Authors’ reply: A sentence on changes in the dairy products was added to P12. Refer to line 263.

Comment 23: P13, L266: Was the treatment effect significant?

Authors’ reply: Sentence amended. Refer to line 273.

Comment 24: P13, L271: Control group had significantly lower diastolic BP at baseline compared to intervention group. This should be addressed in discussion

Authors’ reply: The difference between the two groups in diastolic blood pressure is added in the results section refer to line 224-226. However, we didn’t discuss this difference or the significant increase in the diastolic pressure at 1 year due to levels being within the normal range.

Comment 25: P14, L303. Please provide references for statement in L302-303

Authors’ reply: References were added. Refer to line 310.

Comment 26: P15, L317: One could argue whether the observed weight loss in this study is considered modest. The observed changes in weight were not significant and the study was also not powered to evaluate weight loss

Authors’ reply: We agree with your statement. We have amended the paragraph discussing weight loss. Kindly refer to line 324-320.

Comment 27: P16, L346-347: Please provide references

Authors’ reply: Reference provided. Kindly refer to line 353.

Comment 28: P26, Table 1: Patients enrolled in this study were relatively younger than those enrolled in the larger clinical trials (DPP, DPS, Look Ahead); some of the published literature on clinical and observational studies have demonstrated that older adults report higher adherence to
dietary goals and thus report greater success at meeting weight loss goals (see Wing et al. 2004, Obesity Res). The authors may want to consider this in the discussion and talk about potential barriers to adherence in this younger Emirati sample.

Authors’ reply: We respect your point of view. We have also read the reference (Wing et al. 2004) which you suggested and we understand why age might be a reason for non-compliance to calorie recommendation and physical activity goal. However, we could not support that with similar translational research to our study (reference 13 and 18) that had age group similar to the large clinical trials but didn’t show improvement in physical activity, for instance.