

The effectiveness of an Interactive Toy as an Active Distraction Compared with a Passive Distraction in Alleviating Dental Anxiety and Pain while Administration of Local Anaesthesia in Children: A Randomised Clinical Trial

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ABSTRACT

Introduction: Painless dentistry requires Local Anaesthesia (LA), however, due to the pain of the injection itself, it could be a very anxious process. During invasive dental treatments, distraction can be used as a non pharmacological behaviour management technique by diverting the individual's attention away from painful stimuli.

Aim: To evaluate the effectiveness of an interactive toy as an active distraction compared with the colourful headset with music as a passive distraction in alleviating dental pain and anxiety while administration of LA in children aged between 4 and 9 years.

Materials and Methods: The trial design was an interventional, prospective, parallel-based block randomisation which was conducted on 60 children aged between 4 and 9 years, who were randomly assigned into two groups with 30 each. The study was conducted on children who reported to the Department of Paediatric and Preventive Dentistry, Narayana Dental College and Hospital, Nellore, Andhra Pradesh, India for six months, from April 2023 to September 2023. Children

in Group 1 received interactive toy, whereas Group 2 received colourful headset with music. Using pulse rates and Chhota Bheem Chutki (CBC) scale dental anxiety was evaluated. While pain was evaluated using Faces, Leg, Activity, Cry and Consolability (FLACC) scale and Modified Wong-Baker Faces Pain Rating Scale (MWBFRS). Paired t-test, independent t-test, Wilcoxon rank test and Mann-Whitney U test was used to quantify anxiety and pain.

Results: Anxiety scores were statistically reduced in interactive toy group ($p < 0.05$). The mean pain scores of FLACC and MWBFRS were lower in interactive toy group compared to colourful headset with music group, showing a statistically significant difference ($p\text{-value} < 0.001$). Interactive toy group significantly reduced anxiety and pain in age groups of both (4-6 and 7-9 years) and also among the gender.

Conclusion: Interactive toy, as an active distraction technique, was effective in alleviating anxiety and pain compared to colourful headset with music in children while administering LA. Interactive toy group significantly reduced anxiety and pain in both the age groups and also among the gender.

INTRODUCTION

Human emotions include anxiety, which is characterised by behavioural, emotional and cognitive reactions to perceived threats [1]. Children's behaviour during dental visits and treatments is influenced by their maternal (or parental) anxiety and their beliefs and attitudes regarding dentistry [2]. Effective pain control is the keystone for successful behaviour guidance in paediatric dental office [3]. Even though LA is frequently used to manage pain in dental procedures, the most fearful and anxiety-inducing tool is the injection itself [4].

Distraction technique is a commonly used and endorsed non aversive behaviour management method that reduces children's distress and disruptive behaviour, since it is easy to implement, safe and affordable [5]. Distraction can be of two types; multiple sensory elements-including virtual reality, guided imagery and interactive toys, are used in the active form of distraction to entice children to participate and passive distraction, which involves having a child focus on a stimulus or activity, like watching cartoons or listening to music [6]. Capturing the child's senses-such as touch, hearing and vision- as well as engaging their emotions are necessary for the ideal distraction [7]. Besides, interactive toys activate the audio-visual, kinaesthetic and tactile senses thereby requiring the child to use motor and visual skills [8]. Interactive toy allows the child to engage by producing music, similar sounds, light and by dancing.

As an essential aspect of human existence, music has the power to both elicit and convey emotions [9]. With the aid of music, children can avoid unpleasant stimuli and lower their anxiety levels by concentrate on the audio [10]. Music may enhance audio-analgesic responses during dental procedures by directly suppressing pain through the nervous system [11].

To the authors knowledge, no research has been published on the use of interactive toy as an active distraction for lowering dental anxiety and pain in children in the dental setting. Hence, the aim of the study was to evaluate the effectiveness of an interactive toy as an active distraction compared to colourful headset with music as passive distraction while administration of LA in children aged 4-9 years.

The null hypothesis was the interactive toy would not reduce the dental anxiety and pain in children while administering LA and the alternate hypothesis was the interactive toy would reduce the dental anxiety and pain in children while administering LA.

MATERIALS AND METHODS

The trial design was an interventional, prospective, parallel-based block randomisation. The study was conducted on children who presented to the Department of Paediatric and Preventive Dentistry at Narayana Dental College and Hospital, Nellore, Andhra Pradesh, India for a period of six months, from April 2023 to September 2023. Ethical

clearance was obtained from the Institutional Ethical Committee under reference No. IEC/NDCH/2022/Mar/P-15. Trial was registered in the Clinical Trials Registry of India (CTRI/2023/04/051826).

Sample size calculation: Sample size calculation was done by taking values from a previous study using the G*power software [12]. Effect size of $d=0.748$, power $(1-\beta) = 0.80$, $\alpha=0.05$ and an allocation ratio of 1:1 indicated that the minimum sample required was 58, with 29 individuals in each group. Considering a 10% loss of samples during the study, the final sample size was determined to be 60 with 30 children in both groups.

Inclusion criteria:

- Healthy children aged between 4 and 9 years;
- Children indicated for dental procedures under LA;
- Children who had no prior experience of LA administration;
- Parents who have given written informed consent and assent from their children;
- Children whose behaviours were rated as positive or definitely positive according to Frankl Behaviour Rating Scale.

Exclusion criteria:

- Patients with a known history of allergy to LA;
- Children with special healthcare needs;
- Children with dental emergency which include trauma, acute pulpitis, dental abscess, cysts, pericoronitis, etc.

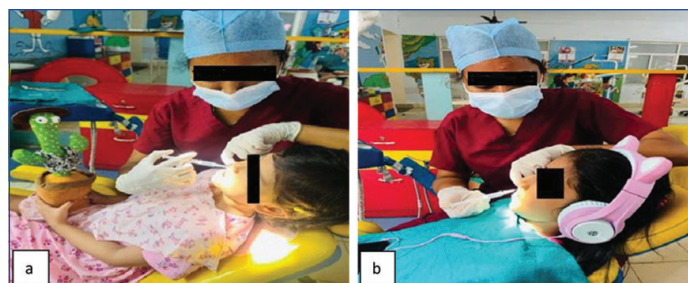
Study Procedure

Randomisation and allocation sequence: Children were divided into subsets (i.e., blocks) and participants from those blocks were randomly assigned to the two intervention groups. A total of 60 pieces of regular-sized papers with the written codes “A” or “B” were prepared. These papers were placed inside the identical, properly sealed envelopes. Each envelope was placed in the appropriate plastic container marked with the letter “A” or “B” in accordance with the treatment code. A block size of four was chosen in order to make sure that the allocation sequence could not be predicted. Corresponding to a block size of four, two envelopes were selected from each plastic container. The four envelopes were shuffled and placed in a separate pile. The children’s parent/caregivers of the children were asked to randomly select one of the envelopes from a pile at the time of clinical procedures. Principal investigator was responsible for supervising, allocating and defining codes in the trial.

Treatment/Clinical procedure: Upon fulfilling the inclusion criteria, 60 children were allocated into two groups ($n=30$ in each group): Group 1: Interactive Toy Group and Group 2: Colourful Headset with Music.

Anxiety levels in both groups were determined using a pulse oximeter and the CBC scale 15 minutes before the administration of LA [13]. With the help of sterile gauge, the needle prick site was dried topical anaesthetic spray was sprayed on the cotton pellet and applied for one minute at the injection site. By using 23-gauge short needle, 1 mL of anaesthetic solution was delivered with the rate of 0.8 mL/min as standard procedure for infiltration. For block anaesthesia, 1-1.5 mL of the solution was administered at a rate of 1 mL/min. The anaesthetic solution used was lignocaine hydrochloride 2% with epinephrine 1:80,000. During LA administration, interactive toy in Group 1 and colourful headset with music in Group 2 were used to distract the children [Table/Fig-1a,b].

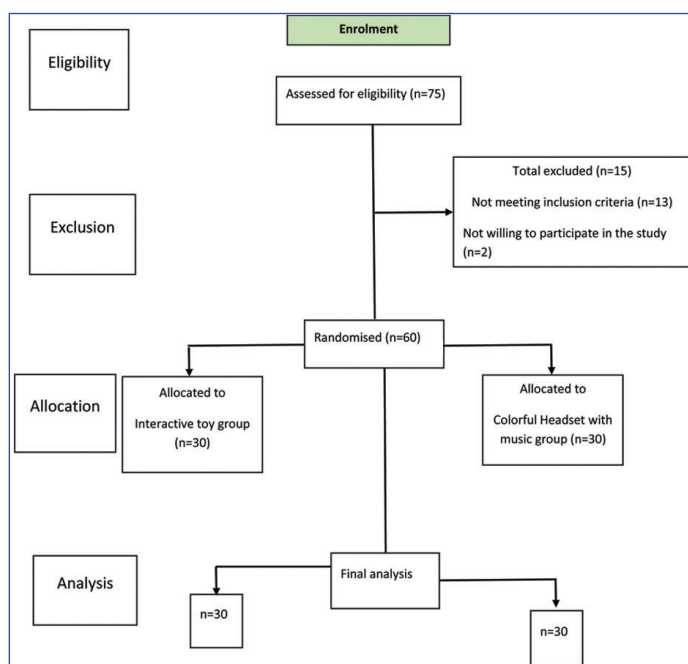
The primary outcome of the study was to reduce dental anxiety in children and secondary outcome is to reduce dental pain in children while giving LA. Variations in the pulse rates were recorded at three clinical situations: before, during and after the injection. The pain assessment during LA administration was done using FLACC scale [14]. Immediately after LA was administered, children were asked to rate their level of pain using the MWBFPRS [15,16]. Using the CBC scale [13], the child’s anxiety level following the application of LA



[Table/Fig-1]: a) LA administration while performing active distraction with interactive toy; b) LA administration while performing passive distraction with colourful headset with music.

was recorded. After obtaining profound anaesthesia, procedures such as extractions and pulp therapy were performed.

Consolidated Standards of Reporting Trials (CONSORT) flow diagram: The flow diagram displays the total number of children considered for eligibility, randomisation, allocation and analysis [Table/Fig-2].



[Table/Fig-2]: CONSORT flow diagram.

STATISTICAL ANALYSIS

The statistical analysis was performed using Standard Package for Social Sciences (SPSS) version 20 (Chicago). Demographic details regarding age and gender were assessed using the Chi-square test. The intergroup and intragroup comparisons of pulse rates were evaluated using independent t-test and paired t-test, respectively. The intergroup comparison of the MWBFPRS and FLACC scale were assessed using Mann-Whitney U-test. The intergroup and intragroup comparison of CBC scale was assessed using Wilcoxon rank test and Mann-Whitney U-test, respectively. All p-values less than 0.05 are considered statistically significant ($p<0.05$).

RESULTS

A total of 60 children were recruited for the present study. Children in the age group of 4-6 years comprised 15 (50%) in interactive toy group and 15 (50%) in colourful headset with music group. Children aged 7-9 years also comprised 15 (50%) in interactive toy group and 15 (50%) in colourful headset with music group. There were 36 male and 24 female participants in the study. Interactive toy group comprised of 19 (63.3%) males and 11 (36.7%) females, whereas the colourful headset with music group comprised 17 (56.7%) males and 13 (43.3%) females.

No significant difference was observed in terms of age ($p=1.000$) and gender ($p=0.792$) between two groups [Table/Fig-3].

| Demographic variables | | Interactive toy group | Colourful headset with music group | Chi-square value | p-value |
|-----------------------|-----------|-----------------------|------------------------------------|------------------|------------|
| Age | 4-6 years | 15 (50) | 15 (50) | 0.000 | 1.000 (NS) |
| | 7-9 years | 15 (50) | 15 (50) | | |
| Gender | Males | 19 (63.3) | 17 (56.7) | 0.277 | 0.792 (NS) |
| | Females | 11 (36.7) | 13 (43.3) | | |

[Table/Fig-3]: Demographic details of the children.
Chi-square test; NS: Non significant

Pulse rates in the intergroup comparison between the two groups showed statistically significant difference before ($p=0.011$), during ($p<0.001$) and after ($p<0.001$) intervals, respectively [Table/Fig-4].

| Groups | Intervals | Mean±SD | Mean difference | t-value | p-value |
|------------------------------------|--------------------------|-------------|-----------------|---------|---------|
| Interactive toy group | Before LA administration | 111.13±5.07 | -3.26 | -2.63 | 0.011* |
| Colourful headset with music group | | 114.41±4.51 | | | |
| Interactive toy group | During LA administration | 95.06±6.12 | -8.86 | -6.08 | <0.001* |
| Colourful headset with music group | | 103.93±5.12 | | | |
| Interactive toy group | After LA administration | 98.46±5.95 | -10.90 | -8.28 | <0.001* |
| Colourful headset with music group | | 109.36±4.06 | | | |

[Table/Fig-4]: Intergroup comparison of pulse rates among the study groups at various intervals.
Independent t-test; $p<0.05$ * Significant

Intergroup comparison of CBC scale scores showed a statistically significant difference ($p<0.001$) between the two groups using Mann-Whitney U test, after administration of LA [Table/Fig-5].

| Groups | Intervals | Median | Mean±SD | Mean difference | U-value | p-value |
|--------------------------|------------------------------|--------|------------|-----------------|---------|------------|
| Before LA administration | Interactive toy | 4 | 4.43±1.16 | 1.00 | 270.5 | 0.086 (NS) |
| | Colourful headset with music | 4.5 | 4.33±1.12 | | | |
| After LA administration | Interactive toy | 2 | 1.96±0.854 | 2.30 | 71.0 | <0.001* |
| | Colourful headset with music | 1.22 | 4.23±1.22 | | | |

[Table/Fig-5]: Intergroup comparison of Chhota-Bheem Chutki (CBC) scale before and after LA administration.
Mann-Whitney U test; $p<0.05$ * significant; NS: Non significant

The intergroup comparison of FLACC scale scores revealed that statistically significant difference ($p<0.001$) between the two groups using Mann-Whitney U test [Table/Fig-6].

| Groups | Scale | Median | Mean±SD | Mean difference | U-value | p-value |
|------------------------------------|-------------|--------|-----------|-----------------|---------|---------|
| Interactive toy | FLACC Scale | 2 | 2.30±1.14 | 3.33 | 67.5 | <0.001* |
| Colourful headset with music group | | 6 | 5.63±1.80 | | | |

[Table/Fig-6]: Intergroup comparison of FLACC scale scores before and after LA administration between two groups.
Mann-Whitney U test; $p<0.05$ * significant

A significant difference ($p<0.001$) was found in the intergroup comparison of MWBFPRS scores among the two groups, using Mann-Whitney U test [Table/Fig-7].

The intergroup comparison of mean pulse rates among males and females showed a significant difference between the two groups ($p<0.001$ and $p<0.001$). A significant difference was also observed in intergroup comparison of CBC scale scores ($p<0.001$ and $p<0.001$)

| Groups | Scale | Median | Mean±SD | Mean difference | U-value | p-value |
|------------------------------|---------|--------|-----------|-----------------|---------|---------|
| Interactive toy | MWBFPRS | 2 | 1.53±1.35 | 3.93 | 75.0 | <0.001* |
| Colourful headset with music | | 6 | 5.46±2.34 | | | |

[Table/Fig-7]: Intergroup comparison of Modified Wong-Baker Faces Pain Rating Scale (MWBFPRS) scores before and after LA administration between two groups.
Mann-Whitney U test; $p<0.05$ * significant

among males and females between study groups. Mann-Whitney U test of intergroup comparison of FLACC scores among males and females showed a statistically significant difference ($p<0.001$ and $p<0.001$) between the two groups. Intergroup comparison of MWBFPRS scores displayed significant difference ($p<0.001$ and $p<0.001$) among males and females between the two groups [Table/Fig-8].

The intergroup comparison of mean pulse rates revealed statistically non significant differences ($p=0.39$ and $p=0.67$) among children aged 4-6 years and 7-9 years between the two groups. In the intergroup comparison of CBC scale scores among the 4-6 years and 7-9 years age groups, a statistically significant difference was noted ($p<0.001$ and $p=0.003$) between the two groups. Mann-Whitney U test of intergroup comparison for FLACC scores revealed statistically significant difference ($p<0.001$ and $p<0.001$) among 4-6 years and 7-9 years between the two groups. Statistically significant difference were found in intergroup comparison of MWBFPRS scores ($p<0.001$ and $p=0.001$) among 4-6 years and 7-9 years age groups between the two groups [Table/Fig-9].

DISCUSSION

Distraction is a behaviour management strategy that diverts the child's attention from the anxiety-inducing stimuli, which helps to relax the child and decrease anxiety throughout the dental process [17]. Distraction can be classified into two types: active distraction and passive distraction. Dahlquist LM et al., first demonstrated the effect of a touch-and-discover electronic toy, an interactive toy used as a distraction method in medical setting and revealed a statistically significant decrease in distress and anxiety with the use of this toy in the children [18].

Considering these benefits in the medical field, a cactus-shaped interactive toy was used as an active distraction technique in the current study. This toy emits different colours of light, which are attractive to the children. Also, the toy produces music and dance to the rhythm which brings enormous joy to the children. This cactus-shaped toy has mechanism of producing sounds made by the child. Thus, making similar sounds, the toy interacts with the child, hence reduces anxiety of the child [18].

While experiencing pain, music can help divert the attention away from anxiety and promote relaxation responses, which can have a therapeutic effect [19]. As, the music is non invasive and inexpensive, it was chosen as passive distraction. The present study aimed to assess and compare the effect of an interactive toy as an active distraction technique with the colourful headset with music as a passive distraction technique during the administration of LA in the children between 4-9 years.

In the present study, the intergroup comparison of mean pulse rates were lower in active distraction group using interactive toy compared to passive distraction group using colourful headset with music group at all intervals. Similar results were seen with Kiani MA et al., concluded that mean pulse rates were considerably reduced in the toy group with that of music group [20]. Likewise, in the other two studies by Guinot F et al., and Shekhar S et al., mean pulse rates were lower in active distraction group to that of passive distraction [21,22]. Contradictory to these, a study conducted by Karaca TN and Cevik Guner U reported that pulse rates were higher in music-moving toy group than in the control group [23]. Furthermore, a study by Mohammed OK and Raslan N revealed a non significant variation

| Groups | Pulse rates | | Chotta-Bheem Chutki (CBC) scale | | FLACC scale | | MWBFRS | |
|------------------------------------|----------------------|----------------------|---------------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| | Males | Females | Males | Females | Males | Females | Males | Females |
| Interactive toy group | 101.94±5.00 | 100.88±4.87 | 2.05±.848 | 1.81±0.87 | 2.15±1.34 | 2.45±0.68 | 1.57±1.57 | 1.46±0.93 |
| Colourful headset with music group | 108.23±3.78 | 110.0±4.05 | 4.23±1.09 | 4.30±1.49 | 4.84±1.67 | 6.23±1.7 | 5.17±2.24 | 5.84±2.51 |
| | t=-5.26 | t=-4.16 | U=19.5 | U=15.5 | U=13.5 | U=18.00 | 32.5 | 8.00 |
| p-value | <0.001* [†] | <0.001* [†] | <0.001* [†] | <0.001* [†] | <0.001* [†] | <0.001* [†] | <0.001* [†] | <0.001* [†] |

[Table/Fig-8]: Gender-wise intergroup comparison – before and after LA administration.

p<0.05* significant; †: Independent t-test; T: Mann-Whitney U test

| Groups | Pulse rates | | Chotta-Bheem Chutki (CBC) scale | | FLACC scale | | MWBFRS | |
|------------------------------------|------------------------|------------------------|---------------------------------|---------------------|----------------------|----------------------|----------------------|---------------------|
| | 4-6 years | 7-9 years | 4-6 years | 7-9 years | 4-6 years | 7-9 years | 4-6 years | 7-9 years |
| Interactive toy group | 104.75±7.47 | 106.37±8.08 | 1.73±0.59 | 2.2±1.01 | 2.13±0.92 | 2.46±1.35 | 1.467±1.40 | 1.60±1.35 |
| Colourful headset with music group | 107.08±7.44 | 107.64±8.04 | 4.8±0.94 | 3.73±1.33 | 6.20±1.78 | 5.06±1.70 | 6.66±1.95 | 4.27±2.12 |
| | T=-0.84 | T= -0.43 | U=0.5 | U=41.5 | U=8.5 | U=28.5 | U=3.0 | U=35.5 |
| p-value | 0.39 (NS) [†] | 0.67 (NS) [†] | <0.001* [†] | 0.003* [†] | <0.001* [†] | <0.001* [†] | <0.001* [†] | 0.001* [†] |

[Table/Fig-9]: Age-wise intergroup comparison before and after LA administration between two groups.

p<0.05* significant; †: Independent t-test; T: Mann-Whitney U test

in mean pulse rates between passive and active distraction groups during LA administration in children [24]. They reported that most of these changes fell within the range of typical physiological conditions.

The subjective evaluation of anxiety was measured using the CBC scale which is a newly developed scale by Sadana G et al., [13]. The child's relationship with the dentist improved as a result of the cartoon characters grabbing their attention. In this study, the intergroup comparison of the mean anxiety scores of the CBC scale indicated that anxiety was considerably decreased in the active distraction group using interactive toy group than passive distraction group. These results were similar with Asokan S et al., reported that anxiety was reduced more by an active distraction compared to other groups in children [25]. Similarly, Kurudirek F et al., concluded that lighted, rotating musical toy significantly reduced anxiety in children during a blood collection procedure [26]. The study results were contradictory with study conducted by Karaca TN and Cevik Guner U, who found that toy distraction was ineffective in lowering anxiety during the intravenous catheter insertion procedure in children [23]. They stated that emergency rooms are places where patients move quickly and may have limited time and space.

On intergroup comparison, the mean pain scores of FLACC were significantly lower in the active distraction group using interactive toy compared to the colourful headset with music group. Similarly, Dahlquist LM et al., reported that the touch-and-discover toy, which is an interactive toy, was effective in reducing distress in children who underwent chemotherapy [18]. Also, Sharma MC and Mendonca TL reported that sound-producing toy was beneficial in decreasing pain in children compared to music group [27]. In contrast, results were inconsistent with those of Jessica MA et al., who found that toy-mediated distraction was ineffective in reducing pain in toddlers during immunisation [28]. They stated that the effect of toy-mediated distraction may have been diminished by delaying its onset until the point of physical contact.

Using a self-reported pain intensity scale is advantageous for children, since it allows them to convey their emotions through the use of facial expressions. MWBFPRS with Doraemon faces, was developed by Nameeda KS et al., as a self-report scale for the assessment of pain [16]. The mean pain scores on the MWBFPRS scale were lower in active distraction group using interactive toy group compared to colourful headset with music. The study results were consistent with Alsibai E et al., who reported a significant decrease in pain in the active distraction group playing video games on tablet device compared to passive distraction of watching video films on tablet device [29]. Similarly, Arkan A and Esenay FI reported that mean pain score was reduced in the active distraction group using rotatable wooden toy in children during venous blood sampling [30].

Contrary to this, MacLaren JE and Cohen LL reported that movie distraction group, as a form of passive distraction, was more beneficial than interactive toy group in children [31]. They found that children in the movie group continued to interact with the stimuli, whereas children in the interactive toy group quickly grew bored with and stopped interacting.

The present study was the first study to evaluate the age and gender comparison in the active distraction using interactive toy.

On intergroup age-wise comparison, the mean pulse rates were lower in interactive toy group compared to colourful headset with music group among both the age groups. Additionally, anxiety was reduced in older children (aged 4-6 years) compared to younger age group children (7-9 years). This could be because anxiety is an abstract phenomenon that requires advanced cognitive skills to cope, together with the ability to exert deliberate control and regulate emotions-all of which the younger children were not yet be fully capable of managing [32].

The intergroup age-wise comparison of CBC scores revealed that interactive toy group significantly decreased anxiety in both younger and older group children. Similar results were reported by Kaur R et al., who found that audio-visual distraction was more effective compared to audio-only distraction [12].

The mean pain scores on the FLACC and MWBFPRS scales in the intergroup age-wise comparison were lower in interactive toy group compared to colourful headset with music group in both the age groups. A possible reason could be due to that children engaged with the active distraction by competing with the signals from the unpleasant stimuli, using various sensory modalities (auditory and kinaesthetic) while actively involving their emotions.

In the current study, the intergroup gender-wise comparison of mean pulse rates was lower in interactive toy group than in the colourful headset with music group among males and females. This could be attributed to physical activity of the children by playing with the interactive toy might have blocked the sight of surrounding environment, hence reduced anxiety in both males and females.

The CBC scores of intergroup gender-wise comparison were significantly reduced in interactive toy group among both the gender. The possible reason could be due to that the interactive toy attracted the child's focus and activated their emotional and nervous centers of the child which brings about relaxation and reduction of anxiety in both the gender.

On intergroup gender-wise comparison of FLACC and MWBFPRS scores were significantly reduced in the interactive toy group among the gender. This might be because both males and females were

completely engrossed in playing with interactive toy that their surroundings becoming non existent to them.

As the interactive toy was effective in reducing dental anxiety and pain in children; null hypothesis was rejected. The interactive toy and colourful headset were easy to use and cost-effective hence can be regular use in dental settings during the administration of LA. The present research can be replicated in the future with a greater number of randomised clinical trials comparing with other active and passive distraction techniques.

Limitation(s)

Because of the nature of the intervention, it was not possible to blind either the investigator or the child. Considering the potential for device contamination, both the interactive toy and colourful headset were disinfected with an alcohol-based disinfectant after each use.

CONCLUSION(S)

Interactive toy was effective in lowering pain and anxiety in children compared to colourful headset with music during administration of LA. Dental pain and anxiety was significantly reduced in the interactive toy group for both younger and older age groups and also among the gender.

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