Author’s response to reviews

Title: Effect of nonsurgical periodontal therapy verses oral hygiene instructions on Type 2 diabetes subjects with chronic periodontitis: a randomised clinical trial

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Author’s response to reviews: see over
Response letter to the Editor

Dear Editor

Thank you for your email and the expert review. The suggestions from the reviewers are constructive and useful and we have tried to amend the manuscript at almost all of these points. The following is our response to each of the comments given by the reviewers and we indicate how we amended the manuscript. The changes to the original text are highlighted in red in the new version of the manuscript.

REVIEWER 1

Comment 1
Lines 124-126: Reference(s) to the diagnostic criteria for moderate to advanced periodontitis are lacking.
Response:
Reference has been added on line 124.

Comment 2
Lines 137-138: The reference Kao et al. 2008 is not included in the reference list.
Response:
Reference has been added on line 137 and included in the reference list.

Comment 3
Lines 144-145: Reference to stated clinical parameters should be accounted for here instead of under heading periodontal examination.
Response:
Reference position has been changed to line 144.

Comment 4
Line 150: Why was a full periodontal examination performed after 2 months? Studies have shown that healing following nonsurgical periodontal therapy appear almost complete at 3 months following intervention.
Response:
Thank you for your comment. The accepted duration of reassessment after non-surgical treatment is 6-8 weeks. To enable the findings of this study to be used practically, standard practices where followed where possible.

Comment 5
Why follow-up after 3 months and not 6 months? It has been shown in several studies as accounted for in the review by Teeuwe et al. 2010 that periodontal therapy for type 2 diabetic patients with periodontitis is favorable and can reduce A1C levels on average by 0.40% more than in nonintervention control subjects after 3 months.
Response:
A minimum of 3 months was required to assess a difference in A1C levels. Due to the strict ethical requirements which did not allow for the OHI group to be left without nonsurgical periodontal treatment for longer than 3 months, we therefore did not have the opportunity of following the patients for a longer duration.

Comment 6
Lines 152-153: References or description to how PPD and PAL were measured are lacking.
Response:
Descriptions have been added on line 154-155.

Comment 7:
Lines 157-168: The trial design is not clear. The OHI group is not accounted for in text. Furthermore the text is inconsistent with Fig 1.
Response:
Further explanation regarding figure 1 has been added to the text on line 161-164 and 170-173.

Comment 8:
Rinsing with CHX confounding factor?
Response:
Possibly and this has been added (line 349-351) into discussion as recommendations for further expansion of study.

Comment 9:
Line 186: Results Age and gender distribution among groups? Ethnicity? BMI? Method of diabetic treatment? Number of subjects with moderate chronic periodontitis and number of subjects with advanced chronic periodontitis and distribution between study groups?
Response:
Thank you for your comment. We have added a new table (Table 1) and the following sentence on line 202-204: “At baseline, there was no significant difference between the NSPT and OHI group in terms of age, gender, ethnicity (Table 1) and distribution of periodontal parameters (Table 2 and 3). All subjects who completed the study were on oral hypoglycaemic drugs. All subjects who completed the study were on oral hypoglycaemic drugs.”

Comment 10:
LINE 239:”…..with good periodontal response to treatment.” It is not possible from the text to distinguish between the NSPT and the OHI group. “16participants demonstrated a ≥ 50% reduction in PPD as an effect of periodontal intervention”- distribution between study groups?
Response:
This data was calculated based on the whole study population. We have looked at all subjects who have an improvement in plaque scores as a result of either NSPT or OHI. We have corrected the sentence on line 250 as: “Out of the total sample population, following either NSPT or OHI intervention, participants with a plaque score reduction of ≥ 50% …”

Comment 11:
Table 2. Division between sites with PPD and PAL< 4mm, sites with PPD and PAL 4-6 mm and sites with PPD and PAL> 6 mm is not explained in text. Distribution of PPD and PAL is reported at site level- what about the distribution of PPD and PAL at patient level?
Response:
The following explanation has been added on line 233-234: “Overall, there were more sites of PPD and PAL of <4mm at the end of the study and fewer sites with PPD and PAL of > 6mm.”
We have added Table 1 which describes distribution of PPD and PAL at patient level.

Comment 12:
Table 4 “Changes in mean HbA1c and CRP for subjects with good response to periodontal treatment”- does this table refer to subjects in the NSPT-group?
Response:
We have changed the title for Table 4 as: “Changes in mean Hba1c and CRP for subjects with good response to periodontal treatment in OHI and NSPT groups”
Comment 13:
Fig 1. NSPT group had to have Plaque scores ≤ 20% before receiving full mouth debridement. Why? How many times did the participants in this group receive OHI before receiving full mouth debridement? OHI group received only one session of OHI?

Response:
To ensure success of non-surgical treatment, good oral hygiene as denoted by low plaque scores were sought. We have added further explanation in the text (line 161-163): “Plaque scores of the subjects in the NSPT group were reviewed at weekly intervals to achieve scores of 20% or below to a maximum of 3 weeks. Subjects were re-motivated and instructed when necessary.” Also on line 170-173: “No interventional treatment was given to the OHI group apart from oral hygiene instructions and motivation. Thereafter at each monthly recall visit, participants in both groups were reviewed and re-motivated. Professional prophylaxis comprising of scaling and polishing was performed only on subjects of the test group.”

REVIEWER 2

Comment 1.
Line 134: the power calculation is based on a rather low (80%) certainty that weakens overall the results. Could the authors comment on why they did not seek a 90% or 95% certainty level?

Response:
Power calculations were based on precedence set by similar studies done in other populations. A higher certainty level would need a significantly larger sample size.

Comment 2.
Line 137: For such a small group, randomisation based on other major periodontal risk factors should ideally have been sought namely diabetic control levels, age, gender, smoking status. Please can you provide these figures within your groups?

Response:
Thank you for your comment. We have included a new table, Table 1, which shows the distribution of the periodontal risk factors mentioned between the 2 groups. We have excluded smokers from the study as mentioned in the exclusion criteria. Table 4 shows the distribution of diabetic control levels (HbA1C) at baseline between the 2 groups. There was no significant difference between the parameters in both groups at baseline.

Comment 3.
Lines: 141-147: plaque and bleeding index reproducibility should have been difficult to achieve considering that probing pocket depths were measured 3 hours following the first measurements. Furthermore, it’s not clear in the material and methods what margins of error where accepted between first and second round of measurement. Can you please provide these?

Response:
The following table shows the reproducibility for all periodontal parameters assessed:
Reproducibility for duplicate recordings of the Visible Plaque Index, Gingival Bleeding Index, Probing Pocket Depth and Probing Attachment Loss

<table>
<thead>
<tr>
<th>Index</th>
<th>Number of sites</th>
<th>Measure of Agreement (Kappa Value)</th>
<th>Asymptotic Standard Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visible Plaque Index</td>
<td>460</td>
<td>0.88</td>
<td>0.103</td>
</tr>
<tr>
<td>Gingival Bleeding Index</td>
<td>460</td>
<td>0.86</td>
<td>0.105</td>
</tr>
<tr>
<td>Probing Pocket Depth</td>
<td>690</td>
<td>0.957</td>
<td>0.025</td>
</tr>
<tr>
<td>Probing Attachment Loss</td>
<td>690</td>
<td>0.957</td>
<td>0.025</td>
</tr>
</tbody>
</table>

Comment 4.
Line 161-162: Unknown duration of NSPT visit or OH visits? Please specify
Response:
Duration between visits after assigned treatment were rendered was 1 month. We have added the following sentence on line 171-173: “Thereafter at each monthly recall visit, participants in both groups were reviewed and re-motivated. Professional prophylaxis comprising of scaling and polishing was performed only on subjects of the test group.”

Comment 5.
Lines 163-164: The use of CHX in one only group could have affected the results; a further control with NSPT without CHX or OH with CHX could have been added. Can you comment in discussion?
Response:
Thank you for your comment. We have added into discussion as recommendations for further expansion of study (line 349-351).

Comment 6.
Line 483: Hs-CRP was markedly lower on OHI group and was reduced only in the NSPT group. NO changes in the OHI group. As there was no statistical significance this may be attributed to the low sample size rather than the true differences. Please comment
Response:
Thank you for your comment. We have added the following sentence (line 305-306): “The lack of a statistical significance should be taken with caution as this may be attributed to the small sample size rather than the true difference.”

Comment 7.
Table 1: some of the SD indicate significant variability a)3 months on NSPT PI and b) 3 months in the OH group BI, can the authors comment on this?
Response:
We have changed Table 1 to Table 2. We have added the following sentence (line 278-281): “At 3 months post therapy, there was however significant variability in the standard deviation seen for the plaque index in the NSPT group and the gingival bleeding index in the OHI group and this may have been due to the variability in the response to treatment for both groups.”
Comment 8.
FIG1: This flow chart indicates that the subject in the NSPT group could have entered a loop of OH reinforcement until they reduce the plaque score to less than 20%. Was there a time limitation for this? If not how long was the average patient in that part of the study?
Response:
To ensure success of non-surgical treatment, good oral hygiene as denoted by low plaque scores were sought. Subjects in the NSPT group were reviewed up to a maximum of 3 times (on weekly basis) prior to commencing full mouth debridement. All participants were able to achieve plaque scores of $\leq 20\%$ by the 3rd week. We have added this information in the text (line 161-163).

Comment 9.
Patients with more than 50% reduction in different clinical findings are very small 7, 2 and 16 in PI, BI and PPD, also grouping together subjects from different treatment modalities and analysing them together is debatable. These results are even weaker and should be treated as such in the discussion.
Response:
We appreciate your comment.
We have added the following sentence (line 333-338): “However, these findings should be taken with caution as the treatment modalities provided to bring about these improvements come from 2 different intervention methods. A future study with a much larger sample size should be conducted to look at the improvements in periodontal parameters from each intervention method and its effect in improving metabolic control and systemic inflammatory challenge.”

Comment 10.
Lines 69-71: needs to be corrected as gingivitis can not lead to tooth loss
Response:
Thank you for your comment and we apologize for our oversight. The correction has been made (line 69).