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A Crossover Randomized Study to Assess the Effect of Music and Aromatherapy on Pain and Anxiety Scores in Children Who are Under-Going Various Dental Procedures under Local Anesthesia

Seethal Rajan[1], Pulkit Jhingan[2], Manvi Malik[3], Shivani Mathur[4]

[1]Resident Pedodontist
rajanseethal[at]gmail.com

[2]Reader
dr.pulkitjhingan[at]its.edu.in

[3]Reader
dr.manvimalik[at]its.edu.in

[4]Professor and Head of the Department
dr.shivanimathur[at]its.edu.in

Abstract: ***Aim: To assess the efficacy of combining aromatherapy and music therapy in children who are undergoing invasive dental procedures. Design: This in-vivo cross-over experimental study was done on 30 patients in the age group of 6-12 years. All of them were given 3 interventions (Group 1-plain water +no Music Therapy/ Aromatherapy, Group 2-Music Therapy, Group 3-Aromatherapy+ Music Therapy) which was separated by 1week. The initial and final responses were scored by the FLACC score. During the administration of L. A, the SEM score were assessed and after completion of the procedure the child was asked to score WBFS. Results: On Intergroup comparison of initial and final FLACC score among the three groups, initial FLACC was not significant, final FLACC score of Group 3 showed statistically significant difference when compared to Group 2 and Group 3. Intergroup comparison of SEM score was statistically significant in Group 3 > group2 > group1 and Intergroup comparison of WBFS score was statistically significant for Group 3 > group 2 >group 1. Conclusion: Combination of aromatherapy and music therapy has the potential to modify the behavior of a child.***

Keywords: Pain, Anxiety, Relaxation therapy, Behaviour modification, Aromatherapy, Music therapy

1. Introduction

Pain is defined as an unpleasant emotional sensory experience, in relation to actual or potential damage that can range from mild discomfort to agony.

American Pain Society and New JCAHO (Joint Commission on Accreditation of Healthcare Organizations) defined it as the fifth vital sign which is very crucial in understanding the physiology of the body. But excessive pain can lead to negative mood conditions such as stress, isolation, anxiety, fear and lack of co-operation. In children it can cause changes such as increase in BP, heart rate, respiratory rate, insomnia, restlessness, nutritional problems etc.

There are multiple options in pharmacological and non-pharmacological techniques that are been practiced to modify the behaviour of uncooperative child. However, the non-pharmacological alternatives have gained a lot of importance over the years. Few of the techniques used in dental and medical practices includes massages, positioning, acupuncture, Cognitive behavioural therapy, mindfulness-based stress reduction, acceptance and commitment therapy, guided imagery, aromatherapy, music therapy etc.

Inhalational Aromatherapy is a technique in which essential oils are used for inhalation, which may aid in decreasing pain, mental stress, and depression, and improve vital signs. Amongst numerous flavours of essence that are available such as lemon grass, eucalyptus, tea tree oil, Lavender (Lavandula Angustifolia) which is an aromatic plant that belongs to the Lamiaceae family exhibits anti-bacterial, anti-fungal, anti-bloating, muscle relaxant, and analgesic effects and amongst multiple properties other properties its best preferred over the others since it can be safely used in children. Similar effects are also found in Music therapy. Among the various forms of music therapy have been practiced in the field of medicine over the years, such as instrumental music, white noise, audio analgesia, prelude, Celtic music etc, Indian classical music has been proven to be effective in modifying moods of an individual. Combining musical and aromatherapy therapy is expected to have a stronger effect in the reduction of anxiety and non-invasive hemodynamic changes, since utilizing the mechanism through smell and hearing have direct contact with the part of the brain in-charge of stimulating the formation of effects induced by music therapy and aromatherapy.

Thus the aim of the study is to examine the combination effect of music and aromatherapy on managing anxiety and

pain levels during the administration of local anesthesia (LA) in children undergoing various dental procedures.

2. Material and Methodology

The present study was an in-vivo cross-over experimental study. The clinical trial ID for this study is

Participants

The study was conducted on 30 children of the age group 6-12 years who require at least 3 appointments on various invasive dental procedures under Local Anesthesia and was conducted in the Department of Pediatric and Preventive Dentistry, I. T. S – Centre for Dental Studies and Research, Muradnagar.

Sample Size:

Sample size was determined based on the results of the pilot study using the following formula: $N = \frac{(\sigma 1^2 + \sigma 2^2)(Z_{1-\alpha/2} + Z_{1-\beta})^2}{\Delta^2}$. Using the above formula we have found the sample size for each group to be 28 which is rounded off to 30 and total 90 interventions was administered on 30 children.

Inclusion criteria

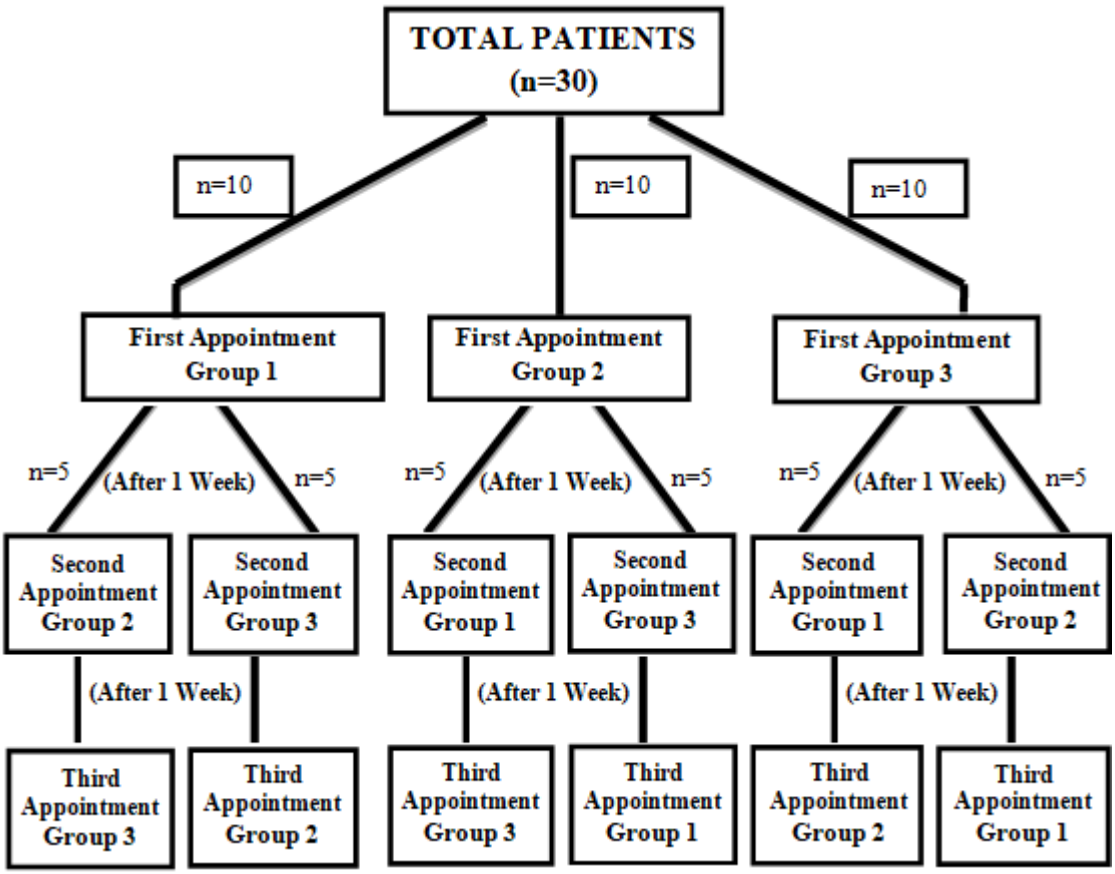
1) Patient in the age group of 6-12 years.
2) Patient who requires administration of Local Anesthesia on at least 3 appointments for various dental procedures like multiple extractions, multiple pulpectomy and RCT etc.
3) Parents should give their consent to participate in the study.
4) Children ranking 3 or 4 in Frankl behavior rating scale.

Exclusion criteria

1) Respiratory diseases like asthma, bronchitis, COPD, anosmia.
2) Allergy to lignocaine (L. A).
3) Allergy to Lavender essence.
4) Child with special needs like Down syndrome, Cerebral Palsy.
5) Children ranking 1 or 2 in Frankl scale.

Study design

The present study was a cross-over experiment design that was tested on a sample of 30 patients, all of whom were administered three types of interventions over a period of time which was separated by a week as washout period to avoid carryover effect. The subjects was divided into 3 groups with each group having 10 subjects which were further sub divided into groups of 5, for the purpose of randomizing the sequence of administration of intervention. The sequence of administration of intervention into each subgroup has been considered based on the method proposed by Putt (2004)



Group1=Plain water+ no music therapy
Group2= Plain water+ Music therapy
Group3=Aromatherapy + Music therapy
Figure 1: Study design

Ethical Clearance
Prior approval of the study was taken from the Ethical Committee of the institution, ITS Centre for Dental Studies and Research, Muradnagar. Informed consent was obtained from each subject's parents/ guardians before enrolling them in the study.

Procedure
The study was conducted on 30 children of the age group 6-12 years who require at least 3 appointments on dental procedures under Local Anesthesia and their pain and anxiety scores were assessed by using the Flacc scale, sound, eye and motor scale and Wong Baker Faces scales. The study was done on 3 different appointments on the same 30 children, who were randomly allocated under 3 distinct groups each time.1 week of washout period was given in between each of the 3 appointments in order to eliminate the carry over effect. The three Groups chosen for the study are as follows-

Group1-(Plain water+ no MT)
Group 2-(Plain water + MT)
Group 3-(AT + MT)

Randomization
Software based (Stat trek. com) random numbers was generated to assign the patients for receiving either of the three interventions in three distinct appointments.

The aroma opted for the present study was Lavender essence and the music selected for music therapy was Indian classical instrumental music based on the raga Hamsdhwani. The link to access the instrumental music is given below –
https://www.youtube.com/watch?v=wz5veR-97Cw

Hamsadhwani Raga - Nerve Disorders & Nerves Weakness Therapeutic Ragas.mp3

As the patient is seated on the dental chair his/her initial FLACC score is evaluated.

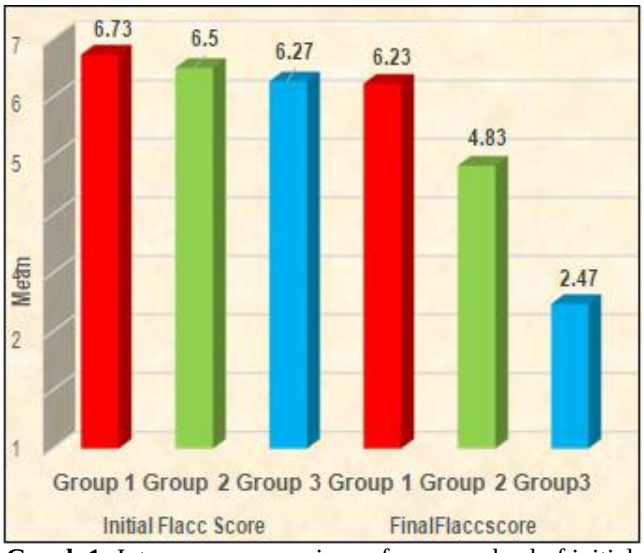
Following which either of the three interventions were administered on each appointment-

- Group1: The patient was given a glass containing 100ml water to smell as placebo, 10 minutes after the therapy, The final FLACC scores were again assessed based on his/her anxiety levels.
- Group 2: The patient was given a glass containing 100ml plain water to smell as placebo and they were given music therapy by playing instrumental music (Indian classical instrumental music based on raga hamsdhwani) through head phones.10 minutes after the therapy, the final FLACC score were again assessed based on his/her anxiety levels.
- Group 3: The patient was given a glass containing 100ml plain water to which, 2 drops of lavender essence was added and the diluted solution was made to smell along with which, music therapy was played through head phones.10 minutes after the therapy, the final FLACC score were again assessed based on his/her anxiety levels.

Before initiating with the invasive procedure, local anesthesia was administered, and at the time of prick SEM scoring was done. Once the treatment was completed, patients were asked if pain was present or not during the treatment. Then patients were given a laminated chart of WBFS which had scores 0-10. They were then asked to rate the pain experienced in the scale, by pointing at the preferred faces.

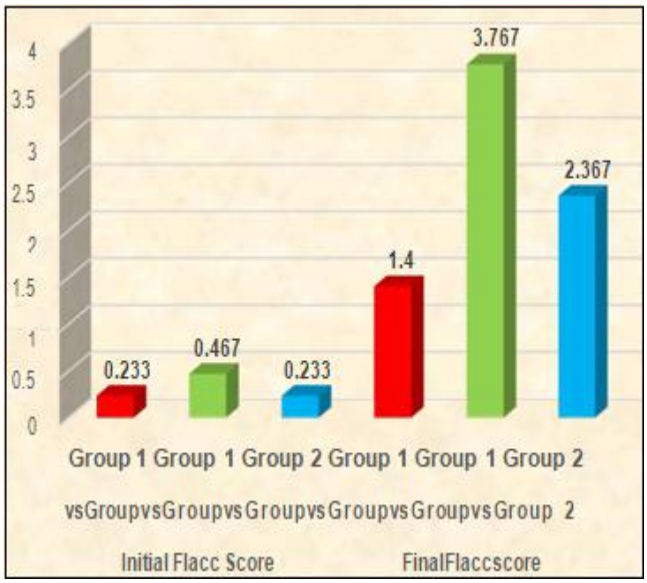
Statistical Analysis:-
Statistical analysis was done by Statistical Package for the Social Sciences (SPSS) software package (SPSS 16 Inc, Chicago IL, USA). The normality of data was tested by Shapiro Wilk's test. The values obtained was statistically analysed and in order to compare the parameters between groups and within groups for normal data parametric test, one way ANOVA followed by Bonferroni test was used and for intra group comparison paired t-test was used among the study population.

3. Results



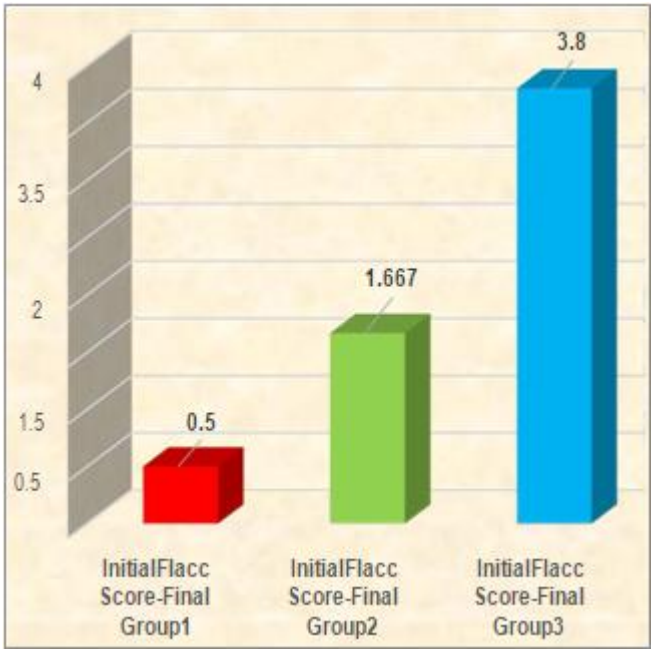
Graph 1: Intergroup comparison of mean and s.d of initial and final flacc score among the three groups

Graph1: Intergroup comparison of means and s. d of initial and final flacc scores among 3groups.
The mean and S. d of initial flacc score of Group 1, 2, and 3 were 6.73±1.437, 6.50±1.196 and 6.27±1.202 respectively, and the mean and S. d of final flacc scores of Group 1, 2 and 3 were 6.23±1.501, 4.83±1.147 and 2.47±.819 respectively. Therefore the mean of final flacc score in Group 3 is significantly lower than other two groups**.**



Graph 2: Intragroup multiple comparison of initial Flacc and final Flacc score by using Bonferroni test

On multiple comparison of means of Initial Flacc score and Final Flacc scores between the three groups by using Bonferroni test, the mean difference of Final Flacc score between Group 1& Group 2 (1.400), Group 1& Group 3 (3.767), Group 2& Group 3 (2.367) is highly significant, $p<0.001$. Therefore the mean of final flacc score in Group 3 is significantly lower than other two groups

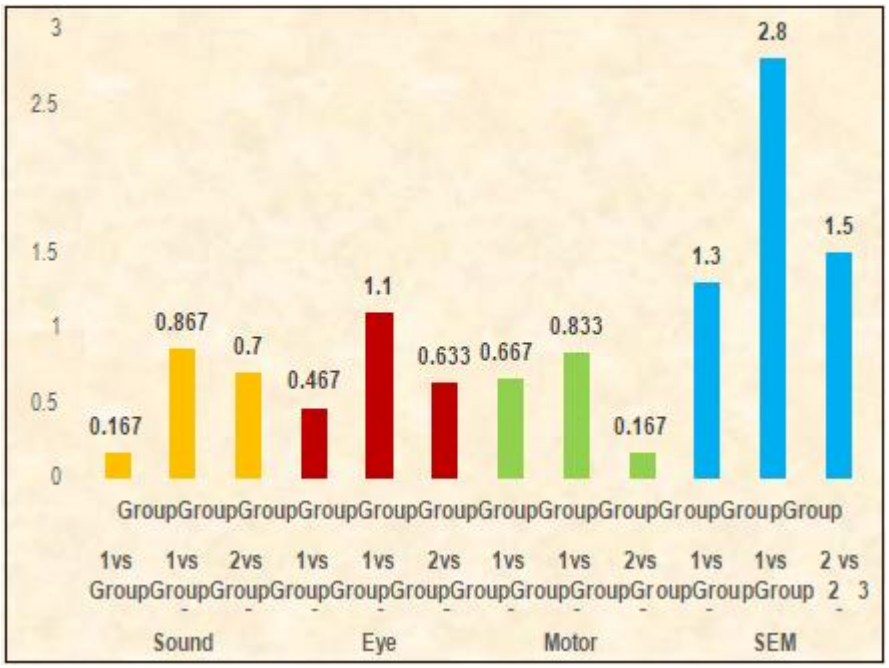


Graph 3: Intragroup comparison of initial and final Flacc score among three groups between two intervals by using paired t-test.

On intra group comparison of means of initial and final flacc scores among three groups between two intervals by using paired t-test, the mean difference of Initial and Final flacc score of Group 1 (.500), Group 2 (1.667) and Group 3 (3.800) respectively, which is highly significant, $p<0.001$

Graph 4: Intergroup comparison of Sound, eye motor, SEM score among the three groups.

On inter group comparison of means of Sound, Eye, Motor, SEM score of among three groups, the mean difference of Sound scores in Group 1, 2 and 3 are 2.40±.498, 2.23±.430 and 1.53±.507 respectively. The Eye scores in Group 1, 2 and 3 are 2.57±.504, 2.10±.607, 1.47±.507 respectively. The Motor scores in Group 1, 2 and 3 are 1.87±.571, 1.20±.407 and 1.03±.183 respectively. The SEM scores in Group 1, 2and 3 are 6.83±.648, 5.53±.900 and 4.03±.718 respectively



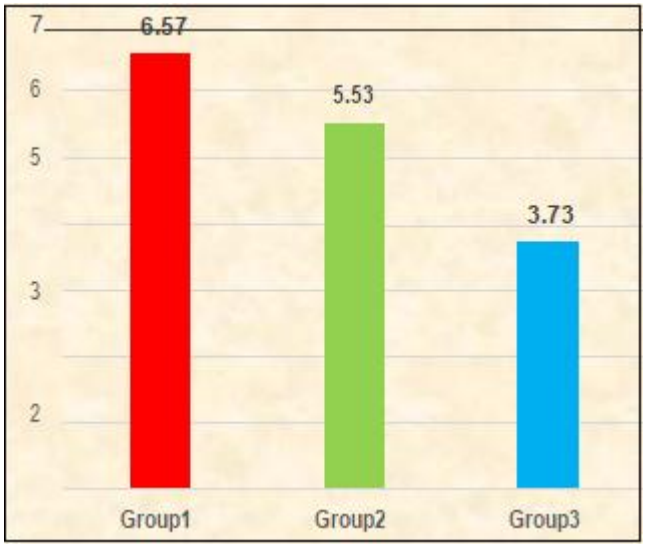
Graph 5: Intragroup multiple comparison of Sound, Eye, Motor and SEM score of the 3 groups by using Bonferroni test

On multiple comparison of means of Sound, Eye, Motor and SEM scores between the three groups by using Bonferroni test the mean difference of Sound score between Group 1& Group 2 (.167) is not significant, $p>0.05$, while Group 1& Group 3 (.867), Group 2& Group 3 (.700) is highly significant, $p<0.001$. Therefore the mean of Sound score (.153) in group 3 is significantly lower than other two groups.

The mean difference of Eye score between Group 1& Group 2 (.467) is not significant, $p>0.05$, while Group 1& Group 3 (1.100), Group 2& Group 3 (.633) is highly significant, $p<0.001$. Therefore the mean of Eye score (.147) in Group 3 is significantly lower than other two groups.

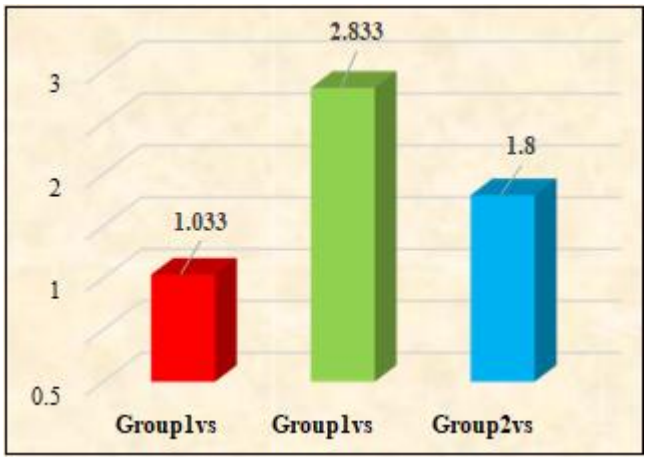
The mean difference of Motor score between Group 1& Group 2 (.667), Group 1& Group 3 (1.100) is highly significant, $p<0.001$, while between Group 2& Group 3 (.833) is not significant, $p>0.05$. Therefore the mean of Eye score (.103) in Group 3 is significantly lower than Group 1.

The mean difference of SEM score between Group 1& Group 2 (1.300), Group 1& Group 3 (2.800), Group 2& Group 3 (1.500) is highly significant, $p<0.001$. Therefore the mean of Eye score (.403) in Group 3 is significantly lower than other two groups.



Graph 6: Intergroup comparison of mean and S. d of WBFS score among the three groups

On intergroup comparison of means of WBFS scores among the three groups, the mean difference of WBFS scores for Group 1, 2 and 3 are 6.57±.817, 5.53±.681 and 3.73±.907 respectively.



Graph 7: Intragroup multiple comparisons of WBFS score among the three groups by using Bonferroni test

On multiple comparison of means of WBFS scores among the three groups by using Bonferroni test, the mean difference WBS score between Group 1& Group 2 (1.033), Group 1& Group 3 (.2.833), Group 2& Group 3 (1.800) is highly significant, $p<0.001$.

4. Discussion

Effects of control group (plain water + no music) on pain and anxiety using FLACC score, SEM score and WBFS scores

The findings of this study showed that the mean difference of Initial and final flacc score in the control group was not significant. The initial flacc score revealed an increase in anxiety and stress severity owing to the fact that children often tend to have a preset notion in their subconscious mind while entering a dental set up which may be due to unfamiliar surroundings, fear of white coats, needle phobia, unawareness of the procedures they have to undergo etc. Likewise, in the final flacc score, the glass of water that was used as placebo has created a negligible psychological effect in the child's behaviour, however the results revealed that the children experienced more intense anxiety and fear in the control group, less pain and anxiety in group 2 and least effects in group 3. These results seems to be in line with other studies by Bikmoradi. A et al (2017) Karaman. S et al (2019). No previous studies assessed the initial and final flacc score.

During the administration of local anesthesia, the mean of SEM score showed the maximum pain severity in the control group (6.83) followed by group 2 (5.53) and least pain was experienced by the children of group3 (4.03).

In order to evaluate if the subjective and objective signs and symptoms corresponds to each other, the WBFS was recorded by the children and the results revealed that children in the group1 (6.57) experienced maximum severity of pain followed by group2 (5.53) and least by group 3 (3.73).

Effects of experiment group 2 (music therapy) on pain and anxiety using FLACC score, SEM score and WBFS scores

The findings of the study showed that the mean difference of the initial and final flacc score is significant. Also the SEM and WBFS showed decrease in pain severity when in comparison to the control group. which could be due to the calming and therapeutic effect of music, since music helps in distraction and diverting the concentration of children. The usage of specific raga based instrumental music also works as an adjunct in elevating the mood of children. these results seems to be in line with studies by Suhartini et al, (2010) Gooding et al, (2016), Tran et al, (2010) etc. However the studies that contradicted the present results Lahmann et al, (2008) concluded that music used in the form of passive distraction is not adequate to control pain. Similarly Dileo and Bradt, (2005) [22]; Pelletier, (2004) emphazised that patients preference of music played important role. Kwekkeboom. (2003) suggested that the usage of headphones would reduce the patient and doctor communication.

Effect of experiment group 3 (music therapy and aromatherapy) on anxiety and pain. using FLACC score, SEM score and WBFS scores

The findings of the study showed that the mean difference of the initial and final flacc score, SEM score and WBFS is significant when in group 3 compared to the other two groups, this could be due to the synergestic effect on combining both music and aromatherapy. The results seems to be in line with other studies Ganong (1999), Dixit. UB et al. (2020) etc. however the study by Muzzarelli et al. (2006) [65] concluded that aromatherapy by using lavender essence is not effective in reducing anxiety in patients before colonoscopy which did not corroborate with the present result.

5. Conclusion

From this study it is evident that least pain and discomfort was felt in the combination group followed by the music therapy group and maximum pain was felt in control group. Therefore Non-pharmacological techniques if used as an adjunct or solely with pharmacological techniques do have the potential to wipe fear and anxiety in children. Selective raga based Indian classical music therapy has the capability to independently produce significant effects on mood elevation. Aromatherapy is a successful non pharmacological technique in reducing the anxiety and stress levels in young patients. Since these techniques do not have much side effects and complications to worry about, dentists can include these non-pharmacological adjuncts in their regular dental practice. Apart from calming the child, aromatizers and classical instrumental music played in the waiting room, inside the dental cabin would help in creating a pleasant environment for the dentists to work, as well as it can also aid in calming the anxious parent who is accompanying their wards.

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