

Original sound compositions reduce anxiety in emergency department patients: a randomised controlled trial

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Emergency departments (EDs) can provoke anxiety among patients.¹ There have been few trials of interventions that might reduce this anxiety. Although live performance has positive effects on patients and staff,² incorporating live music in busy EDs is unrealistic.

Several auditory interventions can modify patients' anxiety in hospital. The positive effect of music on anxiety has been well demonstrated. A review of 42 randomised controlled trials found that about half of them showed that music was effective in reducing perioperative pain and anxiety.³ Reduced preoperative anxiety has also been associated with audio featuring binaural beats,⁴ which are apparent sounds perceived independent of physical stimuli.⁵ Binaural beats are perceived when two sounds of similar but slightly different frequency are presented separately to each ear and produce two apparent new frequencies — the sum and the difference of the original two sounds.⁵ This is an auditory brainstem response to the difference in amplitude of the original two tones. Binaural beat may induce a meditation-like state and also reduce chronic anxiety.⁶

Only a few studies have explored the impact of music on anxiety in the ED setting. Music therapy has been shown to alleviate anxiety among adults accompanying children to the ED,⁷ but not among adults undergoing laceration repair.⁸ One pilot study showed reduced pain⁹ among ED patients, and others showed some benefit on self-rated stress and noise disturbance.^{10,11} No study has investigated possible anxiolytic effects of sound interventions or binaural beat among adult ED patients.

We conducted a randomised controlled trial to investigate whether emergency patients' self-rated levels of anxiety were affected by exposure to purpose-designed musical compositions and non-musical environmen-

Abstract

Objective: To determine whether emergency department (ED) patients' self-rated levels of anxiety are affected by exposure to purpose-designed music or sound compositions with and without the audio frequencies of embedded binaural beat.

Design, setting and participants: Randomised controlled trial in an ED between 1 February 2010 and 14 April 2010 among a convenience sample of adult patients who were rated as category 3 on the Australasian Triage Scale.

Interventions: All interventions involved listening to soundtracks of 20 minutes' duration that were purpose-designed by composers and sound-recording artists. Participants were allocated at random to one of five groups: headphones and iPod only, no soundtrack (control group); reconstructed ambient noise simulating an ED but free of clear verbalisations; electroacoustic musical composition; composed non-musical soundtracks derived from audio field recordings obtained from natural and constructed settings; sound composition of audio field recordings with embedded binaural beat. All soundtracks were presented on an iPod through headphones. Patients and researchers were blinded to allocation until interventions were administered. State-trait anxiety was self-assessed before the intervention and state anxiety was self-assessed again 20 minutes after the provision of the soundtrack.

Main outcome measure: Spielberger State-Trait Anxiety Inventory.

Results: Of 291 patients assessed for eligibility, 170 patients completed the pre-intervention anxiety self-assessment and 169 completed the post-intervention assessment. Significant decreases (all $P < 0.001$) in anxiety level were observed among patients exposed to the electroacoustic musical composition (pre-intervention mean, 39; post-intervention mean, 34), audio field recordings (42; 35) or audio field recordings with embedded binaural beats (43; 37) when compared with those allocated to receive simulated ED ambient noise (40; 41) or headphones only (44; 44).

Conclusion: In moderately anxious ED patients, state anxiety was reduced by 10%–15% following exposure to purpose-designed sound interventions.

Trial registration: Australian New Zealand Clinical Trials Registry ACTRN 12608000444381.

tal sound recordings with and without embedded binaural beat.

Methods

Tool development

Sound compositions were developed in studios at RMIT University. Ambient noise recordings, composition testing, and the clinical study were conducted in the ED at St Vincent's Hospital, Melbourne (SVHM). SVHM is an adult tertiary referral hospital on the fringe of the central business district of Melbourne, with about 40 000 ED attendances annually.

Using the results of a preliminary study to determine patients' listening preferences (Box 1), four 20-minute sound recordings were created:

- electroacoustic musical composition;

- sound compositions from audio field recordings of natural and constructed settings;
- sound compositions from audio field recordings obtained from natural settings with embedded binaural beat;
- reconstructed ambient noise simulating the ED but free of clear verbalisations.

Use of specific sounds, instruments, tempo, dynamics and timbre for both the electroacoustic composition and the audio field recordings were based on feedback from patients in the preliminary study, the composer's aesthetic judgements and feedback from fellow investigators. The electroacoustic musical composition used software-based electronic processing to transform a variety of sounds produced by melodic and percussion instruments. Audio field recordings included sounds of bellbirds, cocka-

1 Preliminary study

In a preliminary study,¹² ten 60-second electroacoustic soundtracks, and ten 60-second composed environmental soundtracks were created. For electroacoustic soundtracks, decisions regarding the inclusion of sounds, instruments, tempo, dynamics and timbre were based on the composer's aesthetic judgements and feedback from fellow researchers — for example, what they liked and what they found relaxing. Environmental soundtracks were created, arranged and mixed to reflect the acoustic and spatial complexities of regional and urban environments, including natural bush habitats, farms, city streets, the beach and factories.

One hundred emergency department patients were recruited using convenience sampling. Patients aged 18 years or over were eligible if they presented between 9 am and 6 pm on weekdays during the data collection period.

The brief tracks were played to patients on iPods through headphones. The play order was random. Participants were administered a purpose-designed survey about their usual listening preferences and their responses to the sound compositions (by rating the extent to which each track evoked each of ten emotions). Before the patient listened to the tracks, the researcher demonstrated use of the iPod, and participants were encouraged to pause between each track to answer the survey. ◆

toos, bullfrogs, green frogs, a glacial stream, footsteps on snow, trees blowing in the wind, water in a lake, sailing-boat masts, crickets, and rain on a tin roof.

The binaural beat was embedded into the background of the audio field recordings. We constructed binaural beat audio using two digital sine-tone generators at 200 Hz and 210 Hz. To alter the depth of the meditative state, the interval between generators was reduced by 2 Hz during the course of the composition until a 4 Hz frequency differential was achieved, gradually increasing to 10 Hz over the final movement of the composition.

To construct the ambient soundtrack, the ED was analysed for key sounds to determine the range of sounds occurring within daily operation. Closed-field condenser microphones captured specific noises such as air conditioning, fluorescent lights, telephones, computers, specialist medical equipment, etc. This type of microphone did not record anything in close proximity (such as human voices). Additional sounds generated by staff, such as footsteps, were later recreated in a studio.

Participants

Patients were eligible to participate if they were ≥ 18 years of age and were classified on arrival in the ED as category 3 according to the Australasian Triage Scale (ATS)¹³ — that is, patients with an acuity level indicating they required medical assessment within 30 minutes. Participation was restricted to these patients to maximise homogeneity in the sample. Patients were excluded if they had a hearing impairment, did not speak English or were

unable to give informed consent (eg, cognitively impaired or highly care-dependent patients). No attempt was made to specifically recruit patients who were anxious.

Main outcome measure

Patients' anxiety levels were self-reported as measured by the Spielberger State-Trait Anxiety Inventory (STAI),¹⁴ a 40-item self-report measure containing 20 items measuring state anxiety (anxiety experienced at that moment) and 20 measuring trait anxiety (usual level of anxiety). Scores for state and trait components each range from 20 to 80, with a higher score corresponding to higher anxiety. This scale is the most widely validated anxiety scale.^{14,15}

Procedure

Between 1 February 2010 and 14 April 2010, one of us (DMB) and another researcher recruited participants between 9 am and 6 pm on weekdays. Category 3 patients were identified using the ED administration system. After each patient was allocated to a cubicle, had an initial medical assessment and gave consent he or she was given the STAI to self-administer (state and trait components). We used a computer-generated block-randomisation sequence (administered by a non-recruiting researcher). Participants and researchers were blinded to allocation until interventions were administered. Allocations were concealed using opaque paper, folded and stapled to data collection instruments. Removal of the paper revealed the allocation. Participants were allocated at random to one of five groups:

- no soundtrack intervention, headphones only (control group);
- reconstructed ambient noise simulating ED noise but free of clear verbalisations;
- electroacoustic musical composition;
- composed non-musical audio field recordings;
- combination of audio field recordings with embedded binaural beat.

Participants were asked to listen to the soundtrack through headphones attached to an iPod. Soundtracks were played through semi-open professional headphones (AKG, k121 studio; Harman International, Stamford, Conn, USA). The headphones were covered with new disposable sanitary covers (SS-3-100; Scan Sound Inc, Deerfield Beach, Fla, USA) for each listener. Headphones and iPods were wiped with alcohol. Patients in the control group wore headphones attached to an iPod but did not hear a soundtrack. The researcher recorded the duration of listening or headphone wearing. Medical and nursing assessment and management took precedence over any study activity. The listening was sometimes interrupted for treatment. Staff were advised to carry on as normal, interrupting patients if they normally would do so. Regardless of the actual listening duration, the STAI (state component) was readministered 20 minutes after the provision of the soundtracks, thereby keeping exposure time consistent. Neither participants nor researchers were blinded to allocation at the post-intervention assessment of outcomes.

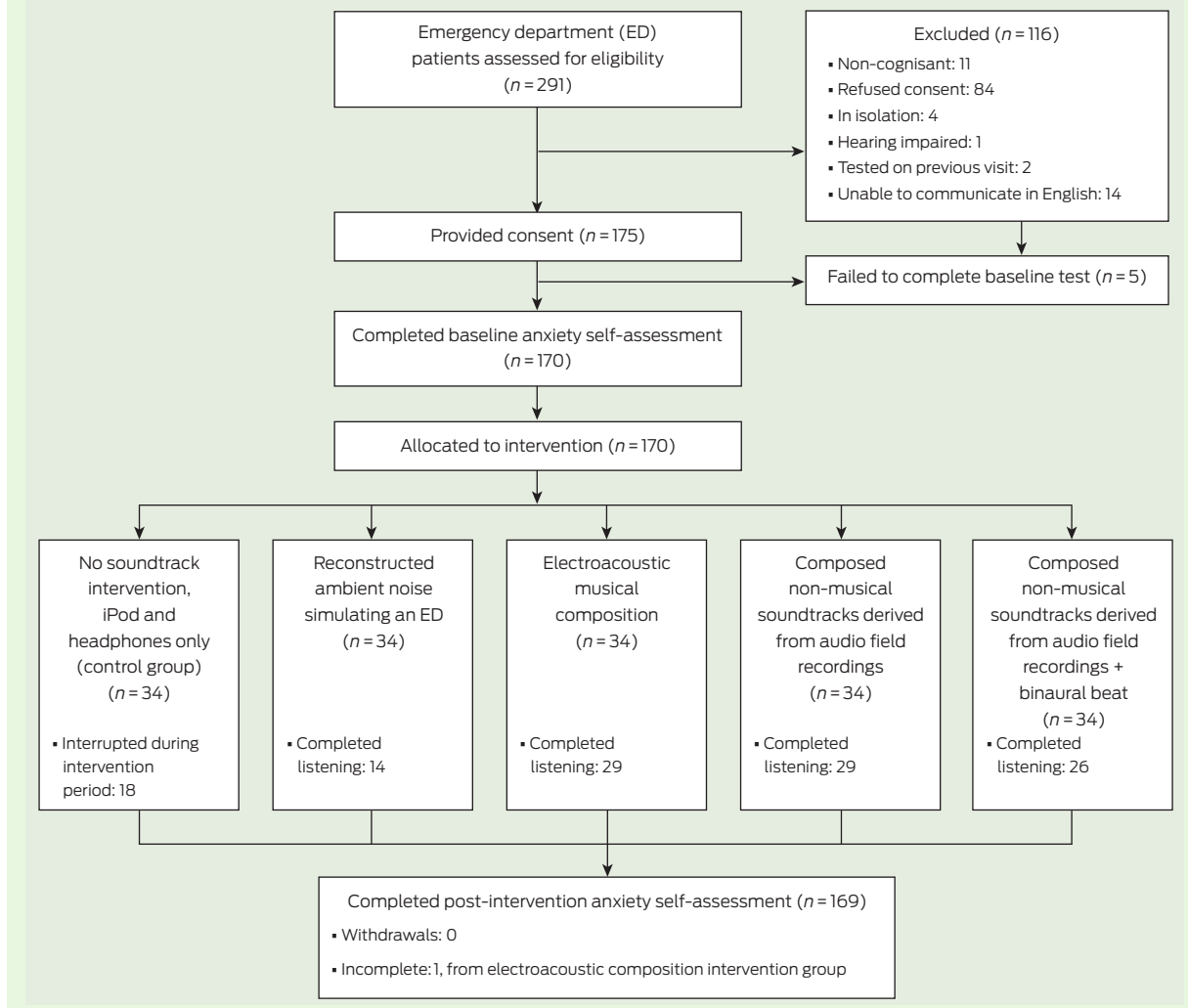
We recorded participants' receipt of analgesia before or during the study. Basic patient demographics (age, sex, country of birth, presenting complaint) were recorded to determine whether the sample was representative of the broader population of category 3 patients.

This study was approved by the Human Research Ethics Committee at SVHM.

Data analysis

We analysed data using SPSS version 15.0 (SPSS Inc, Chicago, Ill, USA) using an intention-to-treat approach. We used descriptive statistics including frequencies, percentages, measures of central tendency and cross

2 Recruitment, randomisation and retention of patients throughout the trial



tabulations. Demographic data were analysed using the Fisher exact test for 2x2 cross-tabulations and the independent samples *t*-test for interval data. Preliminary analyses indicated there was no significant departure from normality. Therefore, data were analysed using repeated measures analysis of variance (ANOVA) to determine any change in anxiety from baseline within each group. Univariate ANOVA was used to compare levels of anxiety for each group after accounting for baseline differences (using percentage difference from baseline). No attempt was made to adjust for multiple comparisons. Alpha was set at 0.05.

Sample size calculation

Our sample size estimate was based on previous studies investigating binaural beat and anxiety using the STAI.^{4,16} With power set at 90%, to

detect a difference between means with a two-sided test at a 5% significance level, a sample size of 34 in each group was required (assuming a difference in means of 13% and a common standard deviation of 10%).

Results

Participation

Between 1 February 2010 and 14 April 2010, 291 category 3 patients in the SVHM ED were considered for participation in our study. Of those approached, 84 refused consent, 32 were considered ineligible and 175 consented (Box 2). Five of those who consented failed to complete baseline STAI and were withdrawn. The remaining 170 participants were equally allocated to one of the five interventions (34 per group). There were no violations of allocation proto-

col; however, one patient did not complete the post-intervention STAI. Those refusing consent did not differ significantly from the sample in terms

3 Comparison of participants with all patients attending the ED during the study period and classified as category 3 on the ATS

Variable	Sample (n = 170)	Eligible* (n = 3117)
Median age in years (range)	52 (35–69)	47 (30–70)
Men (no. [%])	93 (54.7%)	1678 (53.8%)
Country of birth Australia (no. [%])	110 (69%)	1818 (58.3%)
Modal presenting complaint	Abdominal pain	Abdominal pain

ATS = Australasian triage scale. ED = emergency department. *2.9% required an interpreter.

4 Presenting complaints of participants (n = 170)

Presenting complaint	No. (%)
Pain — abdominal	28 (16.5%)
Pain — chest	15 (8.8%)
Shortness of breath	10 (5.9%)
Trauma	10 (5.9%)
Collapse	7 (4.1%)
Headache	7 (4.1%)
Pain — limb	7 (4.1%)
Pain — back	7 (4.1%)
Palpitations	6 (3.5%)
Pain — loin	5 (2.9%)
Seizure	4 (2.4%)
Weakness	4 (2.4%)
Pain other	4 (2.4%)
Other*	56 (32.9%)

* Represents 35 other presenting complaints where $n \leq 3$.

of age, sex, Australian country of birth, or modal presenting complaint.

Demographics and clinical data

The demographic characteristics of the final sample were comparable to all other patients who would have been eligible to participate based on ATS code (Box 3). Sixty-nine percent (118) of participants required pain relief during their ED stay. No significant differences were found between any groups in terms of age, sex or pain relief required. Participants had a broad range of presenting complaints (Box 4).

State anxiety

There was a significant interaction effect between time and intervention ($F_{(4,164)} = 6.28$; $P < 0.001$), indicating a change over time in some, but not all, of the intervention groups. Pairwise comparison based on mean total state anxiety levels (Box 5) revealed a significant decrease in anxiety (post-intervention mean compared with pre-intervention mean) among participants listening to the electroacoustic composition ($P = 0.001$), composed audio field recordings ($P < 0.001$), and composed audio field recordings + binaural beat ($P < 0.001$). When compared with each other, these same three groups showed no significant difference in post-intervention mean level of anxiety.

After accounting for baseline anxiety levels, significant differences were observed between groups, with those allocated to receive the electroacoustic

5 Mean total state anxiety scores before allocation and after the intervention, and number of participants requiring pain relief*

Intervention	Total state anxiety, mean (SEM)		Absolute difference from control [†] (95% CI)	Participants requiring pain relief (no. [%])
	Pre intervention	Post intervention		
Control (headphones only)	43.7 (14.2)	43.7 (16.4)		27 (79.4%)
Simulated emergency department ambient noise	40.3 (11.6)	40.8 (11.5)	2.9 (-2.28 to 8.57)	19 (55.9%)
Electroacoustic musical composition	38.9 (11.5)	33.7 (7.8)	10 (1.9 to 12.9)	21 (61.8%)
Audio field recordings	42.2 (13.9)	34.6 (9.6)	9.1 (-0.1 to 10.8)	27 (79.4%)
Audio field recordings + binaural beat	42.6 (10.9)	36.9 (11.1)	6.8 (-2.3 to 8.6)	27 (79.4%)

State anxiety score ranges: low or no anxiety, 20–37; moderate, 38–44; high, 45–80.¹⁷ * $n = 34$ for each group except electroacoustic composition ($n = 33$). † Based on post-intervention mean values.

composition, composed audio field recordings, or composed audio field recordings + binaural beat reporting significantly lower levels of anxiety after the intervention compared with those in the control group and the group listening to simulated ED sound (Box 6). These effects were unchanged after controlling for provision of pain relief.

Trait anxiety

Mean trait anxiety did not differ significantly between groups and ranged from low to moderate (Box 7).

Discussion

Our study is the first randomised controlled trial to show that sound compositions decrease anxiety in adult ED patients. We showed that the baseline level of anxiety in patients in the mid range of urgency in an Australian ED was moderate at baseline. Mean normal state anxiety scores have previously been reported as 35.7 for men and 35.2 for women.¹⁹ In our study, they ranged between 38.9 and 43.7 for the five groups, indicating moderate anxiety. Mean anxiety was significantly reduced among patients who listened to electroacoustic music, audio field recordings or audio field recordings with embedded binaural beat, to between 33.7 and 36.9 — a level of no or low anxiety. The statistically significant effect size of about 10%–15% was felt to be clinically significant as well. We did not investigate whether the effect persisted beyond the post-intervention assessment or was transient. The

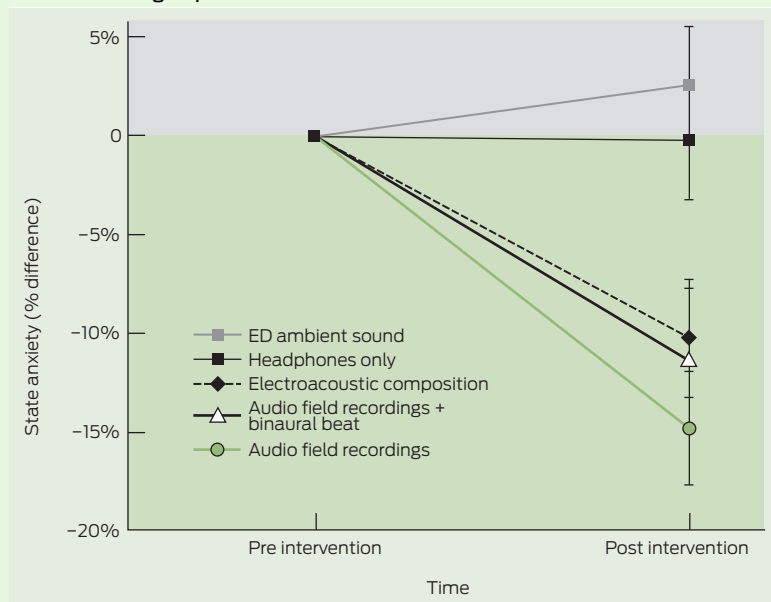
control group and the participants who listened to simulated ED sounds remained moderately anxious after the intervention.

A previous study using music during laceration repair in a Pittsburgh ED showed that listening was associated with reduced pain but not reduced anxiety.⁸ In that study, participants chose the artist and style of music. In contrast, our study used highly original compositions developed by experienced musicians and composers, and we did not record particular anxiety-provoking activities experienced by our patients, who received usual ED care and procedures for category 3 patients. Such patients are typically quite unwell and undergo many investigations and procedures. Our results indicate that these patients gained considerable relief from anxiety by listening to sound compositions and raise the possibility that such original compositions are more effective in alleviating anxiety than simply listening to well known music. This should be explored in future research.

We found that binaural beat provided no additional anxiety reduction over audio field recordings alone, in contrast with the 26% reduction in preoperative anxiety observed elsewhere.⁴ This raises the possibility that binaural beat is less effective in the busy ED environment than in the quiet preoperative area.

As we had no previous experience of applying binaural beat audio to soundtracks, it is possible that this intervention was not delivered appro-

6 Percentage difference in mean (SEM) state anxiety compared with baseline, by intervention group



ED = emergency department. Vertical bars represent SEM. $P < 0.05$ significant. Headphones only v composition, $P = 0.024$; headphones only v audio field recordings + binaural beat, $P = 0.012$; headphones only v audio field recordings, $P = 0.001$. ED sound v composition, $P = 0.004$; ED sound v audio field recordings + binaural beat, $P = 0.002$; ED sound v audio field recordings, $P < 0.001$.

privately, although we followed standard advice in programming. As we only tested these interventions on ATS category 3 patients who had received medical assessment in the ED, we cannot generalise our findings to all ED patients, including those with illness or injury of a different severity, or those who presented outside the hours of recruitment. It is possible that patients requiring more urgent treatment, who are presumably more anxious, might not derive similar benefits.

A potential limitation of this study is the use of the STAI. At a total length of 40 items (20 state, 20 trait), the

length of the scale may limit its clinical utility in the ED. Although a 6-item short version of the STAI exists,²⁰ the validity in a broad range of clinical samples was unknown at the time we began the study. Nonetheless, only five patients (2.9%) failed to complete the pre-intervention STAI.

The use of randomised controlled trial methodology precluded allowing patients to choose preferred or familiar sounds. Although sound preference and familiarity are important factors in the efficacy of sounds to relieve anxiety,⁴ this has not always been observed.⁸

Our findings have important implications for emergency medicine. Original sound compositions delivered in EDs can significantly reduce the anxiety of patients waiting for further management in this busy environment.

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