

Evaluation of the Role of Music and Bach Flower Remedies in the Management of Anxious Pediatric Dental Patients: A Randomised Clinical Trial

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ABSTRACT

Objective: Dental fear and anxiety describe negative feelings towards the dental environment, particularly significant in pediatric dentistry due to their cognitive, behavioral, and physical impacts on children. Managing this anxiety through positive dentist-child relationships and behavioral guidance techniques is crucial. This study aims to evaluate the effectiveness of passive distraction using music and Bach flower remedy in reducing dental fear and anxiety in children aged 6-8 years.

Methods: This randomized controlled clinical study included 12 children (n=4 for each group) aged 6-8 years, randomly assigned to Group 1 (control), Group 2 (Bach flower remedy), or Group 3 (passive distraction with music) for treating superficial dentin caries in primary teeth without local anesthesia. Dental fear and anxiety levels were assessed using objective (heart rate, oxygen saturation, systolic and diastolic blood pressure) and subjective (Facial Image Scale and Venham's Picture Test) measures before and after treatment.

Results: The study included 12 children (6 female, 6 male) with a mean age of 7.3±0.8 years. In Group 2, heart rate significantly decreased after treatment (97.8 ± 10.1 to 90.5 ± 8.8, p<.05). However, no statistically significant differences were found between Groups 1, 2, and 3 in either objective or subjective measures when comparing before and after treatment results (p>.05).

Conclusion: In this study, although passive distraction with music and Bach flowers did not have a significant effect on physiological and projective measurement tools in children with dental fear and anxiety, a decrease in heart rate was observed in children exposed to Bach flowers.

Keywords: Dental fear, dental anxiety, Bach flower remedy, passive distraction with music

1. INTRODUCTION

Dental fear is defined as a reaction to a stimulus perceived as threatening, and dental anxiety is defined as the worry that something negative will happen in the dentist environment. Since it can be difficult to differentiate dental fear and anxiety in clinical situations, the term dental fear and anxiety (DFA) is used to describe negative feelings about the dentist environment. DFA is an important concept in pediatric dentistry and can result in cognitive, behavioral and physical reactions (1,2).

When DFA is considered from a clinical perspective; it causes patients to visit the dentist irregularly or totally avoid treatment, resulting in oral health problems, an increase in the prevalence of tooth decay and extraction, and a decrease in quality of life. At the same time, all these results require more complex treatment planning and may hinder the

physician's success. (1,3,4). The key to overcoming all these consequences is to manage DFA by developing a positive dentist-child relationship with an empathetic approach using behavioral guidance techniques (1,5,6).

Pharmacological behavior guidance techniques should not be preferred in the first step due to their undesirable side effects, risks, costs and invasive nature (4,7,8). Keeping these points in mind, in addition to traditional behavior guidance with documented success, it should be a priority to investigate innovative alternative complementary non-pharmacological behavior guidance techniques such as hypnosis, active and passive distraction, homeopathy and aromatherapy (7,9-11).

The distraction techniques are often used to shift the focus of the child away from the ongoing unpleasant treatment process and include music; video, or a combination of both

(passive distraction) and play therapy (active distraction) (8,9,12). Music theorists such as Bonny and Gfeller report that music distracts people from stressful stimuli and provides physical and mental relaxation. Classical music is used in neuroscience studies as a stimulant of the right temporal region, which is responsible for musical cognition, especially in terms of calming behavior (12). The use of music, one of passive distraction tools, is the subject of many medical and dental studies due to its effects on the mood and vital functions of the human body (8,13-15). Bach flower remedy as an aromatherapy is a complementary and alternative medicine practice developed by British homeopathic physician Dr. Edward Bach in the 1930s, when he discovered 38 essences from wildflowers (11). The practice was recognized by the World Health Organization (WHO) within the scope of Traditional Medicine Strategies in 2013 (16).

The need to further investigate alternative complementary behavior guidance techniques that will potentially contribute to the management of DFA and to obtain more information about these applications in the literature led us to this study.

The aim of this study is to evaluate the effectiveness of the use of passive distraction with music and Bach flower remedy in reducing DFA in children aged 6-8 years.

The null hypothesis of the study is that passive distraction with music and the use of Bach flower remedy have no effect on reducing DFA.

2. METHODS

This study received approval from the Clinical Research Ethics Committee of the Medical School of Tokat Gaziosmanpaşa University (Approval No. 22-KAEK-068 and dated 31.03.2022). The study was conducted in accordance with the Helsinki Declaration guidelines. The study complied with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Informed consent was obtained from all patients prior to the commencement of treatment.

The sample size was estimated using G Power software v.3.1.9.2. A minimum of 12 children was required to detect a significant difference using the “ANOVA: Fixed effects, omnibus, one-way” test, with a type I error (α) of 0.05, power (1-beta) of 95%, and effect size of 1.544 (11).

This randomized controlled clinical study was conducted at Tokat Gaziosmanpaşa University Faculty of Dentistry, Department of Pediatric Dentistry.

Inclusion Criteria:

- Systemically healthy children
- Children aged between 6 to 8 years
- Children with no previous dental experience
- Children with a Children’s Fear Survey Schedule (CFSS-DS) scale value of 35 and above

- Presence of carious lesions in primary molars on the mandibular quadrants that have recently passed from enamel to dentin and can be treated without the need for local anesthesia
- Children who voluntarily agree to work with parental consent

Exclusion Criteria:

- Children with any mental or physical disability
- Children with medication use
- Presence of essential oil allergy

Randomisation was performed by the researchers at the beginning of the study and children were randomly assigned to 3 groups via the “random.org” website, taking into account the order of application.

The CFSS-DS scale was used when the children came to the examination for the first time with the aim of identifying children with DFA (17). Fifteen questions on various aspects of dental treatment were directed to the child by a research assistant (research assistant responsible for the first examination who performs oral and dental examination of the child for the first time). The possible response to each item was scored from 1 (not afraid) to 5 (very afraid). Total scores ranged from 15 to 75 on this scale and 15 children who met the inclusion criteria and scored 35 and above were included in the study (Figure 1).

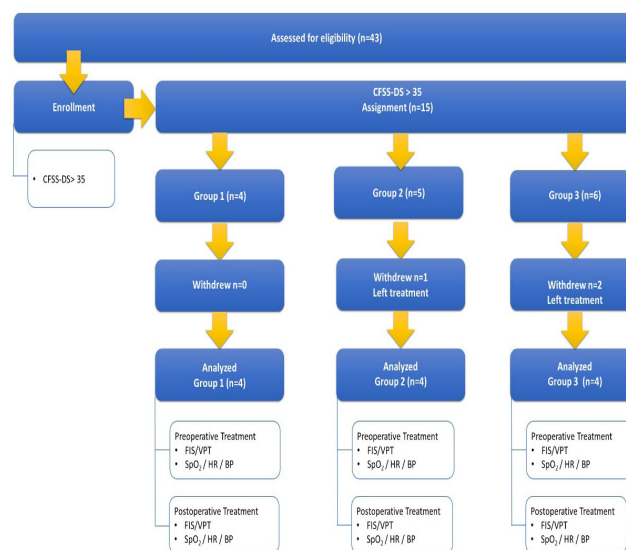


Figure 1. Study diagram

After the examination was completed, an appointment schedule was created for restorative treatments (superficial dentin caries). The assigned group information was delivered to the child and his/her parents in a closed envelope by the research assistant, taking into account the order of the child’s application and the group assigned from the random.org website.

Group 1: Children were treated with the traditional behavioural guidance technique of tell-show-do behaviour management technique (Control).

Group 2: Four drops of “rescue remedy (clematis, star of Bethlehem, impatiens, cherry plum, rock rose)” diluted in 40 mL of water were given orally 15 minutes before the treatment (Bach flower remedy).

Group 3: After the children were given a headset, classical instrumental music (In the Enchanted Garden – Kevin Kern) was played during the planned dental treatment (passive distraction with music).

When the pediatric patients were admitted to the unit for treatment, their dental anxiety was determined with the projective self-report scales Facial Image Scale (FIS) and Venham’s Picture Test (VPT) before and after treatment. With the FIS scale, children were shown a card with printed faces consisting of five faces ranging from very unhappy to very happy. They were asked to show which face they most resembled at that moment. The face with the most positive affect was given 1 point and the face with the most negative affect was given 5 points (18). The VPT scale, consisting of eight pairs of pictures of a child displaying each of the emotional states such as surprise, fear and anger in opposite ways, was shown to the children on the cards on which it was printed. The child was asked to choose one of the pair of pictures that best reflected how he/she felt at that moment, and if he/she chose the anxious picture from the pair of pictures, 1 point was given, and if he/she chose the non-anxious picture, 0 point was given. Thus, the score of the scale varied between 0-8 for each child (19).

For objective parameter measurement, vital signs of each child were evaluated before and after treatment. Heart rate (HR) and oxygen saturation (SpO₂) were recorded by pulse oximetry. Systolic blood pressures (SBP) and diastolic blood pressures (DBP) were determined using a stethoscope. All vital signs were documented by a research assistant (who do not know the intervention groups).

Treatments were carried out by a paediatric dentist with 9 years of experience (CBN) who opened the envelope before starting the treatment following projective self-report and objective measurements.

2.1. Statistical Analysis

Data analysis was performed using the IBM Statistical Package for the Social Sciences (SPSS for Windows, version 26.0, SPSS Inc., Chicago, IL, USA). Descriptive statistics, including frequencies and percentages for categorical data, as well as means and standard deviations for continuous data, were calculated. The normality of the data was assessed using the Shapiro-Wilk test. Participant characteristics were compared using Chi-square tests for categorical variables and one-way analysis of variance (ANOVA) for continuous variables. Paired samples t-tests and Wilcoxon tests were utilized to compare data before and after treatment within the group. One-way

ANOVA was employed to compare the differences in data before and after treatment between groups. A p values less than .05 was considered statistically significant.

3. RESULTS

A total of 12 children, 4 participants in each group, participated in the study (Figure 1). All demographic data of the participants are presented in Table 1. The mean age of the 12 children included in the study was 7.3 ± 0.8 years and there was no statistically significant difference between the groups ($p > .05$). When the genders of the participants were analysed, the number of females and males were equal in each group and no statistically significant difference was found ($p > .05$). When dental fear scores were analysed according to the CFSS-DS scale, the highest value was observed in Group 3 (39.8 ± 12.1) and the lowest value was observed in Group 1 (37 ± 14.7), but there was no statistically significant difference between them ($p > .05$).

Table 1. Characteristics of children included in the study

	Group			Test-statistics	p
	Group 1	Group 2	Group 3		
Age					
N (%)	4 (%33.3)	4 (%33.3)	4 (%33.3)	0.552	.594 ¹
Mean \pm sd	7.5 \pm 0.7	6.9 \pm 0.9	7.5 \pm 0.9		
Gender					
Female	2 (50%)	2 (50%)	2 (50%)		1 ²
Male	2 (50%)	2 (50%)	2 (50%)		
CFSS-DS					
N (%)	4 (%33.3)	4 (%33.3)	4 (%33.3)	0.057	.945 ¹
Mean \pm sd	37 \pm 14.7	37.5 \pm 9.5	39.8 \pm 12.1		
¹ One-way ANOVA					
² Chi-square test					
N: Number of the children, sd:Standart deviation, CFSS-DS: The Children’s Fear Survey Schedule					
p<.05 statistically significant					

When intra-group comparisons before and after treatment were analysed, no statistically significant difference was observed in Group 1 and Group 3 when both vital signs (SpO₂, HR, SBP, DBP) and anxiety scales (FIS, VPT) were considered ($p > .05$). In group 2, HR decreased statistically significantly ($p < .05$), while no statistically significant difference was observed in other vital signs (SpO₂, SBP, DBP) and anxiety scales (FIS, VPT) ($p > .05$) (Table 2).

The comparison of the differences between the groups in vital signs (SpO₂, HR, SBP, DBP) and anxiety scales (FIS, VPT) values before and after treatment is shown in Table 3. When the data obtained from the table are analysed, no statistically significant difference was observed between the groups ($p > .05$) when both vital signs (SpO₂, HR, SBP, DBP) and anxiety scales (FIS, VPT) were considered before and after treatment.

Table 2. Evaluation of intra-group before and after treatment dental fear and anxiety measurements

		Before		ΔChange	r	t/Z	p
		Treatment	Treatment				
Group 1	SpO ₂	92 ± 6.3	90 ± 3.8	2 ± 9.8	-0.888	0.407	.711 ¹
	HR	100 ± 6.3	91.5 ± 10.6	8.5 ± 10.1	0.380	1.686	.190 ¹
	SBP	99.5 ± 7.4	98.8 ± 21.5	0.8 ± 18.9	0.499	0.079	.942 ¹
	DBP	61 ± 10.8	66.8 ± 22.9	-5.8 ± 12.4	-	-0.73	.465 ²
	FIS	2.5 ± 1.9	1 ± 0	1.5 ± 1.9	-	1.567	.215 ¹
	VPT	2.5 ± 3.7	0 ± 0	2.5 ± 3.7	-	-1.633	.102 ²
Group 2	SpO ₂	95.3 ± 6.4	92.3 ± 14.3	3 ± 8.3	0.967	0.724	.521 ¹
	HR	97.8 ± 10.1	90.5 ± 8.8	7.3 ± 2.5	0.975	5.800	.010 ¹
	SBP	103.3 ± 19.8	93.8 ± 17.3	9.5 ± 6.6	0.946	2.897	.063 ¹
	DBP	75.8 ± 18.2	63 ± 3.9	12.8 ± 17.8	0.219	1.432	.247 ¹
	FIS	3.5 ± 1.7	1 ± 0	2.5 ± 1.7	-	2.887	.063 ¹
	VPT	3.5 ± 3.7	0.3 ± 0.5	3.3 ± 3.6	-	-1.604	.109 ²
Group 3	SpO ₂	96.5 ± 3.1	98 ± 2.2	-1.5 ± 2.4	0.645	-1.260	.297 ¹
	HR	91.3 ± 7.5	88 ± 7.1	3.3 ± 7.9	0.412	0.819	.473 ¹
	SBP	99.8 ± 3.6	96.3 ± 5.9	3.5 ± 4.7	0.606	1.504	.230 ¹
	DBP	69 ± 3.4	67.5 ± 5.1	1.5 ± 2.9	0.840	1.039	.375 ¹
	FIS	2.5 ± 1.9	1 ± 0	1.5 ± 1.9	-	1.567	.215 ¹
	VPT	3.5 ± 3.1	0.3 ± 0.5	3.3 ± 3.3	-	-1.841	.066 ²

¹Paired samples t test,²Wilcoxon test,

SpO₂: oxygen saturation; HR: heart rate, SBP: systolic blood pressure, DBP: diastolic blood pressure, FIS: Facial Image Scale, VPT: Venham's Picture Test
 ΔChange: difference between before and after treatment, r: correlation coefficient, t/Z: Test statistics
 p < .05 statistically significant

Table 3. Evaluation of the change in dental fear and anxiety measurements between groups

	ΔChange			F	p
	Group 1	Group 2	Group 3		
SpO ₂	2 ± 9.8	3 ± 8.3	-1.5 ± 2.4	0.392	.687
HR	8.5 ± 10.1	7.3 ± 2.5	3.3 ± 7.9	0.528	.607
SBP	0.8 ± 18.9	9.5 ± 6.6	3.5 ± 4.7	0.570	.585
DBP	-5.8 ± 12.4	12.8 ± 17.8	1.5 ± 2.9	2.172	.170
FIS	1.5 ± 1.9	2.5 ± 1.7	1.5 ± 1.9	0.387	.690
VPT	2.5 ± 3.7	3.3 ± 3.6	3.3 ± 3.3	0.060	.942

One-way ANOVA

SpO₂: oxygen saturation; HR: heart rate, SBP: systolic blood pressure, DBP: diastolic blood pressure, FIS: Facial Image Scale, VPT: Venham's Picture Test
 F: Test statistics

ΔChange: Evaluation of the change in dental fear and anxiety measurements between groups at baseline and after treatment
 p < .05 statistically significant

4. DISCUSSION

Dentistry fear and anxiety in children may result in poor oral health, as well as negative effects on nutrition, sleep disturbance, delay in growth and development, and peer bullying due to the appearance of their teeth (1,4). Due to these results of DFA and the important role of the physician in its management, empirical studies have also been the subject of research, in addition to the increasing evidence of non-pharmacological behavior guidance techniques, in order

to manage this situation and create a positive treatment experience in children (13,16,20).

In this study, the effectiveness of distraction with music and the use of Bach flower remedy was evaluated in pediatric patients with DFA between the ages of 6-8. It has been reported that children at 4-8 years exhibit the most negative behaviors during dental procedures and are the most difficult to manage (21,22). However, considering that the mental status of 4-year-old children is different from 8-year-old children and that cognitive development is insufficient in terms of the reliability of subjective scales in young children under 6 years of age (7,21), the study was conducted on children in the 6-8 age group. In pediatric patients with DFA, a single session and a procedure without local anesthesia was preferred for all children in order to minimize the variables and the importance of performing a simple, painless procedure at the first appointment planned to help them get used to the dentistry environment (16). Considering that anxiety is a two-way psychological and physiological structure, that its physiological component is objectively measured by central nervous system activity, heart rate and respiration, and that measurement tools are used in its psychological component, objective and subjective measurement tools were used together in the evaluation of DFA in the study (4,23,24).

When considering the data obtained from the group in which passive distraction with music was applied in this study, no significant effect was observed although a decrease was observed in the objective-subjective values of DFA. These results are in contradiction with many studies examining the positive effects of distraction with music on anxiety in pediatric patients (4,23,25). In addition, study results showing that music is not an effective tool in reducing anxiety in pediatric patients consistent with the results of this study were presented. In their study examining the effect of listening to music on anxiety in children aged 4-6 in three groups, relaxing music, active music and a control group, Aitken et al. (26) showed that distraction with music did not have a significant effect on anxiety. Similarly, Gupta et al. (6) examined the effect of listening to music on anxiety in children aged 3-7 in three groups: control group, active music group and relaxing music group, and revealed that distraction with music did not have a significant effect on anxiety. When evaluating all these studies, consistent and contradictory with our study results, contradictory results may have been produced due to the number of samples used, patient pool and methodological differences (13,26). The results obtained with the music group in this study may be related to many issues. The limited number of samples, which is among the limitations of the study, may have been the first parameter that affected the result. Due to concerns about the Bach flower remedies in the empirical group of the study, the calculated but limited sample size was not increased. The main cause for concerns is the lack of insufficient data on the application method of the remedy in pediatric patients since the Bach flower remedies have been used in only one study in the literature and it is the first study conducted in the field of dentistry in our country. Secondly,

unlike Singh et al. (25), Jindal and Kaur (23), Janthasila et al. (4), the choice of music was not left to the patient's choice, which may have affected the results. Klein and Winkelstein (27) suggested that when the music selection is made by the child himself/herself, it will help the child gain control over an unpleasant situation. In addition, it has been demonstrated that classical music has a direct effect on the cardiovascular system and respiratory responses, thus acting as a calming and psychosomatic regulator and reducing the effects of sensory stimuli (12). Contrary to all these generalizations that can be made about music, reactions to music are individual and context-dependent; Variations depending on personality, experience, environment, age, taste and cultural background may have affected the study results (13). Finally, patient selection may have affected the results. In the light of current literature, it has been suggested that children's coping styles should be taken into account when using distraction tools. It has been reported that children can be considered in two main points as those who prefer to know what will happen during dental procedures and those who prefer to focus their attention elsewhere, and this issue should be addressed when choosing the behavior guidance technique (1). When all studies, including this study, were examined, this issue was not taken into account.

Considering the data obtained in the Bach group, although a decrease was observed in the subjective values of anxiety, no significant effect was obtained; however, significant difference was obtained in heart rate from vital signs. Since heart rate is a direct measure of physiological arousal and its increase has been associated with stress during dental treatment, these results may have provided important data for studying Bach flower remedies in larger sample groups. In the study of Dixit and Jasani (11), the only study in the literature that deals with Bach flowers on dental anxiety, discussed Bach flowers in three groups as music and control groups in their study and evaluated anxiety measurement tools as preoperative, intraoperative and postoperative. As in the study of Dixit and Jasani (11), rescue remedy from Bach flowers was preferred in this study. "Rescue Remedy", also known as "Five Flower Remedy" is the combination of star of Bethlehem (*Ornithogalum umbellatum*), rock rose (*Helianthemum nummularium*), impatiens (*Impatiens glandulifera*), cherry plum (*Prunus cerasifera*), and clematis (*Clematis vitalba*). It is the only combination of Bach flower remedies identified by Bach himself and has become the preferred choice as it is recommended as a multi-purpose emergency agent in cases of acute anxiety. Considering the results of the Bach group in the Dixit and Jasani study (11), no significant difference was obtained postoperatively in the anxiety self-report measurement tool FIS values compared to the control group. Among the objective measurement tools, only intraoperative significant difference was obtained in pulse rate values, but no significant difference was obtained in systolic blood pressure values. When the music group results were considered in the same study, no significant postoperative difference was observed in FIS values compared to the control group. Significant differences were

obtained only in intraoperative values of pulse rate values and systolic blood pressure values, which are objective measurement tools. When the results of Dixit and Jasani's study (11) and this study are considered together, as the authors we think that the effect of the use of Bach flowers and music is open to discussion. In this study, unlike Dixit and Jasani (11), intraoperative evaluation was not made using subjective-objective anxiety tools, but evaluation was made based on preoperative-postoperative data. This choice was influenced by the fact that the empathic language used between the physician and the patient during the treatment was not interrupted and the possibility that the continuous physiological measurement tools throughout the treatment could increase the patient's anxiety. In addition, as a negative consequence of this choice, children may not have been able to transfer the positive experience they had during the appointment to the post-treatment scales, as they were able to choose a score based on their experience in the last few minutes of the appointment instead of the entire session (26).

In addition to the group-specific conditions that may have affected the above-mentioned results, sufficient effect may not have been obtained from behavioral guidance techniques as the patient pool selected was children with DFA, unlike other studies. At the same time, unlike this study, homogeneity was not achieved in the study groups before treatment in many studies (16,23,25).

When the results of the study were evaluated, it was revealed that musical distraction and Bach flower remedies had no measurable effect on anxiety in children aged 6-8 years. In addition, although there was no significant effect was obtained on anxiety, the Bach flower remedy and passive distraction with music had a positive effect and has been received with pleasure. Contrary to the concerns about Bach flower remedies, parents easily accepted the rescue remedy in the hope that it would benefit their children's treatment anxiety. They were also very interested in the rescue remedy and wondered whether it would provide relief from everyday situations that cause anxiety for both them and their children. Children said that listening to music and Bach flower remedies could be tried again at the next appointment.

When all the results are evaluated; we think that further research should be conducted and new strategies should be designed, taking into account children's coping styles, using higher sample numbers in different age groups, or using alternative behavior management techniques together.

This study has some limitations. The sample group consisted of a small number of child patients within a limited age range. Another limitation is that Bach flower remedies were used only once before the treatment, due to insufficient information in the literature about the anxiety treatment protocol.

5. CONCLUSION

In this study, we attempted to evaluate the use of Bach flowers and passive distraction with music. Although passive distraction with music and Bach flowers did not have a significant effect on physiological and projective measurement tools on children with DFA, the statistical decrease in heart rate in children subjected to Bach flowers should be considered as a result that should be interpreted correctly. There is a need to investigate non-pharmacological behavior guidance techniques in the management of DFA, which is an important issue in pediatric dentistry.

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Ethics Committee Approval: This study was approved by Ethics Committee of the Medical School of Tokat Gaziosmanpaşa University, Clinical Research Ethics Committee (Approval date: 31.03.2022; Number: 22-KAEK-068)

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Author Contributions:

Research idea: CBN, SA

Design of the study: CBN, SA

Acquisition of data for the study: CBN

Analysis of data for the study: CBN

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Drafting the manuscript: CBN, SA

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