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Effects of a combination of non-pharmaceutical psychological interventions on dental anxiety

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Effects of Different Intervention Combinations on the Dental Anxiety of Patients
Journal of Clinical and Translational Research

Dear authors,

Reviewers have now commented on your paper. Three reviewers rendered a minor revision verdict, two a major revision, and one a reject. We would like to give you the opportunity to improve your work based on the reviewers' comments.

If you are prepared to undertake the work required, I would be pleased to reconsider my decision.

For your guidance, reviewers' comments are appended below. Please note that reviewer 4's comments are attached as a Word document and not listed below.

I would like you to pay particular attention to the comments of reviewer 1, who is a true expert in the field. In accordance with that reviewers comments, please specifically address the following elements,

some of which were echoed by the other reviewers: While treatments for dental anxiety are needed, there are some methodological flaws that limit the usefulness of this study. First, this appears to be an under-powered study (n=15 and n=16 in the intervention and control groups, respectively), although the authors did not provide a sample size calculation. Second, due to natural fluctuations in self-reported dental fear, it is not possible to determine whether the participants' dental anxiety decreased from pre-treatment to post-treatment because of an intervention or because individuals nearly always report less anxiety after dental treatment than before. Also, as no dental treatment was done at the follow-up visit, examining self-reported dental anxiety between appointments where there is and isn't dental treatment done is equivalent to comparing "apples and oranges." Although the participants were 'blinded' to their condition assignment, this doesn't seem possible, given the difference between the intervention and control conditions.

If you decide to revise the work, please submit a list of changes or a rebuttal against each point which is being raised when you resubmit your work.

Your revision is due by May 15, 2017.

To submit a revision, go to http://jctres.edmgr.com/ and log in as an Author. You will see a menu item called Submission Needing Revision. You will find your submission record there.

Yours sincerely,

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Reviewers' comments:

Reviewer #1: The goal of this study was to examine the effectiveness of a combined treatment for dental anxiety (psychoeducation, progressive muscle relaxation, and music distraction during treatment) on dental anxiety. Testing a simple, short intervention for dental anxiety can be very useful in the clinical setting. This paper overall is well-written, however, a number of questions about the study arise in the reading of this paper, which are listed below.
* How was the sample size determined? Was there enough power in the study to detect differences between groups? If not, how are the authors able to determine whether their lack of results was due to a true lack of difference between the groups, or a lack of enough subjects to detect a difference?
* Why was a combined set of techniques tested? The authors correctly point out in the Discussion that there are a number of studies that test a single technique. Testing more than one technique in one study does not allow the authors (or readers) to know what the "active ingredient" is in the intervention.
* The authors state that both the participants and the dental providers were blinded to the participants' assignments (intervention or control), but it is not clear how this is the case. It is assumed that the consent form explained the differences between the intervention and control conditions, and that participants who are taught coping skills and who listened to music during treatment would certainly be able to tell that they were in the intervention condition. Additionally, the dental providers would be able to tell which patients listened to music over headphones during treatment. Could the authors explain in more detail how the participants and providers were blinded?
* Related to the point above, please explain the randomization process in more detail.
* On page 4, it is not clear how the second two study goals are different. In the second study goal, the authors said that they would test the effectiveness of the intervention in reducing dental anxiety between groups (intervention and control) before and after treatment, and the third study goal stated that the authors would test dental anxiety between the two groups before and after treatment. Please clarify.

* Please explain the follow-up assessment in more detail. It seems as though participants returned within 2 weeks of the treatment for a consultation about their dental treatment, without any dental treatment involved. It is possible that participants in both groups reported less dental anxiety because they were not anticipating having any dental treatment?
* Similarly, assessment of dental anxiety immediately after dental treatment is typically seen to reflect relief that the procedure is over, rather than a true decrease in dental anxiety. This should be noted in the Discussion section, and may help explain the lack of difference between the two groups in post-treatment dental anxiety.
* How many individuals were approached/surveyed in order to obtain the final sample?
* Why was the Dental Anxiety Scale - Revised used, rather than the Modified Dental Anxiety Scale, which has more studies regarding its psychometric data as well as a question about dental injections?
* Please provide more information about the Dental Concerns Assessment. If there are 26 items and a 4-point Likert Scale for each question, that would suggest that the total scale score would either range from 0-78 (if each item is scored from 0-3) or 26-104 (if each item is scored from 1-4). Why would a score of 2 or more signify significant fear of dental procedures? Please also give psychometric data (reliability and validity) of the DCA.
* Were participants' prior dental treatment experiences assessed? Had these participants been seen for restorative treatment prior to taking part in this study?
* At the bottom of page 9/top of page 10, please report the mean pre-treatment DAS-R score for the control group.
* The first sentence of the Discussion should read, "The present study determined…"
* Overall, it is difficult to determine definitively that participants' dental anxiety in both groups did not decrease because of a typical decrease in pre-treatment and post-treatment dental anxiety due to relief that the procedure was completed. Further, both groups likely had less anxiety at the follow-up appointment because no dental treatment was being done.

Reviewer #2: This small investigation trials a combined intervention for dental anxiety (education, relaxation and music) and suggests this might be beneficial compared to placebo for patients with dental anxiety who are undergoing dental treatment. The authors present a compelling argument that dental anxiety is a public health problem and that a safe and rapid intervention would be of benefit. Therefore I find this pilot investigation interesting but feel the manuscript needs some work to enhance transparency. One limitation is the small sample size which makes analysis of count data with complex distributions challenging. I have suggested a couple of sensitivity analyses (not necessarily to include in the final manuscript) which would help convince me of the resilience of the main findings.

Title:
This is misleading. The article does not asses the effects of 'different intervention combinations' as there is only one experimental group and one control.

Abstract:
The methods should make it clear that this is a study of participants with dental anxiety (defined as DAS-R of 9 or higher)
The results attempt to report baseline, pre-treatment, post-treatment anxiety scores and delta-anxiety and are confusing. The statement 'The experimental group had significantly reduced dental anxiety (P=.03)' appears to contradict ' No differences were found between the experimental and control groups for dental anxiety (P>.13).' This needs revision, for example 'over the course of the study the experimental group showed greater reduction in dental anxiety than the control group'
It would be useful to report an effect size (eg in points of DAS-R) rather than just a p value.
What do you mean by significant? What change in anxiety is needed before it makes a meaningful difference to patients' ability to receive dental care? If you mean significant only in the context of

statistical evidence then consider

Introduction
Page 4 line 12 - avoid using therefore at the start of a sentence. Managming anxiety is only key to improving oral health of patients if we believe that dental attendance is beneficial for oral health - is there any evidence for this in the literature?
Page 4 line 26 - this needs a reference.

Methods
Page 5 line 19 - it may be worth directing the reader to either the flow chart of study recruitment or including a statement as to the number of patients screen for anxiety / included at this stage.

Page 8 line 24 - there is multiple testing (baseline scores, pre- and post treatment scores and score deltas). How did you adjust for multiple testing?

Practical implications
Page 12 line 31 - You say that younger dentists are 'less likely to receive adequate training to screen and dental anxiety'. Compared to who? This is not clear.

Statistical limitations
Power
There is no power calculation. This is not necessarily an issue if this is a pilot study for larger investigation but it would be good to be transparent in this regard. Perhaps include more of this in the discussion

The lack of power is challenging when interpreting this study. For example - in table 1 there are more females than males in the experimental group but equal distribution in the control group. The test for difference here is underpowered and does not help interpretation.

Statistical methods
The authors report means and stardard deviations throughout. Within DAS-R there are likely to be sub-populations of highly anxious individuals whilst the lower border of DAS-R is curtailed at 9 by study recruitment (at least at baseline). Thus, DAS-R is unlikely to be normally distributed.

The authors may wish to include sensitivity analyses which do not rely on normally distributed data. For example, figure 2 could also be presented as median and IQR and it would be interesting to see how this compares to the current format of figure 2.

Table 2 may benefit from a sensitivity analysis using poisson regression (eg modelling DAS-R against group allocation (0/1)) to assess for difference between groups for pre-treatment, post-treatment and follow-up treatment DAS-R.

The final analysis in table 2 reports reduction from pre to post treatment. This is calculated as delta(follow up - baseline) and the deltas are then reported between each group. As a sensitivity analysis, consider modelling this as follows;
poisson regression of DAS-R against time(basline = 0, follow up = 1) with group (control = 0, intervention = 1) as an indicator co variate.

Figures
For figure 2 consider sensitivity analysis. It would be helpful to include some measure of spread around the data points. The 'chart area' title needs removal.

Reviewer #3: Review: Effects of different intervention combinations on the dental anxiety of patients

Overview:

This study is a well-designed randomized controlled trial that assesses the effectiveness of three combined psychological interventions to reduce dental anxiety in patients attending a University dental clinic. Participants were separated into a treatment and control group, the treatment group received psychological teaching, muscle relaxation and music therapy and the control group received normal treatment. The study uses the DAS-R questionnaire which is a well validated method to assess dental anxiety pre- and post-treatment and at 2 week review. The authors show that the intervention is effective at reducing anxiety post-treatment. They also suggest that this study shows reductions in anxiety within the treatment group between pre- and post-treatment. This is a clinically relevant topic as dental anxiety is highly prevalent can lead to increased dental disease, less effective dental treatment and higher rates on non-attendance.

The authors state this is a pilot study but make no reference to a further study based on this one. The manuscript should be adjusted to reflect if this is a pilot or a small study.

I have some concerns about the suitability of the statistical tests which assume the outcome measures are normally distributed. If these associations hold true with statistical tests that make less assumptions and take into account multiple testing they would be much more robust.

On several occasions the authors make comparisons within the treatment group. These do not test the evidence in the framework of a randomized controlled trial, comparisons should be between groups not within.

Title: Effects of Different Intervention Combinations on the Dental Anxiety of Patients
This title suggests a combination of anxiety interventions are compared. The title should state that the study is an RCT and reflect the comparison being made (3 psychological interventions vs control).

Abstract:
The authors state "Managing anxiety is the key to improving oral health" whereas it is only one of several important aspects that are important.

The primary outcome should be made clear.

In the results section of the abstract the authors present a significant reduction in dental anxiety, it is not clear if the author is referring to changes within group between pre- and post-treatment or comparing the control and experimental groups. More clarity would help here.

To assess the clinical relevance of this change in anxiety effect size and its precision should be states alongside a p-value.

Introduction

The final paragraph of the introduction, discussing the aims, starts with a very long sentence. The section would be clearer by stating the aims: Prevalence of anxiety and effectiveness of psychological interventions and then going on to elaborate about the second aim in a new sentence.

In their hypothesis, the authors mention 'significant reduction'. It is not clear whether the authors are referring to something that is statistically significant (at an arbitrary threshold), clinically significant (i.e. a clinically relevant reduction in anxiety) or just using the term as an adjective.

Methods

More details of the randomization process is required to allow the reader to appraise the quality of this process.

The authors state that only sex and age are used to compare the control and experimental groups whereas other variables were collected. Socio-economic status, for example, is strongly correlated with dental anxiety and I feel it is important to at least present this data for the two groups and ideally formally test for evidence of a difference between groups.

What was the reason for choosing this specific piece of music? Has the music, chosen as the intervention, been used for this purpose before? Is there evidence to suggest that it is effective or is there evidence to say this particular type of music is effective?

The authors say the dental officers were blinded to study participation. More detail is required to see if this is robust. How was this achieved? Did all participants wear head-phones for example.

Analysis

I have some concerns about the appropriateness of the statistical tests used. Are the outcome variables normally distributed? If not a median/range may be more appropriate for summarizing the variable. The DAS score is truncated at 9 in the pre-treatment and this may invalidate the assumptions required for the t-test and anova analysis. It may be more appropriate to use a non-parametric test that has less assumptions but is more robust.

Have the authors considered correcting for multiple testing? Several of the reported associations have weak evidence, around the 5% threshold and these may be due to chance due to the number of tests conducted.

Was a power calculation conducted? If not a post-hoc sample size calculation could be included to show the power given the sample size and as this is a pilot study what sample sizes would be required to detect clinically meaningful changes in the outcomes.

Results.

The authors say 31 patients were included in the study. Strictly all 64 patients are included in the study of prevalence. And 31 are included in the interventional section of the study.

Can the authors provide an estimate of precision of this sample's estimate of prevalence.

The authors state there is a difference in mean change of DAS between groups, the actual change should be given alongside the P-value.

The authors discuss the difference between visits of the experimental group. For this they quote an F statistic but this does not have any obvious meaning presented like this. Discussing these results and referring to figure 2 would aid understanding here.

Was the DCA level compared between experimental and control group? This analysis would be more relevant to the aims of this work rather than comparing within each experiment group. I suggest the within group analysis be included but as supplementary material.

Figure 1: Add detail of reason for exclusion to the diagram for clarity.

Figure 2: The figures presented in this graph do not match those in table 2 and the graph does not include an indication of precision. There is also a box saying chart area on the graph.

Consistency of numbering (thirty-one/31)

Discussion

First line "The present…" should this be "The present study/This study"

The authors suggest the interventions were successful at reducing anxiety in the experimental group, this needs to be said in comparison to the control group. I would also be more cautious in this claim. This study (as long as results are consistent with updated statistical methods) provide some moderate evidence of a reduced pre-to post treatment reduction in anxiety in the treatment group compared to the control group.

The authors recommend that a trio of psychological interventions are used by dentists to reduce the anxiety of dentally anxious patients and a single method is not enough. This was not tested here. This study assesses multiple treatments vs no treatment and cannot make these claims.

The authors claim anxiety reduction intervention is effective up to 2 weeks. A comparison of the experiment and control groups between pre-treatment and follow-up is not presented and therefore I cannot see if this claim is substantiated.

The authors suggest that the reason for reduced anxiety at follow up for some of the control group is due to "stronger personality". Although this is plausible it I the comparison between groups that is useful here and the personality type should be evenly distributed if the randomization process was successful. It is also likely that anxiety levels are lower at review appointments of both groups as the patient is not anticipating invasive treatment.

The authors suggest that reductions in specific anxieties (including injections, drills) in the treatment group lends support to their hypothesis. Again, it is the between group (control vs treatment) that is important here not the within group. I would expect all measures of anxiety to reduce post-treatment.

Practical applications

The authors suggest that asking patients to fill in an anxiety questionnaire may increase their anxiety but earlier in the discussion reference Dailey et al who suggest the opposite is true.

Reviewer #5: dear author,

Based on my private and university background, working at Oral Surgery practice I would like to give some notes, suggestions and information that I believe will help the next steps of this pilot study, to provide even more interesting and useful data. I strongly recommend that if possible, you include on your next studies, a private clinic to compare these patients with the university patients. As I experience both worlds daily, I can say that their behavior is a lot different in a big variety of aspects, including dental anxiety, mostly, because at university they will be treated by students. I've never seen such study to proof this statement. Am I wright ? or it's just a single man statement ? would be really great to have an answer! It's a suggestion !

I will post my comments as a list, because I couldn't find a way to doing it in the paper file.

I would like to congratulate all the involved, and look forward to see even more interesting studies from you!

Kindest Regards !

Reviewer #6: Material and methods
Justification of using scales or anxiety relieving practices should be saved for the discussion, not in material and method
After recruiting the patients, nothing has been mentioned about how they were divided among the two groups, which should have followed a random allocation protocol. The first mentioning of randomization was in fig. 1 and then the discussion without stating how this was performed.
Gender might have been included as a variable worthy of comparison since this might reveal a difference between males and females in relation to anxiety. Owing to the small sample size, this could have been stated as one of the limitations of the study.
The officers who completed the restorative treatment couldn't have been blinded to the group to which each patient belonged because during the operative procedures, half of the patients heard music while the other half did not!!
Any anxious patient should be offered at least some sort of verbal reassurance before commencing treatment. Patients of the control group, did not receive any such assistance which is basic practice that should have been mentioned.
Discussion
First line is missing the word "study" after "the present"
When discussing the results, the reduced anxiety values of the control group in the follow up visit were totally ignored. This value dropped below the 9 point threshold as depicted in fig 2. Of course it is expected that after a successful and peaceful first dental intervention, anxiety that has been anticipated in the first visit will automatically decrease. For a fair comparison, this should have been properly discussed.

There is additional documentation related to this decision letter. To access the file(s), please click the link below. You may also login to the system and click the 'View Attachments' link in the Action column.

********Authors response********

Statement to each reviewer: We truly thank you for your valuable and professional comments! We have addressed all of them (hopefully) and we either agreed with them or modified accordingly or we explained our point of view and defended them. Thanks again!

Reviewer #1:
The goal of this study was to examine the effectiveness of a combined treatment for dental anxiety

(psychoeducation, progressive muscle relaxation, and music distraction during treatment) on dental anxiety. Testing a simple, short intervention for dental anxiety can be very useful in the clinical setting.

This paper overall is well-written, however, a number of questions about the study arise in the reading of this paper, which are listed below.

1. How was the sample size determined? Was there enough power in the study to detect differences between groups? If not, how are the authors able to determine whether their lack of results was due to a true lack of difference between the groups, or a lack of enough subjects to detect a difference?

Please refer to page 5, first paragraph, under participants, we have stated the sample size calculation procedures. We have also stated our small sample size as one of the limitation, Refer page 14.

2. Why was a combined set of techniques tested? The authors correctly point out in the Discussion that there are a number of studies that test a single technique. Testing more than one technique in one study does not allow the authors (or readers) to know what the "active ingredient" is in the intervention.

Please refer to page 11, third and fourth paragraphs.

3. The authors state that both the participants and the dental providers were blinded to the participants' assignments (intervention or control), but it is not clear how this is the case. It is assumed that the consent form explained the differences between the intervention and control conditions, and that participants who are taught coping skills and who listened to music during treatment would certainly be able to tell that they were in the intervention condition. Additionally, the dental providers would be able to

tell which patients listened to music over headphones during treatment. Could the authors explain in more detail how the participants and providers were blinded?

We apologize, we wrongly stated in the manuscript. The revised version you can Refer page 14, under limitation, second paragraph, line 5-7.

4. The participants were randomly assigned based on SPSS. Dentist who provided treatment for control group did not know which group the participants are belongs from and they were instructed to do their treatments as usual but dentists who treated the experimental group know they are in the experimental group. This is one of our limitations.

We have stated under limitation. Please refer to page 14, under limitation, line 5-7.

5. Related to the point above, please explain the randomization process in more detail.

The randominisation was done based on SPSS. Please refer page to number 7 under “procedure”, first paragraph.

6. On page 4, it is not clear how the second two study goals are different. In the second study goal, the authors said that they would test the effectiveness of the intervention in reducing dental anxiety between groups (intervention and control) before and after treatment, and the third study goal stated that the authors would test dental anxiety between the two groups before and after treatment. Please clarify.

We have rephrased our aim and hypothesis of this study. Please refer to page number 4, last paragraph.

7. Please explain the follow-up assessment in more detail. It seems as though participants returned within 2 weeks of the treatment for a consultation about their dental treatment, without any dental treatment involved. It is possible that participants in both groups reported less dental anxiety because they were not anticipating having any dental treatment?

All participants came for follow-up visit for their second appointment of the dental treatment after second week, as explained in page 8, line 11-14.

8. Similarly, assessment of dental anxiety immediately after dental treatment is typically seen to reflect relief that the procedure is over, rather than a true decrease in dental anxiety. This should be noted in the Discussion section, and may help explain the lack of difference between the two groups in post-treatment dental anxiety.

We have addressed your comments under discussion, Refer page 12, line 19-20 and limitation, Please refer to page 14, under limitation, line 6-8.

9. How many individuals were approached/surveyed in order to obtain the final sample?

Based on sample size calculation, we collected data from 64 patients attended dental clinic. Refer page

5, line 3-5

10. Why was the Dental Anxiety Scale - Revised used, rather than the Modified Dental Anxiety Scale,
which has more studies regarding its psychometric data as well as a question about dental injections?

Both scales aim to measure dental anxiety and have adequate psychometric properties. We prefer to use Dental anxiety scale revised as it consists of 4 items, whereas modified dental anxiety scale has five items.

11. Please provide more information about the Dental Concerns Assessment. If there are 26 items and a 4-point Likert Scale for each question, that would suggest that the total scale score would either range from 0-78 (if each item is scored from 0-3) or 26-104 (if each item is scored from 1-4). Why would a score
of 2 or more signify significant fear of dental procedures? Please also give psychometric data (reliability and validity) of the DCA.

Dental concern assessment which we had used consist of 26 items, score in four point Likert scale 1 to 4; 1 indicates low while 4 indicates high. We scored participants who scored 2 and above. Total score ranges from 1-104. Refer to page 6 second paragraph

12. Were participants' prior dental treatment experiences assessed? Had these participants been seen for restorative treatment prior to taking part in this study?

This study does not aim to measure participants prior dental treatment experiences and selected participants who exhibited dental anxiety in our study.

13. At the bottom of page 9/top of page 10, please report the mean pre-treatment DAS-R score for the control group.

Since our sample population is not normally distributed, we have used the non-parametric tests. We have stated the control group non-significant results. Please refer to page 9 last paragraph, lines 7-9.

14. The first sentence of the Discussion should read, "The present study determined…"

Noted, and edited

Overall, it is difficult to determine definitively that participants' dental anxiety in both groups did not decrease because of a typical decrease in pre-treatment and post-treatment dental anxiety due to relief that the procedure was completed. Further, both groups likely had less anxiety at the follow-up appointment because no dental treatment was being done.

All participants who came for follow-up assessment received either dental checkup or treatments. We have mentioned how many participants have recovered from dental anxiety as mentioned in Table 4, page 24.

Reviewer #2:

This small investigation trials a combined intervention for dental anxiety (education, relaxation and music) and suggests this might be beneficial compared to placebo for patients with dental anxiety who are undergoing dental treatment. The authors present a compelling argument that dental anxiety is a public health problem and that a safe and rapid intervention would be of benefit. Therefore I find this pilot investigation interesting but feel the manuscript needs some work to enhance transparency. One limitation is the small sample size which makes analysis of count data with complex distributions challenging. I have suggested a couple of sensitivity analyses (not necessarily to include in the final manuscript) which would help convince me of the resilience of the main findings.

Title:

1. This is misleading. The article does not asses the effects of 'different intervention combinations' as there is only one experimental group and one control.

We agree with the reviewer, Modified to “Effects of a combination of non-pharmaceutical psychological intervention on dental anxiety”

Abstract:

2. The methods should make it clear that this is a study of participants with dental anxiety (defined as DAS-R of 9 or higher)

We have modified it to be clearer. Please refer to page 1 under abstract method section

3. The results attempt to report baseline, pre-treatment, post-treatment anxiety scores and delta-anxiety
and are confusing. The statement 'The experimental group had significantly reduced dental anxiety (P=.03)' appears to contradict ' No differences were found between the experimental and control groups for dental anxiety (P>.13).' This needs revision, for example 'over the course of the study the experimental group showed greater reduction in dental anxiety than the control group'

We have revised our result section. Please refer to our result section.

4. It would be useful to report an effect size (eg in points of DAS-R) rather than just a p value.

We have revised our result section. Please refer to our result section.

5. What do you mean by significant? What change in anxiety is needed before it makes a meaningful difference to patients' ability to receive dental care? If you mean significant only in the context of statistical
evidence then consider.

Statistically significant “P value is less than 0.05”.

6.Introduction

Page 4 line 12 - avoid using therefore at the start of a sentence. Managming anxiety is only key to improving oral health of patients if we believe that dental attendance is beneficial for oral health - is there any evidence for this in the literature?

Edited as per reviewer’s suggestion. Please refer to page 3, last paragraph

7. Page 3 line 26 - this needs a reference.

Reference added

8. Methods

Page 5 line 19 - it may be worth directing the reader to either the flow chart of study recruitment or including a statement as to the number of patients screen for anxiety/ included at this stage.

We have attached the flow chart (Please refer to figure-1) and also mentioned in the method section, page 4, first paragraph.

9. Page 8 line 24 - there is multiple testing (baseline scores, pre- and post treatment scores and score deltas). How did you adjust for multiple testing?

We have revised our result. Please refer to the result section.

10. Practical implications

Page 12 line 31 - You say that younger dentists are 'less likely to receive adequate training to screen and dental anxiety'. Compared to who? This is not clear.

We have mentioned with citation. Please refer to page 33 under practical implication, lines 1-2.

11. Statistical limitations Power

There is no power calculation. This is not necessarily an issue if this is a pilot study for larger investigation but it would be good to be transparent in this regard. Perhaps include more of this in the discussion The lack of power is challenging when interpreting this study. For example - in table 1 there are more females than males in the experimental group but equal distribution in the control group. The test for difference here is underpowered and does not help interpretation.

In an experimental study it is difficult to have equal number of same gender in both groups. To ensure the equal number of genders in both groups, the P value should be above 0.05 (no differences between groups). If P value is above 0.05 indicates both groups are similar. This study the P value is >0.05 indicates both group are similar at the pre assessment levels. The another reason is that the groups were divided equally by using SPSS randomization method.

12. Statistical methods

The authors report means and standard deviations throughout. Within DAS-R there are likely to be subpopulations of highly anxious individuals whilst the lower border of DAS-R is curtailed at 9 by study recruitment (at least at baseline). Thus, DAS-R is unlikely to be normally distributed.

Your point is right but this study aimed to measure difference between anxiety and no dental anxiety by using DAS-R cut off score. This study did not aim to measure the moderate and sever levels of dental

anxiety as the hypothesis tested to see the differences between two groups. We have revised our result
section, please refer to result section.

13. The authors may wish to include sensitivity analyses which do not rely on normally distributed data. For example, figure 2 could also be presented as median and IQR and it would be interesting to see how this compares to the current format of figure 2.

We have revised our result section. How many participants secured below 9 and above 9 in DAS-R is mentioned in Table 4.

14. Table 2 may benefit from a sensitivity analysis using poisson regression (eg modelling DAS-R against group allocation (0/1)) to assess for difference between groups for pre-treatment, post-treatment and follow-up treatment DAS-R.

We revised the whole result section as this study population is not normally distributed. Please refer to page 9 and 10.

15. The final analysis in table 2 reports reduction from pre to post treatment. This is calculated as delta(follow up - baseline) and the deltas are then reported between each group. As a sensitivity analysis, consider modelling this as follows; poisson regression of DAS-R against time(basline = 0, follow up = 1) with group (control = 0, intervention = 1) as an indicator co variate.

We revised our result section. Please refer to page 9 and 10

16. Figures

For figure 2 consider sensitivity analysis. It would be helpful to include some measure of spread around the data points. The 'chart area' title needs removal.

We removed figure 2

Reviewer #3: Review: Effects of different intervention combinations on the dental anxiety of patients

Overview:

This study is a well-designed randomized controlled trial that assesses the effectiveness of three combined psychological interventions to reduce dental anxiety in patients attending a University dental clinic. Participants were separated into a treatment and control group, the treatment group received psychological teaching, muscle relaxation and music therapy and the control group received normal treatment. The study uses the DAS-R questionnaire which is a well validated method to assess dental anxiety pre- and post-treatment and at 2 week review. The authors show that the intervention is effective at reducing anxiety post-treatment. They also suggest that this study shows reductions in anxiety within the treatment group between pre- and post-treatment. This is a clinically relevant topic as dental anxiety is highly prevalent can lead to increased dental disease, less effective dental treatment and higher rates on non-attendance.

1. The authors state this is a pilot study but make no reference to a further study based on this one. The manuscript should be adjusted to reflect if this is a pilot or a small study.

We have mentioned this study is a pilot study in abstract and discussion section. Please refer to page 14, under recommendation for future study; we have mentioned study need to be replicated on larger sample size in future.

2. I have some concerns about the suitability of the statistical tests which assume the outcome measures are normally distributed. If these associations hold true with statistical tests that make less assumptions and take into account multiple testing they would be much more robust.

We have revised our result section as we used non parametric tests.

3. On several occasions the authors make comparisons within the treatment group. These do not test the evidence in the framework of a randomized controlled trial, comparisons should be between groups not within.

Please refer page 21, table 2 indicate between two groups differences and Table 3 within pre, post and follow-up differences.

4. Title: Effects of Different Intervention Combinations on the Dental Anxiety of Patients

This title suggests a combination of anxiety interventions are compared. The title should state that the

study is an RCT and reflect the comparison being made (3 psychological interventions vs control).

We agree with the reviewer, title has been modified to “Effects of a combination of Non pharmaceutical psychological intervention on dental anxiety”

5. Abstract:

The authors state "Managing anxiety is the key to improving oral health" whereas it is only one of several important aspects that are important.

Please refer to page 3 , third paragraph 1 line

6. The intention of the statement is that many people (reference provided) neglect their oral health just because of anxiety from dental treatment. We agree that there are multiple key factors can affect the oral health in general.

We have revised the sentence, please refer page 3 second paragraph.

7. The primary outcome should be made clear.

We have mentioned the primary outcome of this study is to reduce dental anxiety and it is mentioned in page 10 and 11

8. In the results section of the abstract the authors present a significant reduction in dental anxiety, it is not clear if the author is referring to changes within group between pre- and post-treatment or comparing the control and experimental groups. More clarity would help here.

We have revised the result section of the abstract

9. To assess the clinical relevance of this change in anxiety effect size and its precision should be states alongside a p-value.

The effect size is mentioned wherever necessary. Please refer to page 9, third paragraph

10. Introduction

The final paragraph of the introduction, discussing the aims, starts with a very long sentence. The section would be clearer by stating the aims: Prevalence of anxiety and effectiveness of psychological interventions and then going on to elaborate about the second aim in a new sentence.

Yes we have mentioned clearly now. Please refer page 4 last paragraph

11. In their hypothesis, the authors mention 'significant reduction'. It is not clear whether the authors are referring to something that is statistically significant (at an arbitrary threshold), clinically significant (i.e. a
clinically relevant reduction in anxiety) or just using the term as an adjective.

We have edited the hypothesis Please refer to page no. 4, last paragraph. Yes significant difference means statistically significant differences.

12. Methods

More details of the randomization process is required to allow the reader to appraise the quality of this process.

Please refer to page 5, first paragraph, line 4-11.

13. The authors state that only sex and age are used to compare the control and experimental groups whereas other variables were collected. Socio-economic status, for example, is strongly correlated with dental anxiety and I feel it is important to at least present this data for the two groups and ideally formally test for evidence of a difference between groups.

Sorry we don’t have data of the participants’ socio economic status, We agree of the importance of this variable

14. What was the reason for choosing this specific piece of music? Has the music, chosen as the intervention, been used for this purpose before? Is there evidence to suggest that it is effective or is there evidence to say this particular type of music is effective?

A musical album by Pravin Mani titled ‘Music for De-stress and Relaxation’ was recommended to be used
in this study by a psychologist.

15. The authors say the dental officers were blinded to study participation. More detail is required to see if this is robust. How was this achieved? Did all participants wear head-phones for example.

We have edited some of the statements as this is not a double blind study. Please refer to page 8, under
procedure, line 6-8.

16. Analysis

I have some concerns about the appropriateness of the statistical tests used. Are the outcome variables normally distributed? If not a median/range may be more appropriate for summarizing the variable. The DAS score is truncated at 9 in the pre-treatment and this may invalidate the assumptions required for the t-test and anova analysis. It may be more appropriate to use a non-parametric test that has less assumptions but is more robust.

You are right, this study population is not normally distributed, we have used the non-parametric test. Please refer to result section page 8 and 9

17. Have the authors considered correcting for multiple testing? Several of the reported associations have weak evidence, around the 5% threshold and these may be due to chance due to the number of tests conducted.

We have revised our result section. Please refer page 8 and 9

18. Was a power calculation conducted? If not a post-hoc sample size calculation could be included to show the power given the sample size and as this is a pilot study what sample sizes would be required to detect clinically meaningful changes in the outcomes.

Please refer to page 5, under participants line 1-10 explains sample size calculation procedures.

19. Results.

The authors say 31 patients were included in the study. Strictly all 64 patients are included in the study of prevalence. And 31 are included in the interventional section of the study.

We have corrected the word. Please refer to page 5, line 7-10.

20. Can the authors provide an estimate of precision of this sample's estimate of prevalence.

Please refer to page 5, line 1-5

21. The authors state there is a difference in mean change of DAS between groups, the actual change should be given alongside the P-value.

We have revised our result section, please refer page 9 and 10.

22. The authors discuss the difference between visits of the experimental group. For this they quote an F statistic but this does not have any obvious meaning presented like this. Discussing these results and referring to figure 2 would aid understanding here.

We removed figure -2 and used non parametric test to show the difference between and within experimental and control group.

23. Was the DCA level compared between experimental and control group? This analysis would be more relevant to the aims of this work rather than comparing within each experiment group. I suggest the within
group analysis be included but as supplementary material.

We had compared the DCA within pre, post and follow levels of both experimental and control group. Please refer to 10, second paragraph.

24. Figure 1: Add detail of reason for exclusion to the diagram for clarity.

Yes, please refer to figure-1

25. Figure 2: The figures presented in this graph do not match those in table 2 and the graph does not include an indication of precision. There is also a box saying chart area on the graph.

We have removed the figure -2

26. Consistency of numbering (thirty-one/31)

We have mentioned 31 throughout the manuscript instead of thirty one

27. Discussion

First line "The present…" should this be "The present study/This study"

Yes we have edited, Please refer to page 10, third paragraph first line

28. The authors suggest the interventions were successful at reducing anxiety in the experimental group, this needs to be said in comparison to the control group. I would also be more cautious in this claim. This

study (as long as results are consistent with updated statistical methods) provide some moderate
evidence of a reduced pre-to post treatment reduction in anxiety in the treatment group compared to the control group.
Please refer to tables 2, 3 and 4
29. The authors recommend that a trio of psychological interventions are used by dentists to reduce the anxiety of dentally anxious patients and a single method is not enough. This was not tested here. This study assesses multiple treatments vs no treatment and cannot make these claims.
You are right we have revised the line. Please refer to 11, second paragraph, line 3-6
30. The authors claim anxiety reduction intervention is effective up to 2 weeks. A comparison of the experiment and control groups between pre-treatment and follow-up is not presented and therefore I cannot see if this claim is substantiated.
Please refer to page 9, fourth paragraph shows post hoc test indicate difference between pre and followup and pre and post assessment differences.
31. The authors suggest that the reason for reduced anxiety at follow up for some of the control group is due to "stronger personality". Although this is plausible it I the comparison between groups that is useful here and the personality type should be evenly distributed if the randomization process was successful. It is also likely that anxiety levels are lower at review appointments of both groups as the patient is not anticipating invasive treatment.
You are right, We have revised the statements in discussion section. Please refer to page 12, line 17-25.
32. The authors suggest that reductions in specific anxieties (including injections, drills) in the treatment group lends support to their hypothesis. Again, it is the between group (control vs treatment) that is important here not the within group. I would expect all measures of anxiety to reduce post-treatment.
Please refer to page 10, second paragraph and Table 5 indicate within pre, post and follow-up level assessment of DCA.
33. Practical applications
The authors suggest that asking patients to fill in an anxiety questionnaire may increase their anxiety but earlier in the discussion reference Dailey et al who suggest the opposite is true.
Text was edited to remove confusion

Reviewer # 4:
The basic reporting in the paper is acceptable.
1. Introductıon:
Introductıon of the study is too long and boring, can be written shorter and clearer. The purpose should be rewritten more clearly and briefly.
Please refer the revised *Introduction section* on Page 3 and 4
2. Method:
There is not enough detail included on how the sample was selected or recruited in partıcipant section. Sample number is too small for this study.
Please refer the page 5, line 1-12.
3. The level of education is an important factor for such studies. Why educational level was not considered when separated into groups? According to level of education as well as in gender and analysis be performed and education level of groups should be similar for standardization.
Please refer to Table 1 indiacte the educational level of both groups
4. How do physicians give psychological education more clearly written. Do dentists receive training or help from a psychologist in this regard?
Please refer to page 6, third paragraph. Yes, researcher who provided psychological training learned these psychological treatments as a part of their dental course requirement and also received training from psychologist and their demonstrated their skills to the psychologist.
5. Did all the patients do the same procedure? For example For example, did all patients have anesthesia or tooth extraction? Please be clear

All the patients underwent restorative dental treatment (dental fillings) were invited to participate in this
study.
6. Why non parametric tests were used? The number of participants in the group is less than 30.
Yes we have used the non-parametric tests Please refer to the result section
7. Result: In prevalence of dental anxiety section, only results should be written. How the groups are separated… written in the method section.
Yes, we have revised the content and mentioned the selection and study design under method section. Please refer to page 5-7.
References:
8. A paper by Talo Yildirim et al in Peerj 2017 seems to be very similar to your manuscript. You may wish to consider citing their research in your paper
We have cited this reference Please refer to, page 19.

Reviewer #5: dear author,
1. Based on my private and university background, working at Oral Surgery practice I would like to give some notes, suggestions and information that I believe will help the next steps of this pilot study, to provide even more interesting and useful data. I strongly recommend that if possible, you include on your next studies, a private clinic to compare these patients with the university patients. As I experience both worlds daily, I can say that their behavior is a lot different in a big variety of aspects, including dental anxiety, mostly, because at university they will be treated by students. I've never seen such study to proof this statement. Am I wright ? or it's just a single man statement ? would be really great to have an answer! It's a suggestion !
We agree with the reviewer and believe that it is an interesting study to do. So we have mentioned under recommendation for the future study in page 15, first three lines
2. I will post my comments as a list, because I couldn't find a way to doing it in the paper file.
I would like to congratulate all the involved, and look forward to see even more interesting studies from you! Kindest Regards!
Thank you!

Reviewer #6:
1. Material and methods
Justification of using scales or anxiety relieving practices should be saved for the discussion, not in material and method.
As per the journal requirement, scales (instruments) details should be mentioned under method section and psychological intervention also method section
2. After recruiting the patients, nothing has been mentioned about how they were divided among the two groups, which should have followed a random allocation protocol. The first mentioning of randomization was in fig. 1 and then the discussion without stating how this was performed.
We have mentioned the randomization of participants in Method section under participants (Please refer to page 5 first paragraph) and procedure (page .Please refer to page 7, last paragraph)
3. Gender might have been included as a variable worthy of comparison since this might reveal a difference between males and females in relation to anxiety. Owing to the small sample size, this could have been stated as one of the limitations of the study.
Yes we have mentioned under limitation, page 14 second paragraph.
4. The officers who completed the restorative treatment couldn't have been blinded to the group to which each patient belonged because during the operative procedures, half of the patients heard music while the other half did not!!
Any anxious patient should be offered at least some sort of verbal reassurance before commencing treatment. Patients of the control group, did not receive any such assistance which is basic practice that should have been mentioned.

You are right, this is single blind study and both the dentist aware about their group participants and we
have mentioned this in detail under page 7 second and third paragraph.

5. Discussion

First line is missing the word "study" after "the present"

We have included the word. Please refer to page 10 third paragraph

6. When discussing the results, the reduced anxiety values of the control group in the follow up visit were totally ignored. This value dropped below the 9 point threshold as depicted in fig 2. Of course it is expected that after a successful and peaceful first dental intervention, anxiety that has been anticipated in the first visit will automatically decrease. For a fair comparison, this should have been properly discussed.

We have revised the result section totally and Table 4 indicates how many participants secured below and above 9 in DAS-R is mentioned in Table 4.

2nd editorial decision
Date: 13-Jun-2017

Ref.: Ms. No. JCTRes-D-17-00004R1
Effects of a combination of non-pharmaceutical psychological intervention on dental anxiety
Journal of Clinical and Translational Research

Dear authors,

Reviewers have now commented on your paper. You will see that they are advising that you revise your manuscript. If you are prepared to undertake the work required, I would be pleased to reconsider my decision.

For your guidance, reviewers' comments are appended below.

If you decide to revise the work, please submit a list of changes or a rebuttal against each point which is being raised when you resubmit your work.

Your revision is due by Jul 13, 2017.

To submit a revision, go to http://jctres.edmgr.com/ and log in as an Author. You will see a menu item called Submission Needing Revision. You will find your submission record there.

Yours sincerely,

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Editor's comments

Dear authors, thank you for resubmitting a revised version of your paper. Four reviewers have assessed you manuscript, of which there are 2 accepts, 1 minor revision, and a reject. The reject is associated with "too small a sample size to support the conclusions drawn, a lack of blinding, and differences among the

groups (e.g., different treating dentists) that may account for differences in outcomes rather than the intervention itself. In addition, there are at least two statements that are copied directly from other sources without being put into quotes or rewritten in the authors' own words" (reviewer 1). You have added the shortcomings of your study and cited some of the same reasons as provided by reviewer 1. Please add the other reason to your manuscript as well if this was indeed the case (different treating dentists). Moreover, reviewers 1 and 6 have provided additional comments to improve the paper, and I kindly ask you to pay very close attention to these and implement the comments to a maximum extent to further improve the manuscript.

Thank you, and do not hesitate the contact the editorial office in case of any questions.

Kindest regards,

Michal Heger.

Reviewers' comments:

Reviewer #1: The goal of this revised manuscript was to describe a pilot study of a combination of techniques for reducing dental anxiety (psychoeducation, progressive muscle relaxation, and listening to music through headphones), and comparing dental anxiety pre-treatment, post-treatment, and at a 2-week follow up period. The authors have addressed several of the reviewers' prior comments, but there are still some unanswered questions, as described below.
* On page 3, the quote "a marked and persistent fear of clearly discernible, circumscribed objects or situations" is taken verbatim from the DSM-IV. This needs to either be put into quotation marks (as above) or reworded into the authors' own words in order to avoid plagiarism. Also, the version of the DSM needs to be indicated in the text (according to the reference, this is the DSM-IV).
* On page 3, what type of "misdiagnosis" do the authors mean? Misdiagnosing a dental condition? Misdiagnosing dental fear?
* To be able to determine whether this study really identifies the prevalence of dental anxiety among the clinic's dental patients, more detail needs to be known about how patients were recruited. Was every patient who arrived at the clinic surveyed for their dental fear? How many patients did not agree to participate in the study? If 64 = the number of unique patients seen in the clinic over the 3-month period, then 33 (51.5%) could be considered the prevalence of dental anxiety in their clinic, as the authors state on page 10. However, if, for example, there were 1,000 unique patients seen in the clinic over the 3-month period, and only 64 agreed to participate (and 33 were fearful), this does not tell you anything about the prevalence of dental anxiety in your clinic. What your current results most likely tell you is that 51.6% of people who agreed to be in your study are dentally fearful, which is very different from an overall prevalence of dental anxiety in your clinic. Please also revise the first sentence of your Discussion if needed, given this consideration.
* It is not clear that the authors understand what the reviewers meant by providing a sample size calculation. It seems as though the authors estimated how many patients would be seen in the clinic in a 3-month period and based their sample size on this. While this is a perfectly reasonable way to estimate how large a sample a researcher can expect to recruit during a period of time, it is not a sample size calculation. In order to determine whether you have enough subjects/patients to detect a difference in your outcome measure (for example, the DAS-R), you need to know how much of a difference you would expect to see in this outcome measure after an intervention (this is usually determined by looking at other,

similar studies). It is recommended that you consult with a biostatistician to determine your sample size (for example, if you determine from the literature that an expected mean difference in DAS-R scores is 3 points after a dental fear intervention, and you would like to have 80% power (which is standard) at a significance level of $p<0.05$ to detect a difference between groups, then you would need how many subjects in each group).
* It still isn't clear how the subjects were randomized - please explain how SPSS was used to randomize the subjects.
* Please give more detail about the consent process. Typically, study participants are told what they can expect from being in both the treatment group and the control group, and that they will be randomly assigned to one of the groups. This way, they have all the information they need to know whether they want to participate (that is, what they'll be asked to do, depending on which group they are assigned to). If participants are told that they will have psychoeducation, progressive muscle relaxation, and music over headphones if they are in the treatment group, then participants who don't have any of these techniques will know that they are in the control group. Yet, the authors state on page 5 that "participants were not aware of which group they were randomized to." This doesn't seem possible, if they were consented to participate. In other words, if I'm a participant in your study and am given headphones and music to listen to, I know I'm in the treatment group, which may lead me to report having less anxiety!
* The description of the DCA still isn't clear - do the authors mean that participants needed to have scored 2+ on all 26 items to be considered to have moderate to severe anxiety?
* Why were some DCA items (extraction, injection, etc.) chosen for additional analyses?
* On page 7, the statement "an anxious emotional state fails to exist in the presence of complete relaxation of peripheral parts" is taken verbatim from Jacobson. As above, this needs to be put into quotes or rewritten into the author's own words to avoid plagiarism.
* Please explain which dentists saw which patients. From the description on page 8, it sounds as though the patients in the treatment group were treated by different dentists than the control group? If this is the case, wouldn't that introduce bias into the study?
* For the DCA results (page 10), please provide the same breakdown as for the DAS-R; that is, pre-treatment vs. post-treatment; pre-treatment vs. follow up; post-treatment vs. follow up.
* On pages 12-13, the statement, "…the participants from the experimental group seemed to recover more (N=11 (73.3%)) from dental anxiety compared with the control group (N=9 (60%))" seems to be too strong, considering it is only a difference of two people. Furthermore, over half of your control subjects were no longer dentally fearful at follow up!
* On page 13, the authors suggest that some participants may not have seen a reduction in their dental anxiety because of "psychopathological issues". Yet, individuals with psychiatric conditions were screened out, correct?
* Reviewer 3 pointed out that on page 13, the authors state that "…completing a psychological questionnaire may aggravate a patient's anxiety," but had cited a study by Dailey et al that showed this wasn't true. In the revised version of this manuscript, the authors seem to have resolved this contradiction by removing the Dailey reference, not by revising or removing their unsupported assertion. The correct course of action is to keep the Dailey citation in and revise the assertion in the Discussion section.
* On page 14, the authors suggest that the lack of difference between groups in post-treatment and follow-up assessments was the short follow up time (that is, if there were a longer follow up time, they may find a significant difference). Yet, treatment effects tend to decrease over time, suggesting that across a longer follow up period, any differences between groups would actually get smaller, not larger.

Reviewer #4: The authors have responded adequately to my critiques. This manuscript is suitable for

publication in this journal.

Reviewer #5: I would like to congratulate the authors on the hard work modifying and reviewing your paper. This will definitely make a difference on your study.

Reviewer #6: The authors addressed all my comments. Nevertheless, a few remarks as regards editing need to be dealt with.

Introduction:
page 4,Lines 46-56
I suggest the following sentence
The present study tested the hypothesis that combined psychological interventions would result in significant reduction in dental anxiety and dental concern
of the experimental group compared with control group, who did not receive such interventions as regards pretreatment, post treatment and follow up scores.
(As such, there would be no need for an additional hypothesis that seems unworthy of mentioning as an additional aim.)

Methods:
Page 5
line 13: were administered……..were asked to fill
line 24: Out of 33 patients exhibited dental anxiety, two were excluded due to
inclusion criteria Total of 31 patients ……..Out of 33 patients who exhibited dental anxiety, two were excluded as they did not fulfill the inclusion criteria. A Total of 31 patients
line 31: by using SPSS ……..by using computer generated random numbers(SPSS version……)
line 34: were randomized to…….were allocated to

Materials
Page 6 line 31: amount of treatment…..What does amount of treatment mean? Does this mean the time spent in offering the treatment, or the number of restorations and/or extractions that were implemented?

Results:
Page 9 line 41: dental anxiety were found in the experimental group….. dental anxiety were found within the experimental group
Discussion:
Page 10 line 48: of the 2 groups……..of the two groups
Page 11 line 16: in reducing dental anxiety…….. in reducing mean dental anxiety

Conclusion:
Page 15 lines 24,26 : Further, patients are willing to use these psychological techniques because they are easy and brief
This statement cannot be stated as a conclusion, since there were no frank parameters tested to measure the acceptance of patients to the interventions.

There is additional documentation related to this decision letter. To access the file(s), please click the link

below. You may also login to the system and click the 'View Attachments' link in the Action column.

********Authors response********

Reviewer #1: The goal of this revised manuscript was to describe a pilot study of a combination of techniques for reducing dental anxiety (psychoeducation, progressive muscle relaxation, and listening to music through headphones), and comparing dental anxiety pre-treatment, posttreatment, and at a 2-week follow up period. The authors have addressed several of the reviewers' prior comments, but there are still some unanswered questions, as described below.

* On page 3, the quote "a marked and persistent fear of clearly discernible, circumscribed objects or situations" is taken verbatim from the DSM-IV. This needs to either be put into quotation marks (as above) or reworded into the authors' own words in order to avoid plagiarism. Also, the version of the DSM needs to be indicated in the text (according to the reference, this is the DSMIV).

We agree with the reviewer. Refer page 3 first paragraph.

* On page 3, what type of "misdiagnosis" do the authors mean? Misdiagnosing a dental condition? Misdiagnosing dental fear?

We have rephrased this sentence. Refer page 3 line 15.

* To be able to determine whether this study really identifies the prevalence of dental anxiety among the clinic's dental patients, more detail needs to be known about how patients were recruited. Was every patient who arrived at the clinic surveyed for their dental fear? How many patients did not agree to participate in the study? If 64 = the number of unique patients seen in the clinic over the 3-month period, then 33 (51.5%) could be considered the prevalence of dental anxiety in their clinic, as the authors state on page 10. However, if, for example, there were 1,000 unique patients seen in the clinic over the 3-month period, and only 64 agreed to participate (and 33 were fearful), this does not tell you anything about the prevalence of dental anxiety in your clinic. What your current results most likely tell you is that 51.6% of people who agreed to be in your study are dentally fearful, which is very different from an overall prevalence of dental anxiety in your clinic. Please also revise the first sentence of your Discussion if needed, given this consideration.

Yes, we agree with you that the prevalence is not the overall prevalence rate of dental anxiety. The prevalence mentioned in the result and discussion section is based on the number of participants willing to participate in this study.

Refer page 11, 1,2, 7,8 and 12th line

* It is not clear that the authors understand what the reviewers meant by providing a sample size calculation. It seems as though the authors estimated how many patients would be seen in the clinic in a 3-month period and based their sample size on this. While this is a perfectly reasonable way to estimate how large a sample a researcher can expect to recruit during a period of time, it is not a sample size calculation. In order to determine whether you have enough subjects/patients to detect a difference in your outcome measure (for example, the DAS-R), you need to know how much of a difference you would expect to see in this outcome measure after an intervention (this is usually determined by looking at other, similar studies). It is recommended that you consult with a biostatistician to determine your sample size (for example, if you determine from the literature that an expected mean difference in DAS-R scores is 3 points after a dental fear intervention, and you would like to have 80% power (which is standard) at a significance level of $p<0.05$ to detect a difference between groups, then you would need how many subjects in each group).

I agree with you that sample size is determined based on the previous study prevalence rate. However, this is a pilot study; we have calculated number of patients attended in the three months in the dental clinical. The sample size calculator is used based on this link.

http://www.raosoft.com/samplesize.html
* It still isn't clear how the subjects were randomized - please explain how SPSS was used to
randomize the subjects.
By feeding data in spss, the software will randomly divide the participants.
* Please give more detail about the consent process. Typically, study participants are told what they can expect from being in both the treatment group and the control group, and that they will be randomly assigned to one of the groups. This way, they have all the information they need to know whether they want to participate (that is, what they'll be asked to do, depending on which group they are assigned to). If participants are told that they will have psychoeducation, progressive muscle relaxation, and music over headphones if they are in the treatment group, then participants who don't have any of these techniques will know that they are in the control group. Yet, the authors state on page 5 that "participants were not aware of which group they were randomized to." This doesn't seem possible, if they were consented to participate. In other words, if I'm a participant in your study and am given headphones and music to listen to, I know I'm in the treatment group, which
may lead me to report having less anxiety!
Not necessary to mention to the participants that which group they belongs from. Second, control group participants also received treatment from dentist as usual. However, experimental group participants were informed that they would receive psychological treatment to manage their dental anxiety.
We have received consent to participate at the pre assessment level. Participants are instructed that if they have dental anxiety at the pre-assessment level, they will be requested to participate in the post and follow up assessment. Consent has been received at all the level of assessment.
* The description of the DCA still isn't clear - do the authors mean that participants needed to have scored 2+ on all 26 items to be considered to have moderate to severe anxiety?
* Why were some DCA items (extraction, injection, etc.) chosen for additional analyses?
These are the only items participants have secured 2+. Refer page 10 line 7-9.
* On page 7, the statement "an anxious emotional state fails to exist in the presence of complete relaxation of peripheral parts" is taken verbatim from Jacobson. As above, this needs to be put into quotes or rewritten into the author's own words to avoid plagiarism.
Noted and edited.
* Please explain which dentists saw which patients. From the description on page 8, it sounds as though the patients in the treatment group were treated by different dentists than the control group? If this is the case, wouldn't that introduce bias into the study?
You are right that is our limitation.
* For the DCA results (page 10), please provide the same breakdown as for the DAS-R; that is, pre-treatment vs. post-treatment; pre-treatment vs. follow up; post-treatment vs. follow up.
We could not find significant differences in the post hoc for DCA.
* On pages 12-13, the statement, "…the participants from the experimental group seemed to recover more (N=11 (73.3%)) from dental anxiety compared with the control group (N=9 (60%))" seems to be too strong, considering it is only a difference of two people. Furthermore, over half of your control subjects were no longer dentally fearful at follow up!.
Following this line “the participants ….the control group (N=9 (60%))" we have mentioned that the control group treatment also effective as participants recover from the dental anxiety but the percentage of recovery is higher in the experimental group.
* On page 13, the authors suggest that some participants may not have seen a reduction in their dental anxiety because of "psychopathological issues". Yet, individuals with psychiatric conditions were screened out, correct?
Psychopathological issues may be due to their personality characteristics
* Reviewer 3 pointed out that on page 13, the authors state that "…completing a psychological

questionnaire may aggravate a patient's anxiety," but had cited a study by Dailey et al that showed
this wasn't true. In the revised version of this manuscript, the authors seem to have resolved this contradiction by removing the Dailey reference, not by revising or removing their unsupported assertion. The correct course of action is to keep the Dailey citation in and revise the assertion in the Discussion section.
We agree with reviewer's comment. Refer page 11 line 20-23 and page 13 line 21.
* On page 14, the authors suggest that the lack of difference between groups in post-treatment and follow-up assessments was the short follow up time (that is, if there were a longer follow up time, they may find a significant difference). Yet, treatment effects tend to decrease over time, suggesting that across a longer follow up period, any differences between groups would actually get smaller, not larger.
What is actually meant is that if the interventions are conducted more than once in multiple visits, it may have better impact on the patients' fear and hence follow up score i.e. the intervention was done once and the participant did not obtain a long term effect. Sentence edited in manuscript.
1. The authors addressed all my comments. Nevertheless, a few remarks as regards editing need to be dealt with. Last paragraph in introduction section: (*words in blue are the suggested corrections)*
The present study tested the hypothesis that combined psychological interventions would result in significant reduction in dental anxiety and dental concern of the experimental group compared with control group, who did not receive such interventions as regards pretreatment, post treatment and follow up scores.
As such, there would be no need for an additional hypothesis that seems worthy of mentioning as an additional aim.
We agree with the reviewer. Refer page 4 last paragraph.
2. Methods:
Page 5
line 13: were administered……..were asked to fill
line 24: Out of 33 patients exhibited dental anxiety, two were excluded due to inclusion criteria Total of 31 patients ……..
line 31: by using SPSS ……..by using computer generated random numbers(SPSS version……)
line 34: were randomized to…….were allocated to
We have addressed your comments under method, refer page 5 line 13, line 24, line 31, and line 34.
3. Materials
Page 6 line 31: amount of treatment…..What does amount of treatment mean? Does this mean the time spent in offering the treatment or the number of restorations and/or extractions that were implemented?
It means number of restorations required.
4. Results:
Page 9 line 41: dental anxiety were found in the experimental group….. dental anxiety were found within the experimental group
Noted and edited.
5. Discussion:
Page 10 line 48: of the 2 groups……..of the two groups
Page 11 line 16: in reducing dental anxiety…….. in reducing mean dental anxiety
Noted and edited.
6. Conclusion:
Page 15 lines 24,26 : Further, patients are willing to use these psychological techniques because they are easy and brief
This statement cannot be stated as a conclusion, since there were no frank parameters tested to measure the acceptance of patients to the interventions.
We agree with the reviewer. This statement is removed. Refer page 15 conclusion section.

3rd editorial decision
Date: 10-Jul-2017

Ref.: Ms. No. JCTRes-D-17-00004R2
Effects of a combination of non-pharmaceutical psychological intervention on dental anxiety
Journal of Clinical and Translational Research

Dear authors,

Reviewers have now commented on your paper. You will see that they are advising that you revise your manuscript. If you are prepared to undertake the work required, I would be pleased to reconsider my decision.

For your guidance, reviewers' comments are appended below.

If you decide to revise the work, please submit a list of changes or a rebuttal against each point which is being raised when you resubmit your work.

Your revision is due by Aug 09, 2017.

To submit a revision, go to http://jctres.edmgr.com/ and log in as an Author. You will see a menu item called Submission Needing Revision. You will find your submission record there.

Yours sincerely,

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Reviewers' comments:

Reviewer #7: Dear authors,

Please use the appended draft to make further modifications in the manuscript. Please use this draft, and not the one sent previously by mail (one more comment was added regarding Figure 1).

Thank you and kindest regards,

Michal Heger
EiC

There is additional documentation related to this decision letter. To access the file(s), please click the link below. You may also login to the system and click the 'View Attachments' link in the Action column.

4th editorial decision
Date: 24-Aug-2017

Ref.: Ms. No. JCTRes-D-17-00004R3
Effects of a combination of non-pharmaceutical psychological intervention on dental anxiety
Journal of Clinical and Translational Research

Dear authors,

I am pleased to inform you that your manuscript has been accepted for publication in the Journal of Clinical and Translational Research.

You will receive the proofs of your article shortly, which we kindly ask you to thoroughly review for any errors.

Thank you for submitting your work to JCTR.

Kindest regards,

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Comments from the editors and reviewers: