

**Title Page**

**Title:** The Effect of Music on Discomfort Experienced by ICU Patients During Turning; A Randomised Cross-over Study

**Running Title:** Music and Discomfort During Turning

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## **Abstract**

**Background:** Research consistently demonstrates that ICU patients experience pain, discomfort and anxiety despite use of analgesics and sedatives. The most painful procedure reported by critically ill patients is being turned. Music diminishes anxiety and discomfort in some populations, however its effect on critically ill patients remains unknown.

**Objectives:** This research aimed to identify the effect of music on discomfort experienced by Intensive Care Unit (ICU) patients during the turning procedure using a single blind randomised cross-over design.

**Methods:** Seventeen post-operative ICU patients were recruited and treatment order randomised. Discomfort and anxiety were measured 15 minutes before and immediately after 2 turning procedures.

**Results:** Findings indicated that listening to music 15 minutes before and during the turning procedure did not significantly reduce discomfort or anxiety for post-operative ICU patients.

**Conclusion:** Findings indicate that pre- and post-operative pain care protocols may effectively be addressing discomfort and anxiety experienced during the turning procedure. Given previous studies have identified turning as painful, current results are promising and it may be useful to determine if this is the situation generally in Australian ICUs. Research is also needed to develop a broader evidence-base and further understand specific and clinical benefits of listening to music during turning procedures for ICU patients.

## **Key Points**

- Music has been shown to decrease anxiety and discomfort in a number of settings

- Music as a nursing intervention has not been tested widely in the ICU setting
- Music did not reduce pain or anxiety associated with turning in this study of ICU patients however patients reported low levels of pain and anxiety prior to turning.

# **The Effect of Music on Discomfort Experienced by ICU Patients During Turning; A Randomised Cross-over Study**

## **Introduction**

Critically ill patients commonly experience anxiety, pain and discomfort as part of their Intensive Care Unit (ICU) stay<sup>1,2</sup>. These experiences can be a result of their illness or from the care health professionals provide. Further, being subject to numerous procedures common in the ICU such as turning, endotracheal suctioning and wound care can also adversely affect patients<sup>1</sup>. Discomfort and anxiety have the potential to lengthen ventilator weaning time and ultimately lengthen ICU stay. The pain associated with these procedures can result in a number of negative stress sequelae for patients that can be detrimental to their health and well-being<sup>3,4,5,6,7</sup>.

The most painful procedure reported by about 6,000 acute and critically ill adult patients in the US Thunder II study was being turned<sup>1</sup>. This was supported in a recent Australian study where results from 61 conscious ICU patients indicated that postural change was one of the routine procedures causing pain<sup>8</sup>. This activity happens every two to three hours in most ICU, thus it is likely experienced by a significant proportion of ICU patients on a daily basis. The challenge for nurses working in ICU settings, where care of necessity incorporates interventions that are unpleasant and painful, is to find ways to reduce these stressful experiences.

Music has been demonstrated to diminish anxiety<sup>9,10</sup> and discomfort<sup>11</sup> in some populations, however its effect on procedural discomfort for critically ill patients remains unknown. A recent systematic review of 51 music for pain relief studies contained 28 studies which specifically investigated the effect of listening to music on

procedural pain<sup>12</sup>. The overall conclusion of the systematic review was that listening to music did reduce pain intensity but the reduction was small and therefore the clinical benefits were unclear<sup>12</sup>. No study in the review investigated music and postural change in ICU patients. There may be distinct differences however between the discomfort experienced during turning to that experienced during other procedures investigated such as chest tube removal<sup>13</sup> or insertion of intravenous devices<sup>14</sup>. Importantly, a group of US nurse researchers have demonstrated that it is feasible for music to be used with ventilated patients<sup>15</sup>. This study sought to demonstrate the effect of music on the discomfort and anxiety experienced by ICU patients during the turning procedure.

## **Method**

### **Aim**

The overall aim of this study was to identify the effect of music on the discomfort and anxiety experienced by post-operative ICU patients during the turning procedure. Previous research and theory supported the idea that the benefits of music can be evidenced immediately following the listening to music for 15 minutes<sup>16</sup>. This study was designed to test the following research hypotheses:

1. Listening to 15 minutes of music will decrease the discomfort experienced by post-operative ICU patient during the turning procedure;
2. Listening to 15 minutes of music will decrease the anxiety experienced by post-operative ICU patient during the turning procedure.

## **Design**

The study used a single blind randomised cross-over design<sup>17</sup>. Participants were randomly assigned to an intervention (music) or control group to begin the study. Participants' discomfort and anxiety were measured 15 minutes prior to and immediately after the turning procedure. After completion of the first arm of the study, participants 'crossed-over' into the opposite arm and the protocol was repeated (Figure 1). Each arm of the research took approximately 20 minutes with an approximate 2 hour wash-out period between arms (Figure 1).

The University and Institutions' human research ethics committees gave ethics approval and all participants signed a consent form.

[

FIGURE 1 about here]

## **Sample and Setting**

Two sites were used to recruit participants for this study. One site had 200 hospital and 7 ICU beds and the other has 580 hospital and 9 ICU beds. The inclusion and exclusion criteria were:

Inclusion criteria:

- Patients who were scheduled for surgery and had a planned post-operative stay in ICU (ventilated and non ventilated);
- Patients who had an expected ICU LOS greater than 8 hours; and
- Patients who were able to respond to pre- and post-turning discomfort and anxiety questions.

Exclusion criteria:

- Patients who were scheduled for neurosurgery;
- Patients less than 18 years (because the Thunder II project suggests that the pain experienced by children and teenagers during procedures may differ to adults);
- Patients who did not like music;
- Patients who were hearing impaired; and
- Patients who had difficulty wearing earphones.

### **Intervention**

The intervention in this study was listening to music of the participant's choice for 15 minutes before and during the turning procedure. Participants were invited in the pre-admission material to bring in a CD for this purpose or they could choose pre-operatively from a selection of classical, jazz, country and western, new age, easy-listening or 'other' (mostly by contemporary artists) music provided by the researchers. A portable Compact Disk (CD) and earphones were used to deliver the music.

The control group in this study wore earphones attached to a portable CD player but no music was played. This allowed the nurse collecting outcome data to be blinded to treatment allocation, thus limiting the potential for detection bias.

### **Data Collection**

The primary outcome for this study was patient discomfort. Chlan et al.<sup>11</sup> defined discomfort as “the physical sensation of experiencing pain or of being

uncomfortable” and used a numeric rating scale (NRS) from “0 = No Discomfort” to “10 = Worst Possible Discomfort” to measure this discomfort: which we adopted for this study. NRS correlate well with Likert-type measures of pain intensity from 0.65 to 0.88<sup>18</sup> and are easy to administer and score and produce higher rates of correct responses<sup>11</sup>. Puntillo et al.<sup>1</sup> used NRS in their large Thunder II study and report that construct and concurrent validities have been established.

The secondary outcome for this study was patient anxiety. The Faces Anxiety Scale (FAS) has been developed and tested as a measure of anxiety in critically ill patients<sup>19</sup>. It is easy to administer and has minimal participant burden. The FAS requires participants to choose which of the 5 faces illustrates how much anxiety they are feeling at the time<sup>19</sup>. McKinley, Stein-Parbury, Chehelnabi & Lovas<sup>20</sup> have assessed the validity of the FAS and found that the “correlation between the objective clinical judgement of the interviewer and the patients’ self-reports of anxiety on the Faces scale is well within the recommended range of 0.4 to 0.8 for criterion validity” (p.150). The research team had previously used this FAS on ICU patients<sup>21</sup>.

As well, to allow for description of the sample, demographic and clinical data was collected. Demographic data was collected just after consent and included age, gender, previous hospitalisations, nature of surgery, and current medications. Post-operative clinical data was collected from the medical chart during the study period. This data included the frequency and type of medications administered during the study period including number of hours post-operative, presence or absence of an endotracheal tube and hours of mechanical ventilation.

## **Data Analysis**

Descriptive statistics are reported providing completion numbers, and using appropriate measures of location and spread. Comparisons of pre-test values using appropriate nonparametric methods (Wilcoxon's rank sums test and Fisher's exact test) were undertaken to assure that the randomisation process had been successful. The generalised linear method (GLM) of analysis advocated by Senn<sup>22</sup> was employed; investigating the treatment effect only after the period effects and carry-over effects had been tested and eliminated. Tests of normality on the outcome variables were undertaken for the GLM analyses and data transformation was undertaken where necessary. Data was analysed using SAS version 9.1<sup>23</sup> for all statistical comparisons, and a significance level of  $\alpha=0.05$  was employed.

## **Results**

### **Sample**

A total of 17 participants were enrolled into the study. The median age of participants was 72 years and almost three quarters were male. Almost half had abdominal surgery, with over 80% of the sample having abdominal, vascular or thoracic surgery. Most had received some form of analgesic but had not received sedation. Table 1 outlines the demographic and clinical data.

[TABLE 1 about here]

Of the n=17 participants, 10 received the intervention in the first period and 7 received the control. There were no baseline differences between the randomized groups in age (Wilcoxon's rank sums test, exact P=0.98), gender (Fisher's exact test,

P=0.99), previous admissions (Wilcoxon's rank sums test, exact P=0.91), Surgery type (Fisher's exact test, P=0.55), or analgesic use (Fisher's exact test, P=0.55). The median time taken between pre-turn test and post-turn test for period 1 was 23 minutes (range: 10, 45 minutes), between pre-turn test and post-turn test for period 2 was 25 minutes (range: 15, 40 minutes), and between periods was 2 hours 40 minutes (range: 1 hour 10 minutes, 14 hours 55 minutes).

### **Discomfort and Anxiety**

There was no difference in pre-turn discomfort or anxiety scores between intervention and control groups at period 1 (Wilcoxon's rank sums test, exact P=0.16 and P=0.31, respectively) or between intervention and control groups at period 2 (Wilcoxon's rank sums test, exact P=0.85 and P=0.46, respectively). There was also no difference in pre-turn discomfort or anxiety scores between period 1 and period 2 (Wilcoxon's signed rank test, P=0.59 and P=0.34, respectively).

Table 2 gives the unadjusted mean and 95% confidence intervals (95% CI) of pre-turn measurements, post-turn measurement and changes for discomfort by intervention and control treatments. Data checks revealed that a logarithmic transformation of discomfort scores was required to fulfil the GLM assumptions. In GLM analysis of the transformed discomfort scores, no treatment effect (P=0.12), order effect (P=0.53) or treatment×order interaction effect (P=0.25) was seen. There was no evidence to reject the assumption of normality in the Studentized residuals of the final analysis (Shapiro-Wilk's test, P=0.84). For the GLM analysis of anxiety scores, no data transformation was required. Again, no treatment effect (P=0.12), order effect (P=0.48) or treatment×order interaction effect (P=0.24) was seen. The Studentized

residuals of the final analysis did not significantly differ from the normal assumption (Shapiro-Wilk's test,  $P=0.11$ ).

[TABLE 2 about here]

Table 3 shows the number and percentage of participants receiving the various forms of analgesia (some participants received more than one form of analgesia) during the study. Importantly, nine (53%) were on some form of continuous narcotic infusion.

[TABLE 3 about here]

## **Discussion**

It is apparent from the findings that the results did not support the research hypothesis. The mean levels of discomfort (range = 1 - 10) and anxiety (range = 1 - 5) however were quite low pre-turning on both occasions for both treatment groups so it is not surprising that music did not show a statistically significant effect. These findings are contrary to previous studies reviewed by Gelinas<sup>25</sup> that suggest that 50% of critically ill patients experience moderate to severe pain and that this proportion has not improved from studies conducted in the early 1980s. The results of this current study however suggest that post-operative care at both ICUs was effectively addressing these issues.

The research by Siffleet et al.<sup>8</sup> identified that positional change caused pain for ICU patients also found that only 32.6 % of patients received morphine in the hour previous to the procedure. Gelinas<sup>25</sup> found that although 75% of patients experienced pain in relation to such procedures as turning and chest tube removal and all had

received a continuous fentanyl infusion, rarely was bolus analgesia used in preparation for procedures. In the current study 53% of participants received continuous analgesia and 35.3 % (see Table 3) received a bolus one hour before the turning procedure and given the mean discomfort scores, post-operative pain management protocols would appear to be effective. This finding suggests that effective pre-operative patient education may have also played a part in the apparent effective pain management protocol with some participants receiving bolus doses of analgesia (patient-controlled) before the turning procedure in anticipation of the discomfort.

Given that participants were post-operative, their low discomfort and anxiety levels may also have been residual from the general anaesthetics received. Unfortunately, the time period between sedative and analgesic medication used during general anaesthetic and the first turn was not recorded. It maybe that if we had waited until after the initial post-operative period, say 12 hours, discomfort and anxiety levels in relation to the turning procedure may have been higher. However, participants had to be awake enough to respond to questions prior to the study protocol beginning.

Recruitment into the study was extremely problematic. The calculated sample size using the primary outcome, discomfort from the Chlan, et al.<sup>11</sup> study determined that 50 participants were required. However despite continued efforts to recruit and strategies employed to ensure that all potential participants were screened and invited to participate, recruitment into the study was extremely slow. Many reasons were apparent such as, around 60% of elective cases were neurosurgery and therefore

excluded, high numbers of emergency post-operative patients, patients were admitted over the week-end for surgery and some elective cases had no ICU bed booked. The time period for the study was extended twice before it was decided that extending it further was not feasible. Recruitment into clinical research projects in critical care areas is complex and as Grap and Munro<sup>24</sup> indicate it presents unique issues and problems. Grap and Munro<sup>24</sup> reviewed the literature about recruitment problems with clinical trials and although they found literature in relation to difficulties in recruitment into studies involving such participants as the elderly, children, and individuals with cancer and Human Immunodeficiency Virus (HIV) there was limited discussion within the critical care setting. They did however examine recruitment effectiveness of 13 North American National Heart, Lung, and Blood Institute clinical trials and found that commonly planned sample sizes were not achieved over the expected time period and recruitment problems were common<sup>24</sup>.

The largest proportion of not enrolled participants from the current study related to 60% not being eligible which is similar to other research that found over an 11 month period that of 593 critically ill patients screened 77.1% were not enrolled in the study as they were ineligible<sup>24</sup>. The strength of the cross-over design used in this study however is that participants acted as their own control ensuring that the intervention and control groups were similar for many known and unknown confounders, an additional benefit in that it provides strong evidence of causation<sup>17</sup>.

### **Limitations**

The number of participants recruited into this study may have reduced chances of finding any true effect (if it existed)<sup>26</sup>. Additionally, if the effect of music is small, the

sample size was likely too small to detect this effect. Further, these participants may have been atypical of the population of interest with regard to critical variables as a large percentage of neurosurgical patients were excluded<sup>25</sup>.

## **Conclusion**

The findings indicate that pre- and post-operative care management may be effective at the two participating study sites as participants had lower than expected levels of discomfort and anxiety during the turning procedure. Previous studies have consistently identified turning as the most painful procedure that critical care patients experience. Given the results of this study it may be useful to determine the current situation in relation to care protocols and discomfort and anxiety levels of critically ill patients in Australian ICUs. Further research is also needed to develop a broader evidence-base and further understanding of specific and clinical benefits of listening to music during the turning procedure for ICU patients. As such, it maybe useful to wait a certain period of time post-operatively before examining discomfort and anxiety in relation to the turning procedure.

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Figure 1. Study Design

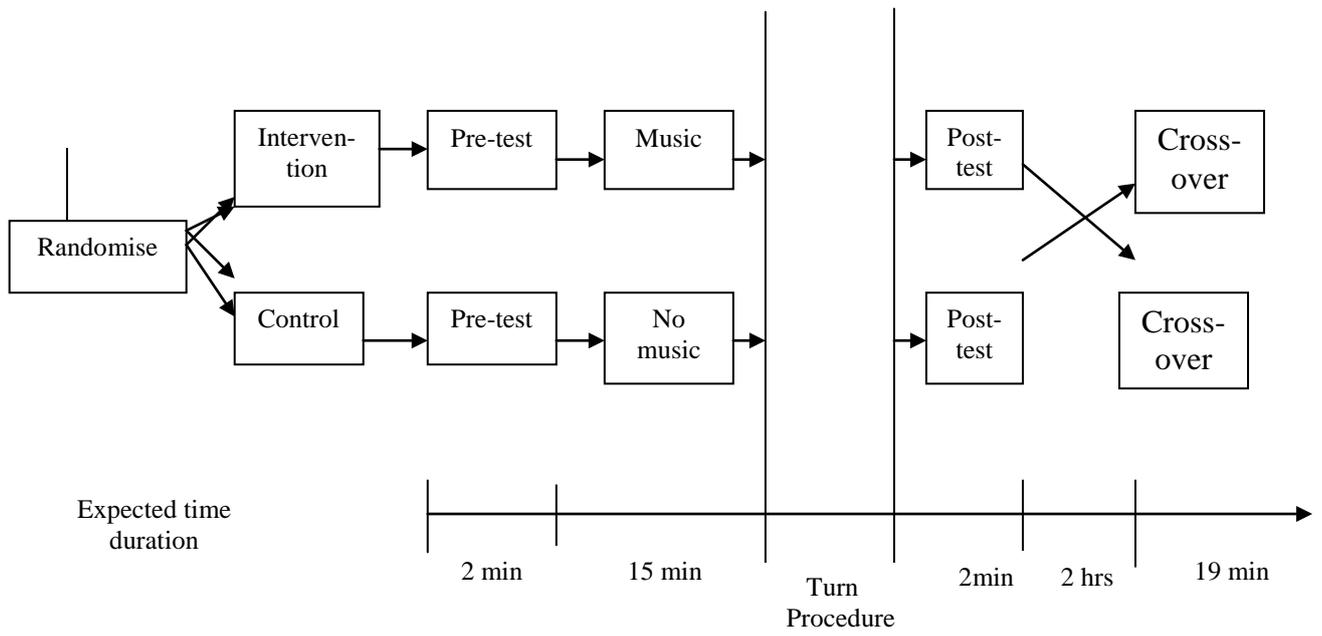


Table 1. Baseline characteristics of the n=17 study participants

	median	(min, max)
<i>Age (years)</i>	72	(19, 87)
<i>Number of previous hospital admissions</i>	4	(0, 20)
<i>Gender</i>	n	(%)
Male	12	(71)
Female	5	(29)
<i>Surgery</i>		
Abdominal	8	(47)
Vascular	3	(18)
Thoracic	3	(18)
Neurosurgery	1	(6)
Genatourinal	1	(6)
Neck	1	(6)
<i>Taking anti-anxiety medication on admission?</i>		
No	17	(100)
<i>Analgesics taken from the time of admission to the completion of the 2nd turn post-survey?*</i>		
Yes	13	(81)
No	3	(19)
<i>Sedatives taken from the time of admission to the completion of the 2nd turn post-survey?*</i>		
No	17	(100)

\*Information missing for 1 patient.

Table 2. Mean and 95% confidence intervals (95% CI) of pre-turn measurements, post-turn measurement and changes for discomfort and anxiety scores by intervention and control treatments.

	Pre-turn		Post-turn		Difference	
	mean	(95% CI)	mean	(95% CI)	mean	(95% CI)
<i>Discomfort</i>						
Intervention	2.7	(1.7, 3.7)	3.6	(2.0, 5.2)	0.9	(-0.4, 2.2)
Control	3.4	(2.2, 4.6)	2.8	(1.3, 4.2)	-0.4	(-1.2, 0.5)
<i>Anxiety</i>						
Intervention	1.9	(1.4, 2.4)	1.9	(1.2, 2.5)	0.0	(-0.7, 0.7)
Control	2.4	(1.8, 2.9)	2.2	(1.5, 2.8)	-0.1	(-0.4, 0.2)

Table 3. Use of Analgesia Pre-Turn

Analgesia	n (%)
Continuous Fentanyl or Fentanyl Mix Infusion	8 (47)
Bolus Fentanyl within 1 hour of procedure	2 (12)
Continuous Morphine Infusion	1 (6)
Bolus Morphine within 1 hour of procedure	4 (24)
Oral Morphine within 2 hours of procedure	1 (6)
Oral Panadol within 2 hours of procedure	2 (12)