

Relaxing music as pre-medication before surgery: a randomised controlled trial

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Introduction: Patients who await surgery often suffer from fear and anxiety, which can be prevented by anxiolytic drugs. Relaxing music may be an alternative treatment with fewer adverse effects. This randomised clinical trial compared pre-operative midazolam with relaxing music.

Method: Three hundred and seventy-two patients scheduled for elective surgery were randomised to receive pre-operative prevention of anxiety by 0.05–0.1 mg/kg of midazolam orally or by relaxing music. The main outcome measure was the State Trait Anxiety Inventory (STAI X-1), which was completed by the patients just before and after the intervention.

Results: Of the 177 patients who completed the music protocol, the mean and (standard deviation) STAI-state anxiety scores were 34 (8) before and 30 (7) after the intervention. The corresponding scores for the 150 patients

in the midazolam group were 36 (8) before and 34 (7) after the intervention. The decline in the STAI-state anxiety score was significantly greater in the music group compared with the midazolam group ($P < 0.001$, 95% confidence interval range -3.8 to -1.8).

Conclusion: Relaxing music decreases the level of anxiety in a pre-operative setting to a greater extent than orally administered midazolam. Higher effectiveness and absence of apparent adverse effects makes pre-operative relaxing music a useful alternative to midazolam for pre-medication.

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PATIENTS who await surgery usually suffer from varying degrees of fear and anxiety¹, which the anaesthetic staff attempt to reduce by providing anxiolytic drugs. Anxiety has been described as a subjective feeling of tension, apprehension, nervousness and worry, and by activation or arousal of the autonomic nervous system.²

Benzodiazepines are effective, but many patients exhibit untoward effects in the form of prolonged amnesia and even agitation and hyperactivity.^{3,4} Amnesia can be troublesome because the patient may not remember the orally given information before discharge from the hospital.⁵ Especially in elective day-surgery and short-stay surgery, it is important that patients do not experience the side-effects associated with the administration

of these drugs. In spite of this, in many hospitals – including ours – oral midazolam has been the standard pre-medication.

Music therapy is used in various fields in medicine.^{6–8} Relaxing music has been studied in the pre-operative, intra-operative and post-operative settings^{9–11} but only one study compared music with a benzodiazepine (diazepam) in the pre-operative state.¹² The authors of that study concluded that music was as effective as diazepam. However, to our knowledge, no study has compared music and midazolam.

Music is most relaxing when it mimics the heart rate at rest, i.e. has a pace of 60–80/min and without a high dynamic amplitude.¹³ Furthermore, music containing lyrics should probably be avoided inasmuch as such music may be distracting and activating.¹⁴ Consequently, in the present study, in a randomised-controlled setting we investigated whether such relaxing music has a greater anxiolytic effect than a standard dose of midazolam before surgery.

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Methods

Between October 2004 and May 2007, patients older than 18 years of age who were scheduled for an elective day or short-stay surgery at Södertälje Hospital were eligible to participate in the study. Patients with hearing difficulties or confusion of language i.e. difficulties in speaking and understanding Swedish and patients with malignant diseases were excluded. The music therapist informed and recruited the patients on the day of surgery and all patients gave informed consent orally.

The study was approved by the Ethics Committee of the Karolinska Institutet, Stockholm, Sweden (DNr 453/03).

The music therapist randomised the patients through sealed envelopes immediately before the intervention. After the informed consent she drew the first envelope in a row of previously randomly mixed envelopes consisting of an equal number of both allocations. About 1 hour before the scheduled start of the operation, the patient received the intervention as allocated. Normally, the first scheduled case in the morning could not be included due to shortage of time. In the midazolam group, the patients received orally our standard pre-medication, midazolam solution 1 mg/ml. Those who were younger than 60 years and ASA 1–2 were given 0.1 mg/kg body weight while those 60 years and older or ASA 3–4 were given 0.05 mg/kg body weight. In the music group the patients were invited to choose one of six different music genres. The music was compiled on CDs by a professional music therapist (Table 1). Each CD consisted of 80 min of music. All music was without lyrics and had a pace of 60–80 beats/min (b.p.m.). The music was selected to lack a marked variation in dynamic sound, because variation in amplitude may cause arousal during listening. The patients listened to the music on portable CD players with earphones. The patients adjusted the volume of the music according to their preferences. Both groups were lying down in a hospital bed in the pre-operative area during the intervention. Three to five minutes before the patients were brought to the operating room, the study interventions were completed. The music therapist gave the State Trait Anxiety Inventory (STAI X-1) form for all patients in both groups to complete and recorded the blood pressure and heart rate (Riester fully automatic digital blood pressure monitor, Riester, Germany) before and after the intervention (the treatment with music or midazolam).

Table 1

The music compilations consisted of 10–22 tracks/CD.

CD1	
Classical music	
Cavallerina Rusticana	Mascagni
Air	Bach
Adagio	Albinoni
CD2	
Soft pop/film music	
Feelings	Romantic guitars
The Mission	Film music
Mot skärgården	Stefan Nilsson
CD3	
Soft jazz	
Seven Bridges	Tim Timmermanns
Miracles	Kenny G
The Winters Tale	Nils Landgren
CD4	
Music with sounds from nature	
From CD 'Deep Blue' and 'Sky's beyond'	
Earthrise	
The Garden	
So here we are	
CD 5	
Piano, Harp, Flute, Panflute	
Carpe Diem	Carpe Diem
Dreaming	Ad Dios
The Dove	Yasuragi
CD6	
Mixed	
Smile	Palle Mikkelborg
Lake District	Björn J-son Lindh
Pie Jesu	Andrew Lloyd-Webber

Table 1 shows examples of these tracks.

The STAI-state anxiety scale (state) consists of 20 questions that determine how the respondents 'feel right now'. The STAI has been evaluated in previous studies and is often used to evaluate anxiety in a clinical setting.^{15–17} Scores on the state anxiety scale increase in response to physical danger and psychological stress and decrease as a result of relaxation training. The scale has also been used extensively to assess the level of anxiety induced by stressful experimental procedures and by unavoidable real-life stressors such as imminent surgery, dental treatment, job interviews or important school tests, and is a sensitive indicator of changes in anxiety. The score may vary from a minimum of 20 to a maximum of 80. The normal score in a population matched to the study population is 33.^{2,18}

The patients in both groups were given the same attention and care by the music therapist during the study period.

Statistics

The main outcome measure was the STAI-state score. In a normal population, elderly women

have a score that is four points lower than young women and elderly men have a score that is two points lower than young men.^{2,18} Based on this information, the study group decided that a difference of three points between the groups would be of clinical importance. Assuming 80% power and $\alpha = 0.05$, we calculated that 176 patients in each group would be needed. We also estimated that about 5% would be excluded. Thus, the required sample size was calculated to be 370 patients.

Results were analysed using a two-way analysis of variance (ANOVA) with repeated measures on one factor. The within-subjects variable was Time (pre vs. post) and the between-subjects variable was Group (music vs. midazolam). When the Group \times Time interaction was significant, simple main effects tests were examined, i.e. effects of one factor holding the other factor fixed. Inter- and intra-group differences with 95% confidence intervals (CI) were estimated from the ANOVA model.¹⁹ $P < 0.05$ was considered statistically significant, and data are given as mean [standard deviation (SD)].

The data were analysed using Statistica (v 7.1, StatSoft Inc., Tulsa, OK).

Results

In the study 372 patients were randomised. Thirty-six patients were excluded (Fig. 1). The reasons for exclusion were logistic in the majority of cases, mainly due to a too early call to the operating room, which had the effect that the time between the intervention and the evaluation was too short. Hence, 177 patients in the music group and 159 in the midazolam group went through the study protocol; however, nine patients in the midazolam group were too sedated to be able to complete the second STAI X-1. There was no difference between these nine patients and the other 150 regarding the baseline characteristics.

The groups were comparable regarding baseline characteristics with no statistically significant differences. (Table 2). Minor procedures were e.g. inguinal hernia repair, arthroscopy, varicose vein, scrotal or vaginal surgery. Medium procedures were e.g. laparoscopy or ventral hernia repair while major procedures were e.g. laparotomy or hip replacement. All patients were operated on for benign diseases. The majority of the patients underwent their operation under general anaesthe-

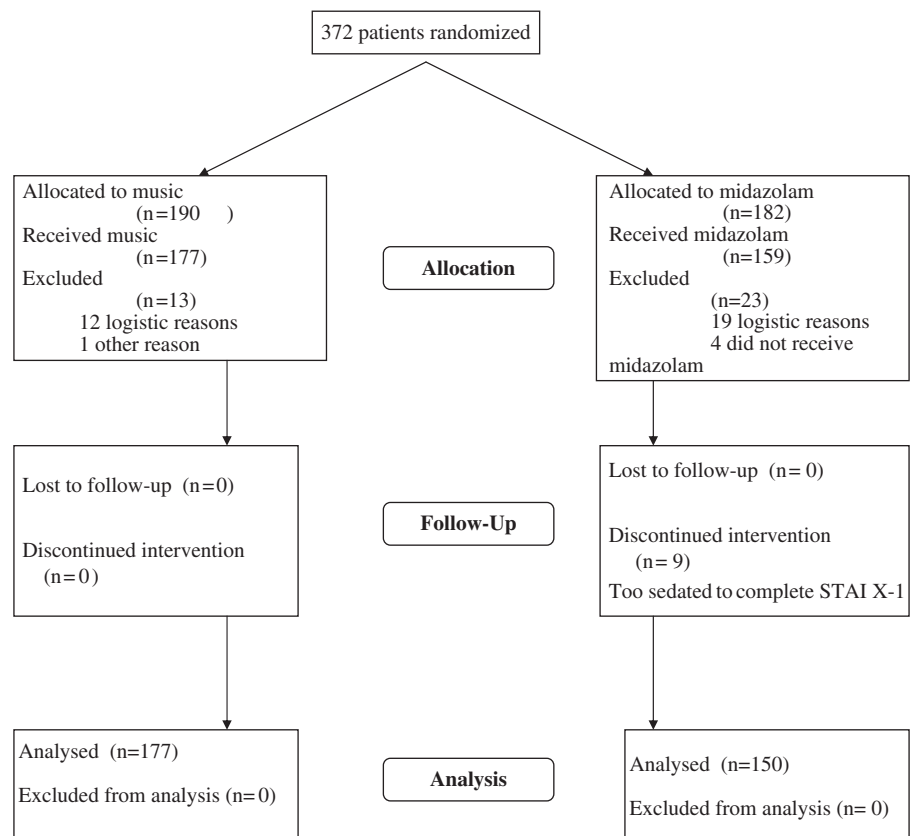


Fig. 1. Participant flow.

sia in the day-case setting and most had previous experience of surgery (Table 2).

The duration of the intervention was 42 (17) min in the music group and 51 (22) in the midazolam group before the second evaluation ($P = 0.46$).

In the music group the STAI-state anxiety score was 34 (8) before and 30 (7) after the intervention ($P < 0.001$; 95% CI range -5.2 to -3.8). The corresponding figures in the midazolam group were 36 (8) before and 34 (7) after the intervention ($P < 0.001$; 95% CI range -2.4 to -1.0). The difference between the groups in the baseline STAI-state anxiety score was not significant ($P = 0.06$;

95% CI range -3.5 to 0.06). The decline in the STAI-state anxiety score was significantly greater in the music group compared with the midazolam group ($P < 0.001$; 95% CI range -3.8 to -1.8).

Heart rate decreased more in the music group during the intervention than in the midazolam group ($P = 0.018$; 95% CI -3.4 to -0.3). (Table 3).

Systolic blood pressure ($P = 0.005$; 95% CI 1.2 to 6.7) and mean arterial pressure ($P = 0.01$; 95% CI 0.6 to 4.9) decreased significantly more in the midazolam group than in the music group (Table 3). However, there was no significant difference between the two groups in the decrease in diastolic blood pressure (Table 3).

Table 2

Baseline characteristics (SD).		
	Music (177)	Midazolam (159)
Sex		
Male	77	61
Female	100	98
Age mean	49 (14)	51 (13)
Type of surgery		
Minor	124	111
Medium	50	42
Major	3	6
Anaesthesia		
General	134	122
Regional	20	21
Local	23	16
Day surgery		
Yes	116	100
No	61	59
Previous surgery		
Yes	141	131
No	36	28
β -blocker		
Yes	30	28
No	147	131
Blood pressure (mmHg)		
Systolic	136 (18)	138 (22)
Mean	110 (14)	111 (17)
Diastolic	83 (13)	85 (17)
Heart rate (beats/min)	70 (11)	69 (10)
STAI	34 (8)	36 (8)

SD, standard deviation; STAI, State Trait Anxiety Inventory.

Discussion

The present study shows that relaxing music reduced anxiety to a greater extent than midazolam before surgery. To our knowledge, this is the first report showing that a non-pharmacological treatment has a better anxiolytic effect than midazolam.

Music pre-operatively has been compared with control groups receiving no intervention in several studies^{16,20-22} in which music has been superior. One previous study found a similar anxiolytic effect of relaxing music and diazepam before surgery,¹² but the study had a lower power than ours. Several authors have reported the effect of relaxing music pre- and intra-operatively,⁹ intra-operatively,^{10,11,23-26} post-operatively²⁷ both intra- and post-operatively,¹¹ and during endoscopy.^{28,29} However, different from the present study, none of these previous reports randomised the patients between music and a sedative drug.

The decline in the STAI-state anxiety score was comparable to other authors' findings in a peri-operative setting using midazolam¹⁷ or music.³⁰

When using music in order to decrease anxiety, it has been suggested that the best choice is calm

Table 3

Blood pressure and heart rate pre- and post-intervention.							
Mean (SD)	Music (177)		Midazolam (159)		P	95% CI	95% CI
	Pre	Post	Pre	Post			
Heart rate (beats/min)	70 (11)	67 (11)	69 (10)	68 (10)	0.018	-3.4	-0.3
Blood pressure (mmHg)							
Systolic	136 (18)	131 (16)	138 (22)	129 (18)	0.005	1.2	6.7
Mean arterial pressure	110 (14)	106 (13)	111 (17)	105 (14)	0.01	0.6	4.9
Diastolic	83 (13)	81 (12)	85 (17)	81 (14)	0.22	-4.8	-2.2

CI, confidence intervals.

music with 60–80 b.p.m., i.e. the same pace as the heart at rest.¹³ The patient should not be distracted with words, i.e. no music with lyrics should be considered.¹⁴ The patients' preferences of music can also influence the cognitive effect of the music.³¹ In a recent study, the anxiolytic effect of patient-selected music was greater than that of new-age music.⁹

In most studies, however, the definition of what kind of music that was used was either specified as 'calm', 'relaxing' or remains unclear.^{9,11,12,16,20,23,25,26,30,32,33} Most authors have chosen the music by themselves before distributing it to the patients. By involving music expertise in a study, as in the current study, it is conceivable that the possibility to choose the appropriate music for each patient may increase. Previous studies have not involved a music therapist or a musician in the study execution but some authors have consulted musicians.^{16,28}

During the pre-operative period, patients can be distracted and disturbed by several environmental factors. These may be of importance in studies focused on this period if, e.g. not the same care provider takes care of the patient in both groups.^{9,16,33} In our study, we minimised this environmental bias because the same person gave the same care and information in both groups.

Heart rate and blood pressure were reduced in both groups after the intervention. Heart rate decreased significantly in the music group compared with the group given midazolam, but it was the other way around concerning the arterial pressure. The heart rate finding in the current study is in agreement with previous studies on the effect of music during surgery.^{16,23} The haemodynamic effect of midazolam has previously been demonstrated to have a greater influence on the arterial pressure than on the heart rate, which is consistent with our findings.³⁴ The difference in the heart rate and blood pressure between the groups is, however, not necessarily clinically relevant.

The difference in the side-effects of relaxing music and midazolam is obvious. Music had no side-effects in our study but nine patients in the midazolam group were too sedated to complete the STAI form. Also, it does not cause any post-operative hangover.

A limitation of the study is that the music had an effect from the beginning of the intervention while the onset of the orally administered midazolam was not immediate. Hence, the duration of the intervention may have influenced the results. Moreover, it may also be a matter of dosage, but the fact that nine

patients in the midazolam group were too sedated to complete the study protocol indicates that the duration and dose were sufficient.

In summary, relaxing music decreases the level of anxiety in a pre-operative setting to a greater extent than a normally used dose of orally administered midazolam, and it has no side-effects. On the basis of these findings, we suggest that the use of pre-operative relaxing music instead of midazolam as well as the involvement of music expertise in the care of surgical patients should be encouraged.

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