

Comparison of the effectiveness of Bach flower therapy and music therapy on dental anxiety in pediatric patients: A randomized controlled study

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ABSTRACT

Background: Dental anxiety is a primary cause of missed dental appointments, delayed treatment, and untreated dental caries in children. Alternative techniques such as music therapy (MT) and Bach flower therapy (BFT) have potential to reduce anxiety. Lack of randomized controlled studies evaluating effectiveness of these methods in reducing dental anxiety led us to this study. **Aim:** To compare the effectiveness of BFT and MT on reduction of dental anxiety in pediatric patients. **Materials and Methods:** A total of 120 children (aged 4–6 years) were selected and randomly allocated to three groups: BFT, MT, and control. All children received oral prophylaxis and fluoride treatment. Dental anxiety was evaluated using North Carolina Behavior Rating Scale, Facial Image Scale (FIS), and physiological parameters. **Results:** Significantly better behavior was seen in children from the BFT group as compared to the control group ($P = 0.014$). FIS scores measured postoperatively did not show significant differences among the groups. Children from the BFT and MT groups showed a significant decrease in the pulse rates intraoperatively from the preoperative period. Intraoperative systolic blood pressure in children from the MT group was significantly lower than both the BFT and the control groups. Diastolic blood pressure significantly increased in the control group intraoperatively, whereas other groups showed a decrease. **Conclusion:** The results of this study demonstrate significant effects of both single dose of BFT and exposure to MT, on reduction of dental anxiety in children aged between 4 and 6 years.

KEYWORDS: Bach flower therapy, behavior, behavior management, child, dental anxiety, distraction, music therapy

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Introduction

Children with dental anxiety have been found to miss their dental appointments, suffer from poor oral health, have frequent episodes of pain and swelling, and generally have low quality of life.^[1] The prevalence of dental anxiety in children varies from 6.3% to 43%.^[2-5] Dental anxiety is seen to decrease with increasing age.^[6]

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Dixit and Jasani: Music distraction, Bach flower therapy, and dental anxiety

Dental anxiety in children results in more behavioral problems during dental treatment^[7] and considerable stress in treating dentists.^[8] Dental anxiety is shown to be an important reason for the treatment of children under general anesthesia.^[9] However, pharmacological techniques have higher risks and involve higher costs and therefore are not easily accepted by the parents.^[10]

Alternative complementary nonpharmacological techniques, including hypnosis, music therapy (MT), audiovisual distraction, acupressure, and homeopathic and ayurvedic remedies, for managing anxiety are gaining popularity on the merit of being noninvasive.

Music interventions provide a viable alternative to sedatives and anti-anxiety drugs for reducing preoperative anxiety in patients awaiting surgical procedures.^[11] However, very few randomized controlled studies are available that evaluate the effect of music on dental anxiety in children.

Bach flower therapy (BFT) was developed by Dr. Edward Bach.^[12] He believed that most human illnesses are caused by negative states of mind and could be cured if related negative feelings are alleviated with the help of the flower remedies derived from the naturally grown flowers from the wild.

Flower remedies are classically prepared in water in two ways: the sun method and the boiling method.^[13] The water is believed to retain the vibrations or energy of the flower. According to Bach, this vibration interacts on a subtle energy level with the individual to rebalance the conscious and unconscious and dissolve old patterns of behavior.^[14] The remedies can be taken diluted in water and consumed orally or applied directly on pulse points such as the wrists, temples, and behind the ears.^[15]

Rescue remedy is the combination of five remedies, namely, star of Bethlehem (*Ornithogalum umbellatum*), rock rose (*Helianthemum nummularium*), impatiens (*Impatiens glandulifera*), cherry plum (*Prunus cerasifera*), and clematis (*Clematis vitalba*). It functions as an emergency remedy in events of acute anxiety or distress.^[14]

Randomized controlled trials are available in the literature that have studied the efficacy of rescue remedy or other flower remedies in alleviating situational anxiety, symptoms of attention-deficit hyperactivity disorder (ADHD), pain, or other psychological illnesses. A randomized controlled trial reported no benefits of rescue remedy in the reduction of trait anxiety, when applied on tongue every 20 min for 3 h, as compared to a placebo. However, the authors reported a significant reduction in anxiety in students with high levels of anxiety at the baseline.^[16] Rescue remedy was recommended for children as a preventive

measure before a dental or medical appointment, a surgery, or examination.^[17]

A systematic review by Thaler *et al.* concluded that available evidence failed to show efficacy of Bach flower remedies over placebo in reducing pain and anxiety in adults. However, they commented that this conclusion was associated with a high level of uncertainty due to lack of methodologically sound trials.^[18]

Potential of both MT and BFT in alleviating dental anxiety in children and inconclusive evidence in the literature led us to this study. The aim of this study was to compare the effectiveness of BFT and MT with the control group, where no intervention was used, on reduction of dental anxiety in children between the age of 4 and 6 years.

Materials and Methods

Study design

This study was designed as a randomized controlled study with three parallel groups and was approved by the University Ethical Committee. Selected children were randomly allocated to three groups (1:1:1) using block randomization method with thirty blocks of four participants each. Three groups, namely, BFT, MT, and control, were assigned forty children each, irrespective of their age, sex, or the baseline anxiety level. Allocation table was held by a senior faculty of the department, who was not involved in the study.

Although the operator and children could not be completely blinded due to the nature of the interventions, attempts were made to do so. Outcome assessors were blinded to the interventions used.

Participants

A total of 120 children visiting the department and fulfilling the selection criteria were selected for this study. Healthy children between the age of 4 and 6 years, having no prior experience of dental visit, and indicated for dental treatment including oral prophylaxis and fluoride treatment were included in the study. Children with significant medical history or taking any medications were excluded from the study.

Parents of the selected children were informed regarding the purpose and the course of the study. Informed consent was obtained from the parents who agreed to allow their children to participate in the study.

Interventions

- BFT group: Children from this group were administered orally four drops of “rescue remedy” diluted in 40 mL of water 15 min before the treatment. Children were asked to wear headphones without playing any music during the dental treatment

- MT group: Children from this group were provided with a headphone, and Indian classical instrumental music (Raag Sohni played by Pandit Shiv Kumar Sharma on santoor) was played during the scheduled dental treatment. Children were also given 40 mL plain water to drink 15 min before the treatment
- Control group: Children from this group were given 40 mL plain water 15 min before the treatment. During the treatment, children were asked to wear the headphone without playing any music.

Children from all the groups received oral prophylaxis and fluoride treatment uniformly. Baseline dental anxiety of children from all the groups was assessed using Children's Fear Survey Schedule-Dental Subscale.^[19] This was a 15-item questionnaire consisting of questions pertaining to anxiety related to various aspects of dental treatment. Questionnaire was filled by a trained assistant after asking the questions directly to the child. The possible response to each item was scored between 1 (not afraid) and 5 (very afraid). The total scores ranged between 15 and 75. Children with a score of 38 or above were considered to be anxious.

Outcome assessment

Operator-evaluated dental anxiety

Dental anxiety in children during the procedure was assessed as child's behavioral display, scored by two trained assessors with the North Carolina Behavior Rating Scale (NCBRS).^[20] This was determined as a primary outcome of this study. The outcome assessors were blinded to the type of intervention used. The assessors independently viewed the recorded videos of the treatment and noted occurrence of each of the four disruptive behaviors, every 30 s. NCBRS score for each patient was then calculated as an average of the scores recorded by the two assessors.

Patient-reported dental anxiety

Dental anxiety of children from all three groups was measured using Facial Image Scale (FIS) before and

after the dental procedure. FIS comprises a row of five faces ranging from very unhappy to very happy.^[21] Each child was shown this card with printed faces and was asked to point at which face he/she felt most like at that moment, assigning score 1 to the most positive affect face and 5 to the most negative affect face.

Standard behavior modification techniques including tell-show-do and contingency management were used for all children undergoing the treatment irrespective of the assigned group.

Physiological outcomes

Vital signs were recorded for each child preoperatively (in the waiting area 15 min prior), intraoperatively, and postoperatively (15 min after completion). Pulse rate and oxygen saturation were recorded with the help of a pulse oximeter. Systolic and diastolic blood pressures were recorded using a manual sphygmomanometer and a stethoscope. All vital signs were recorded by a trained assistant, who was blinded to the intervention.

Statistical analysis

Normality of the distribution was evaluated with Kolmogorov-Smirnov test for continuous variables. FIS scores (categorical ordinal), NCBRS scores (continuous), and various physiological parameters (continuous) were analyzed statistically with intra- and intergroup comparisons. Comparisons in pre- and postoperative FIS scores across the three groups were performed using Chi-square test. NCBRS scores were compared across the three groups using Kruskal-Wallis test. Pair-wise comparisons were made with Mann-Whitney test. Significance level was determined at 0.05.

Results

Distribution of sample

Table 1 presents group-wise comparison of characteristics of children included in the study. Distribution of children among the three groups was found to be uniform according to gender and baseline

Table 1: Characteristics of children included in the study

Characteristics	Groups			Comparison
	BFT	MT	C	
Age in months (mean±SD)	58.4±1.3	62.8±1.3	63±1.4	ANOVA: $P=0.024$ Pair-wise comparison BFT-MT: $P=0.072$ BFT-C: $P=0.05$ MT-C: $P=0.99$
Gender (%)				
Males	25 (62.5)	22 (55)	26 (65)	$\chi^2=0.909$, $P=0.635$
Females	15 (37.5)	18 (45)	14 (35)	
CFSS-DS score (mean±SD)	20.9±1.53	17.7±0.55	20.3±1.1	ANOVA: $P=0.114$

BFT=Bach flower therapy; MT=Music therapy; SD=Standard deviation; CFSS-DS=Children's Fear Survey Schedule-Dental Subscale

anxiety score. Pair-wise comparison revealed statistical difference in the mean age of children in the BFT and the control groups ($P = 0.05$). No statistical differences were found between the BFT and control and between BFT and MT groups.

Child's behavior during procedure

Table 2 presents comparison of NCBRBS scores between the three groups. Pair-wise comparisons showed that behavior was significantly better in children from the BFT group as compared to those in the control group ($P = 0.014$). No differences were found in the behavior between the BFT and MT groups and the MT and the control groups.

Patient-reported dental anxiety

All three groups showed a decrease in the patient-reported dental anxiety at the postoperative time period as compared to the preoperative

time period. Table 3 presents comparison of frequency of children in different FIS categories at postoperative time period across all three groups. No statistical difference was found among the three groups ($P = 0.243$).

Physiological parameters

Pulse rate

Preoperatively, the mean pulse rates of children from all three groups were statistically similar. In both the BFT and MT groups, participants exhibited a statistically significant decrease in the pulse rate intraoperatively ($P < 0.001$ for both). In children from the control group, however, the pulse rate showed a significant increase intraoperatively ($P < 0.001$). Postoperatively, the pulse rate decreased in children from all three groups, with BFT group showing a statistically significant decrease as compared to the preoperative pulse rate ($P < 0.001$).

Between-subjects comparisons in the pulse rates across the three groups revealed that intraoperatively, the mean pulse rate of children in the control group was significantly higher than that from the BFT group ($P < 0.001$) and MT group [$P < 0.001$; Table 4].

Oxygen saturation

Oxygen saturation values of the children from the BFT group were statistically significantly higher than those of the children from the control group

Table 2: Comparison of North Carolina Behavior Rating Scale scores of child's behavior measured during the dental procedure between the three groups

Groups	NCBRBS score, mean±SD (95% CI)	Statistical comparison
BFT (n=40)	0.5±0.5 (0.35-0.66)	Kruskal-Wallis $\chi^2=6.543$, $P=0.03$ Pair-wise comparison: BFT-MT: $P=0.298$ BFT-C: $P=0.014$ MT-C: $P=0.165$
MT (n=40)	1.88±0.9 (1.6-2.2)	
C (n=40)	5.98±2.4 (5.2,-6.7)	

NCBRBS=North Carolina Behavior Rating Scale; BFT=Bach flower therapy; MT=Music therapy; SD=Standard deviation; CI=Confidence interval

Table 3: Comparison of postoperative patient-reported dental anxiety as measured by Facial Image Scale among the three groups

FIS score	Frequency of postoperative FIS scores			Cramer's test
	BFT (n=40), n (%)	MT (n=40), n (%)	C (n=40), n (%)	
0=very happy	28 (70)	19 (47.5)	24 (60)	$V=0.182$, $P=0.243$ (NS)
1=happy	7 (17.5)	16 (40)	10 (25)	
2=neutral	4 (10)	5 (12.5)	6 (15)	
3=sad	0 (0)	0 (0)	0 (0)	
4=very sad	1 (2.5)	0 (0)	1 (0)	

NS=Not significant; BFT=Bach flower therapy; MT=Music therapy; FIS=Facial Image Scale

Table 4: Effects of group and time on the mean pulse rates of children in the three groups

Time periods	Pulse rate, mean±SD			Statistical analysis		
	BFT	MT	C	Group-wise comparison	Mean difference (SE)	Significance
Preoperative	109.2±11.6	105.5±13.6	108±12.6	BFT-MT	3.7 (2.8)	0.597 (NS)
				BFT-C	1.2 (2.8)	1 (NS)
				MT-C	-2.4 (2.8)	1 (NS)
Intraoperative	100.8±11.7	98.4±13	113.1±11.6	BFT-MT	2.5 (2.7)	1 (NS)
				BFT-C	-12.3 (2.7)	<0.001 (S)
				MT-C	-14.8 (2.7)	<0.001 (S)
Postoperative	103.9±12.3	102.9±13.5	108.3±11.8	BFT-MT	1 (2.8)	1 (NS)
				BFT-C	-4.4 (2.8)	0.35 (NS)
				MT-C	-5.4 (2.8)	0.167 (NS)

NS=Not significant; BFT=Bach flower therapy; MT=Music therapy; SE=Standard error; SD=Standard deviation; CI=Confidence interval

at preoperative ($P = 0.007$) and postoperative time periods [$P = 0.011$; Table 5]. Other comparisons between the groups were statistically not significant.

Blood pressure

Table 6 presents systolic blood pressure values for children in the three groups at the three time periods. Preoperative systolic blood pressure was significantly higher in children from the BFT group than those in the MT group ($P < 0.001$). Intraoperatively, systolic blood pressure in children from the MT group was found to be the lowest and statistically different than that from the BFT ($P = 0.024$) and the control ($P = 0.001$) groups. No significant differences were found in the postoperative systolic blood pressure values among children in the three groups.

In children from the BFT and MT groups, diastolic blood pressure decreased than the preoperative levels [Figure 1]. In the control group, however, diastolic blood pressure increased intraoperatively from the preoperative level. Intraoperatively, diastolic blood pressure in children from the control group was the highest and statistically different than the MT group ($P = 0.016$). Postoperatively, children from the MT group exhibited the lowest diastolic blood pressure and difference between the MT and the BFT was statistically significant ($P = 0.006$).

Discussion

Assessment of dental anxiety caused by a dental procedure in children is complex. Pain during such a procedure may accentuate the dental anxiety, reducing the reliability of the instrument. In our study, we attempted to eliminate or minimize the effect of pain by including a painless procedure like oral prophylaxis and fluoride treatment. Although painless, it has a

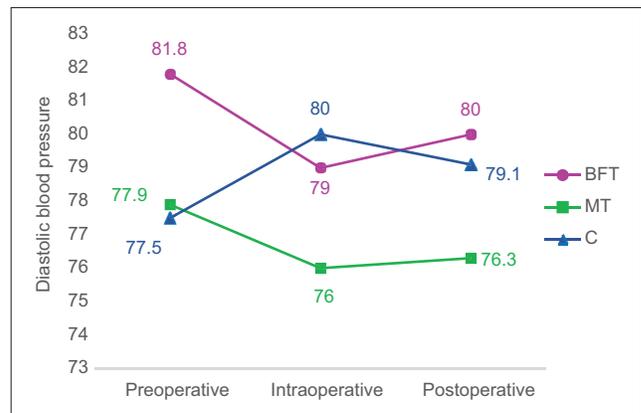


Figure 1: Variation of the mean diastolic blood pressure measured at preoperative, intraoperative, and postoperative time periods in children of the three groups included in the study

Table 5: Pair-wise comparison of oxygen saturation measured at the three time periods (preoperative, intraoperative, and postoperative) between the three groups

Time periods	Oxygen saturation, mean±SD			Statistical analysis	
	BFT (n=40)	MT (n=40)	C (n=40)	Group-wise comparison	Significance
Preoperative	99.1±0.78	98.3±1.99	98.1±1.99	BFT-MT	0.216 (NS)
				BFT-C	0.007 (S)
				MT-C	0.285 (NS)
Intraoperative	98.9±1.38	98.6±2.34	98.8±1.68	BFT-MT	0.81 (NS)
				BFT-C	0.867 (NS)
				MT-C	0.631 (NS)
Postoperative	98.8±1.83	98.6±1.99	98.3±1.33	BFT-MT	0.666 (NS)
				BFT-C	0.011 (S)
				MT-C	0.058 (NS)

NS=Not significant; BFT=Bach flower therapy; MT=Music therapy; SD=Standard deviation

Table 6: Comparison of systolic blood pressure (mean), measured at the three time periods (preoperative, intraoperative, and postoperative) between the three groups

Time periods	Systolic blood pressure, mean±SD			Statistical analysis	
	BFT (n=40)	MT (n=40)	C (n=40)	Group-wise comparison	Significance
Preoperative	115.5±8.0	109±6.0	112.3±7.4	BFT-MT	$P < 0.001$ (S)
				BFT-C	$P = 0.119$ (NS)
				MT-C	$P = 0.04$ (NS)
Intraoperative	113.2±8.8	108.5±5.4	113.7±6.8	BFT-MT	$P = 0.024$ (S)
				BFT-C	$P = 0.491$ (NS)
				MT-C	$P = 0.001$ (S)
Postoperative	113.1±7.6	110±7.1	112.2±8.5	BFT-MT	$P = 0.085$ (NS)
				BFT-C	$P = 0.579$ (NS)
				MT-C	$P = 0.288$ (NS)

NS=Not significant; BFT=Bach flower therapy; MT=Music therapy; SD=Standard deviation; S=Significant; CI=Confidence interval

potential to evoke dental anxiety. All children were rendered the same treatment to minimize the variation.

Our results revealed significant effects of both BFT and MT, on children's behavior during dental treatment. Because the dental treatment rendered in our study did not evoke pain, the child's behavior could be assumed as sole reflection of his/her dental anxiety.

Only one study was found in the literature that evaluated the effect of music on behavior of children during dental treatment.^[11] These authors reported no significant difference in the behavior when exposed to music as compared to the control children. The authors themselves described the limitations of the study that children were exposed to music only for 5 min during dental treatment. Furthermore, their dental treatment included a pain-provoking restorative procedure with administration of local anesthesia.

We did not find any published study evaluating BFT on children's behavior in the dental setting. One randomized control study that attempted to compare the effects of "rescue remedy" on children with ADHD reported no significant change in children's behavioral performance as evaluated by teachers.^[22]

Our results failed to show any effect of the interventions on the patient-reported dental anxiety. Previous study evaluating the effect of MT on patient-reported dental anxiety, as measured by Venham Picture Test, also reported no significant effects.^[23] However, Jindal and Kaur reported significant effect of MT on reduction of dental anxiety, as measured by Venham Picture Test, in children between 4 and 8 years of age.^[24]

A randomized control study by Toyota, where adult patients scheduled for surgery were administered either rescue remedy or plain water before surgery, showed no significant differences in anxiety and tension of the patients, as measured by visual analog scale, between the two groups. This is the only study, by far, that has used only one dose of "rescue remedy" in an attempt to reduce anxiety.^[25]

In our study, interestingly, patient-reported dental anxiety showed a decrease in the dental anxiety of children once exposed to oral prophylaxis and fluoride treatment, irrespective of the intervention. Contrary to our findings, Aitken *et al.*^[10] reported no significant changes in the patient-reported anxiety, as assessed by Venham Picture Test, between preoperative and postoperative periods in their music distraction study. The dental treatment included in their study was restorative treatment that required administration of local anesthesia. This stresses the importance of subjecting a dentally anxious child to a simple, painless dental procedure in the first scheduled appointment to make him/her acclimatize to the dental setting. Such an exposure would help in the reduction of child's

dental anxiety. However, patient-reported scales for younger children may lack sufficient sensitivity to measure child's anxiety, as child might select a score based on his/her experience at the last few minutes of the appointment instead of the entire span of the appointment.

Our results revealed that both BFT and MT resulted in lowering of pulse rate, systolic pressure, and diastolic pressure in children during the dental procedure as compared to their preoperative levels.

Previous studies evaluating the effect of MT on dental anxiety in children reported no significant decrease in the intraoperative pulse rates when compared to the control group.^[23,26] This could be explained by the fact that the treatments rendered in their studies were pain provoking, that included administration of local anesthesia, and were not uniform across the groups. Use of such pain-inducing treatments could have a significant effect on the physiological parameters that would mask the effects of dental anxiety. It is believed that pain or vasoconstriction can increase the pulse rate and thus affect the results. Furthermore, in the study by Aitken *et al.*, they exposed children in their test group to music for 5 min during dental treatment, which could be insufficient duration to cause any changes in the physiological parameters.^[10]

Similarly, other studies that used music to alleviate anxiety in adults during dental treatment did not show any significant decrease in the physiological parameters intraoperatively.^[27,28] These studies included invasive treatments such as surgical third molar extractions and root canal treatments, again masking the anxiety alleviating the effect of music. As we used a noninvasive and painless procedure for dental treatment and kept it uniform across the groups, the changes in the physiological parameters can be entirely attributed to the dental anxiety in our sample.

Both BFT and MT had no appreciably clinically significant effects on oxygen saturation in our study. Situations of great anxiety in apprehensive patients may lead to hyperventilation and respiratory alkalosis. Some authors have observed changes in oxygen saturation at various stages of surgical removal of mandibular third molars.^[29] However, previous research in children has found no such changes during checkups, restorative treatment, or extractions.^[30,31]

The psychophysiological responses produced by anxiety are associated in general with an increase in the activity of the sympathetic branch of the autonomic nervous system, which causes increase in the level of catecholamines and leads to increase in the physiological parameters such as the pulse rate and blood pressure.^[32] Studies conducted to find changes

in physiological parameters during dental treatment due to anxiety in children have found increase in the heart rate and blood pressure. No changes in the oxygen saturation level and respiratory rate have been found.^[31] In a study to evaluate the reduction of presurgical anxiety with rescue remedy in adult surgery patients, no reduction in either the pulse rate or the blood pressure was observed.^[25] No other study has reported the effects of Bach flower remedies on physiological parameters.

Conclusion

This randomized controlled study found significant effects of both single dose of BFT and exposure to MT, on reduction in the dental anxiety in children aged between 4 and 6 years. Reduction in the dental anxiety was demonstrated by better behavior of children, decrease in the pulse rates, and blood pressure during dental treatment. Patient-reported dental anxiety measured by FIS did not show any significant differences between the groups. Our findings suggest that physiological parameters and behavior scoring during dental treatment are reliable methods to assess dental anxiety.

Further investigations are required to evaluate the effects of these interventions on pain-provoking, complex dental treatments, to evaluate if they can be effective in the reduction of both pain and anxiety.

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Conflicts of interest

There are no conflicts of interest.

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