Title: Acupuncture for anxiety in dental patients: systematic review and meta-analysis

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ABSTRACT

**Introduction**

Dental anxiety affects an estimated 4% to 30% of the adult population in countries world-wide. The objective of this study was to conduct the first systematic review and meta-analysis of randomised controlled trials of acupuncture to reduce anxiety in dental patients.

**Methods**

Online databases (OVID/AMED, Cochrane Library, CINAHL, OVID/Medline, EMBASE, PROSPERO, PsycINFO, PubMED, as well as databases in Chinese, Portuguese, Spanish and German) were searched up to July 2017 for eligible trials involving dental patients receiving an acupuncture intervention with measured anxiety scores. Comparators were placebo, usual care, or another dental anxiety intervention. Included studies were assessed using the Cochrane Risk of Bias Tool.

**Results**

From 129 trials identified as potentially eligible, six trials with 800 patients were included in this review. Two trials (combined n= 267) were rated as moderate-to-high or high quality, both used auricular acupuncture, and were the only two trials to report continuous post-intervention anxiety scores, both using the (80-point) State-Trait Anxiety Inventory (STAI). A meta-analysis comparing acupuncture with no-intervention controls found a statistically significant and clinically relevant reduction in anxiety of -8.43, 95% CI (-11.90, -5.00). A meta-analysis comparing acupuncture to placebo/sham acupuncture found a clinically irrelevant and non-significant reduction of -1.54, 95% CI (-4.73, 1.64), a contrast that might be explained by context effects.

**Conclusions**

There is limited evidence from two good quality trials that auricular acupuncture can achieve a significant and clinically meaningful reduction of anxiety in dental patients. There is no conclusive effect of acupuncture when compared with a sham/placebo control.

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Keyword list: Acupuncture, anxiety, dental, systematic review

**Introduction**

Some dental patients experience anxiety about dental treatment, affecting an estimated 4% to 30% of the adult population in countries around the world.(1) The presence of anxiety, fear, and phobia are often accompanied by changes to blood pressure, pulse rate and other biomarkers. These reactions to dental treatment by patients are also a source of stress and anxiety for the dentist. Pharmacological interventions for managing anxiety in dental patients include conscious sedation and general anaesthetic.(2) In the United Kingdom, midazolam is a benzodiazepine commonly used as a pharmacological (sedative) intervention for pre-operative anxiety. Non-pharmacological interventions/techniques for managing anxiety in dental patients in the UK and other countries include: behaviour management techniques, relaxation techniques, guided imagery, biofeedback, hypnotherapy, acupuncture, distraction, enhancing control, systematic desensitization or exposure therapy, positive reinforcement, cognitive behavioural therapy (CBT), electronic dental anaesthesia, and Computer-assisted relaxation learning.(2)

Acupuncture has been applied in dentistry for a number of purposes, chiefly: managing dental pain, analgesic effect, post-operative pain relief, dental anxiety and gag reflex, management of temporomandibular disorders and orofacial pain, xerostomia (dryness in the mouth), and the management of Bell’s Palsy.(3)(4) However, a 2005 survey of 20 dentists in the UK using acupuncture in their practice found that the dentists used acupuncture most frequently to reduce anxiety in anxious patients.(5)

The most recent systematic review of studies on the effectiveness of acupuncture for treating anxiety more generally focussed on summarising the findings of 6 RCTs (421 total patients) in three countries, published between 2001 and 2013, but also assessed 13 other studies, of various designs, for the quality of evidence presented. The authors concluded that acupuncture was associated with clinically significant reductions in anxiety, but the studies were of low methodological quality, so firm conclusions could not be drawn.(6)

In a prior scoping search, no registered prospective or completed systematic review on acupuncture for dental anxiety was found. The objective of this study was to conduct the first systematic review of randomised controlled trials of acupuncture for anxiety in dental patients, summarising findings and conducting a meta-analysis of pooled data where possible. The systematic review addresses the research question: What evidence is there for the effectiveness of acupuncture in reducing anxiety in dental patients?

**Methods**

The protocol for this review was registered on PROSPERO 2017, Registration CRD42017072862, <http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017072862>

*Eligibility criteria*

Eligible studies were randomised controlled trials (RCTs) that had a population of dental patients, of any age group(s), with anxiety as a presenting symptom, and with treatment with acupuncture, whether skin was penetrated or not (i.e. laser), used alone, or in combination with conventional therapy compared to the same conventional therapy alone. Included comparators were sham/placebo, no treatment, usual care, or another acupuncture intervention or dental anxiety intervention. Outcomes included measures of anxiety such as: Modified Dental Anxiety Scale (MDAS), Beck Anxiety Inventory Score (BAI), Zung Self-rated Anxiety Scale (SAS) (a commonly used anxiety assessment scale in China), Visual Analogue Scale (VAS), Hamilton anxiety scale, and the State Trait Anxiety Inventory (STAI). RCTs were the chosen study design.

*Information source and search strategy*

A search was made of the following electronic databases from inception to July 2017 for relevant published research studies: English language (OVID/AMED,Cochrane Library (Wiley), CINAHL, OVID/Medline, EMBASE, PROSPERO, PsycINFO, PubMED), Chinese language databases (CNKI, VIP, CBM and WanFang), German language databases (DAHTA and SMS (Societas Medicinae Sinensis) Literaturdatenbank), a Spanish language database (LILACS), and a Portuguese language database (SciELO)*.* Reference lists of studies included in this review were also searched by hand. See Appendix A for the English language (MEDLINE) search strategy used. Construction of the Chinese, German, Spanish and Portuguese language database search strategies was based upon the MEDLINE search strategy, see Appendix B.

*Study selection*

English language database search result titles (and abstracts, where available) were entered into, and managed with, Zotero reference manager software, filed by database searched. Duplicates were removed from these lists of records. Titles/abstracts were screened for inclusion or exclusion from the review, by the first reviewer. For quality assurance purposes, a second reviewer independently screened titles and abstracts of 10% of the studies identified in the English language database searches. Full-text articles were acquired for potentially ‘included’ studies, and shared between reviewers, so as to reach consensus on which studies to include in the review.

*Data collection/extraction*

A data extraction form was piloted by the lead author, and then used for all studies eligible for inclusion in this review. For English language studies, one reviewer extracted data from full-text articles using the data extraction form. For studies in languages other than English, independent reviewers extracted data directly from studies, using this same data extraction form. In the event of missing data, study authors were contacted by email.

*Data items*

Data items extracted were as follows: Study authors, country in which study took place, year of publication of study, sample and group sizes, randomisation methods, setting of treatment delivery, description of the treatment intervention group(s), description of the control group, treatment duration (if known), outcomes (and relevant summary statistics) measured: pre- and post-treatment STAI anxiety scores, gagging severity (GS), pre- and post-treatment VAS anxiety scores, and practitioner and patient evaluation scores, key results reported: comparisons of anxiety scale scores (i.e. mean differences in post-intervention STAI scores for intervention and control groups) and GS scores where available, follow-up duration/frequency and attrition rate (if known/reported), key self-reported study limitations.

*Risk of bias in individual studies*

Bias of included studies was assessed for internal validity using the Cochrane Risk of Bias Tool intervention evaluation scores and p-values, in one study.

*Synthesis of results*

Studies were synthesised provided there was a continuous post-intervention outcome measure of anxiety. STAI scores were the only continuous post-intervention outcome measure used in both the two studies with data suitable for meta-analysis. For the meta-analyses these studies were entered into the open-source program MetaLight(7) for calculation of pooled effects. In the first meta-analysis, mean differences of post-intervention STAI scores between acupuncture (intervention) and no-treatment control groups were compared between studies. Heterogeneity (i.e. P-value and I² value) for the calculated pooled effect was evaluated. In the second meta-analysis, mean differences of post-intervention STAI scores between acupuncture and placebo/sham acupuncture groups were compared between studies and pooled. These results were also assessed on accepted measures of significance and statistical heterogeneity (i.e. conventional significance threshold of 5% or p ≤ .05 and I² value) and clinical relevance.(8)

**Results**

*Study selection*

From the English language database searches, 59 studies were identified as follows: OVID/AMED (0), Cochrane Library (Wiley) (3), CINAHL (3), OVID/Medline (8), EMBASE (0), PROSPERO (0), PsycINFO (32), PubMED (13). See Figure 1 for PRISMA flow diagram. For the Chinese language databases, a separate flow diagram shows how 68 potential studies were identified, see Appendix C. After removal of duplicates and application of inclusion criteria, 13 full-text publications were assessed as potentially eligible: seven English language(9)(10)(11)(12)(13)(14)(15), four Chinese language(16)(17),(18)(19), one German language(20) and one Portuguese language(21). A final decision on inclusion/exclusion was agreed upon by two reviewers, resulting in six studies included in this review: Elbay et al 2016)(9), Karst et al (2007)(10), Michalek-Sauberer et al (20012)(11), Lu et al (2000)(12), Liang (2015)(19), and Bremenkamp et al(2005)(20). Appendix D provides an explanation of why a number of English and Portuguese language studies were excluded from this review at the final full-text article screening stage.

**Insert Figure 1 here**

*Study characteristics*

Relevant characteristics of individual studies are provided in Table 1. More detailed descriptions of each study are presented in Appendix E.

**Insert Table 1 here**

*Risk of bias within studies*

Assessment of the risk of bias using the Cochrane Risk of Bias Tool is presented in Table 2.

**Insert Table 2 here**

The studies of Karst et al (2007)(10) and Michalek-Sauberer et al (2012)(11) were associated with moderate-to-high and high methodological quality, respectively. Comments on details of risks of bias in all studies included in this review can be found in Appendix E.

*Synthesis of results*

Of the six included studies, only two had available outcome data for meta-analysis with continuous measures of anxiety post-intervention that could be synthesised: Karst et al (2007)(10) and Michalek-Sauberer et al (2012)(11). They were at least moderate-to-high quality and used the same continuous outcome scale, the (80-point) State-Trait Anxiety Inventory (STAI). This resulted in their selection for meta-analysis. Of the four studies not included in the meta-analysis, two had only baseline continuous anxiety scores, measured pre-intervention(9)(20), and two studies had categorical outcome measures.(12)(19).

The primary comparison was of acupuncture vs. no treatment control group utilising STAI scores at the post-intervention point in time, primary because it answers a practical question, namely whether the addition of acupuncture makes a difference. The secondary comparison with an explanatory focus was of acupuncture vs. placebo/sham acupuncture group again utilising STAI scores at the post-intervention point in time. Controls other than sham/placebo acupuncture or no treatment were not included in the meta-analyses due to lack of data.

*Primary meta-analysis – Acupuncture vs. no treatment control groups*

The mean difference (MD) between post-intervention STAI scores for intervention and control groups was calculated for each of the two studies: Karst et al (2007)(10) and Michalek-Sauberer et al (2012)(11). The pooled effect for the two studies comparing the acupuncture and the no treatment control arms was calculated in MetaLight, based on fixed effects and random effects models. In the fixed effect model, anxiety scores were reduced in the acupuncture arm: -8.43, 95% CI (-11.9, -5) (Figure 2). A decrease of over 8 points on this scale is considered clinically relevant.(8) Based on a random effects model the reduction in anxiety was: -9.22, 95% CI (-14.7, -3.69) (Figure 3).

**Insert Figure 2 here**

**Insert Figure 3 here**

For a null hypothesis (Ho), MetaLight calculated a Q-value of 1.97, a P-value of 0.161 and an I² value = 49.2% for the pooled effect (Appendix F). The expected Q-value, if there was no statistical heterogeneity at all, would be equal to the degrees of freedom, in this case, 1. The P-value, if there was no statistical heterogeneity, would be P≤0.10. The I² value of 49.2% also indicates some statistical heterogeneity between the studies. The Cochrane Handbook suggests 30%-60% may represent moderate (but not quite substantial) heterogeneity.(22) Therefore, because in this instance there are only two studies to draw data from, and the statistical heterogeneity is not substantial, the fixed effects model (ignoring statistical heterogeneity) was considered the more reliable model to use to determine appropriate weighting of studies, as shown in Figure 2. It offers the more conservative of the calculated pooled effects of the two models.

*Secondary meta-analysis – Acupuncture vs. placebo/sham control groups*

The pooled effect for the comparison of acupuncture and placebo/sham acupuncture groups was also calculated based on fixed effects and random effects models, Figure 4 and 5. This analysis was undertaken to investigate the size of the acupuncture effect when context effects were similar between arms. Acupuncture, when compared to placebo/sham acupuncture, reduced anxiety levels by -1.54, 95% CI (-4.73, 1.64). This difference is identical in both plots and neither statistically significant, nor clinically meaningful.

**Insert Figure 4 here**

**Insert Figure 5 here**

For a null hypothesis (Ho), MetaLight calculated a Q-value of 0, a P-value of 0.963 and an I² value of 0 for the pooled effect (Appendix G). This statistically non-significant P-value, which is greater than P=0.050, suggests large uncertainty about the presence of statistical heterogeneity.

**Discussion**

*Principal findings*

Six studies (total number of study participants: n=800) were included in the review. Data was pooled in a meta-analysis of two of these studies, Karst et al (2007)(10) and Michalek-Sauberer et al (2012)(11), as both measured anxiety post-intervention on a continuous scale. They were assessed to be, respectively, of a moderate-to- high, and high methodological quality. The primary meta-analysis compared acupuncture to no treatment and found that acupuncture was associated with a clinically meaningful, and statistically significant, reduction in anxiety of -8.43, 95% CI (-11.9, -5) on STAI scores. A decrease of 8 points on the STAI scale is considered a Minimum important Difference (MiD) for a clinically meaningful reduction of anxiety. The secondary meta-analysis compared acupuncture with placebo/sham acupuncture and found a non-statistically significant, non-clinically meaningful pooled reduction in anxiety of -1.54, 95% CI (-4.73, 1.64) on STAI scores. That the reduction in anxiety was much smaller when acupuncture was compared to sham acupuncture is likely to be as a result of the context effects (such as additional practitioner contact time, expectations, etc) in the sham treatment arm, as such beneficial effects would not be present in a no-treatment arm. Moreover the selection of sham points is widely considered to be controversial(23), as the physiological impact of needling sham points is unknown, as is their potential effect on anxiety. In part this may explain the reduced effect of acupuncture relative to sham.

 *Strengths and limitations of the review*

A key strength of this review is that appropriate effort was made to include more than English language studies including, importantly, Chinese. While there have been a number of systematic reviews and protocols registered on either acupuncture for anxiety, this is the first review specifically on acupuncture for dental anxiety. A strength of the meta-analyses undertaken in this review was the consistency in outcome measurement across the two studies included in the meta-analyses.

Only two studies were found to be of moderate-to-high or high quality methodology. All other RCTs were of lower quality. These two studies both used the auricular style of acupuncture, so caution must be used in generalising the meta-analyses results to other styles of acupuncture. As there was only a limited degree of hand-searching grey literature, there is a possibility that publication bias may have been introduced into the results of the review. Limited resources precluded the possible inclusion of one non-English language study from grey literature(21) in this systematic review. Another limitation of this version of the review is the fact that all English language study data was extracted by one reviewer. A key limitation of the meta-analyses in this review is that only two studies’ data was included. Moreover, a better analysis if the data had been available from the Karst et al (2007)(10) and Michalek-Sauberer et al (2012)(11) studies, would have been to compare anxiety change scores between groups, however this was not done due to lack of data. An Individual Participant Data (IPD) meta-analysis would have provided a better analysis of the study data - this was not done due to time and resource constraints. Such an analysis would give greater clarity and confidence to the anxiety score differences between groups (i.e. intervention and control) between pre- and post-intervention points in time.

*Meaning of the review’s findings*

The results found in this review are comparable to those reported in Wang et al (2001)(24) regarding acupuncture for pre-operative anxiety, but represent a smaller effect size than results on acupuncture for anxiety reported by Errington-Evans (2015)(25) in a randomised controlled trial and on acupuncture for anxiety in a case series by Rosted et al (2010)(26). The results found in this review are on par with the systematic review Wide Boman et al (2013)’s(27) findings on the effectiveness of Cognitive Behavioural Therapy (CBT), both interventions (acupuncture and CBT) resulting in an approximately 10% reduction in anxiety in study participants.

In a survey on the use of acupuncture by UK dentists, Rosted and Warnakulasuriya (2005)(5) found that dentists reported using acupuncture most frequently for anxious patients receiving routine care. Given the findings in this review, of some limited yet good quality evidence of the clinical effectiveness of acupuncture in reducing anxiety, dental practitioners may wish to bear these findings in mind when considering the range of interventions at hand to help their patients reduce their anxiety.

*Implications for future research*

Well designed, larger scale RCTs on this topic, with sufficient statistical power, would add robustness to the evidence for the effectiveness of acupuncture for dental anxiety found in this review. Future researchers of acupuncture for dental anxiety should consider a study design measuring anxiety scores at three points in time, baseline/pre-intervention, post-intervention/pre-dental treatment, and post-dental treatment. This would give as broad as possible a picture of the effects of the various interventions before, during and after dental treatment. A cost effectiveness analysis of acupuncture for anxiety would be a helpful adjunct to any RCT on acupuncture and anxiety. Qualitative work, exploring improvements in quality of life resulting from interventions for dental anxiety such as acupuncture, would likely help inform the direction of further quantitative research on this topic. Studies for the purpose of establishing a protocol for standardising a set of clinically relevant point locations for dental anxiety would give clinicians and researchers a common basis from which to further assess the effectiveness of acupuncture for dental anxiety.

**Conclusions**

Some limited yet good quality evidence was found from two of the six included studies in this review, one with high methodological quality, and one with moderate to high methodological quality. Meta-analyses of these two studies found that acupuncture compared to no treatment provided patients with a clinically meaningful reduction of dental patients’ anxiety. The difference between acupuncture and sham/placebo acupuncture was inconclusive, and neither clinically nor statistically significant. Context effects provide a likely explanation for this contrast. Well designed, larger scale RCTs on this topic would increase the robustness of these findings, and qualitative research could help deepen understanding of the difference that reducing dental anxiety can make.

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**Conflicts of interest**

None known

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**Figure legends**

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Figure Appendix C: Flow chart for Chinese studies

Figure Appendix F Acupuncture vs. no treatment - meta-analysis data

Figure Appendix G: Acupuncture vs. sham/placebo - meta-analysis data

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**Appendix A: MEDLINE search strategy\***

#1. Acupuncture.af.

 #2. Acupuncture therapy/

 #3. Medicine, Traditional Chinese/

 #4. Needling.af.

 #5. Dry needling.af.

#6. Myofascial trigger.af.

#7. Chinese Medicine.af.

#8. Exp acupuncture/

#9. Dent\*.af.

#10. Oral surg\*.af.

#11. Odontophobia\*.af.

#12. Anxiety.af.

#13. Dental anxiety/

#14. Phobia\*.af.

#15. Fear\*.af.

#16. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8

|#17. (#9 and #12) or (#10 and #12) or (#9 and #14) or (#9 and #15) or (#10 and #14) or (#10 and #15) or #11 or #13

#18. #16 and #17

#19. Randomized controlled trial.pt.

#20. Controlled clinical trial.pt.

#21. Randomized.ab.

#22. Placebo.ab.

#23. Clinical trials as topic.sh.

#24. Randomly.ab.

#25. Trial.ti.

 #26. #19 or #20 or #21 or #22 or #23 or #24 or #25

#27. exp animals/ not humans.sh.

#28. #26 not #27

#29. #18 and #28

**\***Used in OVID/Medline, AMED, Embase, and PsycINFO searches

**Appendix B: Non-English language search strategies**

**German language search strategy**For the German-language search, an independent reviewer electronically searched the Datenbank der Deutschen Agentur für Health Technology Assessment (DAHTA) (search term ‘akupuntur’), the Societas Medicinae Sinensis (SMS) Literaturdatenbank (search terms adapted to German from OVID/MEDLINE search strategy, and strung together using AND and OR, as permitted by the database website search fields), and www.google.de (again, adapting search terms to German from OVID/Medline search strategy, and conjoining using AND and OR). The DAHTA database (<http://www.dimdi.de/static/en/db/dbinfo/dahta.htm>) *“...indexes reports equivalent to NICE reports for health technologies submitted for approval in Germany*”. The SMS database (<http://www.literatur.tcm.ch/>) *“...indexes German and English articles involving any aspect of Chinese Medicine (including acupuncture and acupressure)”.* (All database descriptions quoted from correspondence between author and independent reviewer).

**Chinese language databases search strategy**

The following databases were searched: National Knowledge Infrastructure Databases (CNKI) (1979-2017), the Chinese Science and Technology Periodical Database (VIP) (1989-2017), the Chinese Biomedical Database web (CBM) (1978-2017), and the WanFang Database (1985-2017). Search terms included were “acupuncture” “acupressure” “acupoint” “Acupuncture therapy” “Medicine, Traditional Chinese” “Needling” “Dry needling” “Myofascial trigger” “Chinese Medicine” “Dental” “oral surgery” “Odontophobia” “Anxiety” “Dental anxiety” “Phobia” “Fear” “Randomized controlled trial” “Controlled clinical trial” “Randomized” “Placebo” “Trial”

**Spanish language LILACS database search strategy**

en el campo “Palabras”: acupuntura OR terápia acupuntura OR medicina tradicional china OR MTC OR perforación en seco OR puntos trigger OR medicina china

AND

en el campo “Palabras”: dent\* OR cirugía\* oral OR odontofobia\*

AND

en el campo “Palabras”: ansiedad OR ansiedad dental OR fobia\* OR miedo\*

Translated from:

acupuncture OR acupuncture therapy OR traditional chinese medicine OR needling OR dry needling OR myofascial trigger OR chinese medicine

AND

dent\* OR oral surg\* OR odontophobia\*

AND

anxiety OR dental anxiety OR phobia\* OR fear\*

**Portuguese language search strategy**

For the Portuguese language search, another independent reviewer searched the SciELO database (search terms acupuncture AND dent\*) and Google Scholar for grey literature (search terms acupuntura, cirurgia odontológica, ansiedade).

**Appendix C: Chinese language search flow diagram**

Insert Figure Appendix C here

**Appendix D: Descriptions of English and Portuguese language full-text articles of studies excluded from this review**

Luciano de Mello Fonseca’s (2009)(21) dissertation reported the findings of a small Brazilian RCT (n=37) of body and auricular acupuncture interventions for pre-operative anxiety in dental patients, that may have fit the eligibility criteria for inclusion in this review. The independent reviewer who found this study did not have time to translate the full dissertation, to make a final decision on inclusion or exclusion from the review. So due to a lack of time and resources necessary for adequate translation, this study was excluded from the review.

Lu and Lu conducted two studies, in 2007(13) and 2013(14), both on dental anxiety control/reduction using acupuncture in combination with other interventions. However neither of these non-randomised studies used a validated anxiety scale, nor did they measure a pre- and post- intervention anxiety score of any kind. These studies were excluded based on lack of application of randomisation methods in each of their study design.

Acar et al (2013)(15) was an RCT done in Turkey on acupuncture for pre-operative anxiety, but was excluded from this review because the population of study participants were not dental patients, but hospital patients with pre-operative anxiety due to undergo anaesthesia and surgery.

**Appendix E: Study characteristics summary**

Bremenkamp (2005)(20)

This study was a prospective five-armed RCT (n=96) of male (only) dental patients, aged 18-65 years, carried out in a dental practice in Germany in 2001. Interventions compared were needle acupuncture, placebo needle acupuncture, laser acupuncture, and placebo laser acupuncture, with a control group receiving no treatment. Acupuncture and placebo acupuncture needles were left in for 15 minutes, and laser acupuncture treatments lasted 30 seconds per treatment point. The duration of the study was one treatment session and the attrition rate zero.

The author used a list of random numbers for allocation, resulting in an assessed high risk of potential bias for Allocation concealment (see Table 2). Blinding was also assessed to be at high risk of bias in this study, because the author did clinical work and then analysed the findings himself.

Outcomes measured in this study, once (baseline) in each trial arm, were: Dental Fear Survey (DFS), State-Trait Anxiety Inventory (STAI), Defensiveness, and Patient questionnaire data. Outcomes measured both pre- and post-intervention were: Visual Analogue Scale (VAS), Pulse, Salivary cortisol. The STAI and VAS are two of the validated outcomes listed amongst the eligibility criteria in the protocol of this review, as example outcomes to extract from studies included in the review. Incomplete Outcome data and Selective outcome reporting were two more Cochrane Risk of Bias criteria assessed to be at high risk of bias in this study, because the reporting of psychometric data was omitted in the results/discussion section of the study, only stated to be not statistically significant. It was unclear from the study what happened to data from psychological questionnaires, i.e. whether or not it was combined in a unplanned way.

No statistically significant difference (p>0.05) was found between pre- and post-intervention VAS scores. As already mentioned, baseline STAI scores were measured just once (pre-intervention). Two unsuccessful attempts were made to contact the author at his dental practice, by email, to request further information about analysis of the STAI scores. However, without post-intervention scores, any such information could only offer, at most, supplementary information about patients’ pre-intervention anxiety levels. In line with the outcomes to be extracted from included studies, as per the protocol for this review and reporting limitations, only VAS anxiety data has been summarised in the results (Table 1), not physiological data. Follow-up did not occur on this study, and the attrition rate was given as 0. The omission of part of some potentially key results in this study suggests that methods and results in this study may be unreliable and are at high risk of potential bias, and given the lack of post-intervention STAI scores, the data from this study was not included in the meta-analyses.

Elbay et al (2016)(9)

This small (n=25) double-blinded prospective RCT of children (aged 6-12 years) with a gagging reflex, comparing the effectiveness of low level laser therapy (LLLT) on acupuncture point Pc6 for 14 seconds, one time (prior to dental treatment), with a placebo group receiving an intervention that appeared to patients and practitioner to be the same, but with no active laser treatment. The attrition rate for this study was zero.

Whilst this study appears to have used sound randomisation and study methodology with regards to studying the intervention’s effect on the gag reflex, the data reported did not allow for a straightforward pre- and post-intervention comparison of anxiety scores between the intervention and control arms. Although not listed in the protocol as an outcome to extract, Gagging Severity (GS) pre- and post-intervention were the only measures compared, in this study, between intervention and control. Even so, the way the data was reported was not straightforward to interpret – it was difficult to ascertain from the study whether or not a GS score was taken at pre- and post-intervention points for both intervention and non-intervention groups, or just for the intervention group, or that perhaps the “control” summary data presented was a pre-intervention GS score and the “intervention” data presented was post-intervention summary data. GS score outcomes were extracted as follows, and summarised in the table of study characteristics (see Table 1): Mean Intervention group GS score = 0.36 +/-0.638, Median 0.00, Max. 2, Mean Control group GS score = 2.16 +/-0.746, Median 2.00, Max. 3. Gagging severity criteria were rated as follows: 0 – no or mild gagging, 1 – moderate gagging, 2 – severe gagging, 3 – worst gagging.

With regards to anxiety, only baseline (pre-intervention) Dental Anxiety Scale (DAS) scores of patients were recorded and reported in this study. No post-intervention DAS scores were assessed. As baseline DAS scores were taken pre-intervention, the authors calculated and reported summary statistics (Mean DAS score 10.60 +/-3.014, Median 10.00, Max 17) of this outcome for the entire study cohort as one group, not broken down by intervention and control group. According to the study, no significant correlations between the gag reflex and anxiety scores were expected, as per previous research.

Incomplete outcome data and Selective outcome reporting in this study were assessed to be criteria for which there was an unclear risk of bias (see Table 2), because data for GS scores were only presented as summary statistics. Given the risk of bias assessment, this study was considered to be of moderate methodological quality. The lack of a clear presentation of all data in this study, together with a lack of clinical homogeneity with other study outcomes, prevented prudent use of study data in the meta-analyses in this review.

Karst et al (2007)(10)

This well-designed study, a four arm prospective RCT (n= 67), compared the effectiveness at treating dental anxiety, of auricular acupuncture, intranasal midazolam, placebo acupuncture, and no treatment. Study participants were aged 18-65 years, and the study was carried out in the outpatient clinic of the Department of Oral and Maxillofacial Surgery of the Hannover Medical School in 2003 and 2004. The study was planned to have 85% power to detect a group difference of 7 to 25 on the STAI scale, resulting in a 2:1 allocation of populations of each intervention group, relative to the size of the control group. With such a small sample size however, although not explicitly stated by the authors, it is clear that this statistical power was not achieved in this study. The duration of the study was one treatment session. A 5% attrition rate was accounted for in sample size calculations, due to potential drop out. However, the actual study was reported to have an attrition of zero. As in the Bremenkamp (2005)(20) study, the allocation concealment process was assessed to be at high risk of introducing potential bias (see Table 2) because a list of random numbers was used (termed by Cochrane as an ‘open random allocation schedule’)… therefore investigators enrolling participants could possibly foresee assignments and thus introduce selection bias.

Two separate teams of investigators carried out the clinical work and data processing, blinded from potential bias-inducing details of each others’ work. Within each team, blinding was also achieved between investigators. For example, the investigator assessing all anxiety scores worked independently, unaware of the treatment. Patient blinding, considering the nature of the interventions, could not be achieved, except for between the acupuncture and placebo acupuncture groups. The authors also stated that *“Before the study no patient had experienced any of these techniques for reducing anxiety. Therefore there was no specific patient expectation regarding any of the interventions.”* (Karst et al, 2007)(10) Such expectations/preferences could introduce preference bias to the results of the trial.

Baseline/pre-intervention STAI and VAS scores were taken 40 minutes before dental treatment. Interventions began at 35 minutes before dental treatment, and continued until 5 minutes before dental treatment. The acupuncture group received auricular acupuncture at the Relaxation, Tranquilizer, and Master Cerebral points. The Wang et al (2001) study was cited as a reference for this choice of treatment points. The placebo arm participants received auricular acupuncture at the Finger and Liver points (which do not have any documented effect on anxiety). STAI and VAS post-intervention scores were taken again at that point, and again, after dental treatment. Outcomes measured, reported, and extracted were: STAI and VAS (anxiety) baseline/pre-intervention scores of study participants, post- intervention STAI and VAS scores, and post-dental treatment STAI and VAS scores, and standard deviations of all of the aforementioned outcomes. Physiological outcomes were also measured in the study, but data for these outcomes was not extracted for use in this review.

In terms of the interventions’ effects on dental patients’ anxiety, the acupuncture intervention arm was reported to have STAI scores reduced from 50.47+/-8.83 pre-intervention, to 43.53+/-9.99 post-intervention, and 41.84+/-12.72 after dental treatment. By comparison, the placebo auricular acupuncture arm was reported to have had STAI scores reduced from 49.32+/-13.49 pre-intervention, to 45.21+/-10.82 post-intervention, and 39.16+/-9.87 after dental treatment. By further comparison, the intranasal midazolam arm was reported to have STAI scores reduced from 56.53+/-9.61 pre-intervention, to 42.16+/-9.12 post-intervention, and 38.68+/-9.19 after dental treatment. And as a final comparison, the control arm was reported to have had STAI scores rise from 53.00+/-9.61 pre- (no-) intervention, to 56.50+/-9.10, and then fall to 47.20+/-12.78 after dental treatment.

Previously the accepted value for a clinically meaningful difference on the STAI scale has been reported as 8. (Fisher and Durham, 1999)(8) Calculating the relevant changes in anxiety from the above data (these mean values were not given, however their confidence intervals were, as follows), we have -6.94 (acupuncture group, pre- to post-intervention) – (+3.50) (Control group pre- to post-intervention) = - 10.44 (reported 95% Confidence Interval (CI) (-18.93, -1.97)), a clinically meaningful and statistically significant (p=0.012) difference in anxiety changes, between the auricular acupuncture and control groups. Next, making further calculations of anxiety change data, we have -14.37 (midazolam group, pre- to post-intervention) – (+3.50) (control group pre- to post-intervention) = - 17.87 (reported 95% CI (-26.35, -9.39)), a clinically meaningful and statistically significant (p<0.001) difference in anxiety changes, between the midazolam and control groups.

VAS scores (0-10 scale) for the auricular acupuncture group dropped from 4.25+/-3.02 at baseline/pre-intervention to 3.03+/-2.16 post-intervention, to 1.73+/-1.71, after dental treatment. Likewise, VAS scores for the placebo acupuncture group dropped from 4.36+/-3.00 at baseline/pre-intervention to 3.21+/-2.74 post-intervention, to 1.20+/-1.65, after dental treatment. VAS scores for the intranasal midazolam group dropped from 5.35+/-2.41 at baseline/pre-intervention to 3.32+/-2.41 post-intervention, to 1.72+/-1.68, after dental treatment. VAS scores for the control/no-treatment group rose from 5.57+/-2.53 at baseline/pre-intervention to 5.71+/-2.83 post-intervention, and then fell to 1.61+/-1.56, after dental treatment. According to study authors, concerning VAS scores, only the pre- and post-intervention difference, compared between midazolam and control groups, was statistically significant (p=0.011, 95% CI -3.91, -0.43).

The study concluded that both auricular acupuncture and intranasal midazolam were effective at reducing dental anxiety. Despite its small sample size, the otherwise moderate to high methodological quality of this study and availability of outcome data led to inclusion of its results in the meta-analyses in this review.

Key self-reported study limitations:

* Inclusion of patients ‘consecutively’ in the study, (rather than grouping participants by measured baseline anxiety level)
* Blinding of patients regarding receiving midazolam or acupuncture as an intervention was reported as a possible source of significant bias.
* Placebo/sham acupuncture’s limitations – possibly eliciting a physiological effect
* Small sample sizes of trial arms
* Lack of assessment of pain

Liang (2015)(19)

The member of the review team in China corresponding with the review team in the UK writes: *“The RCT involved 200 dental anxiety patients. The participants were ages 18–62, and the disease duration was 2 weeks. The trial used MDAS as the diagnostic criteria. The intervention group received acupoint massage combined with psychological intervention on the basis of routine nursing, while the control group received routine care and psychological intervention. Compared with the MDAS score before and after intervention, the effective rate of intervention group was 70%, and that of control group was 45%. The two groups had statistical significance (P < 0.05). The conclusion is acupoint massage combined with psychological intervention is better than psychological intervention for adult dental anxiety patients.”*

The duration of this study was one treatment session, and the attrition rate given was zero. The author of this study set a criterion of a reduction of one level on the MDAS scale to equate to ‘effectiveness’. The MDAS scale levels referred to in the study were: Level 1: an MDAS score of 4-9, Level 2: 10-12, Level 3: 12-14, and Level 4: 15-20. The 70% ‘effectiveness’ rate reported appears to reflect that 70 of the 100 patients of the intervention acupoint massage group indeed experienced this minimum one level reduction of MDAS anxiety score, from pre- to post-treatment, on the 20 point MDAS scale.

Allocation concealment, Blinding, Incomplete outcome data, and Selective outcome reporting, all were assessed to be at an unclear level of risk in this study (see Table 2). Firstly, neither blinding, nor the method of allocation concealment were mentioned in the study. Secondly, regarding Incomplete outcome data: In terms of results, the study basically presented two figures - 70% and 45% side by side, suggesting the possibility of an incomplete analysis of data or incomplete presentation of analysis results. It is difficult to determine if this potentially missing outcome data/analysis masked any significant result, or not. The predominance of unclear risks of bias in this study suggested a poor methodological quality, overall. Primarily for this reason, this study was excluded from the meta-analyses in this review.

Lu et al (2000)(12)

The authors’ stated aim in this RCT (n=230) was to assess the anti-gagging effect of acupuncture point Pc6 (or P-6 as termed in the study). The authors cited 5 studies for evidence of efficacy of the choice of the Pc6 point to serve the purpose of reducing gagging. Study participants were dental patients referred for gagging problems, aged 17-76. Patients were *“allotted randomly into several groups for a double-blind study...”.* Evidence for, or a description of, double blinding, or even single-blinding, was not provided, other than a brief description of what was told to study participants. This study was assessed to be at high risk of bias on the Blinding Cochrane Risk of Bias criterion (see Table 2), as patient preference for the intervention was mentioned specifically to have been found by the authors to have been present in patients (but not mentioned as a potential source of preference bias).

This ambitious study used non-validated evaluation scales for comparing the effects of electro-acupuncture on acupuncture point Pc6 (n=14), presumably for the length of the dental treatment (but duration of interventions were not stated in the study), with electro-acupuncture on a dummy site (n=12), presumably for the length of the dental treatment, with acupressure with an investigator’s thumb held at Pc6 (n=17), with thumb acupressure at a dummy site (n=13), with acupressure with a tourniquet and device (shown only in photo) at Pc6 (n=16), with acupressure with a tourniquet and the same device at dummy site (n=18), with a Sea-band (commercially available) on Pc6 (n=10), with a Sea-band on a dummy site (n=9), all without conscious sedation, and separate intervention arms as described above, each with conscious sedation. The sizes of the intervention plus conscious sedation arms were, respectively, n=19, 15, 21, 18, 13, 14, 9, and 12. Despite having started with a large overall number of study participants, 8 intervention groups (total n=119) and another 8 control (placebo) groups (total n=111) were thus created, undermining the potential statistical power of the study. The attrition rate for this study was zero.

The authors created an ‘Operating team’ evaluation form and scoring system, and a patient evaluation form and scoring system, to evaluate the ‘effectiveness’ of each of the above 16 groups. These evaluations were made post-intervention. Study results were presented as a table of Operating Team evaluation scores and Patient evaluation scores (and p-values of statistical significance of score results), ranging from Excellent to Poor, and a table summarising the numbers of patients undergoing the three dental procedures undertaken during the study.

The authors concluded that *“this study and others indicate that stimulation of the Neikuan P-6 point with an acupuncture needle or acupressure device has an anti-gagging effect for dental procedures.”* (Lu et al, 2000)(12) However, as indicated above and in Table 2, the number of ‘unclear’ risk criteria assessed for this study, and presence of a high risk of bias criterion assessment, casts doubt as to the reliability of results, and suggests poor methodological quality, overall. The study results described above, due to lack of homogeneity with outcomes of other studies included in this review, were deemed inappropriate for use in the meta-analyses.

Michalek-Sauberer et al (2012)(11)

This three-arm prospective RCT (n=182) was designed to investigate the effectiveness of auricular acupuncture in comparison to placebo/sham acupuncture and no treatment, for anxiety in dental patients. Study participants were dental patients, age 18+, at the outpatient clinic of the Bernhard Gottlieb Department of Oral Surgery, Medical University of Vienna, in 2007 and 2008.

The study’s sample size was calculated to have 85% power, to detect a minimum relevant 6 points difference between groups, on the STAI scale. It was assumed that the authors here referred to minimum clinical relevance. The attrition rate was projected to be zero for this study, based on experiences in a pilot phase of the study. The authors stated in the study that the clinical investigator *“...was not involved in data collection and data assessment...*” and *“...outcome data were assessed by an investigator (AG) who never had any patient contact”.* (Michalek-Sauberer et al, 2012)(11) Limitations of single blinding, due to the impossibility of double blinding in clinical procedures involving acupuncture, were specifically mentioned in the study as having the potential to introduce bias into the results. The duration of this study was one treatment session, and the attrition rate was actually zero, as projected.

Baseline VAS scores were measured and used to include (cutoff point ≥3 VAS score) or exclude patients (<3 VAS score) from the study. Baseline/pre-intervention STAI scores were assessed and recorded prior to interventions. The acupuncture group study participants received auricular acupuncture at the Relaxation, Tranquilizer, and Master Cerebral points. As in the Karst study(10), the Wang et al (2001)(24) study was cited as a reference for this choice of treatment points. The placebo acupuncture group study participants received auricular acupuncture at the Finger, Shoulder, and Tonsil points (which do not have any documented effect on anxiety). All study participants in the intervention arms received auricular acupuncture on the ear contralateral to their dominant hand. *“Needles were left in situ for approximately 20 minutes until the start of the dental treatment”.* (Michalek-Sauberer et al, 2012)(11) Post-intervention STAI scores were then assessed, as in Karst et al (2007), just prior to dental treatment. No further scores were taken in this study.

The authors of this study reported the auricular acupuncture intervention group to have had STAI anxiety scores reduce from 54.7+/-10.8 pre-intervention, to 46.9+/-10.4 post-intervention. By comparison, the placebo acupuncture group was reported to have had STAI scores fall from 51.9+/-10.2 pre-intervention, to 48.4+/-10.0 post-intervention. And by further comparison, the control group was recorded to have had STAI scores rise from 51.0+/-11.7 pre- (no-) intervention, to 54.0+/-11.6 post- (no-) intervention.

A clinically meaningful and statistically significant 9.9 point difference (compared to the accepted minimum value of 8, as already stated) (p<0.001, 95% CI (7.1, 12.6)) was found between the auricular acupuncture and control groups’ differences between pre- and post-intervention scores. A statistically significant (p=0.008), but not clinically meaningful 3.6 point difference, 95% CI (0.8, 6.4) was found between the auricular acupuncture and placebo/sham groups’ differences between pre-and post-intervention scores. Study authors found that baseline levels of anxiety had no influence on the effects of acupuncture (p=0.888) and there were no significant differences in the effects of acupuncture between women and men (p=0.198) nor between types of dental treatment (p=0.188).

Pre-intervention VAS scores in this study were used only to establish eligibility for participation in the study, however for completeness, mean pre-intervention VAS scores are summarised here, as reported in the study: auricular acupuncture group: 5.9, CI (4.2 , 7.7), placebo/sham acupuncture group 5.1, CI (4.0, 6.7), and control/no-intervention group 5.3, CI (3.8, 6.5). It was noted in this study that generally women presented a higher degree of ‘state’/baseline (p=0.003) and ‘trait’ (p=0.434) STAI scores, as well as of baseline/pre-intervention VAS scores (p=0.017), compared to men.

One-way ANOVA and ANCOVA models were used to compare STAI scores between intervention groups. Information on patient preference was gathered, examined and reported in depth in this study. As mentioned previously, patient preference is a potential source of preference bias in trials.

Key self-reported study limitations:

* Loud, busy atmosphere in which interventions took place may have affected outcome
* Bias due to lack of blinding of control group patients may have confounded results
* Although no effect of baseline anxiety was found on the anxiety-reducing effects of auricular acupuncture, exclusion of patients with a baseline VAS score of 3 or less was thought by the authors to have possibly biased the results. However, it is unclear how, given the ‘no effect of baseline anxiety’ principle.

The authors concluded that *“auricular acupuncture, acupuncture of the outer ear, effectively reduces state anxiety before dental treatment with negligible side effects”.* The authors also noted that *“...98% of study participants would want to use auricular acupuncture to reduce their anxiety on future occasions.”* (Michalek-Sauberer et al, 2012)(11) The high methodological quality of this study (Table 2) led to the inclusion of its results in the meta-analyses in this review.

**Appendix F: Acupuncture vs. no-treatment and control - meta-analysis data**

Insert Figure Appendix F here

**Appendix G: Acupuncture vs. sham/placebo - meta-analysis data**

Insert Figure Appendix G here