Original Article

The effect of combined external cold and vibration during immunization on pain and anxiety levels in children

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Abstract

Context: Pain associated with needle procedures is very common among children and causes discomfort among them.

Aim: The purpose of this study is to evaluate the effectiveness of combined external cold and vibration during immunization on pain and anxiety levels in children.

Setting and Design: This study was a randomized clinical trial in the Abdullahi Comprehensive Health Services Center in Qom, Iran, in 2019.

Materials and Methods: One hundred and five eligible children were allocated into experimental (external cold and Buzzy), placebo (off Buzzy device without cold), and control groups (no intervention). Simultaneous external cold and vibration (with Buzzy device) and appalling off Buzzy device were used in the experimental and placebo groups, respectively. Children in the control group had received routine care during immunization. The pain and anxiety levels of the children were measured using the Wong–Baker FACES Scale and Children's Emotional Manifestation Scale.

Statistical Analysis Used: Data were analyzed using Chi-square, one-way ANOVA, ANCOVA, and Scheffe *post hoc* analysis.

Results: Pain during immunization in the experimental group (3.71 ± 1.61) was significantly lower than the placebo (5.25 ± 1.37) and control groups (4.45 ± 4.45). The difference between before and after anxiety level was not significant in the three study groups ($P < 0.001$).

Conclusion: The simultaneous external cold and vibration (with Buzzy device) can be used as an effective intervention in pain reduction during intramuscular vaccine injection in children.

Keywords: Anxiety, Buzzy, Children, External cold, Immunization, Pain, Vibration

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INTRODUCTION

Pain caused by procedures such as intramuscular (IM) and intravenous injections can lead to discomfort in children, which can have numerous physiological, psychological, and emotional consequences.[1-4] Anxiety associated with these procedures is one of these consequences, which can also increase the intensity of pain. In addition, pain and anxiety can lead to avoidant behaviors such as rejecting painful treatments and delay in seeking healthcare in adulthood.[5-7]

A considerable number of IM injections are given annually for vaccination, which often causes pain in children;[6] therefore, pediatric nurses need to make an effective evaluation of pain and manage it accordingly.[8] For this reason, nonpharmacological methods are implemented to reduce the pain and anxiety caused by painful invasive interventions in various studies, such as venipuncture and vaccinations in children.[9,10] The advantage of nonpharmacological methods is that they could increase the patient's satisfaction by decreasing pain and reducing the use of analgesics.[4,8,11,12] Although there is robust evidence supporting the distraction efficacy in reducing pain and distress in children and adolescents, more trials in this area are needed to improve the quality of life in children.[13,14]

Distraction techniques are often provided by nurses or parents, and distraction can lead to the reduction in procedure times, the number of staff members required for the procedure,[15] and being more economical than the use of certain analgesics.[16] The application of cold, vibration, and distraction methods of different, touching, relaxation and electrical stimulation of the skin are effective in pain reduction;[14,17,18] however, problems such as time limitations in the procedures implementation, costs, and other limitations in the procedure execution result in the reduced use of these methods.[1,19]

Simultaneous implementation of vibration and cold using the Buzzy device is one of the common methods to reduce pain which is easy to use, and its effectiveness in pain control of needle-operated procedures has been confirmed.[20,21] However, most of these studies have been done in the intravenous injection procedure, and limited studies have been conducted on the pain associated with IM during vaccination. Furthermore, results of some studies indicated that future research should evaluate the distraction effectiveness in different societies and populations, so the evidence of cultural influences on pain expression and measurement are further explored.[22,23] On the other hand, there is a need to advance the quality of design and methodology and rigor in the intervention to achieve the efficacy of the Buzzy device.[24] The Buzzy is a battery-operated plastic vibrating motor resembling a bee that combines cold and vibration using a thin ice pack in wings. As a result, this study was carried out with the aim of investigating the effects of combined topical application of cold and vibration on the intensity of pain and anxiety during vaccine injection in Iranian children.

MATERIALS AND METHODS

Study design

This study was a randomized, placebo-controlled clinical trial with parallel group design. The trial was registered in the Iranian Registry of Clinical Trials (IRCT20190603043812N1). One hundred and five eligible children (7 years old) were allocated into experimental (external cold and vibration via Buzzy), placebo (off Buzzy device), and control (no pain reducing) groups. Considering the effect size (ES) of pain difference between the intervention and control groups (ES = 2)[20] and at a confidence level of 95% and a test power of 80%, the minimum sample size was estimated as 30 for each group. Considering of the possible sample attrition, 35 children were selected for each group (intervention, placebo, and control). Finally, there was no sample drop and the analysis was performed on 105 samples (35 children per group).

The study was conducted in the Abdullahi Comprehensive Health Services Center in Qom, Iran, from May 22, 2019, to July 22, 2019, where approximately 40 vaccines are performed daily. The standard regimen in this center did not include pain management play intervention.

Participants

The inclusion criteria for the children were (1) being a parent or child who is prepared to participate in the study, (2) the children not having taken an analgesic during the last 6 h, (3) being 7 years old, (4) the children were not to have neurodevelopmental delays or verbal difficulties, (5) no previous exposure to the Buzzy device, and (6) undergoing routine vaccination injection according to Iran's vaccination program. In this program, DTaP vaccine (diphtheria, tetanus, and pertussis) should be given at 7 years of age. Exclusion criteria were lack of cooperation during intervention at any stage for any reason and the mothers facing severe stressful factors during the study.

Randomization

The rationale for selecting children 7 years of age was children who require immunization before entering school in Iran. All children were selected by the sequential sampling

method and were randomized into one of the three groups of experimental ($n = 35$), placebo ($n = 35$), and control ($n = 35$) groups. Online software (www.randomizer.org) was used for random allocation of the samples into three groups. In this method, 105 closed envelopes were prepared with the numbers 1–105 placed inside. The child is asked to pick up one of the 105 sealed envelopes, open the envelope, and show it to the person in charge of the vaccination when entering the vaccination room. Finally, based on the numbers obtained from the online software, the allocation was made between the three groups [Figure 1].

Measures

The Wong–Baker FACES pain rating scale was used for child pain assessment. This tool was originally created for children to help them communicate about their pain. It can be used for people aged 3 and older. The scale is a self-report 0–10 scale that shows six cartoon faces that range from a neutral expression (0 - very happy/not hurt) to a crying face (10 - hurts as much as you can imagine).[25] In this study, children and the observer nurse scored each response independently.

The child anxiety was assessed by the Children's Emotional Manifestation Scale (CEMS) before and after IM injection. The CEMS was developed by Li and Lopez to provide a simple, objective, and consistent method for nurses to document children's emotional behavior during stressful medical procedures. This tool evaluates five observable behaviors. The five behaviors include "facial expression," 'vocalization," "activity," 'interaction," and "level of cooperation." These items rate on a 5-point scale, ranging from 1 to 5, and the total score will be 5–25. The psychometric study results showed that CEMS had adequate inter-rater reliability, high internal consistency reliability, and good content validity. The inter-rater reliability coefficient of the CEMS is reported as 0.96. Internal consistency of the scale was found to have alpha coefficients of 0.92, and the content validity

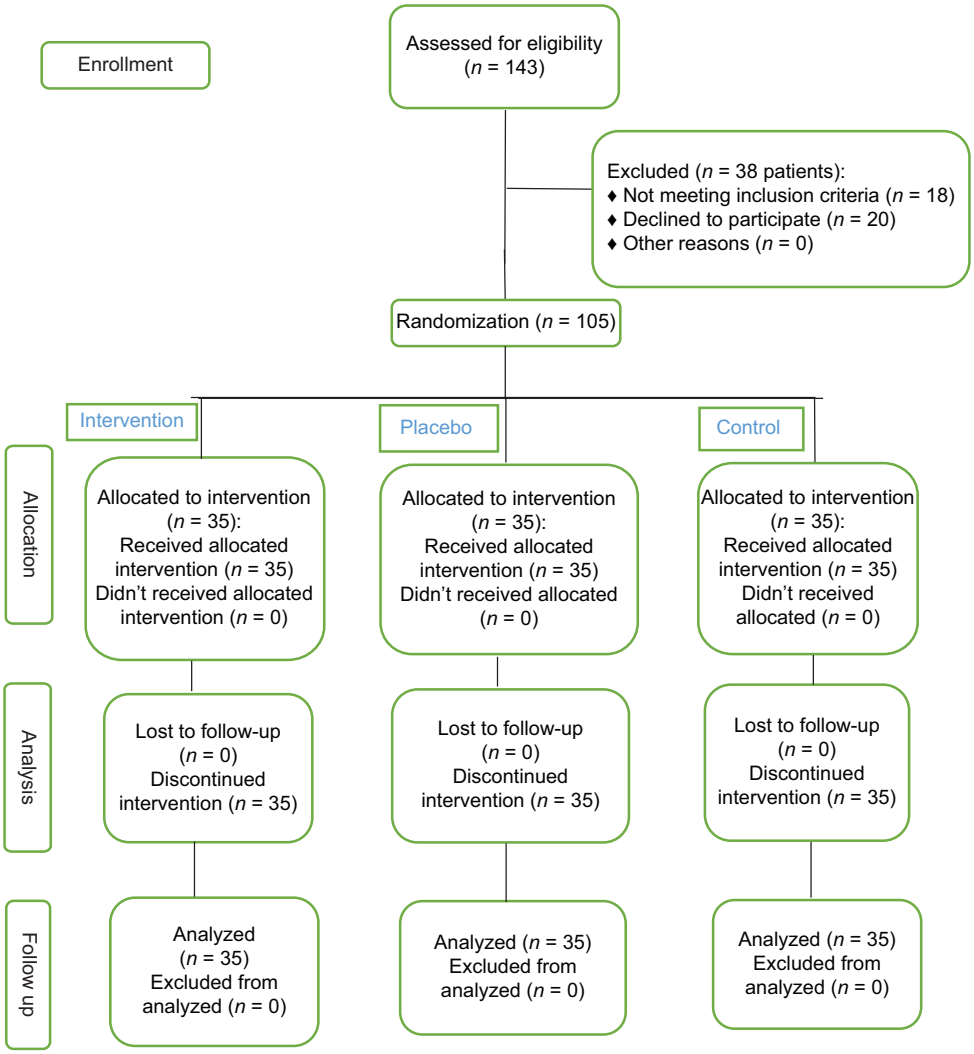

Figure 1: The study flowchart

index was 96%.[26] Simultaneous translations and blind back-translations were conducted on this questionnaire, followed by group consultations with bilinguals, and then the final Persian version was provided. In a preliminary study among 30 nurses, the reliability of the questionnaire was confirmed by Cronbach's alpha ($\alpha = 0.87$) and inter-rater reliability ($r = 0.89$).

Children's demographic information such as age and sex, parental education, and physical examinations such as height, weight, and blood pressure were collected from a preprepared checklist. The questionnaire was then distributed among parents of children, and they were asked to complete the questionnaire in a relaxed, stress-free environment and return it.

The Buzzy device

The Buzzy device (MMJ Labs, Atlanta, GA, USA) is a reusable, battery-operated plastic vibrating motor resembling a bee (8 cm × 5 cm × 2.5 cm) that combines cold and vibration using a thin (disposable or reusable) ice pack (wings). In this study, disposable ice packs were used and were solidly frozen before every application.

The study was approved by the Research Ethics Committee of Iran University of Medical Sciences (IR.IUMS.REC.1397.248). The trial was conducted based on the Declaration of Helsinki on research ethics, and all techniques performed in the trial were in accordance with the ethical standards of the Institutional Research Committee.[27] Before the study, the objectives and intervention techniques were explained to all children and their parents, using the face-to-face method by the principal researcher. Further, all parents were assured that they had the right to withdraw from the study at any time and an opportunity to receive routine treatment. Moreover, written informed consent was obtained from the parents of each child who volunteered.

Procedure

This project was conducted at a Comprehensive Health Services Center affiliated to Qom University of Medical Sciences that offers medical care to an ethnically and culturally diverse group of patients. Before intervention, the parents and their children were informed about the procedures, and their written and verbal consents were received using a face-to-face interview by the researcher. The child was instructed to mark the Wong-Baker FACES pain rating scale because the child was required to sign the emoticon similar to the severity of pain experienced. Furthermore, the CEMS instrument was completed by the same nurse observer (researcher) in two stages: (1) before entering the vaccination room and (2) during intervention. The vaccinator had a list according to which the three groups of control, placebo, and intervention with specific random numbers, and only the vaccinator knew the type of group and the child and mother did not know the type of group. Further, the observer nurse (researcher) was not aware of the type of intervention group (on Buzzy) and placebo (off Buzzy). All of the DTaP vaccine injections were performed in three groups by the same midwife with a bachelor's degree and 12 years' experience. The IM was performed in the left or right deltoid muscle, depending on whether the children were left handed or right handed. The right deltoid muscle was used for left-handed children, whereas the left deltoid muscle was used for right-handed children. If child randomized to the intervention group, the vaccinator used turn on vibration and attached the ice pack under the Buzzy device; in placebo group, the off Buzzy device was used, and in the control group, the injection was performed without any device. Based on the manufacturer's instructions, the Buzzy device was administered about 5 cm above the application area just before the procedure and continued through the end of the procedure. Anxiety was measured and recorded during the vaccine injection, when the site of injection was disinfected, and the vaccine was injected into the muscle. Furthermore, immediately following the injection, the observer rated the child's reaction and experience of pain before the child's rating. Then, the child was asked to rate how much the injection hurt using the Wong-Baker FACES pain scale by the nurse observer. All procedures lasted for approximately 20–30 min for each child.

All injections and evaluations in the placebo and control groups were similar to the intervention group except that the off Buzzy device was used in the placebo group and the injection was performed without any intervention in the control group.

Data analysis

All the data were analyzed using Statistical Package for the Social Sciences (SPSS) software version 22 (SPSS, Inc., Chicago, IL, USA). Chi-square test (or Fisher's exact test) and one-way ANOVA were used to test the homogeneity of groups for demographic and clinical data. To compare the mean changes of the pain VAS score between the experiment, placebo, and control groups after the intervention, we employed one-way ANOVA and Scheffe *post hoc* analysis. Further, to compare the before and after mean difference in changes of the anxiety score in the three study groups, we used one-way ANOVA and the Scheffe *post hoc* analysis. ANCOVA analysis was used to control the effects of some baseline variable (weight and body mass index [BMI]) and anxiety pretest

score on primary outcomes. A $P < 0.05$ was considered to be statistically significant.

RESULTS

The final sample size was 105 children 7 years of age. Fifty-three (50.4%) children were male. As shown in Table 1, no significant differences were found between the three groups in terms of demographic and clinical characteristics. Pain score of the three groups (Buzzy device, placebo, and control) are presented in Table 2. One-way ANOVA indicated a significant difference in the child and observer nurse reported pain score between the three groups after the intervention ($P < 0.001$). According to the Scheffe *post hoc* test, the mean difference in pain reported by the children in the intervention and placebo groups was − 1.25, and this difference was statistically significant ($P = 0.001$), while the mean difference in pain reported by the nurse in the intervention and control groups was − 0.85, which was statistically significant ($P = 0.02$). The pain reported by children and nurses was not significantly different between the placebo and control groups ($P = 0.45$). ANCOVA analysis showed that after controlling the effects of weight and BMI, the difference between pain scores (child and nurse report) in the three groups was still significant [Table 3]. The difference of pretest anxiety scores of children in the three groups was significant ($P = 0.001$), and also, the posttest anxiety score was statistically significant ($P = 0.003$) [Table 4]. The pre- and post-intervention anxiety mean difference compared in the intervention, placebo, and control group was not significantly different between the three groups ($P > 0.05$).

DISCUSSION

Needle-operated procedures are the most common cause of pain and anxiety among children referred to in healthcare systems and interventions that reduce pain can improve patient comfort and subsequently improve the quality of healthcare.[28,29]

In the present study, it was specified that applying vibration and cold using the Buzzy device led to demonstrating a statistically significant effect on reducing self-reported procedural pain and observer-reported procedural pain in comparison to children in placebo and control groups, but the level of anxiety in these three groups did not have a statistically significant difference after the intervention. In a study by Brown *et al.*, it was revealed that pain control is associated with increased patient satisfaction in the emergency department.[30] It has even been specified that pain and anxiety associated with receiving health services such as IM and intravenous injections as well as other cases which are done by needle can affect patient referrals to healthcare providers and in some cases result in delays in seeking healthcare.[7]

In a clinical trial, Redfern *et al.* showed that vibration with the Buzzy device was effective on pain associated with vaccination of children between 3 and 18 years old, but injection-related anxiety reported by children was not much different between the two groups and was in line with the results of our study.[16] In the clinical trial by Schreiber *et al.*, the use of the Buzzy device reduced pain during intravenous administration.[31] In the study carried out by Moadad *et al.*, application of external cold and vibration significantly led to pain reduction (reported by child and nurse observer) during intravenous administration in children between the ages of 4 and 12 years.[20] In the study by Canbulat *et al.*, which was conducted among 7-year-old children receiving vaccination, applying external cold and vibration by the Buzzy device resulted in significant reduction in the intensity of pain reported by children and nurse observers in the intervention group compared to the control group. Further, the intensity of anxiety reported by the researcher and the nurse observer was lower in the intervention group than in the control group.[12] Report of decreased anxiety was not supported by our study.

The effect of the Buzzy device on pain due to triple-vaccine injection was investigated in a study conducted in Turkey, and it was indicated that using the device among 7-year-old children participating in the study led to significant reduction in the amount of pain.[32] However, the results of a study on children between 2 months and 7 years of age indicated that the use of the Buzzy device did not have a significant effect on pain due to IM.[33] In the nursing profession,

Table 1: Comparison of characteristics in study groups (n=105)

Characteristics	Intervention	Placebo	Control	χ^2 or F	P
Gender[a]					
Male	13 (37.1)	18 (51.4)	22 (62.9)	4.64	0.09
Female	22 (62.9)	17 (48.6)	13 (37.1)		
Age (m) [b]	77.94 (3.86)	77.77 (3.23)	77.97 (3.26)	0.03	0.96
High (cm) [b]	118.10 (5.52)	116.26 (5.53)	119.14 (6.02)	3.38	0.105
Weight (kg) [b]	21.91 (3.93)	19.95 (3.93)	22.81 (4.22)	3.56	0.03
BMIb	15.67 (1.89)	14.72 (2.23)	15.94 (2.75)	2.67	0.07

[a]Data were presented as n (%), [b]Data were presented as mean±SD. SD: Standard deviation, BMI: Body mass index

Table 2: Comparison of means and standard deviation pain between study groups after vaccine injection (n=105)

Variables	Intervention (n=35)	Placebo (n=35)	Control (n=35)	F	P
Child report Pain (0–10)	3.71 (1.61)	5.25 (1.37)	4.45 (4.45)	8.25	<0.001
Observer nurse Pain (0–10)	3.37 (1.43)	4.62 (1.16)	4.22 (1.35)	8.22	<0.001

Higher scores indicate higher pain

Table 3: ANCOVA analysis for controlling of the participant's weight and body mass index effect on intramuscular pain

Parameter	*B*	SE	*t*	Significance	95% CI (lower bound–upper bound)
Pain (nurse report)					
Intercept	3.219	1.027	3.135	0.002	1.182–5.255
Weight	0.105	0.066	1.603	0.112	−0.025–0.236
BMI	−0.143	0.131	−1.098	0.275	−0.403–0.116
Group	0.401	0.164	2.442	0.016	0.075–0.726
Pain (child report)					
Intercept	4.191	1.262	3.320	0.001	1.687–6.695
Weight	0.111	0.081	1.375	0.172	−0.049–0.271
BMI	−0.181	0.161	−1.129	0.261	−0.500–0.137
Group	0.346	0.202	1.716	0.028	−0.054–0.746

BMI: Body mass index, SE: Standard error, CI: Confidence interval

Table 4: Comparison of anxiety (before and after mean differences) between study groups after vaccine injection

Variables	Intervention	Placebo	Control	*F*	*P*
Anxiety (before intervention)	7.62 (2.62)	9.34 (4.13)	9.37 (1.66)	7.97	0.001
Anxiety (before intervention)	9.37 (2.62)	11.71 (4.13)	12.11 (1.66)	6.34	0.003
Anxiety (before and after mean differences)	1.74 (2.62)	2.37 (4.13)	2.74 (1.66)	1.001	0.37

Higher scores indicate the manifestation of more negative emotional behavior

provision of patient comfort is one of the most important goals in the nursing process, and this has led to investigating and performing various types of nonpharmacological pain management interventions to achieve this goal.[34]

In general, the preparing of conditions for the injection has caused anxiety in children before the procedure;[29] in our study, the level of anxiety before and during the injection has increased in all three groups of the study, which due to the nature of people's reaction to expected severe and painful conditions is normal.[18] However, the rate of increase in anxiety in the intervention group was lower compared to the placebo and control groups. This level of anxiety reduction is clinically important in the intervention group, but further studies in this field are needed to reveal the effect of this type of intervention on children's anxiety.

Applying topical cold and vibration to control pain is easy compared to other nonpharmacological methods of pain management, and there are fewer restrictions to implement it. In addition, this method has fewer side effects than pharmaceutical methods such as the use of topical anesthetics and is also cost-effective.

Limitation

Lack of knowledge about how to perform this method and the existence of resistance to injection along with the use of Buzzy device was one of the implementation obstacles that tried to solve this problem with appropriate explanations. The limitation of the present study is relying on results from a specific region, which may not be reflective of behaviors in other regions of Iran. All samples in this study were 7-year-old children who received only one IM of the vaccine, so it seems that using this intervention at other ages and other similar interventions can be effective in generalizing the positive effects of applying this pain relief method.

CONCLUSION

Based on the findings of the present study, simultaneous application of cold and vibration using the Buzzy device can be effective in controlling the pain caused by IM of the vaccine in children. Thus, due to the capability of being easy to use for procedures like IM as well as being affordable, it is recommended to use the mentioned method to control children's pain to increase the quality of provided services and boost patient satisfaction.

Conflicts of interest

There are no conflicts of interest.

Authors' contributions

SK contributed in study design, interpretation, and editing the manuscript. HH contributed in statistical analysis and interpretation of finding. HA contributed in data collection, writing, and editing manuscript. MK contributed in data collection, writing the first draft of manuscript.

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