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Background Music Used to Reduce Anxiety in Infants during an Ear Examination

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Abstract

Objective: To evaluate the impact of music on the level of anxiety in infants between 0-3 years during an ear examination.

Study design: A randomized controlled trial between May 2012 and June 2013 at the Emek Medical Center, Afula, Israel. The study included 97 infants aged 0 to 3 years who were referred to the ear nose and throat (ENT) clinic.

Infants in the interventional group listened to music during a standard ear examination, while infants in the non-interventional group did not. Following the examination, the investigator filled out a FLACC (Face, Legs, Activity, Cry, Consolability) scale questionnaire aimed at assessing the anxiety level of the infant during the examination.

Results: The anxiety levels in the interventional group were statistically significantly lower than those in the non-interventional group.

According to the FLACC values a statistically significant correlation was found between listening to music during the ear examination and low levels of anxiety in the girls sub-group ($p < 0.001$); in the sub-group of infants aged 1-2 years only ($p < 0.001$); and only in the group of children whose parents have attained higher education.

Conclusions: Music was shown to reduce levels of anxiety in infants aged 0-3 years during an ear examination by an ENT physician. The sub-groups in which music was most effective were girls, infants aged 1-2 years, Hebrew speaking families and parents with a higher education. No correlation was found between the parental and child anxiety.

Keywords: Ear examination; Children; Music; Anxiety

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Introduction

Every physician who treats children, especially infants, encounters difficulties examining them, principally when cooperation from the patient is required, as during an ear examination under a microscope.

Children's anxiety and lack of cooperation, in front of strange people and situations, make the examination difficult and sometimes inaccurate. Moreover, increased pre-intervention anxiety is reported to result in negative psychological effects including nightmares, separation anxiety, eating problems and increased fear of doctors [1]. These effects are present and also persist in further encounters, and thus the first experience is crucial. Therefore, every effort needs to be exerted to find a way

to decrease the anxiety of a child undergoing medical procedures.

Medication treatment has proven to be effective in reducing pre-procedural anxiety. However, considering possible side effects, drug interactions, young age of the patients, and logistic issues, physicians seek for alternative ways for preventing pre-procedural anxiety in children [2]. Many trials have been carried out testing diverse non-pharmacological interventions for reducing anxiety in children, the success rate of those approaches was variable. Videogames, clown doctors, hypnosis, acupuncture and music are some of the methods used worldwide [3].

In 1914, Kain argued that intraoperative music therapy could distract patients from the fear of surgery [4]. In a systematic review of randomized controlled trials, McPherson showed

that listening to music helped reducing self-reported anxiety, physiological indicators of anxiety or sedation requirements in 23 out of 25 studies [5].

Furthermore, previous studies demonstrated a correlation between preoperative parental anxiety and their child's preoperative anxiety [2,4].

In a large study in 2009, Bringman et al. [6] examined 177 pre-op patients. One group received sedation (midazolam) and the second group listened to background music. They found that music lead to lower levels of anxiety compared to sedation [6].

As ear nose and throat (ENT) clinicians we examine ears of children and infants on a daily basis. Usually this examination requires two adults to restrain the child and the clinician examines and cleans the child's ear. Children's behavior during an ear examination often show some degree of anxiety ranging from quiet crying to kicking and temper tantrums that are difficult to control.

To the best of our knowledge, no previous publication specifically investigated the effect of music on reducing anxiety during a child's ear examination. Background music may have a positive calming effect thus reducing the child's anxiety levels allowing for a more comfortable ear examination.

The study objectives were: 1) To assess whether background music was successful in reducing anxiety in infants aged 0-3 years during an ear examination.

2) To examine a possible correlation between the parental anxiety before the examination to their child's anxiety level during the ear examination.

3. To examine whether demographic characteristics as the child's age, sex, and the family's native language and parent's level of education have an effect on their child's level of anxiety during the ear examination.

Methods

Study population

A randomized controlled trial was carried out between May 2012 and June 2013 at the Emek Medical Center, Afula, Israel. Emek Medical Center is a 500-bed regional hospital.

The study included 97 infants aged 0 to 3 years who were admitted to the ENT clinic for an ear examination. The children were referred from pediatricians in the emergency room to be tested for suspected otitis media. At least one of the parents was present during the examination.

Infants who suffered from chronic diseases, deaf or blind infants, hospitalized infants, or premature babies were excluded from the study.

The course of the study was as follows:

The parent/s entered the examination room with their child. The parent who was present filled out three forms: Demographic questionnaire (sex and age of the infant, the parent's level of education and native language (Hebrew, Arabic, Russian); an informed consent form for study participation, and the STAI

(State, Trait, Anxiety, Inventory) questionnaire to assess the parent's anxiety level. The STAI questionnaire is a widely used self-reporting instrument that estimates situational and baseline anxiety in adults based on 20 statements answered on a 1-4 scale, total score range from 20 to 80, with higher scores reflecting higher levels of anxiety [7,8].

All the infants were randomly divided into two groups; the randomization was based on the following: infants admitted on odd days underwent the examination with music, interventional group, while infants admitted on even days underwent standard examination with no music, non-interventional group.

Infants in the first group, the interventional group listened to music during the examination procedure, while infants in the second group, the non-interventional group did not. While two adults (parent and nurse or both parents) restrained the child the ENT clinician (MP primary investigator) performed the ear examination. The examination procedure entailed inserting an ear speculum into the external ear canal, examination through a microscope, earwax removal with an ear suction device or a removal spoon, if required, and examination of the tympanic membrane to determine the presence of middle ear inflammation. The ear examination was identical in both groups carried out by the same clinician (MP). The only difference was the presence or absence of the background music.

The parents could choose music from a collection of 15 CDs of children's music, including ten CDs in Hebrew, one CD in Arabic and one in Russian and another three CDs with universal relaxing music. The parents were advised by the physician to choose their child's most familiar, favorite music. The music source was a CD player, located inside the examination room, about 1.5 meters from the examination bed.

At the end of the examination procedure, the music was turned off. The primary investigator (MP) filled out a FLACC scale (Face, Legs, Activity, Cry, Consolability) questionnaire aimed at assessing the anxiety level of the infant during the examination. This scale, used to measure anxiety levels in children between 2 months to 7 years was introduced in its Hebrew version by Keidan in 2006 [9]. The scale contains 5 categories: Face, Legs, Activity, Cry, Consolability each of which is scored from 1-2 with a total between 0-10. Higher scores reflect higher levels of the child's anxiety. When the examination was over the child returned to the pediatric emergency room.

The STAI questionnaire and the FLACC scale evaluation tools were selected and analyzed in order to determine whether the various demographic characteristics, the parental anxiety before the examination or listening to music during the examination have an impact on the infant's level of anxiety during the ear examination.

The study was authorized by the Institutional Review Board according to the Declaration of Helsinki.

Statistical analysis

Categorical variables are presented as frequencies or percentages

and the continuous variables are presented as mean \pm standard deviation, median and range. The association between the study groups and categorical variables was examined using Chi-square test (or Fisher's exact test). For continuous variables T-test was used (or Wilcoxon two sample test). The correlation between the parental anxiety before the examination and their child's anxiety levels during the examination was estimated with Pearson correlation. The statistical analyses were performed using SAS 9.2. software (SAS Institute Inc., Cary, NC, USA). p values <0.05 were considered significant.

Results

A total of 97 infants were examined and enrolled in the study. Forty infants were included into the interventional group, where the subjects were exposed to background music during the examination, and 57 into the non-interventional group, where the subjects underwent standard ear examination with no background music.

There were no statistical differences in demographic characteristics between the study groups (Table 1).

Primary end point

The mean anxiety levels as measured by the FLACC scale showed a statistically significant difference between the study groups with lower levels of anxiety in the interventional group compared to the non-interventional group (6.5 ± 1.7 vs. 8.7 ± 1.6 , $p < 0.001$), respectively (Figure 1).

Parental anxiety: No correlation was found between the parental anxiety before the examination and their child's anxiety levels during the examination ($p < 0.05$).

Comparison between the interventional group and the non-interventional group, on the basis of the FLACC scale results, by sub-groups:

Based on the child's gender: Music had a statistically significant impact in the girls sub-group ($p < 0.001$). According to the FLACC values a correlation was found between listening to music during the ear examination and low levels of anxiety. In the boys sub-group there was a statistically borderline difference, ($p = 0.0489$).

Based on the child's age: Music had a statistically significant impact according to the FLACC values as demonstrated in the group of infants aged 1-2 years ($p < 0.001$). While in the group of infants aged 0-1 year, ($p = 0.0021$), and in the group of 2-3 year olds listening to background music showed no statistical significance on anxiety levels ($p = 0.2801$).

Family native language: A statistically significant difference in the FLACC values was apparent in the Hebrew speaking sub-group ($p < 0.001$). In the Russian speaking sub-group there was a statistically borderline difference, ($p = 0.0429$). In the Arabic speaking sub-group no statistically significant differences were observed, ($p = 0.2801$).

Notably, there were fewer infants in the Russian and Arabic speaking subgroups, (9 and 10, respectively). Furthermore, there were 10 CD's with music in Hebrew and only one each in Arabic and Russian. Thus, an infant from a Hebrew speaking family had a significantly higher chance to listen to familiar music than the infants from Arabic or Russian speaking families.

Parents level of education: Difference in the FLACC values was statistically significant only in the group of infants whose parents have attained higher education ($p < 0.001$). In the sub-groups of infants whose parents have elementary, high school

		Group		
		Interventional with music	Non-interventional without music	P value
Gender				
	Female	18 (44.74)	35 (59.62)	0.1623
	Male	22 (55.26)	22 (40.38)	
Age				
	0-1 years	19 (47.5)	30 (52.63)	0.6602
	1-2 years	17 (42.5)	24 (42.11)	
	2-3 years	4 (10)	3 (5.26)	
Language				
	Hebrew	35 (89.74)	41 (71.43)	0.183
	Arabic	2 (5.13)	8 (14.29)	
	Russian	2 (5.13)	7 (12.5)	
	Amharic	0 (0)	1 (1.79)	
Accompanying parent				
	Mother	27 (67.5)	40 (70.18)	0.779
	Father	13 (32.5)	17 (29.82)	
Accompanying parent's Educational level				
	Elementary	2 (5)	6 (8.77)	0.5766
	High school	13 (32.5)	13 (22.81)	
	Occupational	7 (17.5)	7 (12.28)	
	Higher education	18 (45)	31 (52.63)	

Table 1: Demographic characteristics.

or occupational education no statistical differences were found. Notably, the large sub-group of infants whose parents have a higher education comprised half of the participants (N=48), while the sub-groups of infants whose parents have elementary, high school or occupational education were much smaller (N=7, 28, 14), respectively.

Discussion

Preoperative anxiety has been shown in adults to correlate with increased post-op pain, higher post-op analgesic requirements and prolonged hospital stay [4]. Additionally, reports show 50% of children undergoing elective surgery, exhibit at two weeks post op new onset of maladaptive behavioral changes, such as nightmares, separation anxiety, eating disorders and fear of doctors. In 6% of these children, the behavioral changes last for about one year [4]. Therefore, relieving preoperative and pre-procedural anxiety is an important element in treating patients, both adults and children.

Pharmacological interventions, such as midazolam, have proven effective in relieving pre-procedural anxiety. However, due to side effects, drug interactions, after sedation observation time required, and challenging logistic issues in outpatient settings, other non-pharmacological techniques have been tested in the past years [5]. Music is widely used to help individuals to relax and divert their attention from stressful situations [8]. The proposed mechanism of the therapeutic effect of music claims that the child is not able to focus his attention on more than one significant stimulus at a time, as listening to music while experiencing pain. This distraction stimulates the brainstem, which leads to the inhibition of pain perception [10].

In the current study, we prospectively studied whether listening to music can reduce the levels of anxiety in infants during an ear examination. Ear examinations are not considered painful procedures but can definitely arouse anxiety in children and even in adults. We examined 97 infants aged 0-3 years, divided into two groups: the interventional group listened to background music chosen by the parents during the examination procedure, while infants in the non-interventional group underwent the ear examination without listening to music.

The two groups were similar in all demographic data comparisons: gender, age, native language, parents' level of education. No statistically significant difference between the two groups was found for any of the parameters listed above (**Table 1**).

According to our assessment no direct correlation was found between parental anxiety prior to the ear examination (as assessed with the STAI questionnaire) to their child's level of anxiety. This finding contradicts the results of earlier studies [2,4] which showed a direct correlation between high parental anxiety prior to their child undergoing surgery and the child's anxiety, showing a direct affect in which the parental anxiety "fuels" their child's anxiety. One of the possible explanations why our study showed no such direct correlation may be that parental anxiety was already low, prior to the ear examination, since it is considered a simple procedure posing no danger to their child, as opposed to surgery that involves general anesthesia, which was the case in these previous studies.

Next we examined the main study question: whether familiar background music has a positive effect on infants' anxiety levels during the procedure of an ear examination.

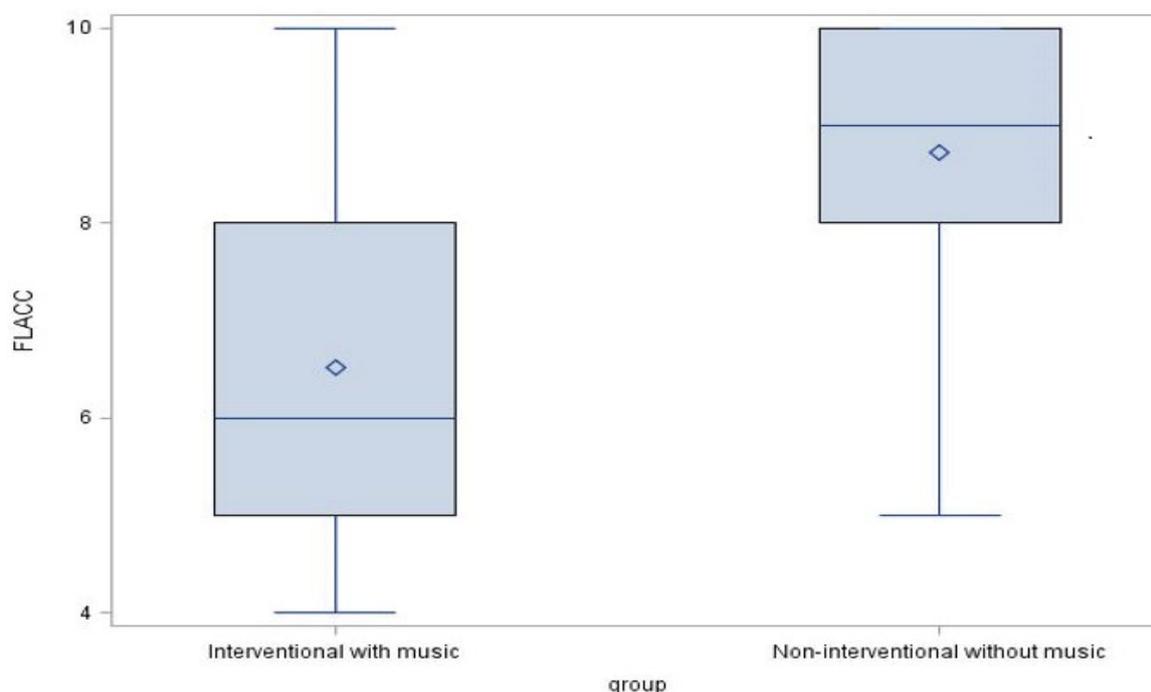


Figure 1 Infants' anxiety levels according to study group.

Table 2 Infants anxiety levels according to study group.

Group	N	Label	N	Mean	Std Dev	Minimum	Median	Maximum
Interventional with music	40	FLACC	39	6.5	1.7	4	6	10
Non-interventional without music	57	FLACC	56	8.7	1.6	5	9	10

P<0.001

The findings of our study demonstrated that there was a statistically significant correlation between listening to music during an ear examination and anxiety levels of infants undergoing the examination compared to the non-interventional group (6.5 ± 1.7 vs. 8.7 ± 1.6), respectively (**Table 2**).

At this point we examined all of the study sub-groups.

1. In terms of gender: the most significant effect of music was demonstrated in the sub-group of girls ($p < 0.001$), while in the boys sub-group the influence was statistically borderline ($P = 0.0489$).

Gender factor has an impact on anxiety levels as previously demonstrated in earlier studies, female gender represents a risk factor for elevated anxiety levels [11,12], although other studies did not support this finding [13]. However, it is important to mention that these studies examined anxiety levels in adults, in cases different than ear examinations.

2. In terms of age: we showed that music had a statistically significantly positive effect in infants between 0-2 years, in the first year $p = 0.0021$ while the greatest impact was demonstrated in the group of 1-2 year olds ($p < 0.001$). Between 2-3 years, music had no effect on the infant's anxiety levels ($p = 0.2801$). This finding is not supported by earlier studies, which warrants further examining whether infants in their third year are less sensitive to distractions than in their first two years of life.

3. In terms of the family's native language: the findings of our study show that the statistically significant positive effect of music was dominant in the sub-group of infants from Hebrew speaking families, ($p < 0.001$). While in the sub-group of infants from Russian speaking families, the effect was statistically borderline, ($p = 0.0429$). In the sub-group of infants from Arabic speaking families, music had no effect ($p = 0.28$). Native language is a mirror to the culture, education and worldview the child is raised with. Although this issue is beyond the scope of this study, clearly native language is an important factor that has an effect on the infant's response to external distractions.

4. In terms of parents' educational level: our study showed that infants whose parents have higher education were statistically significantly more affected by listening to music, ($p < 0.001$). In infants of parents with high school education this correlation was also statistically significant although to a lesser degree ($p = 0.0239$). No effect of music was observed in infants whose parents have occupational or elementary education, (p levels of 0.0572 and 0.3103, respectively).

Similar to native language, the parents' level of education reflects different cultural and educational backgrounds of the children. Therefore, it is possible that this factor also influences children's

ability to cope with fear. Similar findings have been previously demonstrated, although in a study that examined anxiety experienced by adults not children [12].

Conclusion

The current study is, to the best of our knowledge, the first published study that examines the positive impact of familiar background music as a means of reducing anxiety during ear examination in infants.

The study results demonstrated the common knowledge that music in general helps reducing anxiety, and in this study we proved that music can also be an important tool used as an aid during ear examination in toddlers.

The results of the study may be divided into three:

- 1) A strong correlation between music and decreased levels of anxiety was demonstrated in the following sub-groups: girls, infants between 1-2 years of age, infants from Hebrew speaking families and in infants of parents with higher education.
- 2) Moderate correlation, $0.001 < p < 0.05$, was found in boys, infants between 0-1 years of age, with Russian speaking parents and infants whose parents have high school education.
- 3) No statistically significant correlation was found in sub-groups of infants 2-3 years of age, infants with Arabic speaking parents, and with parents who have elementary or occupational education levels. No correlation was found between the parental level of anxiety prior to the ear examination and the level of their child's anxiety during the examination.

The results of our study demonstrate that the use of music is an effective technique to reduce anxiety in infants during an ear examination, at least in some of the sectors of the population. This solution is cost effective, simple with no contraindications or complications. Implementing the use of music requires additional time spent in the examination room, but taking into consideration that examining an infant with less anxiety is probably faster, the use of background music may even shorten the duration of entire procedure.

This study has a number of limitations:

- 1) The examination is subjective. Although, all the ear examinations were carried out by the same investigator and, hence, there were no deviations caused by various doctors' personality impact within the doctor-patient setting, indeed the whole system is subjective. Earlier works applied objective criteria, such as blood pressure and pulse measurements, blood tests examining hormone levels, etc. In our opinion,

these tests would increase infants' levels of anxiety, therefore we decided against their implementation.

- 2) The number of infants in some of the sub-groups was too small to reach conclusions.
- 3) The principal investigator was the clinician present in the room and was, in fact, part of the study. Therefore, plausibly

the clinician's behavior may have had an effect on the infants' anxiety levels and on the study results.

It is important to carry out additional studies to determine which sub-categories would benefit from a simple, cheap and safe technique as listening to background music during an ear examination.

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