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Research Article

"AN INTEGRATION OF THERMOMECHANICAL STIMULATION (BUZZY) AND CRYOTHERAPY ON PAIN IN CHILDREN". -A RANDOMISED CLINICAL TRIAL

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Buzzy device; Distraction card; Children; Fear; Physical modalities.

A B S T R A C T

Context: Pain is identified as `unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. `
The most recent and advanced technique was using a small vibrating device to the conventional injection technique.
Objective: The current study aimed to evaluate buzzy efficacy with distraction cards versus the traditional method for reducing pain and parents' satisfaction during healthy children's operative procedure.
Design: A prospective clinical study.
Setting: Private hospital and Private dental clinic.
Subjects: The purposive sample composed of (n=180) participants aged six to14 years and their parents. The study's participants were randomly assigned to two groups.
The Intervention Group included (n=90). Among them established pain distraction (Buzzy more Distraction cards group(n=45) and distraction cards group(n=45) by the researchers.
On the other hand, the control group was included in the same number (n=90), and no strategy was used.
Tools: The pain levels were evaluated with the ***FLACC scale*** or Face, Legs, Activity, Cry, Consolability scale.
Statistical Analysis: The obtained data were compared and statistically analysed using SPSS version 22. The following descriptive analysis, like Student's t-test and ANOVA (Univariate Analysis of Variance), was applied to determine the significant difference between them.
Results: Pain and fear were similar in the two groups in which a pain management strategy was applied. Pain and fear were more tremendous when no strategy was adopted.
Conclusion: The study results suggest that the Buzzy more Distraction cards method effectively decreased children's pain levels than the control group, according to observer-report and parent-report.

INTRODUCTION

Medical procedures, particularly needle insertions, are among the most feared experiences reported by children. Acceptable pain control practices are not easy to apply because of reluctance from caregivers' sick children are subjected to many painful experiences (Ramandeep Kaur *et al*., 2019). And Kleinknecht RA *et al*., 1973)

Pain perception in children is complex. Children frequently undergo medical procedures that are applied using a needle, which is considered the most common sources of pain for children causes considerable stress and anxiety for children and their parents. Fear of the syringes and needle insertion is common among children and adults (Jacobson A.F *et al*.,1999).

Intravenous cannulation is a minor invasive procedure for paediatric practitioners; however, it is often accompanied by pain, fear, and anxiety (Ogle OE *et al*., 2011).

Several methods have been described to reduce pain and anxiety caused by local anaesthesia administration. These include buffering the local anaesthetic, warming the local anaesthetic, applying topical anaesthesia before injection, reducing injection speed, and using fine needles with electric delivery devices (Elbay U¨S *et al*.,2016).

Intraoral local anaesthesia injection is often perceived as a painful and anxiety-causing dental procedure(Aydin D *et al*.,2016).

The reduction of such pain, fear and anxiety become the responsibility of health care professionals to an extent as

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possible while maintaining patient safety by using various pharmacological and nonpharmacological interventions (Çelik N, 2012).

Nonpharmacological measures have advantages: reduced cost, low incidence of adverse effects, and may help manage anxiety in parents. When selecting the non-pharmacologic methods, it is required to consider a child's age, cognitive competence, culture, behavioural factors, coping skills, personal differences, and pain type (Redfern RE *et al*., 2018).

Buzzy® and ShotBlocker® have been reported to be two valuable devices in reducingpain. Buzzy, which is composed of a bee-shaped gadget producing vibrations and cooling through freezable wings. The effect of Buzzy is based on the gate-control theory discovered by Melzack and Wall in 1965, which suggests that barriers can control the flow of pain information utilising the activation of nociceptive fibres (Melzack R,1965).

In this present study, the purpose of the cold and the vibrations is to block pain signals transmission.

Distraction methods are procedures like refocusing the child to take their attention from the unpleasant, painful situation to something attractive. The pain receptors are distrusted, as the child's attention is moved to others rather than painful procedure (Yeonsil Moon *et al*.,2017).

A behavioural scale, which assesses pain intensity by the medical personals through observing the patients, is usually considered more reliable.

Some of the behavioural measures of pain intensity have been widely used; Numeric Rating Scale (NRS), Face Pain Scale (FPS), and the Face, Legs, Activity, Cry, and Consolability (FLACC) scale (Voepel-Lewis T *et al* 2010).

In the present study, the pain levels were evaluated using the FLACC scale.

The present study aims to investigate the efficacy of three interventions Buzzy with directed distraction (BDG) method, distracting cards (D.G.) and magic gloves (control group-C.G.), on mitigating pain and anxiety associated with invasive procedures in a group of paediatric patients.

Aims

Evaluate the Buzzy System's efficacy in reducing pain during an operative procedure in children compared to routine technique (magic gloves) used in the ambulatory where the study took place.

Study Objectives

Primary objective

- To study nonpharmacological measures' effectiveness (buzzy device and distraction card) to reduce pain and anxiety in children between 6 and 14 years old.

Specific Objectives

- To describe the socio-demographic characteristics of the study population.
- Evaluate the parent/caregiver's satisfaction concerning the Buzzy System's distractive techniques and their willingness to use them again for future procedures.

RESEARCH METHODOLOGY

Research Hypotheses: It was hypothesised that; the buzzy device with distraction cards will positively affect reducing pain and increasing parent's satisfaction during venipuncture and dental operative procedure in the respondent.

Research design: This study was a randomised, cross- over, single-blinded design.

Trial design and study settingand Study Period: The present study was conducted at two different settings, a private hospital and a private dental clinic. The study period was from Dec 2020 to Feb 2021.

Research methodology: This study protocol was developed as per the Standard Protocol Items: Recommendations for Interventional Trials recommendations (Piaggio *et al* 2012).

Subjects: The purposive sample composed of (n=180) participants and their parents. The study's participants were randomly assigned to two groups. The Intervention Group included 90 participants. The researchers established pain distraction (Buzzy more Distraction cards group) 45 participants and distraction cards group 45 participants. On the other hand, the control group were included in the same number (n=90).

Inclusion criteria

- Children aged between 6 years old and 14 years old (Voepel-Lewis T *et al* 2010).
- Children required a venipuncture procedure.
- Children required infiltration L.A. for the dental treatment procedure. At least one caregiver/parent distracted the child with the distraction cards (in the Intervention Group).

Exclusion criteria

- A break or abrasion on the skin or nerve damage or limited sensation where the needle-related procedure will be performed.
- Absence of a caregiver/parent during the procedure
- Children unable to quantify or express their pain (e.g., severe cognitive deficit).
- Lack of parental consent.
- Participants use an analgesic within the last 6 hours.
- Participants with known behavioural management problems, previous experience with Buzzy®, anaesthetic or similar creams, sedated, hemodynamically unstable, developmental delay, or pathologies.

Sample Size Determination: Based on the previous studies (Kearl YL., 2015)and using pain as the primary outcome variable, an alpha level of 5% for a power of 90%, and a type I error of 0.05, it was necessary to compare 21 children per group. Anticipating that some children would probably drop out of the study increased the sample size by 25%. Therefore, the total number of children enrolled was 45 patients per group using the following formula (Bijttebier P *et al*.,1998).

$$n = \frac{(Z_\alpha + Z_\beta)^2 \times \sigma^2}{d^2}$$

were,

Z- a constant.

Z_α - set by convention according to the accepted α error and whether it is a one-sided or two-sided effect.
Z_β)- set by convention according to the power of the study.
σ^2- standard deviation (estimated)
d^2- the difference in the effect of two interventions which is required (estimated effect size).

Tools of data collection

Three tools were developed for collecting data.

The tool I: *Structured Interview Schedule:* It was developed by the research team after reviewing the related literature and collecting data related to the parents and children.

This tool included Two parts:

- Part A: Social-demographic Variables of Respondents such as Age (years), Gender, Birth order and Operative procedures. (Table. 1)
- Part B: Social-demographic Variables of Parents of Studied groups of buzzy intervention Respondents such as age (years), Caregiver attending the procedure, Parents' educational level and Residence. (Table. 2,3)

Tool II: Criterion measured: The criterion measures used in the study were the level of pain measured by the FLACC scale (for the Experimental and Control group). (Table. 6)

The Face, Legs, Activity, Cry, and Consolability (FLACC) scale was first published in 1997. The FLACC scale or Face, Legs, Activity, Cry, Consolability scale is a measurement used to assess pain for children between the ages of 2 months and seven years or individuals unable to communicate their pain. The scale is scored in a range of 0–10, with 0 representing no pain. The scale has five criteria, which are each assigned a score of 0, 1 or 2.(Voepel-Lewis T *et al*., 2010).

Tool III: Parents` satisfaction (Likert-scale Rating): Adapted from Friedel *et al*., 2014, it was used to assess parents' satisfaction regarding the cold device (Buzzy System), this scale formed of 4 variables: (**Table. 3)**

The Likert scale consists of 4 statements and was based on five points 1:no, 2: probably not, 3: do not know, 4: yes, 5: definitely.

1. My child was comforted using the buzzy system during the procedure.
2. It was a positive experience.
3. I think the buzzy system is easy to use.
4. I would like to use the buzzy system in the future for tests carried out on my son/daughter.

Study instrument (Buzzy system): used in this study, associates three different components and modulations of pain:

- ***Cryotherapy effect:*** by a changeable cold liquid device that the bee-shaped device.
- ***Vibration:*** a mechanical effect formed by applying a bee-shaped device a few centimetres from the needle entry point.
- ***Distraction method*****:** distracting the child with (distraction cards). (Figure.1)

Validity and reliability of study tools: Content validity was ascertained by a group of experts, three Dental and Medical Specialties, respectively. Their opinions were elicited regarding the tools format layout, consistency, scoring system. Modifications for the tools were done according to the experts' judgment on the clarity of sentences, appropriateness of the content, and items' sequence. The experts were agreed on the intervention but recommended minor language skills changes that would make the information clearer. Reliability of all items of the tools was done. The reliability test was established by using the Cronbach alpha to assess internal consistency construct validity. Cronbach alpha r= 0.86.

Ethical Considerations: All children and their parents were informed about the study's aim, its benefits and obtain their acceptance to participate. The researchers informed them that the study's participation is voluntary; they have the right to withdraw from the study at any time, without giving any reason, and their responses would be held confidentially. The secrecy and privacy of all the data will be assured. Written or verbal consent were obtained from those who welcome to participate in the study.

A pilot Study: Power analysis was approved on 10% of the total sample (n=180) children and their parent to test the study tools' clearness and applicability as well as an approximation of the time needed to complete each study tool. Those who contributed to the pilot study were later excluded in the study as there were no modifications to the tools.

Procedure*:* After obtaining consent, the study's aim was explained to children and their parents under study.

The researchers started to collect data from the children and their parent in the selected setting.

Each child was interviewed individually to determine his level of pain during the treatment procedure.

The age group's choice was based on scientific literature, which asserts that children in this age range were incredibly responsive to a distraction technique. Patients aged 6–14 years were selected for the study because children in this age group have good cognitive skills.(Birnie KA *et al*., 2014).

The procedure was explained for the children in both groups.
In one of the Intervention Group, a combination of a Buzzy® with directed distraction (BDG) method of reducing pain opted during the Invasive procedure.

In the other, the Intervention Group, children were involved in distraction cards (D.G.) techniques during the Invasive procedure.

The Buzzy® is a device in the shape of a bee whose body vibrates with cold gel wings (cooled in a freezer).

The device is reusable, battery-operated, and a vibrating toy fish contained two vibrator motors of 1.5 volts attached to a 9-watt battery.

The researcher placed the buzzy with the frozen wings on children's skin by attaching it to the arm or manually holding it in place, as close as possible above the needle insertion site (about 5-10 cm above the insertion site).

Children were requested to focus on the sensations of the-Buzzy rather than look at the needle insertion procedure. A 30 to 60 s rest was selected between the fixing of the device before the procedure. The buzzy device remained on till the end of the procedure. Finally, the researchers assessed pain using the appropriate pain and anxiety assessment tool, which took 3 to 5 minutes.

The parents were asked to interact with their children using distraction cards, a small number of cartoon images.

The parents' evaluated was the level of satisfaction with the distraction device method of pain control in the child and their desire to use it again in the future, with the appropriate parent's satisfaction assessment tool.

The buzzy component contains 20 g of ice and can be removed and kept in the freezer between procedures. Each pair of wings can stay frozen for about 10 min at room temperature and could be used up to 10 times.

Distraction Cards: The distraction cards consisted of 9 x8 cm graphic cards with various pictures and shapes. The children could examine the cards, and then the researcher asked the children what they could see on the cards. Distraction with the cards began immediately before the invasive procedure and continued until the procedure had been completed.(Hanan Mohamed Mohamed Tork, 2017).

Standard Care / (Control Group)

In the study setting's control group, no distraction or device (C.G.) was implemented. The magic glove technique is traditionally used. The children in the control group were permitted to keep their family nearby. The Invasive routine procedure was applied, and the level of pain in each child was evaluated using appropriate pain and anxiety assessment tools. Before starting the procedure, the researcher gently rubbed the area where the needle was positioned to free it from the pain. The child, imagining that the researcher is placing the glove and feeling the massage's influence on his site and his body, would feel certain numbness in the same area where the sensitivity is lowered(Birnie KA, Noel M *et al*.,2014).

Statistical Design

Analysis of data was done per the objectives. Statistical analysis was performed using SPSS version 20.0 software. Descriptive statistics were performed for sample characteristics calculating (percentage, mean and standard deviation).

The inferential statistics calculating (analysis of variance ANOVA (F) and independent t-test) was performed to compare groups in categorical variables.

When the p-value was less than 0.05, it was considered significant, and less than 0.001 was considered highly significant.

RESULTS

Demographics and clinical characteristics

A total of 200 children were enrolled between December 2020 and January 2021, Of the 200 children enrolled, 180 children and their caregivers were approached during the study period. Among them Parent did not give consent: (n=5); Not meeting inclusive criteria: (n=12)

Protocol violation: (n=3) were excluded as they displayed a significantly altered emotional state when the operative procedures could compromise a valid expression of the actual perceived pain.

Enrolled children were subdivided into two groups of 90 children in the Intervention Group and 90 in the control group. Procedural pain scores among study groups were presented in table 1-5. The pain level was evaluated based on observer report and parent report and. The pain levels of children showed statistically significant.

Table 1 Social-demographic Variables of Respondents

Individual scenario.								
Variables		Treatment group			ANOVA			
		Intervention Group n=90 (50%)		Control Group n=90 (50%)	Frequency n=180 (100%)	Mean ± SD Comparisons	Z-score Comparisons	Inferential Statistics
		BDG n=45 (25%)	DG n=45 (25%)					
Total no of respondents					**180 (100%)**			
Age (years).	6-8 yrs.	16 (35.5%)	17 (37.7%)	46 (51.1%)	79 (43.8%)	20 ± 10.12	15.81	p< 0.0001 HS*
	9-11 yrs.	14 (31.1%)	16 (35.5%)	28 (31.1%)	58 (32.2%)			
	12-14 yrs.	15 (33.3%)	12 (26.6%)	16 (17.7%)	43 (23.8%)			
Gender.	Male.	26 (57.7%)	23 (51.1%)	39 (43.3%)	88 (48.8%)	30 ± 11.34	13.22	p< 0.0001 HS*
	Female.	19 (42.2%)	22 (48.8%)	51 (56.6%)	92 (51%)			
Birth order.	First.	18 (40%)	19 (42.2%)	43 (47.7%)	80 (44.4%)	30 ± 11.16	13.20	p< 0.0001 HS*
	Second.	27 (60%)	26 (57.7%)	47 (52.2%)	100 (55.5%)			
Operative procedures.	Venipuncture.	19 (42.2%)	20 (44.4%)	44 (48.8%)	83 (46.1%)	30 ± 10.90	13.76	p< 0.0001 HS*
	Dental procedure.	26 (57.7%)	25 (55.5%)	46 (51.1%)	97 (53.8%)			

Citation:
Volkan Susam, Marie Friedel, Patrizia Basile, Paola Ferri, Loris Bonetti. Efficacy of the Buzzy System for pain relief during venipuncture in children: a randomized controlled trial. Acta Biomed for Health Professions 2018;89(S.6):6-16.

Significance level p< 0.0001, *Significant; HS: Highly significant.

BDG: Buzzy more Distraction cards group.
DG: Distraction cards group.
CG: Control Group.

Table 2 Social-demographic Variables of Parents of Studied groups of buzzy intervention Respondents

Individual scenario.								
Variables		Treatment group			Frequency n=180 (100%)	ANOVA		
		Intervention Group n=90 (50%)		Control Group n=90 (50%)		Mean ± SD Comparisons	Z-score Comparisons	Inferential Statistics
		BDG n=45 (25%)	DG M, n=45 (25%)					
Total no of respondents					**180 (100%)**			
Age (years).	20-30 yrs.	14 (31.1%)	13 (28.8%)	28 (31.1%)	55 (30.5%)	20 ± 8.35	19.16	**p< 0.0001 HS***
	30-40 yrs.	21 (46.6%)	20 (44.4%)	37 (41.1%)	78 (43.3%)			
	40-50 yrs.	10 (22.2%)	12 (26.6%)	25 (27.7%)	47 (26.1%)			
Caregiver attending the procedure.	Mother.	23 (51.1%)	18 (40%)	42 (46.6%)	83 (46.1%)	20 ± 9.87	16.21	**p< 0.0001 HS***
	Father.	8 (17.7%)	11 (24.4%)	18 (20%)	37 (20.5%)			
	Grandparents.	14 (31.1%)	16 (35.5%)	30 (33.3%)	60 (33.3%)			
Parents' educational level.	Illiterate.	4 (8.8%)	5 (11.1%)	19 (21.1%)	28 (15.5%)	15 ± 7.86	20.99	**p< 0.0001 HS***
	Primary.	10 (22.2%)	8 (17.7%)	16 (17.7%)	34 (18.8%)			
	Secondary.	20 (44.4%)	21 (46.6%)	31 (34.4%)	72 (40%)			
	University.	11 (24.4%)	11 (24.4%)	24 (26.6%)	46 (25.5%)			
Residence.	Urban.	24 (53.3%)	22 (48.8%)	38 (42.2%)	84 (46.6%)	30 ± 11.38	13.18	**p< 0.0001 HS***
	Rural.	21 (46.6%)	23 (51.1%)	52 (57.7%)	96 (53.3%)			

Citation:
Sahar Sedky Faheem. Efficacy of Buzzy with Distraction Cards Versus the Traditional Method for Reducing Pain and Parent's Satisfaction during Venipuncture in healthy Children. IOSR Journal of Nursing and Health Science. 2019;8(03):78-89.

Significance level p< 0.0001, *Significant; HS: Highly significant.

BDG: Buzzy more Distraction cards group.
DG: Distraction cards group.
CG: Control Group.

Table 3 Description of the Results of Caregivers' Satisfaction Questionnaire for the Buzzy System-Likert scale

Individual scenario.						
Total no of respondents			**90 (100%)**			
Variables	**Frequency- Scores n (%)**					
Parents' satisfaction	No n (%)	Probably not n (%)	Do not know. n (%)	Yes n (%)	Definitely n (%)	
Total no of respondents			90 (100%)			
My child was comforted using the Buzzy System during the procedure.	0	2	5 (5.5%)	7 (7.7%)	6 (6.6%)	
It was a positive experience.	1 (1.1%)	2 (2.2%)	4 (4.4%)	8 (8.8%)	9 (10%)	
I think the Buzzy System is easy.	0	0	3 (3.3%)	5 (5.5%)	9 (10%)	
I would like to use the Buzzy System for tests done on my son/daughter's future.	0	0	5 (5.5%)	6 (6.6%)	18 (20%)	
	ANOVA					
Mean ± SD Comparisons			4.5 ± 4.33			
z-score Comparisons			19.74			
Inferential Statistics			p< 0.0001 HS*			

Citation:
- Friedel M, Whitman J, Magnani L. Boosting pain awareness through Buzzy Bee. Poster presentation at the 2nd European Congress on Pediatric Palliative Care, Fondazione Maruzza, Rome, 19-21st November 2014.
- Hanan Mohamed Mohamed Tork. Comparison of the Effectiveness of Buzzy, Distracting Cards and Balloon Inflating on Mitigating Pain and Anxiety During Venipuncture in a Pediatric Emergency Department. American Journal of Nursing Science. 2017;6(1):26-32.

Significance level p< 0.0001, *Significant; HS: Highly significant.

Table (1) illustrated that the age of children ranged from 6 years to 14 years, the major ranged from 4 < 8 were 36%(n=33) of the experimental group and 51.1% (n=46) control group.

As regards gender, for both the experimental and control groups, it was found that45% (n=41) and 56.6% (n=51) were females, compared to 54.4% (n=49) and 43.3% (n=39) being males, respectively.

Less than half, 47.7% (n=43), 52.2% (n=47) of children were second order for both the experimental and control groups, respectively.

Regarding the reason for venipuncture 46.1% (n=83) and 53.8% (n=97) of children for Dental procedure.

Table (2) illustrated that parents' mean age was 34.1 ± 8.45 years in the experimental group compared to 37.3 ± 8.82 years in the control group.

Concerning Caregiver attending the procedure, for both groups, it was found that 45% (n=41) and 46.6% (n=42) were mothers with a non-significance difference (P>0.05) between the two groups.

Regarding parents' educational level 45.5% (n=41) and 34.4% (n=31) of parents in experimental and control groups had secondary education respectively. More than half, 53% (n=96) of parents live in a rural area while (n=84) 46.6%of parents live in an urban area with a significant difference (p< 0.0001) between the two groups regions.

Table (3) illustrated the Caregivers' Satisfaction Questionnaire for the Buzzy System.

20%(n=18) of parents said they would reuse the Buzzy System in the future for tests done.

1%(n=1) negative opinions were expressed for any of the questions regarding the Buzzy System.

FLACC Scale

Table (4) illustrated the study population's distribution according to projective scales (FAPS and MFAS) during the invasive procedure.

With FAPS, the distribution was uniform for “fearful” and “not fearful” in both phases were Statistics significant. (Wilcoxon signed ranks test, Z = 6.74, p< 0.0001 (HS)

However, with MFAS, the percentage of children with "anxiety scales" during the procedure phase was statistically significant. {Wilcoxon signed ranks test, Z = 8.66, p< 0.0001 (HS)}.

Table (5) and Graph (1) illustrated **the FLACC Scale.**

In the intervention group, most of the children, 6.6 % (n=12), described the pain score '0', which refers to 'no pain'. Only 43.3% (n=78) children expressed pain score '1and 2', which refers to 'very much pain' and were Statistics non-significant? (P = 0.608 NS).

Only 8.8 (n=16) children (small group) in the control group described pain score '0', which refers to 'no pain'. The second majority of the group, 41.1% (n=74), responded pain score of '10', which refers to 'very much pain'.

As shown in table (5), there was a significant increase in pain scores in the intervention group compared to the control group. Table (5) showed that there was an enormously significant (P = 0.0036 SS).

The use of directed distraction did not show significant weight either for pain or for fear. The use of the colder vibration device did not show significant correlations with pain and fear variables.

Figure 1

Table 4 Distribution of study population according to Frankl’s behaviour rating scale versus projective scales (FAPS and MFAS)- FLACC Scale

Individual scenario.					
Total no of respondents	**180 (100%)**				
Frankl’s behaviour rating scale	**MFAS n=180 (100%)**			**FAPS n=180 (100%)**	
	No anxiety	**Some anxiety**	**Very high anxiety**	**Fearful**	**Not fearful**
Definitely positive (+ +) n=10	10 (5.5%)	0	0	1 (0.5%)	9 (5%)
Positive (+) n=18	13 (7.2%)	5 (2.7%)	0	6 (3.3%)	12 (6.6%)
Negative (−) n=97	5 (2.7%)	62 (34.4%)	30 (16.6%)	26 (14.4%)	71 (39.4%)
Definitely negative (− −) n=55	0	12 (6.6%)	43 (23.8%)	7 (3.8%)	48 (26.6%)
		ANOVA			
Mean ± SD Comparisons		15 ± 19.05		22.5 ± 23.36	
Z-score Comparisons		8.66		6.74	
Inferential Statistics		p< 0.0001 HS*		p< 0.0001 HS*	

Citation:

- Merkel SI, Voepel-Lewis T, Shayevitz JR, Malviya S. The FLACC: a behavioural scale for scoring postoperative pain in young children. Pediatric Nursing, 1997;23(3):293-297.
- Voepel-Lewis T, Zanotti J, Dammeyer JA, Merkel S. "Reliability and validity of the face, legs, activity, cry, Consolability behavioural tool in assessing acute pain in critically ill patients". Am. J. Crit. Care. 2010;19(1):55–61.

FAPS: Fear assessment picture scale.
MFAS: Modified facial affective scale.
Significance level p< 0.0001, *Significant; HS: Highly significant

No differences were found for fear. The Tukey test showed differences between the BDG-CG and DG-CG groups for both pain and anxiety in companions. No differences were found for any variable between the GBD-GD groups (Table 2).

DISCUSSION

Fear of dentists and dental procedures and the associated anxiety is common among children. Age is among the factors that influence the level of dental anxiety among pediatric patients (Hanan Mohamed Mohamed Tork, 2017).

This study protocol provides the rationale and methods associated with a randomised controlled non-inferiority trial. It compares the Buzzy device to an invasive procedure to improve procedural pain and distress management in children undergoing needle-related procedures.

Baxter *et al*. 2011; Inal and Kelleci. 2012 had investigated the Buzzy method's application in pediatric populations during venipuncture.

The present study showed that more females presented for the invasive procedure than males, which may explain the higher proportion of females presenting with pain.

Stefano Pieretti *et al*.,2016 presented an extreme gender difference in the female to male ratio of 3:1 for orofacial pain attributed to the lower pain threshold and better health motivation of females, resulting in a higher prevalence of females who 'actively' seek treatment for health complaints generally.

According to von Baeyer's FLACC scale has been chosen as the best, most comfortable, and most compatible scale with self-evaluating scales.

Table 5 FLACC Scale

Individual scenario.					
Total no of respondents			**180 (100%)**		
Variables	**Scores**	**Respondents**	**Frequency- Scores n (%)**		
			BDG n=45 (25%)	**DG n=45 (25%)**	**CG n=90 (50%)**
Face.	0	No expression or smile.	2 (4.4%)	1 (2.2%)	3 (3.3%)
	1	Occasional grimace or frown, withdrawn, disinterested.	3 (6.6%)	1 (2.2%)	6 (6.6%)
	2	Frequent to constant quivering chin, clenched jaw.	7 (15.5%)	9 (20%)	11 (12.2%)
Legs.	0	Normal position or relaxed.	1 (2.2%)	2 (4.4%)	4 (4.4%)
	1	Uneasy, restless, tense.	3 (6.6%)	3 (6.6%)	6 (6.6%)
	2	Kicking or legs were drawn up.	0	0	1 (1.1%)
Activity.	0	Lying quietly, the normal position moves easily.	1 (2.2%)	2 (4.4%)	3 (3.3%)
	1	Squirming, shifting back and forth, tense.	2 (4.4%)	2 (4%)	6 (6.6%)
	2	Arched, rigid or jerking.	4 (8.8%)	4 (8.8%)	6 (6.6%)
CRY.	0	No cry (awake or asleep).	1 (2.2%)	1 (2.2%)	2 (2.2%)
	1	Moans or whimpers; occasional complaint.	10 (22.2%)	10 (22.2%)	18 (20%)
	2	Crying steadily, screams or sobs frequent complaints.	3 (6.6%)	2 (4.4%)	6 (6.6%)
CONTROLLABILITY.	0	Content, relaxed.	1 (2.2%)	0	4 (4.4%)
	1	Reassured by occasional touching, hugging, or being talked to, distractible.	7 (15.5%)	8 (17.7%)	12 (13.3%)
	2	Difficult to console or comfort.	0	0	2 (2.2%)
		ANOVA			
		Mean ± SD Comparisons	BDG 3.9 ± 3.04	DG 3.5 ± 3.57	CG 7.4 ±4.75
		Student's t test	t = 0.51 df = 88		t = 2.9 df = 178
		Inferential Statistics Comparisons (BDG + DG)		P = 0.608 NS*	
		Inferential Statistics Comparisons (BDG + DG + CG)		**P = 0.0036 SS***	

Citation:

- Merkel SI, Voepel-Lewis T, Shayevitz JR, Malviya S. The FLACC: a behavioural scale for scoring postoperative pain in young children. Pediatric Nursing, 1997;23(3):293-297.
- Voepel-Lewis T, Zanotti J, Dammeyer JA, Merkel S. "Reliability and validity of the face, legs, activity, cry, Consolability behavioural tool in assessing acute pain in critically ill patients". Am. J. Crit. Care. 2010;19(1):55–61.

BDG: Buzzy more Distraction cards group.
DG: Distraction cards group.
CG: Control Group.
FAPS: Fear assessment picture scale.
MFAS: Modified facial affective scale.
Significance level p< 0.0001, *Significant; NS: Statistically Non-significant; SS: Statistically significant.

Our results demonstrated the Buzzy System's efficacy combined with distraction cards to reduce pain perception during invasive procedures compared to other distractive techniques.

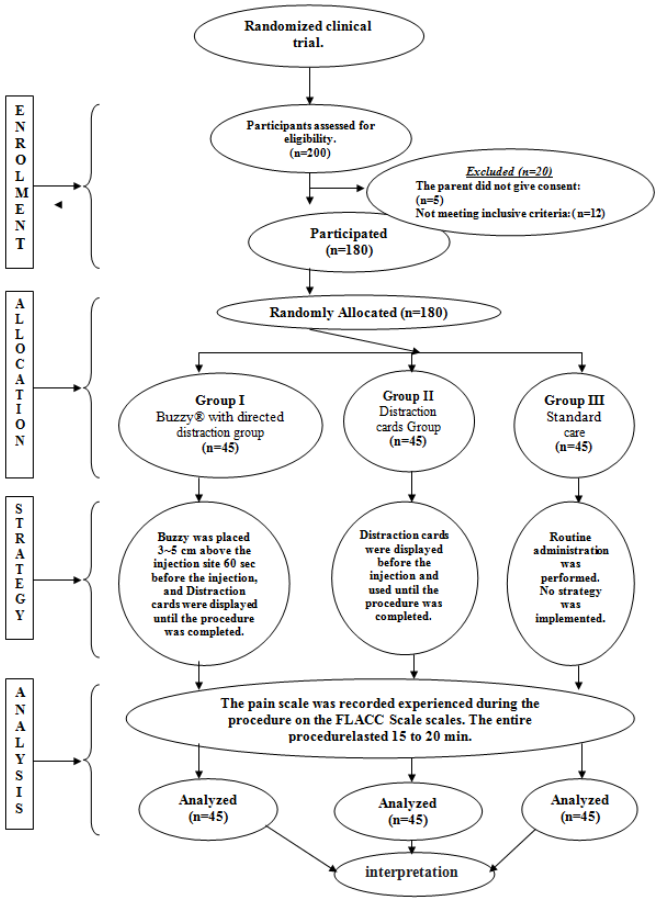
Their grades range between 0 and 10 simultaneously with the FLACC scale. Breau *et al*. found that Body, Limbs and Social categories in their pain tool were less reliable to pain (Breau LM., 2002).

In contrast, Terstegen *et al*. showed that facial expressions were more sensitive indicators of pain than motor behaviour(Terstegen C *et al* 2003).

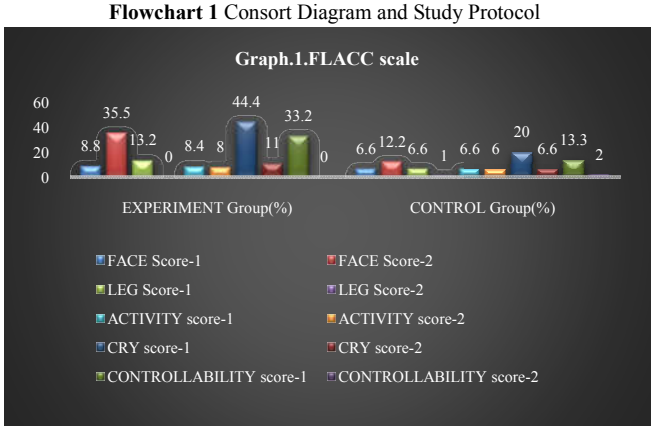
In the current study, the FLACC scale has fulfilled the construct validity due to the rising pain level during the injection procedure compared with placebo.

Impact of combined cryotherapy, vibration, and distraction

In our study, the impact of combining the cold effect (frozen wings of the Buzzy) with the vibration (produced by the Buzzy) seems to be more efficacious than the magic gloves techniques alone. The lowered pain scores founded in our study confirmed those founds in other studies related to many invasive procedures (Sahiner NC *et al*., 2016).



Flowchart 1 Consort Diagram and Study Protocol



Distraction is strongly correlated to hypnosis. Some characteristics are similar, namely the specific involvement of adult (nurses or parents), the possibility of the child making a choice, and finally, the child's interactivity with an adult. Compared to the complete absence of any form of treatment, the Buzzy System has shown itself efficacious in various invasive procedures, reducing the child's pain. In our study, Buzzy System was efficacious in pain reduction compared to other distractive techniques (Moadad N *et al*., 2016).

Shilpapriya *et al*., 2016 studied the effectiveness of DentalVibe on 30 patients between the ages of 6- and 12-years using Frankel's behaviour scale. The study showed a significant reduction in pain level using Dental Vibe, which contrasted with the present study using buzzy.

Impact of distraction

Vetri Buratti C *et al*., 2015 studies have shown that distraction can diminish the perception of procedural pain in children and adolescents, like the present study.

Sahiner NC *et al*., 2016 stated that distraction cards were potent in reducing pain and anxiety levels during venipunctures than other distraction techniques such as listening to music or balloon inflation.

Distraction is a behaviour management technique that involves distracting the patient from stimuli that caused anxiety and reducing it. The objective of this technique is to relax the patient and reduce anxiety during treatment. According to previous studies, the ideal distracter should possess optimal attention, which involves using multiple sensory modalities (visual, auditory, and kinesthetic), active emotional involvement, and the patient's participation to compete with the signals from the noxious stimuli (Ebrahimpour F *et al*., 2015).

Active forms of distraction promote a child's participation involving different sensory components such as interactive toys, virtual reality, controlled breathing, guided imagery, and relaxation, and writing in the air using their leg. Conversely, the passive forms can be used for distraction by asking a child to observe an activity or stimulus rather than explicitly involve them in a specific activity such as listening to music or watching television (Allani S *et al*., 2016)

The role given to caregivers/parents during painful procedures

Acceptability of the Buzzy System by parents was largely confirmed. Five had a negative experience during its use. Five parents would reuse the system in the future. In this aspect, our results confirmed those of Friedel *et al*., 2014.

Goffaux *et al*., 2007 stated that allowing parents to have an active role using distraction cards might empower parents to comfort their child's pain and anxiety instead of feeling helpless and anxious. For children having their parents secured might lower their anxiety. Nevertheless, the Buzzy System's impact may be less efficacious among children who experienced a high level of pain in the past and developed needle phobia, which was not on par with the present study.

Limitations

1. A single researcher stayed with the children during the intramuscular injections and later assessed the self-reported pain in children after the procedure. Having one person administer the intervention and evaluate the results may have induced bias in the children's answers.
2. Objective measurement methods cannot assess pain level.

3. Comparison with Buzzy System with pharmacological intervention, such as anaesthetic not conducted.
4. More extensive studies with larger sample sizes should be conducted to obtain more statistically significant results and make them commercially available.
5. The parent's questionnaire results with children's pain scores were not compared because questionnaires were strictly anonymous.

CONCLUSION

Our study's relevance is that the Buzzy System with distraction cards has proved efficacious in reducing pain even compared to other distractive techniques, which underlines all three components' relevance (vibration, cryotherapy, and distraction).

Family-centred care and partnership with parents are the core elements of quality care provided to children.

Clinical implication

- Health care professionals should be aware of the harmful effects of procedural pain and anxiety in children.
- One of the most common painful procedures in paediatrics.
- The WHO and several Pediatric Societies advocates improving the approach to pain and anxiety in children in a medical environment.
- Use distraction methods and know different nonpharmacological methods that may reduce their impact.

Conflict of interest & source of funding

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Ethical disclosures

- ***Protection of human and animal subjects:*** The authors declare that no experiments were performed on humans or animals for this study.
- ***Confidentiality of data:*** The authors declare that no patient data appear in this article.
- ***Right to privacy and informed consent:*** The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author owns this document.

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Reference

1. Ramandeep Kaur, Vandna, Harsh Vardhan Gupta. A study to assess the cough trick method's effectiveness in reducing pain among (6-12yrs) old children undergoing intravenous cannulation. *International Journal of Medical and Health Research* 2019;5(11):127-129.
2. Kleinknecht RA, Klepac RK, Alexander LD. Origins and characteristics of fears in dentistry. *J Am Dent Assoc* 1973; 86:842-848.
3. Jacobson A.F. Intradermal standard saline solution, self-selected music, and insertion difficulty effects on intravenous insertion pain. Heart Lung 1999; 28:114-22.
4. Ogle OE, Mahjoubi G. Advances in local anaesthesia in dentistry. Dent Clin North Am 2011; 55:481-499.
5. Elbay U¨S, Albay M, Yıldırım S, Kaya E, Kaya C. Evaluation of the injection pain with the use of the DentalVibe injection system during supraperiosteal anaesthesia in children: a randomised clinical trial. *Int J Paediatr Dent* 2016; 26:336-345.
6. Aydin D, Sahiner, NC, Çiftçi EK. Comparing the effectiveness of three different methods in decreasing pain during venipuncture in children: ball squeezing, balloon inflating and distraction card. *J Clin Nurs* 2016; 25:2328-35.
7. Çelik N. Investigation of the effect of "ShotBlocker" on reducing pain and anxiety associated with intramuscular injection. İzmir: Ege University Institute of Health Sciences 2012. p.1-185.
8. Redfern RE, Chen JT, Sibrel S. Effects of thermomechanical stimulation during vaccination on anxiety, pain, and satisfaction in pediatric patients: A randomised controlled trial 2018;38:1-7.
9. Melzack R, Wall P.D. Pain mechanisms: a new theory. Science 1965; 150:971-9.
10. Yeonsil Moon, Yoon-Sook Kim, Jongmin Lee, and Seol-Heui Han. The validity of the Korean Version of the Face, Legs, Activity, Cry, and Consolability Scale for Assessment of Pain in Dementia Patients. *J Korean Med Sci* 2017; 32:1852-1856.
11. Voepel-Lewis T, Zanotti J, Dammeyer JA, Merkel S. Reliability and validity of the face, legs, activity, cry, consolability behavioural tool in assessing acute pain critically ill patients. *Am. J. Crit. Care* 2010;19(1):55-60.
12. Piaggio G, Elbourne DR, Pocock SJ. CONSORT Group. Reporting of non-inferiority and equivalence randomised trials: extension of the CONSORT 2010 statement JAMA 2012; 308:2594–604.
13. Kearl YL, Yanger S, Montero S, Morelos-Howard E, Claudius I. Does Combined Use of the J-tip® and Buzzy® Device Decrease the Pain of Venipuncture in a Pediatric Population? *J Pediatr Nurs* 2015; 30:829-33.
14. Bijttebier P, Vertommen H. The Impact of Previous Experience on Children's Reactions to Venepunctures. *J Health Psychol* 1998; 3:39-46.
15. Merkel SI, Voepel-Lewis T, Shayevitz JR, Malviya S. The FLACC: a behavioural scale for scoring postoperative pain in young children. Pediatric Nursing 1997;23(3):293-297.
16. Voepel-Lewis T, Zanotti J, Dammeyer JA, Merkel S. "Reliability and validity of the face, legs, activity, cry, consolability behavioural tool in assessing acute pain in critically ill patients". *Am. J. Crit. Care* 2010;19(1):55-60
17. Friedel M, Whitman J, Magnani L. Boosting pain awareness through Buzzy Bee. Poster presentation at the 2nd European Congress on Pediatric Palliative Care, Fondazione Maruzza, Rome, 19-21st November 2014.
18. Hanan Mohamed Mohamed Tork. Comparison of the Effectiveness of Buzzy, Distracting Cards and Balloon Inflating on Mitigating Pain and Anxiety During

Venipuncture in a Pediatric Emergency Department. *American Journal of Nursing Science* 2017;6(1):26-32.
19. Birnie KA, Noel M, Parker Jal.Systematic review and meta-analysis of distraction and hypnosis for 1needle-related pain and distress in children and adolescents. *J Pediatr Psychol* 2014; 39:783-808.
20. Inal S, Kelleci M. Distracting children during blood draw: Looking through distraction cards effectively reduces children's pain relief during the blood draw. *Int J Nurs Pract* 2012; 18:210–9.
21. Stefano Pieretti, Amalia Di Giannuario, Rita Di Giovannandrea, Francesca Marzoli, Giovanni Piccaro, Paola Minosi and Anna Maria Aloisi. Gender differences in pain and its relief. Ann Ist Super Sanità 2016; 52(2):184-189
22. Breau LM, Finley GA, McGrath PJ. Validation of the noncommunicating children's pain checklist-postoperative version. Anesthesiology 2002; 96: 528–535
23. Terstegen C, Koot H.M., de Boer JB *et al*. Measuring pain in children with cognitive Impairment: pain response to surgical procedures. Pain 2003; 103: 187–198.
24. Sahiner NC, Bal, MD. The effects of three different distraction methods on pain and anxiety in children. *J Child Health Care* 2016; 20; 277-85.
25. Moadad N, Kozman K, Shahine R, Ohanian S, Badr L.K. Distraction Using the BUZZY for Children During an IV Insertion. *J Pediatr Nurs* 2016; 31: 64-72.
26. Shilpapriya M, Jayanthi M, Reddy VN, Sakthivel R, Selvaraju G, Vijayakumar P. Effectiveness of new vibration delivery system on pain associated with injection of local anaesthesia in children. *J Indian Soc Pedod Prev Dent* 2015;33: 173–176
27. Vetri Buratti C, Angelino F, Sansoni J, Fabriani L, Mauro L, Latina R. Distraction to control pain in pediatric patients during venipuncture. A narrative review of the literature. Prof Inform 2015; 68: 52-62.
28. Sahiner, NC, Bal, MD. The effects of three different distraction methods on pain and anxiety in children. *J Child Health Care* 2016; 20; 277-85.
29. Ebrahimpour F, Sadeghi N, Najafi M, Iraj B, Shahrokhi A. Effect of Playing Interactive Computer Game on Distress of Insulin Injection Among Type 1 Diabetic Children. *Iran J Pediatr* 2015; 25: e427.
30. Allani S, Setty JV. Effectiveness of distraction techniques in the management of anxious children in the dental operatory. *IOSR J Dent Med Sci* 2016; 15: 69-73
31. Goffaux P, Redmond WJ, Rainville P, Marchand S. Descending analgesia--when the spine echoes what the brain expects. Pain 2007, 130: 137-43

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