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Listening to music prior to bronchoscopy reduces anxiety – a randomised controlled trial

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ABSTRACT

Background: Listening to music as a means of relieving anxiety before and during endoscopy has been examined in several studies but results so far are contradictory and inconclusive.

Aims: We aimed to determine whether listening to music could reduce anxiety prior to and during bronchoscopy, and whether it is influenced by the patient's preference in music.

Methods: 300 patients undergoing bronchoscopy for suspected lung cancer were randomly assigned to: self-selected music, specially-designed music (MusiCure^{TM}), or control (no sound). Spielberger's State-Trait Anxiety Inventory (STAI) was administered three times: at admission, after 20 min with or without music (preceding bronchoscopy), and shortly before discharge. The primary outcome was STAI state score after 20 min, with or without exposure to music prior to bronchoscopy.

Results: On average, music reduced the STAI score by 2.5 points (95% CI, 1.1 to 4.0; $p < 0.001$) compared with the control group. This reduction was largest in the self-selected music group (3.4; 95% CI, 1.5 to 5.3; $p < 0.001$). In contrast, specially designed music did not significantly reduce STAI score (1.7; 95% CI, −0.3 to 3.6; $p = 0.1$).

Conclusion: Listening to music reduces anxiety in patients undergoing bronchoscopy, provided that the music complies with the patient's preferences.

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KEYWORDS
Bronchoscopy; lung cancer; anxiety; music; self-selected music; MusiCure

Introduction

Bronchoscopy is an important invasive tool in the diagnosis of lung cancer. Fear and anxiety related to bronchoscopy are quite common in patients, much like emotions observed in patients facing other invasive procedures [1–3]. Since anxiety is an unpleasant sensation, which negatively affects patients' tolerance of the procedure, it is important that healthcare staff address and seek to relieve anxiety [2]. With administration of sedatives comes an increased risk of respiratory depression [4–6].

In a previous randomised investigator-blinded study, we examined the effect of specially designed music (MusiCure^{TM}), played for 10 min before bronchoscopy and throughout the procedure. Anxiety was measured by Spielberger's State-Trait Anxiety Inventory (STAI) on arrival, after 10 min with or without music, and at discharge. We found no significant effect of music when adjusting for baseline anxiety and sex [7].

Anxiety and music in relation to bronchoscopy have also been studied in a randomised controlled trial by Colt et al. Patients were exposed to pre-recorded piano improvisations versus no music during bronchoscopy, and STAI was used as primary outcome. It was concluded that there was no significant effect of music on anxiety [8].

A major limitation in both studies is the use of investigator-selected music. While some evidence exists that music influences anxiety, further research is needed to establish the effect of patient-selected music in relation to investigator-selected music [9,10].

The aim of this study was to investigate the anxiety-reducing effect of self-selected and investigator-selected music, played for a period of 20 min prior to bronchoscopy.

Material and methods

Subjects

The study was approved by the Danish Ethics Committee (Protocol no. H-3–2014-065), and patients were consecutively included in the study among

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Take home message: Listening to music prior to bronchoscopy reduces anxiety if it complies with patients' preferences.

patients referred for examination for pulmonary nodules in the period between October 2016 and November 2017. In total, 1162 patients were assessed for eligibility, 671 patients were excluded, due to exclusion criteria, and a further 191 eligible patients refused to participate, leaving 300 patients to be included in the study and randomised to three groups (Figure 1). Baseline characteristics were not significantly different between the three groups (Table 1), and no clinically significant differences were observed between those 266 who were analysed per protocol, and those 34 who were not. There is no difference in conclusions when analysing data as intention-to-treat and per-protocol analysis.

However, there were significant differences in some baseline values between those who were excluded prior to randomisation and the 300 patients included in the study. The excluded patients were older, had lower weight and height and lower levels of lung function. There was, however, no significant difference regarding gender.

Study design

Randomisation was performed by block randomisation in blocks of 15 patients, using Statistical Package for the Social Sciences (SPSS) version 22.0. Patients were assigned to one of three treatment groups:

(1) self-selected genre of music (Table 2)
(2) specially-designed music (MusiCure™)
(3) control (no sound)

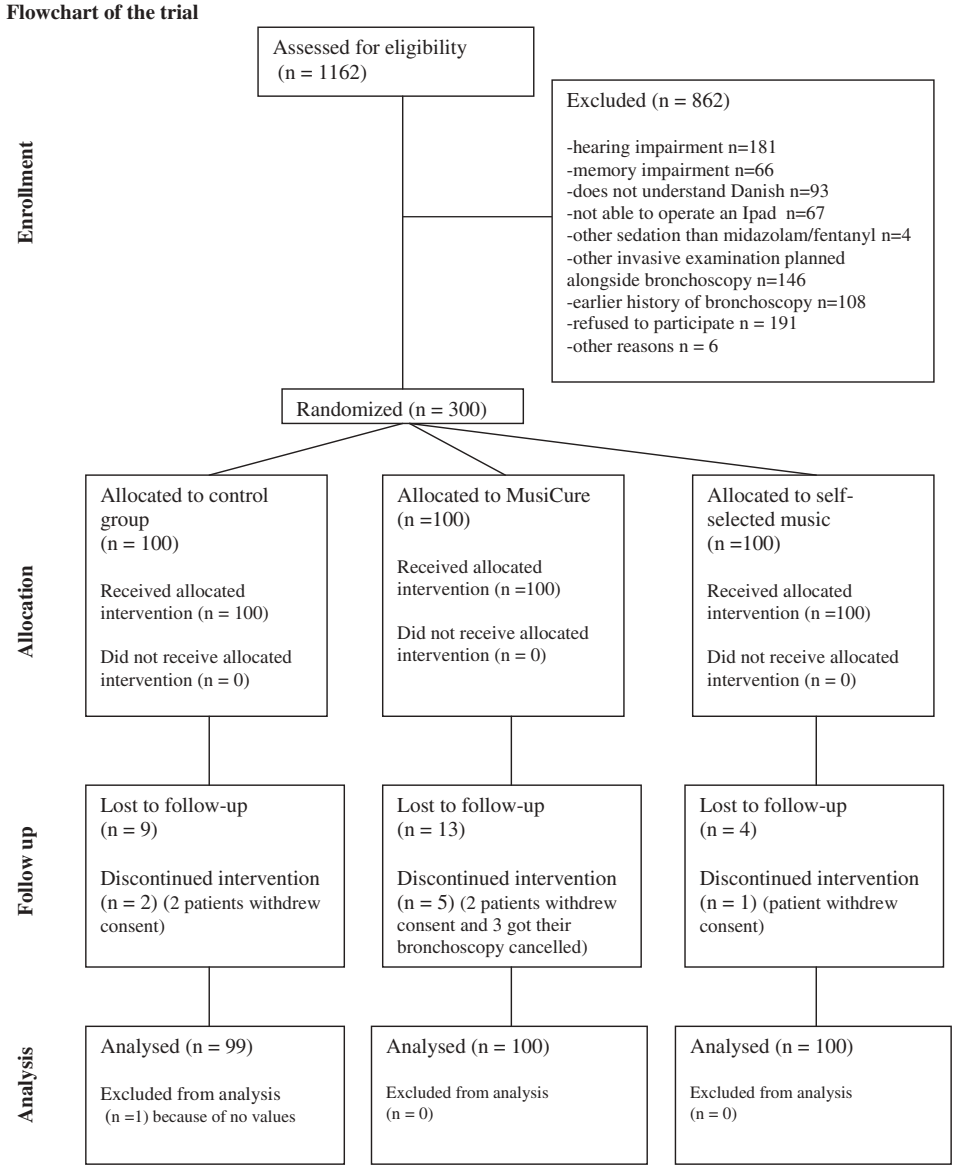

Figure 1. Flowchart of the trial (CONSORT flow diagram, www.consort-statement.org).

Table 1. Baseline characteristics.

	All (n = 300)	Controls (n = 100)	MusiCure (n = 100)	Self-selected (n = 100)	p
Female/male	154/146	48/52	51/49	55/45	*0.6*
Age in years	61 (12)	61 (14)	61(12)	61 (12)	*0.9*
Height in cm	172.4 (9.7)	172.7 (9.1)	171.6 (9.7)	172.9 (10.2)	*0.6*
Weight in kg	76.9 (17.9)	76.3 (17.8)	76.0 (16.4)	78.5 (19.4)	*0.6*
BMI	25.8 (5.1)	25.5 (5.2)	25.8 (5.1)	26.1 (5.0)	*0.7*
FEV1 percent of predicted	79.2 (21.7)	81.4 (20.1)	79.9 (20.4)	76.2 (24.3)	*0.2*
FEV1/FVC ratio	71.1 (11.9)	72.3 (11.7)	71.2 (10.6)	69.9 (13.2)	*0.4*
Systolic blood pressure	140 (19)	137 (18)	141 (19)	143 (19)	*0.07*
Diastolic blood pressure	85 (12)	83 (13)	86 (12)	86 (12)	*0.2*
Mean arterial pressure	104 (13)	101 (13)	105 (13)	105 (13)	*0.09*
Heart rate	78 (14)	77 (14)	79 (15)	80 (15)	*0.3*
Plasma cortisol (nmol/L)	364 (139)	386 (149)	344 (128)	361 (136)	*0.1*
Baseline anxiety					
-State	41.5 (12.6)	40.0 (11.5)	41.4 (14.0)	43.0 (11.9)	*0.2*
-Trait	33.6 (10.0)	34.3 (10.8)	32.8 (9.8)	33.6 (9.4)	*0.6*

Data are expressed as mean (standard deviation, SD).

Table 2. Track list for the categories in the group of self-selected music.

EASY LISTENING:
1. More, by Alex Alstone, Boston Pops Orch. Dir. Arthur Fiedler
2. Some Enchanted Evening, by Rogers & Hammerstein, The Mantovani Orch.
3. Moon River, by Henry Mancini, James Last Orch.
4. El Condor Pasa, trad. performed by Georges Zamfir
5. Love Story, by Francis Lai, played by Richard Clydermann
6. Lounge jazz, Cafe Music BGM Channel, Free library music
7. The Dream of Olwen, by Charles Williams, Russ Conway Orch.
8. La Vie En Rose, by Édith Piaf, played by 101 Strings Orch.
Total: 24:44

EVERGREENS:
1. A Nightingale Sang at Berkeley Square, lyrics by Eric Maschwitz and music by Manning Sherwin, performed by Nat King Cole
2. Moonlight Serenade, by Glenn Miller, played by the Glenn Miller Big Band
3. Raindrops Keep Falling on My Head, by Hal David and Burt Bacharach, performed by B. J. Thomas
4. As Time Goes By, by Herman Hupfeld, piano solo performed by Shirin
5. Singin' in The Rain, by Lennie Hayton, instrumental version by Arthur Freed
6. Summertime, by George Gershwin, instrumental version performed by 101 Strings Orch.
7. Greensleeves, trad, performed by London Festival Orch.
8. Gone With The Wind (Tara's Theme), by Max Steiner, performed by The Royal Philharmonic Orch.
9. Limelight, by Charles Chaplin, André Rieu, violin
Total: 26:24

JAZZ:
1. Softly, as in a Morning Sunrise, by Sigmund Romberg and Oscar Hammerstein II, performed by Modern Jazz Quartet
2.Take Five, by Paul Desmond, performed by The Dave Brubeck Quartet
3. Georgia On My Mind, by Hoagy Carmichael and Stuart Gorrell, performed by Oscar Peterson trio
4. 'Blue in Green' from the album 'Kind Of Blue', Miles Davis Group
5. Solitude, Ben Webster – From the album 'Big Ben Time' recorded by the Ben Webster Quartet
Total: 24:11

CLASSICAL:
1. J.S. Bach: Air – Suite No. 3 in D major, BWV 1068, Performed by The Berlin Philharmonic Orchestra, Conducted by Sir Simon Rattle
2. W.A. Mozart: Klarinetkoncert 2. sats. David Shifrin: Clarinet, Mozart Festival Orchestra Conducted by Gerard Schwarz
3. F. Chopin: Nocturne op. 9 no. 2 Eb dur, Valentina Lisitsa piano
4. A. Vivaldi: 4 Seasons, Winter, Largo, Performed by the Stuttgart Chamber Orchestra conducted by Martin Sieghart, solo violin: Rainer Kussmaul
5. J.S. Bach: Prelude C major BWV 846, from the Well Tempered Clavier Book One, Robert Hill, harpsichord
6. J. Massenet: Meditation from 'Thais', Joshua Bell, violin; Royal Philharmonic Orchestra; Andrew Litton, conductor
Total: 26:25

POP/ROCK:
1. ABBA: I Have A Dream, by Benny Andersson and Bjorn Ulvaeus, from the 1979 album, Voulez-Vous
2. Bruce Springsteen: The River, by Bruce Springsteen, from the album 'The River' 1980
3. Elvis: All Shook Up, by Otis Blackwell, performed by Elvis Presley1957
4. David Bowie: Life On Mars, by David Bowie, from the album 'Hunky Dory' 1971
5. Prince: Diamonds and Pearls, by Prince, from the album 'Diamonds and Pearls' 1991
6. Michael Jackson: You Are Not Alone, by R. Kelly and Michael Jackson, from the album HIStory 1995
Total: 25:29

We employed a randomised design and did not consider baseline anxiety, aiming to include a clinically relevant 'real-life' study population rather than those most likely to benefit from an anxiety-reducing intervention, i.e. patients having a high baseline anxiety score

The sample size was set at 300, using estimates from study by Colt et al. [8]. The standard deviation was set at 10.4 for STAI state, and a difference of five points was interpreted as clinically relevant. The significance level was set at 0.05, power at 0.90, and a 20% dropout was estimated.

The primary endpoint in the study was anxiety score after 20 min with or without music measured with Spielberger's STAI (State, form Y). The inventory consists of 40 self-reported items including 20 assessing state anxiety and 20 assessing trait anxiety. The scores of each item vary from 1 to 4, and each inventory has a minimum score of 20 and a maximum score of 80. Higher scores indicate higher levels of anxiety [11,12].

Methods

Patients subjected to examination of pulmonary nodules were informed about the study when they were scheduled for bronchoscopy at the outpatient clinic at Bispebjerg University Hospital, Copenhagen. Written informed consent was obtained from the patients on admission. Subsequently, blood pressure, heart rate, respiratory rate, and oxygen saturation (SaO_2) were recorded, and a blood sample was taken from the peripheral venous catheter for analysis of serum cortisol. Participants completed an electronic version of the STAI on a tablet device (iPad, Apple, Cupertino, CA, USA). A staff member not involved with the patient at any time opened the sealed envelope containing the randomised treatment: MusiCure™, self-selected music or control (no sound). The same staff member also fitted the in-ear earphones (Flying Tiger, Copenhagen, Denmark) into the patient's ears and adjusted the volume on the mp3 player (SanDisk, Clip Sport, Milpitas, CA, USA). All patients, including the control group, wore earphones during the procedure, to ensure blinding of the staff. The patients were not blinded, and the written information stated that the aim of the study was to investigate if MusiCure™ could reduce anxiety.

After 20 min with or without music the second blood sample was collected from the peripheral venous catheter for analysis of s-cortisol. Blood pressure, heart rate, respiratory rate, and SaO_2 were recorded, and the participants completed the State part of the STAI.

On admission to the operating theatre, blood pressure, heart rate, respiratory rate, and SaO_2 were recorded again. An accelerometer (ActiGraph, GT3X+, Pensacola, FL, USA) was attached to the patient's chest. The device recorded movement with epoch lengths of 10 seconds measured in hertz.

Afterwards, the patients were sedated with midazolam and fentanyl, with an initial standard dose of 5 mg midazolam and 50 microgram fentanyl, titrated until sedation. All patients underwent bronchoscopy lying in the supine position while being exposed, through earphones, to either specially-designed music (MusiCure™), self-selected music or no sound (control), and throughout the bronchoscopy blood pressure, heart rate, respiratory rate and SaO_2 were recorded every 15 min.

On discharge, approximately 60 min after bronchoscopy, patients completed the STAI and a visual analogue scale (VAS) indicating the overall perception of sound before and during bronchoscopy, ranging from very bad to very good. After 28 days, the number of re-examinations was registered (Figure 2).

Plasma cortisol was analysed with competitive electrochemiluminescence immunoassay (ECLIA) (Cobas 8000, e801 module, Roche, Basel, Schweiz).

Analysis

Normally distributed continuous variables were compared using one-way ANOVA. When not normally distributed the Kruskal–Wallis test was used. The χ^2-test was used for categorical variables. Statistical analyses were completed using SPSS version 22.0 (Chicago, IL, USA). Results are reported in intention-to-treat values. Missing values are replaced with last-observation-carried-forward regarding STAI and replaced by 0 regarding the VAS scale.

Results

There were no significant differences between the three groups on the absolute values of STAI state or STAI trait at the time of admission, nor after 20 min with or without music, or at discharge (Table 3).

However, music did have a significant effect in reducing state anxiety when analysing the change (Δ-STAI) after 20 min [F (2, 297) = 8.68, $p < 0.001$, ω = .05]. On average, music reduced the STAI state score by 2.5 points (95% CI, 1.1 to 4.0; $p < 0.001$) compared with the control group. This reduction was greatest in the self-selected music group (3.4; 95% CI, 1.5 to 5.3; $p < 0.001$), whereas specially designed music showed a smaller and nonsignificant reduction in STAI state score (1.7; 95% CI, −0.3 to 3.6; $p = 0.1$).

Tukey-adjusted *post-hoc* comparisons indicated that the change in STAI state score was significant with self-selected music (mean±SD) (−6.3 ± 6.2) compared with that for the control group (no sound) (−2,9 ± 5.1) ($p < 0.001$; d 0.6). MusiCure™ (−4.6 ± 5.9) did not significantly differ from no music ($p = 0.1$) nor from self-selected music ($p = 0.09$) in terms of change in STAI state score (Figure 3).

Analysing the results of the VAS at discharge, reporting patients' self-perception of the sound, there

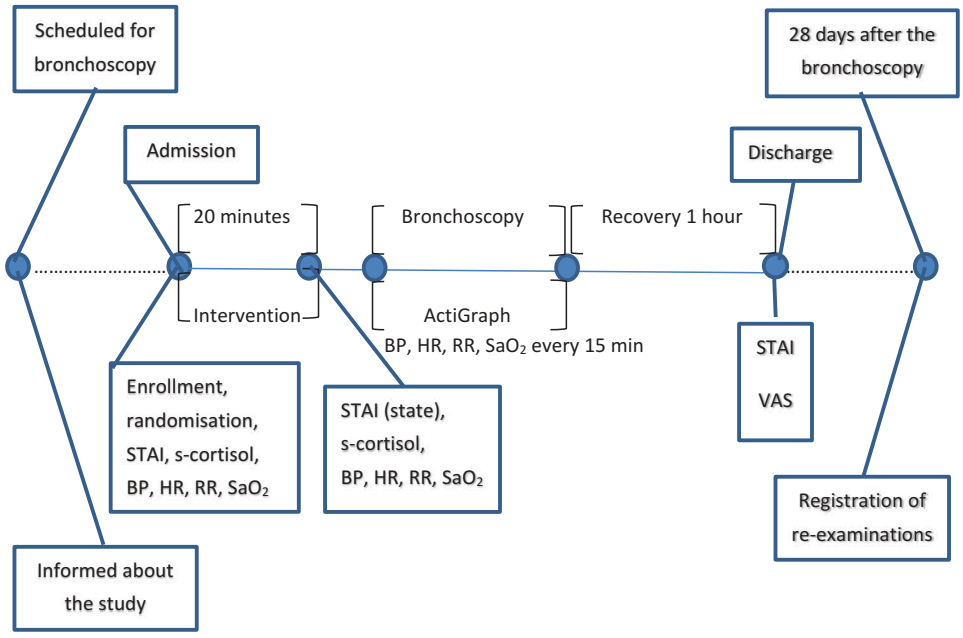

Figure 2. Timeline.

BP = blood pressure; HR = heart rate; RR = respiratory rate; SaO_2 = oxygen saturation; STAI = Spielberger's state trait anxiety inventory; VAS = visual analogue scale.

Table 3. Comparison of STAI scores.

	On admission				After 20 min with intervention				On discharge			
	Control	MusiCure	Self-selected	*p*	Control	MusiCure	Self-selected	*p*	Control	MusiCure	Self-selected	*p*
STAI State PP	40.1 (11.7) *N* = 95	41.9 (14.1) *N* = 91	42.9 (11.9) *N* = 99	***0.3***	36.3 (11.3) *N* = 91	36.7 (13.0) *N* = 86	36.7 (11.7) *N* = 95	***1.0***	31.9 (10.3) *N* = 80	32.4 (10.4) *N* = 87	32.2 (9.0) *N* = 93	***1.0***
STAI state ITT	40.0 (11.5) *N* = 99	41.4 (14.0) *N* = 100	43.0 (11.9) *N* = 100	***0.2***	37.1 (12.4) *N* = 99	36.9 (13.0) *N* = 100	36.8 (11.6) *N* = 100	***1.0***	32.8 (10.6) *N* = 99	32.8 (10.9) *N* = 100	33.1 (9.5) *N* = 100	***1.0***
STAI Trait PP	34.1 (11.0) *N* = 91	33.3 (9.9) *N* = 92	33.4 (9.5) *N* = 97	***0.9***	–	–	–	–	34.9 (11.1) *N* = 86	33.1 (10.6) *N* = 83	32.6 (9.3) *N* = 88	***0.3***
STAI Trait ITT	34.3 (10.8) *N* = 96	32.8 (9.8) *N* = 99	33.6 (9.4) *N* = 100	***0.6***	–	–	–	–	34.6 (11.1) *N* = 96	32.9 (10.0) *N* = 99	33.3 (9.4) *N* = 100	***0.5***

Data are expressed as mean (standard deviation, SD).
PP, per-protocol analysis.
ITT, intention-to-treat analysis with the principle last-observation-carried-forward.

was a highly significant difference between the music groups and the control group [H (2) = 33.81, $p < 0.001$] (Figure 4). When analysing the differences between the three treatments, the median VAS score of the control group (median (IQR); 4.5 mm (8.1)) compared with that for the group receiving MusiCure™ (8.3 mm (2.4); $p < 0.001$) and that of the group receiving self-selected music (8.1 mm (2.9); $p < 0.001$) was highly significant. No significant difference was found between MusiCure™ and self-selected music ($p = 1.0$).

When dividing the groups by VAS tertiles and looking at change in STAI state score, the significant change in STAI state is found in the top VAS tertile (Figure 5).

No significant differences were found in physiological variables, as blood pressure, heartrate, oxygen saturation, respiratory rate and s-cortisol. Nor were there any significant differences between the groups in duration of the bronchoscopy, amount of sedatives, movement during the bronchoscopy or number of re-examinations. Furthermore, there were no statistically significant differences between the groups in confounders like attending staff (nurses and doctors) and diagnostic procedures performed during bronchoscopy.

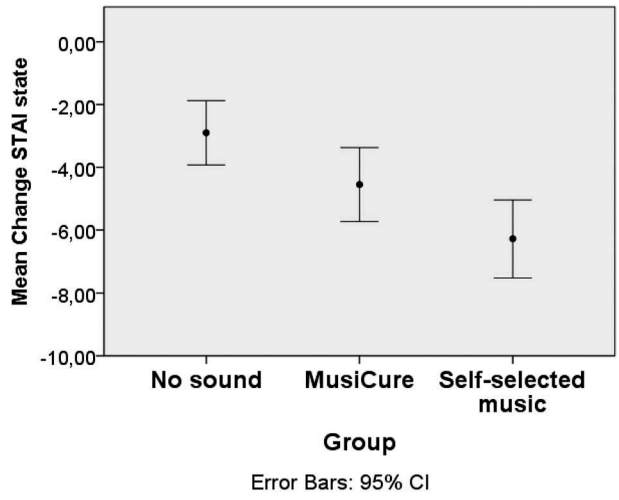

Figure 3. Mean difference of STAI state score (Δ-STAI) from admission to 20 min with or without music prior to bronchoscopy.

There was a significant effect of music on change of STAI score from admission to 20 min with or without music [F (2, 297) = 8.68, $p < 0.001$, ω = .05]. Tukey-adjusted *post-hoc* comparisons indicated that the change in STAI state score was significant with self-selected music (mean±SD) (−6.3 ± 6.2) compared with that for the control group (no sound) (−2,9 ± 5.1) ($p < 0.001$; d 0.6). MusiCure™ (−4.6 ± 5.9) did not significantly differ from no music ($p = 0.1$) nor from self-selected music ($p = 0.09$) in terms of change in STAI state score.

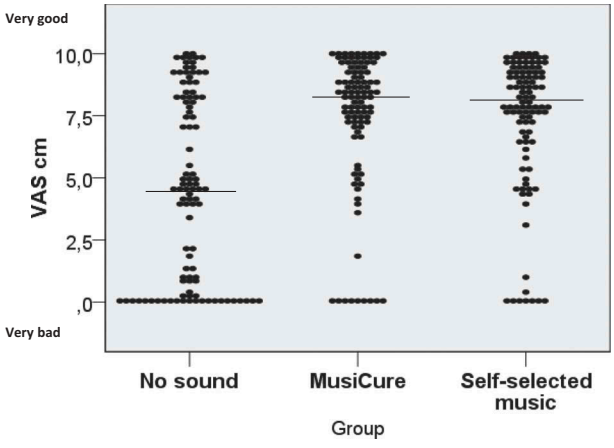

Figure 4. Patients overall perception of the sound prior to and during bronchoscopy.

There was a highly significant difference between the music groups and the control group [H (2) = 33.81, $p < 0.001$]. When analysing the differences between the three treatments, the median VAS score of the control group (median (IQR); 4.5 mm (8.1)) compared with that for the group receiving MusiCure™ (8.3 mm (2.4); $p < 0.001$) and that of the group receiving self-selected music (8.1 mm (2.9); $p < 0.001$) was highly significant. No significant difference was found between MusiCure™ and self-selected music ($p = 1.0$).

Discussion

In this RCT study, we were able to detect differences in anxiety score by STAI state when comparing the changes in anxiety from admission (baseline) to 20 min after exposure to self-selected music. We found a significant reduction in anxiety for those who listened to self-selected music compared to the control group. This reduction persisted after adjusting for sex and baseline anxiety.

Interestingly, patients in both music groups had similar perception ratings of the sound environment (VAS). It has been hypothesized that self-selected music reduces anxiety because it provides patients with a sense of control over their situation [13,14]. In a sub-analysis, the meaningful change in STAI state occurred when the patients responded in the top tertile of the self-perceptive VAS scale (Figure 5). Those who either disliked the sound or were neutral did not experience any significant reduction in anxiety compared to the control group. It seems, therefore, that the possibility of selecting music is, in and of itself, not enough. Nor is it enough to be satisfied with the sound. It seems that the music must comply with the patient's personal preference and that it is, perhaps, the element of familiarity that causes the positive effect on decreasing anxiety.

Brain research indicates that music is processed differently in the brain depending on an individual's musical background and competence [15,16]. This might explain why patients in the two music groups are equally satisfied with the sound but vary in changes in anxiety.

There is no consensus on what a minimal clinically important difference in STAI state should be [10]. A change of 6.3 points found in the present RCT study from admission to 20 min after listening to music is a small difference on a scale from 20 to 80 points, but in line with several other studies, which also study the effect of music on anxiety [10,17–19]. One principle when calculating the minimal important difference is that the change should be greater than half the standard deviation at baseline [20]. In this study, the standard deviation of STAI state baseline is 12.6, and 6.3 is just the half. Calculating the effect size the partial eta squared for the change is ranged as medium (η = .06), but the less biased omega squared is characterised as small, but close to medium (ω = .05). Another measure of effect size is Cohen's d, and again the effect size is ranged as medium ($d = 0.6$).

It can be questioned whether a huge effect can be seen, when the mean of STAI state was 41.5 at admission. The STAI manual indicates a mean of working adults of 35.5 points [11]. This is not far below the mean of participants in this study, though the mean in this study also corresponds with similar studies [8–10]. Patients who declined to participate commonly responded that they were too nervous to focus on anything other than the forthcoming bronchoscopy and therefore too nervous to concentrate on

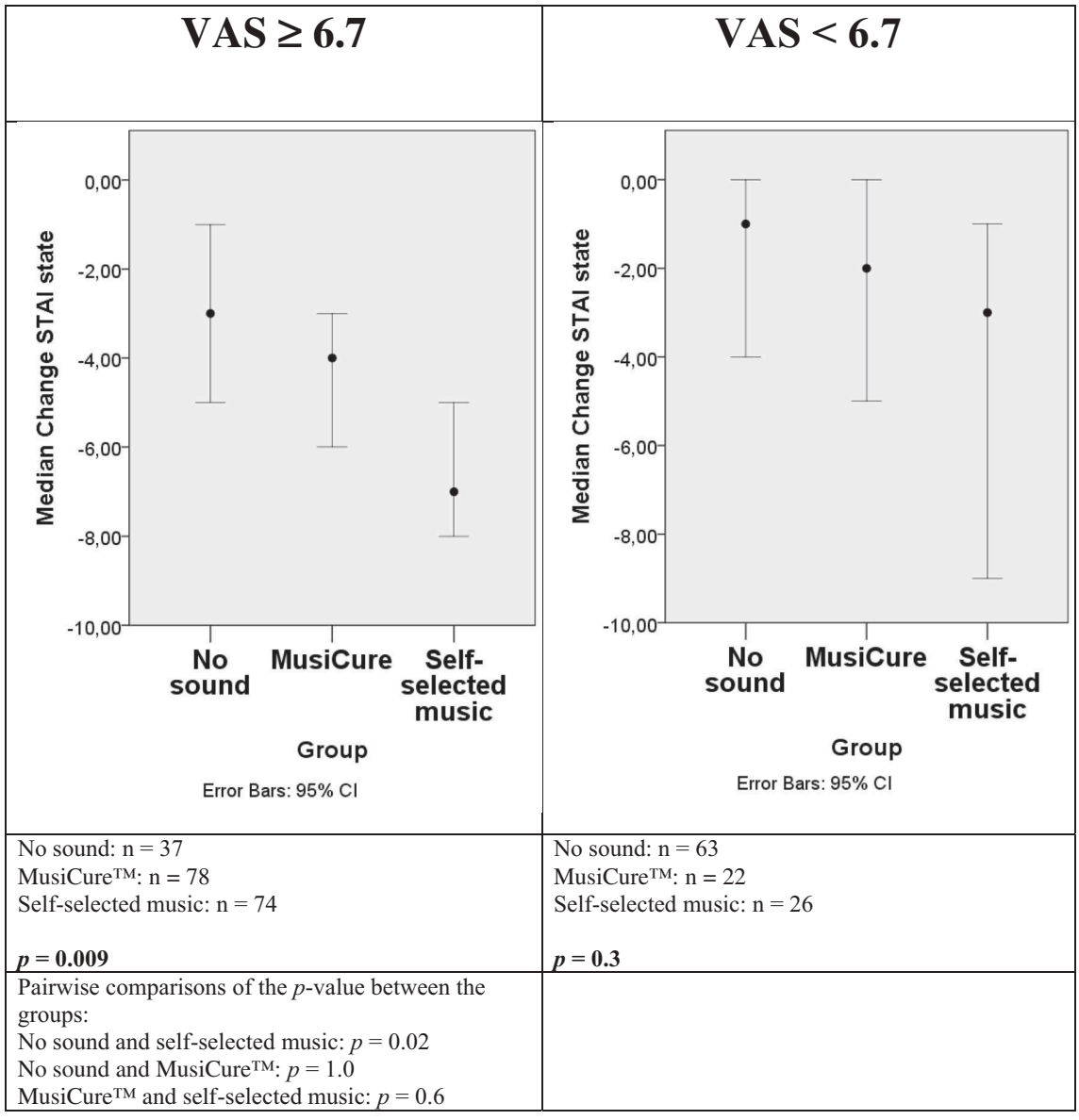

Figure 5. STAI change from admission to after 20 min with or without music divided by how the patients appreciated the sound measured by VAS.

There is only a significant difference in STAI change in the upper tertile of VAS measuring how patients appreciated the sound. (Kruskal–Wallis test is used because of the very different sizes of the groups).

completing questionnaires. Regardless, we were able to show an effect in the present group with moderately increased STAI state score.

We found no significant differences between the groups regarding vital signs such as blood pressure, heartrate, respiration rate and s-cortisol. This might be due to the fact that moderate anxiety does not create physiological arousal, because the physical change is so small that it is impossible to detect, or due to physiological arousal not following the same pace as subjective changes in anxiety. In the current study, we did not control confounders such as antihypertensive and cardiac medications.

There are discrepancies in earlier studies regarding the effect of listening to music on vital signs. A recent meta-analysis about the effect of music during bronchoscopy concludes that music during bronchoscopy is an effective way of reducing patients´ blood pressure and heartrate [21]. Whereas a review found only a small effect on physiological variables [10] and another review found no effect of music [9]. It can be questioned whether there is a cultural aspect in the findings because the conclusion of the meta-analysis is built on four Chinese studies and one European. Approximately half of the studies included in the review that finds a small difference in physiological

parameters are Asian, in contrast to the review with no clear findings, which only includes a quarter of Asian studies.

In the present study, we found no significant differences in re-examinations of patients. In the present study, every patient with a history of bronchoscopy was excluded. The significant difference of re-examinations in our previous study is probably confounded by an uneven distribution of patients with a former history of bronchoscopy.

In the former study, we also questioned whether the exposure time of 10 min to MusiCure™ was long enough. In a recent RCT, the duration needed to reduce preoperative anxiety measured with STAI was investigated. Sessions of self-selected music for 15 and 30 min were investigated, and it appeared that as little as 15 min of listening to self-selected music provided a significant change in STAI state [17].

Low-cost single-use earphones were chosen for reasons of hygiene. The impact of sound quality can be queried and seen as a limitation. Another limitation is that, during bronchoscopy, the music interventions were probably confounded by the sedatives, making it unlikely that the sensor recording chest movements, and every other measurement recorded during the bronchoscopy, truly reflected the music intervention.

In relation to the self-perceptive VAS, the difference between the intervention groups and the control group might be due to disappointment within the control group with not receiving music and could also be biased by the patients´ awareness of their participation in a study whose objective was to measure the effect of listening to music. Another bias in connection with that was that the patients were aware of that the aim of the study was to investigate the effect of MusiCure™ and this could impact their rating.

There were no group differences in re-examinations (diagnostic yield), amount of sedatives required and physiological parameters; however, the study was not powered to detect such differences in secondary outcomes.

Reduction of anxiety is certainly desirable, yet it is important that any adjunct intervention does not impact negatively on diagnostic yield [22]. Optimal patient satisfaction and optimal diagnostic yield are however not mutually exclusive and both should be sought for the benefit of the patient.

Conclusion

Music prior to bronchoscopy reduces anxiety for patients undergoing bronchoscopy for suspected lung cancer if the music is consistent with the patient's own preferences. There is, overall, more satisfaction among patients, with the sound environment before and during bronchoscopy, when listening to any type of music. Due to its low cost and safety, self-selected music pre-procedurally can reasonably be offered to patients undergoing bronchoscopy.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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