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ORIGINAL ARTICLE

Auricular acupuncture effectively reduces state anxiety before dental treatment—a randomised controlled trial

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Abstract
Objectives The objective of this study was to analyse whether auricular acupuncture, acupuncture at the outer ear, could reduce state anxiety before dental treatment.
Methods This prospective, randomised patient-blinded study with 182 patients compared anxiety before dental treatment following auricular acupuncture at the relaxation-, tranquillizer- and master cerebral points (auricular acupuncture group) versus acupuncture at sham points (finger-, shoulder- and tonsil points; sham group) and a non-intervention control group. Anxiety was assessed using the Spielberger State Trait Anxiety Inventory (German version) before auricular acupuncture and 20 min thereafter, immediately before dental treatment.
Results Auricular acupuncture reduced state anxiety score more effectively from 54.7±10.8 to 46.9±10.4 (mean ± SD) than sham acupuncture from 51.9±10.2 to 48.4±10.0. In contrast, state anxiety in the control group increased from 51.0±11.7 to 54.0±11.6 (mean increase +3.0; CI +4.7 to +1.2). The decrease in state anxiety in both intervention groups was statistically significant ($p<0.001$) when compared to the non-intervention control group. After correcting for group differences in baseline state anxiety, the reduction in anxiety was −7.3 score points (CI −9.0 to −5.6) in the auricular acupuncture group and −3.7 score points (CI −5.4 to −1.9) in the sham group ($p=0.008$).
Conclusion Auricular acupuncture, a minimally invasive method, effectively reduces state anxiety before dental treatment.
Clinical relevance Auricular acupuncture could be an option for patients scheduled for dental treatment, who experience an uncomfortable degree of anxiety and request an acute intervention for their anxiety.

Keywords Acupuncture · Ear · Anxiety · Dental · Complementary therapy · Therapy · Alternative

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Introduction

Dental anxiety is highly prevalent in Western countries, ranging from 40% to 60% [1–4]. Higher levels of dental fear prevent patients from seeking medical treatment and are associated with more decayed and missing teeth [5]. Thus, dental anxiety is associated with a negative impact on oral health [6].

Treatment options for dental anxiety are pharmacological, typically using benzodiazepines, and non-pharmacological methods, including biofeedback, hypnosis, musical distraction and behavioural interventions. Patients prefer non-

pharmacological techniques [7]. Another non-pharmacological technique is acupuncture, which has an anxiety-reducing effect [8]. Auricular acupuncture, acupuncture at the outer ear, has already been shown to reduce general [9] and preoperative anxiety [10–12]. Auricular acupuncture is minimally invasive and the auricle is easily accessible for the dentist. To determine whether auricular acupuncture effectively reduces state anxiety before dental treatment, we performed a prospective randomised study in an ambulatory dental treatment setting.

Methods

Design and patient selection

This prospective, randomised, sham-controlled, patient-blinded study was approved by the Ethics Committee at the Medical University of Vienna and performed at the outpatient clinic of the Bernhard Gottlieb Department of Oral Surgery, Medical University of Vienna, Austria, between June 2007 and March 2008. One hundred and eighty-two adult patients (aged ≥18 years), scheduled for elective dental procedures, were enrolled in this study after having given written informed consent. Exclusion criteria were dental emergencies, previous experience with acupuncture, language difficulties, history of drug abuse, chronic pain therapy, neurological or psychiatric disorders, malignomas, lesions at the external ear, immunosuppression, pregnancy, asthma and coagulation disorders.

Groups

Using a computer generated randomization table provided by the Center for Medical Statistics, Informatics and Intelligent Systems, Medical University of Vienna, Austria, patients were randomised to three groups (block randomization):

1. Auricular acupuncture group—Patient received auricular acupuncture at three points with a demonstrated anxiety-reducing effect [10]: relaxation point, tranquillizer point and master cerebral point (Fig. 1).
2. Sham group—Auricular acupuncture was performed at acupoints finger, shoulder and tonsil. These points are located in comparable regions of the external ear but do not have any documented effect on anxiety (Fig. 1).

The needles were placed at the ear contralateral to the patient's dominant hand.

3. Non-intervention control group—Patients did not receive any anxiety-reducing intervention.

Randomization was stratified for the patients' gender. Sealed opaque envelopes were used for allocation to the groups by the investigator performing acupuncture.

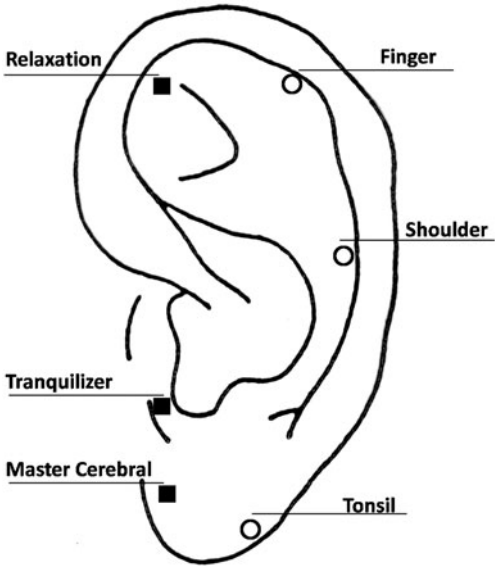

Fig. 1 The anatomic location of the auricular acupuncture points: *filled square*, auricular acupuncture group; *empty circle*, sham group

Protocol

All patients in the waiting area of the department's outpatient clinic, who fulfilled the inclusion criteria, were asked, if they would like to participate in the study. If willing, patients rated their anxiety on a visual analogue scale (VAS). The VAS is an undivided 10-cm long line, where patients are instructed to mark their present anxiety as 0 = no anxiety and 10 = maximum anxiety. To exclude patients that did not feel any anxiety, only patients with a VAS score of ≥3 were enrolled in the study.

A baseline anxiety rating was obtained using the German version of the Spielberger State Trait Anxiety Inventory (STAI) [13]. The STAI is a validated questionnaire consisting of two parts: STAI-X1 measures state anxiety, which is defined as the anxiety in response to a given situation. STAI-X2 assesses trait anxiety, i.e. the "baseline" anxiety usually felt by the person. Both parts of the STAI yield a score between 20 and 80, with higher values indicating a higher level of anxiety. Commonly STAI-scores of ≥40 are considered to represent a high level of anxiety, values of ≥50 are classified as very high [14].

Thereafter auricular acupuncture was performed in the auricular acupuncture and sham groups. The same investigator (EG; Diploma of Acupuncture, Austrian Medical Chamber; no clinical experience), who was not involved in data collection and data assessment, performed acupuncture in all patients. Silicone-coated, sterile, single-use acupuncture needles (diameter 0.2 mm, length 15 mm; no. 3, B-type needle, Seirin Corporation, Shizuoka, Japan) were used. A point-finding device (Punktsuchgerät PS 3, DIng. Silberbauer Vertriebsgesellschaft m.b.H. & Co. KG, Vienna, Austria) facilitated the

identification of the respective acupoints. The needles were left in situ for approximately 20 min until the start of the dental treatment. In order to prevent any possible bias, participants were informed that the aim of this study was to determine "which acupoint on the external ear is more effective in reducing preoperative anxiety".

Immediately before the dental treatment, already seated in the dentist's chair, all patients rated their anxiety with the state anxiety form (STAI-X1) for a second time. Patients in the auricular acupuncture and sham groups were also handed a second questionnaire which included questions concerning blinding success and the patient's evaluation of acupuncture effect. Thereafter the needles were removed. Outcome data were assessed by an investigator (AG) who never had any patient contact.

Statistics

The sample size was calculated to have 85% power, at a 5% overall significance level, to detect a minimal relevant difference of 6 points in the STAI-X1 scale between the auricular acupuncture and either sham group or non-intervention control group. Assuming a pooled standard deviation of 10 points [9, 10], an effective sample size of 61 patients per group was required (a total of 183 patients; no withdrawals expected due to experiences in a pilot phase).

Baseline state and trait anxiety values were compared between intervention groups using one-way ANOVA models. Pairwise post hoc comparisons were adjusted for multiple testing using Dunnett's method. The same was done for baseline anxiety VAS score after log-transformation due to its left-skewed distribution. Baseline state and trait anxiety values as well as (log-transformed) VAS score were compared between sexes using independent-samples t tests. Within-group reductions in state anxiety were compared between groups using an ANCOVA model in order to adjust for group differences with respect to baseline state anxiety [15]. Least squares means (with 95% confidence intervals) from this model were used to estimate and test within-group reductions as well as intergroup differences between reductions. Confidence intervals and p values for post hoc pairwise group comparisons were adjusted for multiple testing using Dunnett's method. An ANCOVA model was used for additional adjustment with respect to gender, age, type of dental treatment, pain before treatment and baseline trait anxiety. The effect of baseline state anxiety or gender on the acupuncture effect was investigated by testing for an interaction of the respective variable with the intervention group factor. All significance tests are two sided. All computations were performed using SAS software Version 9.2 (SAS Institute Inc., Cary, NC, USA, 2008).

Results

One thousand two hundred seventy-four patients were screened for eligibility. Of the patients, 1092 did not fulfil the inclusion criteria, in particular an anxiety of ≥ 3 on the VAS, or refused to participate, mainly because of time constraints; 182 patients were enrolled into and completed the study.

Patients in the three groups were comparable with regard to age, gender, pain before dental treatment as well as their belief concerning the possible anxiety-reducing effects of acupuncture (Table 1). Type of dental treatment varied significantly among the groups. However, this did not affect baseline anxiety (trait: $p=0.931$, state: $p=0.501$). Anxiety VAS values, state and trait anxiety before the intervention did not differ between the groups (Table 2) with high to very high values for state anxiety in all groups. Generally, women presented a higher degree of baseline state and trait anxiety and anxiety VAS values than men (VAS: $p=0.017$, trait: $p=0.434$, state: $p=0.003$).

Auricular acupuncture effectively reduced state anxiety scores before dental treatment. In both acupuncture groups, state anxiety scores decreased significantly ($p<0.001$) immediately before dental treatment (auricular acupuncture group: 54.7±10.8 to 46.9±10.4, sham group: 51.9±10.2 to 48.4±10.0), whereas in the non-intervention control group state anxiety score increased significantly ($p=0.004$) from 51.0±11.7 to 54.0±11.6 (+3.0; CI: +4.7 to +1.2).

After correcting for intergroup differences in baseline state anxiety by way of an ANCOVA model, the reduction in anxiety was −7.3 (CI −9.0 to −5.6) in the auricular acupuncture group and −3.7 (CI −5.4 to −1.9) in the sham group. Thus, average reduction in state anxiety in the auricular acupuncture group was 3.6 score points (CI: 0.8 to 6.4) greater than in the sham group ($p=0.008$) and 9.9 score points (CI: 7.1 to 12.6) greater than in the non-intervention control group ($p<0.001$). Additional adjustment for gender, age, type of dental treatment, pain before treatment and baseline trait anxiety showed similar results (2.9 points vs. sham group and 8.6 points vs. non-intervention control group).

The baseline level of state anxiety had no influence on the effects of acupuncture ($p=0.888$). There were no significant differences in the effects of acupuncture between women and men ($p=0.198$) nor between different types of dental treatment ($p=0.188$).

Patients' beliefs as to which acupuncture intervention they had received (i.e. "proper intervention" or "placebo/sham") and the associated anxiety-reducing effects of acupuncture perceived by the patients did not differ between the two acupuncture groups (Table 3).

Patients judged the comfort of auricular acupuncture as good. Approximately 20% of patients in both intervention groups reported warmth or a strange feeling at the treated

Table 1 Demographic data

Sample size (*n*)	Auricular acupuncture 61	Sham group 60	Control 61	*p*
Age (years)[a]	34 (26.5–45.5)	39.5 (26–51.1)	39 (26–51)	0.546[d]
Gender: male *n* (%)	20 (32.8%)	21 (35.5%)	24 (39.3%)	0.744[e]
Type of dental procedure *n* (%)				0.007[e]
Consultation/Examination	10 (16.4%)	22 (36.7%)	28 (45.9%)	
Extraction	4 (6.6%)	9 (15.0%)	6 (9.8%)	
Localized tooth pain[b]	19 (31.1)	17 (28.3%)	13 (21.3%)	
Parodontological treatment	7 (11.5%)	5 (8.3%)	4 (6.6%)	
Other	10 (16.4%)	4 (6.7%)	1 (1.6%)	
Not recorded	11 (18.0%)	3 (5.0%)	9 (14.8%)	
Pain before dental treatment *n* (%)				0.486[e]
Yes	25 (41.0%)	33 (55.0%)	32 (52.4%)	
No	25 (41.0%)	24 (40.0%)	20 (32.8%)	
Not recorded	11 (18.0%)	3 (5.0%)	9 (14.8%)	
Belief in acupuncture[c] *n* (%)				0.183[e]
Yes	33 (54.1%)	21 (35.0%)	26 (42.7%)	
No	0 (0.0%)	1 (1.7%)	2 (3.2%)	
Don't know	28 (45.9%)	38 (63.3%)	33 (54.1%)	

[a]Age is presented as median (lower and upper quartiles)

[b]Due to various dental lesions and intrabony dental infections

[c]"Do you think that acupuncture can affect the anxiety before a dental treatment?"

[d]Wilcoxon rank–sum test

[e]Chi-square test

ear or dizziness as side effects (Table 3). Although only 45% of all patients believed that the acupuncture actually did reduce their anxiety, 98% would want to use auricular acupuncture to reduce their anxiety on future occasions (Table 3).

Discussion

This study demonstrates that auricular acupuncture, acupuncture of the outer ear, effectively reduces state anxiety before dental treatment with negligible side effects. Auricular acupuncture for reduction of anxiety was performed at the relaxation-, the tranquillizer- and the master cerebral point for 20 min before ambulatory dental treatment (Fig. 1). Patients with no intervention had an increase in state anxiety, when seated in the dentist's chair immediately before treatment. The difference in state anxiety immediately before the dental treatment between the auricular acupuncture group and the control group amounted to approximately 10 points. A decrease by more than 8 points is generally considered to be clinically meaningful [16].

For better comparison of our results to those of other studies, we chose to measure anxiety using the STAI instead of a more specific instrument to assess dental anxiety. However, there is a significant correlation for state anxiety and dental anxiety as measured by the dental anxiety scale [17].

Table 2 Anxiety: Baseline VAS score and state- and trait anxiety before acupuncture intervention as well as state anxiety after acupuncture

Sample size (*n*)	Auricular Acupuncture 61	Sham group 60	Control 61	*p* auricular acupuncture vs. sham	*p* auricular acupuncture vs. control
VAS anxiety	5.9 (4.2–7.7)	5.1 (4.0–6.7)	5.3 (3.8–6.5)	0.512[a]	0.754[a]
STAI-trait	40.7±11.5	38.9±9.2	39.6±12.1	0.547[a]	0.898[a]
STAI-state before intervention	54.7±10.8	51.9±10.2	51.0±11.7	0.272[a]	0.853[a]
STAI-state before dental treatment	46.9±10.4	48.4±10.0	54.0±11.6	0.008[b]	<0.001[b]

VAS patients rating of their dental anxiety on a visual analogue scale. Values are presented as median (lower and upper quartiles)

STAI-trait trait anxiety score, *STAI-state* state anxiety score (mean ± standard deviation)

[a] One-way ANOVA model with Dunnett-corrected post hoc comparisons

[b] ANCOVA model (baseline adjusted) with Dunnett-corrected post hoc comparisons

Table 3 Patients' evaluation of acupuncture

Sample size (*n*)	Auricular Acupuncture 61	Sham group 60	p^b
Patients' belief as to group *n* (%)			0.742[c]
Proper treatment	34 (55.7%)	30 (50.0%)	
Placebo	5 (8.2%)	7 (11.7%)	
Don't know	22 (36.1%)	23 (38.3%)	
Belief of acupuncture efficacy[a] *n* (%)			0.363[c]
Anxiety reduction	30 (49.2%)	26 (43.3%)	
No anxiety reduction	5 (8.2%)	10 (16.7%)	
Don't know	26 (42.6%)	24 (40.0%)	
Comfort of acupuncture *n* (%)			0.973
Good	53 (86.9%)	53 (83.3%)	
Moderate	8 (13.1%)	7 (16.7%)	
Bad	0 (0.0%)	0 (0.0%)	
Ready to repeat acupuncture *n* (%)			0.082
Yes	58 (95.1%)	60 (100.0%)	
No	3 (4.9%)	0 (0.0%)	
Side effects *n* (%)			0.693
Side effects	14 (23.0%)	12 (20.0%)	
No side effects	47 (77.0%)	48 (80.0%)	

[a]Patient's belief whether acupuncture actually did reduce dental anxiety

[b]Chi-square test

[c]In a sensitivity analysis the category "don't know" has also been treated as missing or merged with the category "placebo". This again resulted in non-significant group differences.

A recent small study (n=30) [11] described the anxiolytic effects of auricular acupuncture at the relaxation-, the tranquillizer- and the master cerebral points as equally effective as intranasal midazolam. However this result may be due to a too small sample size and low power of that study. Placebo needles at auricular acupoints with no known effect on anxiety were used as control. The reduction in state anxiety did not differ significantly to the true acupuncture.

Auricular acupuncture was also effective for reducing preoperative anxiety in elective ambulatory surgery patients [10]. Furthermore, with auricular acupuncture at the same acupoints, parental preoperative anxiety was also reduced significantly [12]. Even the children of mothers that had received true auricular acupuncture were less anxious and more compliant during induction of anaesthesia.

In our study, the effect of true auricular acupuncture at anxiety-reducing acupoints compared to sham acupuncture, while statistically significant, might not seem impressive. It could thus be argued that our data show that acupuncture reduces anxiety independent of the selected points. One possible explanation is the busy, rather loud environment in the waiting room of the outpatients' dental clinic offers little room for adequate relaxation, which probably limited the effects of acupuncture in our study population. More important is the problem of defining an adequate placebo intervention in acupuncture trials. A large placebo component of auricular acupuncture effect is highlighted by the fact that in our study acupuncture at sham points with no demonstrated effect on anxiety was also better than no intervention. It is generally accepted that every needling, i.e. skin penetration, regardless at which point, produces physiologic responses. Even non-penetrating, placebo needles do not constitute an inert intervention. Sham acupuncture is associated with particularly potent nonspecific effects, which reportedly produce a larger placebo effect than would be expected of pharmacological placebos [18].

While blinding in our study was adequate with regard to the acupuncture groups, patients in the non-intervention control group were not blinded. A certain bias therefore could have confounded our results. Although applying the acupuncture needles did only take a few minutes, the additional attention the patients got when the acupuncture was performed, or the distraction from the upcoming dental treatment created, might have further helped to reduce anxiety.

A possible limitation of our study is the patient selection. Only 14% of all screened patients could actually be enrolled in the study. Most patients had to be excluded because they did not fulfil our arbitrary definition of "dental anxiety" i.e. a score of ≥3 on an anxiety VAS ranging from 0–10 (maximum). Evidence suggests that non-pharmacological anxiety-reducing techniques are more effective in highly anxious subjects [7]. Therefore, our study was designed to include only patients with a certain degree of anxiety. Consequently, "baseline" state anxiety values in our study are higher than in most other studies [7, 10, 11]. We found no effect of baseline anxiety on the anxiety-reducing effects of auricular acupuncture.

Up to now there are no data on the potential mechanism by which auricular acupuncture could reduce anxiety. Advantages of auricular acupuncture are that it requires minimal equipment and is quick and easy to perform. Contrary to body acupuncture, auricular acupuncture is not based on the complex theoretic background of traditional Chinese medicine [19] and is therefore easier to learn. Compared to pharmacological anxiolytic interventions, auricular acupuncture has a rapid onset, short duration of action [11] and minimal side effects. In our study 98% of the patients, regardless of the perceived benefit, would want to use auricular acupuncture on future occasions. We did not investigate the patients' willingness to pay for the acupuncture intervention; however, it has been found that patients' willingness to pay for any anxiety-reducing intervention is low and only increases after having experienced beneficial effects [20].

Cost effectiveness has not been investigated in our study. The cost of the acupuncture needles used is approximately 0.25€ per patient. The acupuncture procedure itself, allowing generous time for information about possible risks and side effects of the acupuncture, can be performed in less than 5 min. Auricular acupuncture therefore could be an option for regular patients seeking dental treatment, who experience an uncomfortable degree of anxiety and request an acute intervention for their anxiety. Auricular acupuncture can certainly be no substitute for a more extensive behavioural intervention with lasting effects on coping strategies for anxiety required by patients attending specialised dental fear clinics.

In conclusion, auricular acupuncture at the relaxation-, tranquillizer- and master cerebral points effectively reduces state anxiety before dental treatment in anxious patients attending dental treatment. Even acupuncture at sham points with no demonstrated effect on anxiety is better than no intervention.

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Conflict of interest The authors declare that they have no conflict of interest.

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