Cogitare Enfermagem

ORIGINAL ARTICLE

The effectiveness of Buzzy® in reducing pain associated with intramuscular injection in children: randomized clinical trial

HIGHLIGHTS

1. Buzzy® for 15 or 30 seconds before the intramuscular injection.
2. There was no statistical difference between the groups.
3. Similar clinical effect between Buzzy® for 15 and 30 seconds.
4. Lower report of moderate/severe pain in the experimental group.

Jefferson Wildes da Silva Moura[1]
Gabriela Ferreira Silva[2]
Thiago Lopes Silva[1]
Patrícia de Amorim Rodrigues[1]
Taynarianne Ferreira Alves[1]
Luciano Marques dos Santos[3]
Patrícia Kuerten Rocha[1]

ABSTRACT

Objective: To analyze the effectiveness of the Buzzy® device positioned 15 and 30 seconds before the intramuscular injection in reducing pain in children between one and three years old. **Method:** Randomized clinical trial conducted in two Pediatric Emergencies in Southern Brazil between May 2023 and March 2024. The sample was randomized into two groups: Experimental (Buzzy® 15 seconds before the procedure) and Control (Buzzy® 30 seconds before the procedure). The outcomes were pain and behavior. Data analysis was performed using frequencies, relative risks, and statistical tests (Pearson's X^2 and Fisher's Exact), adopting a 95% confidence interval. **Results:** The experimental group had mean pain scores of 4.35 ± 1.2, while the control group had 4.52 ± 1.0. The child with moderate pain/severe discomfort cried during the procedure ($p = 0.08$) and the behavior with the least association with pain was whimpering ($p = 0.08$). **Conclusion:** There was no statistically significant difference between the groups, but there was a similar clinical effect in both groups. The experimental group showed lower pain scores and fewer reports of moderate pain or severe discomfort.

DESCRIPTORS: Biomedical Technology; Injections, Intramuscular; Pain; Pediatric Nursing; Randomized Controlled Trial.

HOW TO REFERENCE THIS ARTICLE:
Moura JWS, Silva GF, Silva TL, Rodrigues PA, Alves TF, dos Santos LM, et al. The effectiveness of Buzzy® in reducing pain associated with intramuscular injection in children: randomized clinical trial. Cogitare Enferm [Internet]. 2025 [cited "insert year, month and day"];30:e100209en. Available from: https://doi.org/10.1590/ce.v30i.100209en

[1]Universidade Federal de Santa Catarina, Programa de Pós-Graduação em Enfermagem, Florianópolis, SC, Brasil.
[2]Universidade Federal de Santa Catarina, Departamento de Enfermagem, Florianópolis, SC, Brasil.
[3]Universidade Estadual de Feira de Santana, Mestrado Profissional em Enfermagem, Feira de Santana, BA, Brasil.

INTRODUCTION

Hospitalized children or those seen in the emergency room are subject to experiencing pain due to the numerous procedures performed. Pain can be understood as discomfort or unpleasant sensations related to sensory or motor factors, which may or may not involve tissue damage[1].

Despite the limitations of studies on pain in pediatrics, it is known that children are more vulnerable to painful experiences. In addition, they have different ways of expressing pain, hence the importance of knowing the developmental stage they are in, as well as the age group[2], aiming to use appropriate instruments for pain measurement.

One of the causes of pain in children when treated for health issues is the intramuscular injection, widely used due to its benefits. The intramuscular route of administration, besides being a viable option to replace the oral route when necessary, has a faster absorption than the subcutaneous route, allows for the administration of a larger volume of drug, and is less susceptible to irritation that some medications may cause[3].

Although it seems like a simple procedure, the intramuscular injection can cause fear, pain, and concern in children[4], which can result in altered behaviors such as crying, screaming, and thrashing, requiring, in some cases, restraint with the support of a guardian to proceed with the procedure.

In this sense, health professionals need to be trained to manage the pain felt by children, in order to reduce it, and for this, they can use pharmacological and non-pharmacological methods, such as the Buzzy® device[5-6]. The Buzzy® uses thermomechanical stimulation, with a wing-shaped bag containing non-toxic gel, which should be frozen and attached to the central device that produces vibration, and then placed on the child's skin[6].

The Buzzy® should be positioned at the site where the procedure will occur, for approximately 30 to 60 seconds before performing it. After this period, the device should be moved above the needle insertion site and the procedure performed. Subsequently, it is recommended that the Buzzy® be repositioned at the injection site for another 30 to 60 seconds, before being turned off and removed[6]. The Buzzy® acts according to the Gate Control Theory of Pain, by stimulating nerve endings with different sensations and causing a distraction that decreases the perception of pain in the affected area[7].

A systematic review with meta-analysis, conducted with 19 studies involving 2,846 children under twelve years of age, investigated the efficacy and safety of the Buzzy® device in reducing pain in needle-related procedures and showed that the Buzzy® device significantly reduces pain levels and outperforms other methods such as whistle-blowing, benzocaine gel, and Distraction Cards[5].

A randomized clinical trial conducted in Turkey, involving 96 children, aimed to determine the effects of the Helfer skin tap technique and the application of the Buzzy® on pain and fear levels in children during measles-mumps-rubella vaccination, performed intramuscularly, demonstrated that the Buzzy® was the most effective in pain relief[8].

Although studies demonstrate the effectiveness of using the Buzzy®, it is believed that the indicated time of 30 to 60 seconds is a prolonged period for children between one and three years old, which may cause suffering and consequently intensify pain, in addition to being challenging for the healthcare professional. Thus, the objective of this study was to analyze the effectiveness of the Buzzy® device positioned 15 and 30 seconds

before the intramuscular injection in reducing pain in children between one and three years old.

METHOD

Randomized clinical trial (RCT), controlled and open, registered in the Brazilian Clinical Trials Registry (ReBEC) under the number RBR-57m3wnw. It is noteworthy that the results presented in this work refer to the secondary analysis of RCT, with pre-specified groups: Buzzy® positioned for 15 or 30 seconds before the intramuscular injection, in the age range of one to three years old. Furthermore, the recommendations of the CONsolidated Standards Of Reporting Trials (CONSORT)[9] were followed. It is emphasized that this research is linked to the macroproject "Assistive and Educational Technologies for the Prevention of Adverse Events in Intramuscular Injections and Intravenous Therapy in Pediatrics".

The study was conducted in two Pediatric Emergency units belonging to two public hospitals in Southern Brazil, one being a university hospital and the other specialized in pediatrics. Data collection occurred from May 2023 to March 2024. Children between one and three years old participated in the research, receiving care in the aforementioned emergency units with a medical prescription for intramuscular injection.

Regarding the eligibility criteria, children aged one to three years old were included, with a medical prescription for intramuscular injection. Children with cognitive impairment or clinical conditions that could alter pain perception were not included in the research; those who had used local anesthetic prior to the procedure; those who underwent invasive procedures on the same day of data collection; as well as those diagnosed with Raynaud's disease, vasospastic disorders, excessive sensitivity to cold, heart diseases with local circulation impairment, or rheumatological or hypertensive diseases[10]. Children for whom the guardian requested the withdrawal of the data collected during the research were excluded. It is emphasized that these criteria were verified together with the guardians of the children.

The sample size for this study was calculated using G*Power software (version 3.1.9.7, University of Düsseldorf, Germany). The X^2 test was employed, with an effect size (Cohen's f) set at 0.5, a significance level (α) of 0.05, and a desired statistical power ($1 - \beta$) of 0.8. Thus, the calculations indicated a minimum size of 39 individuals in the sample, adding 20% for losses, resulting in a total of at least 48 individuals, equally divided into two groups (control and experimental) to compose the sample.

Children were randomly allocated by a combined method of stratified randomization in blocks of six children, for each of the groups: experimental or control. A researcher not linked to the project used the RANDOM program (www.random.org) to create the randomization list, with the sequence stored and sealed in opaque envelopes, which were opened only during the recruitment of research participants. The envelope contained the designation of the randomization groups, indicated by the letters A (experimental group) and B (control group).

After the study was approved by the Research Ethics Committee, training was conducted for the nursing professionals who would participate in the research. The mentioned professionals were invited to collaborate with the study and, after acceptance, the Informed Consent Form was read and signed. The training was conducted during

the work shift, either individually or in pairs. At the first moment, the sociodemographic and professional characterization instrument was filled out.

In the second moment, a dialogued expository class was held, in which the Buzzy® device and the research protocol[11], constructed based on relevant literature, were presented. Subsequently, a low-fidelity simulation was conducted in which the professional had the opportunity to administer an intramuscular injection with the Buzzy® on a low-fidelity simulator (doll). Professionals were allowed to clarify doubts during the training, and as new professionals were incorporated into the sector, after invitation and acceptance, training was conducted with them.

Regarding data collection with children, the following steps of the protocol were adopted: the child indicated for an intramuscular injection, after medical evaluation and confirmation of inclusion criteria, was invited to participate in the study along with their guardian, with the invitation directed to the guardian due to the age range of the participating children. After acceptance, the researcher led the child and their guardian to an available office or, in the absence of one, to the procedure room. Next, the research and the stages of data collection were presented, possible doubts were clarified, and the Informed Consent Form was provided for the guardian's signature.

After obtaining consent, the sociodemographic characterization data of the child and the guardian were recorded in the data collection instrument. Then, the randomization envelope was opened, indicating the group to which the child would be allocated. Subsequently, a Therapeutic Instructional Play session was conducted, in which the steps for administering the intramuscular injection and the use of the Buzzy® device, positioned for 15 seconds (experimental group) or 30 seconds (control group) before the procedure, were explained.

It is worth noting that the Therapeutic Instructional Play is recommended for children from 4 years of age; thus, the session was aimed at the guardian, who had the opportunity to observe the procedure being performed on a low-fidelity simulator (doll) and clarify doubts. Additionally, the guardian was allowed to perform the procedure on the simulator if they wished, and it is highlighted that the child remained with the guardian the entire time.

The continuous presence of the child next to the guardian was fundamental, as it allowed them to have prior contact with the Buzzy®, observe its functioning in a controlled environment, and thus reduce anxiety associated with using an unknown device. In this way, although the activity was primarily aimed at the guardian, the Therapeutic Instructional Play session also impacted the child, helping to familiarize them with the technique and reinforcing their trust in the guardian and the researcher.

After the Therapeutic Instructional Play session, the child and the guardian were directed to the procedure room, where the intramuscular injection was administered by the nursing professional in the sector, with the assistance of the Buzzy® device, according to the time determined by randomization. During the administration of the injection, the researcher assessed the child's pain using the Face, Legs, Activity, Cry, Consolability (FLACC) scale, whose classification is based on the score obtained by the child: 0 indicates relaxed or comfortable; from 1 to 3 corresponds to slight discomfort; from 4 to 6 represents moderate pain; and from 7 to 10 indicates severe discomfort, pain, or both[12]. Concurrently, some behavioral variables derived from the Observation Scale of Behavioral Distress (OSBD)[13] were analyzed. At the end of the procedure, the researcher thanked the child and the guardian for their participation, concluding the data collection.

The intervention variable was the assessment of the effectiveness of the Buzzy® device positioned 15 seconds before the intramuscular injection, while the control intervention variable was the positioning of the Buzzy® for 30 seconds. Regarding demographic variables, age, sex, education, skin color, and nutritional status of the child were evaluated. Additionally, the child's score on the FLACC Scale was measured. As for behavioral variables, it was checked whether the child cries, whines, screams, and is immobilized[13]. In relation to the intramuscular injection, the medication, dose, needle gauge, application site, and position of the child were verified. The outcome variables were divided into primary (pain) and secondary (behavior). Regarding the variables for characterizing the guardians, age, sex, degree of kinship, and education were evaluated.

The data were tabulated in Excel® (Microsoft 365) and analyzed using OpenEpi® software, version 3.01. For the characterization of children, guardians, and intramuscular injection, absolute and relative frequency measures were used for categorical variables. To ensure comparability of baseline variables in the characterization of allocation groups in the research and the relationship between intervention variables and outcomes, Pearson's X^2 test and Fisher's Exact test were employed for categorical variables, considering a significance level of 5%, relative risks, and a confidence interval of 95%.

The norms established by Resolution No. 466, of December 12, 2012, of the National Health Council of the Ministry of Health[14] were followed. The study was approved by the Research Ethics Committee of the Federal University of Santa Catarina, under opinion number: 5.901.237/2023 and by the Research Ethics Committee of the Joana de Gusmão Children's Hospital, under opinion number: 6.036.546/2023.

RESULTS

Of the 77 children evaluated for eligibility criteria, 11 were not included in the study, seven due to lack of time to apply the research protocol and four due to a diagnosis of autism or cognitive deficit (reported by the guardian). Four children were excluded, three due to a change in the route of administration (from intramuscular to intravenous) and one due to hospital discharge. Thus, 62 were included and received intramuscular injection using the Buzzy® device positioned for 15 or 30 seconds before the procedure, according to randomization (Figure 1).

Regarding the characteristics of the children, 34 (54.8%) were male, 24 (38.7%) were one year old, 45 (72.6%) attended daycare, 33 (53.2%) were white, and 31 (50%) were eutrophic. Regarding the guardians, 56 (90.3%) were female, 59 (95.2%) were the child's mother or father, and 34 (54.8%) had completed or incomplete high school (Table 1).

The intramuscular injection was mostly performed in the ventrogluteal muscle (n= 59, 95.2%), with a 0.60 mm x 25 mm needle (n= 59, 95.2%), with the child positioned in a prone position (n= 60, 96.8%) (hospital practice). Regarding medication, ondansetron was mainly administered (n= 23, 37.1%), followed by the combination of ondansetron and dipyrone in the same syringe (n= 20, 32.3%).

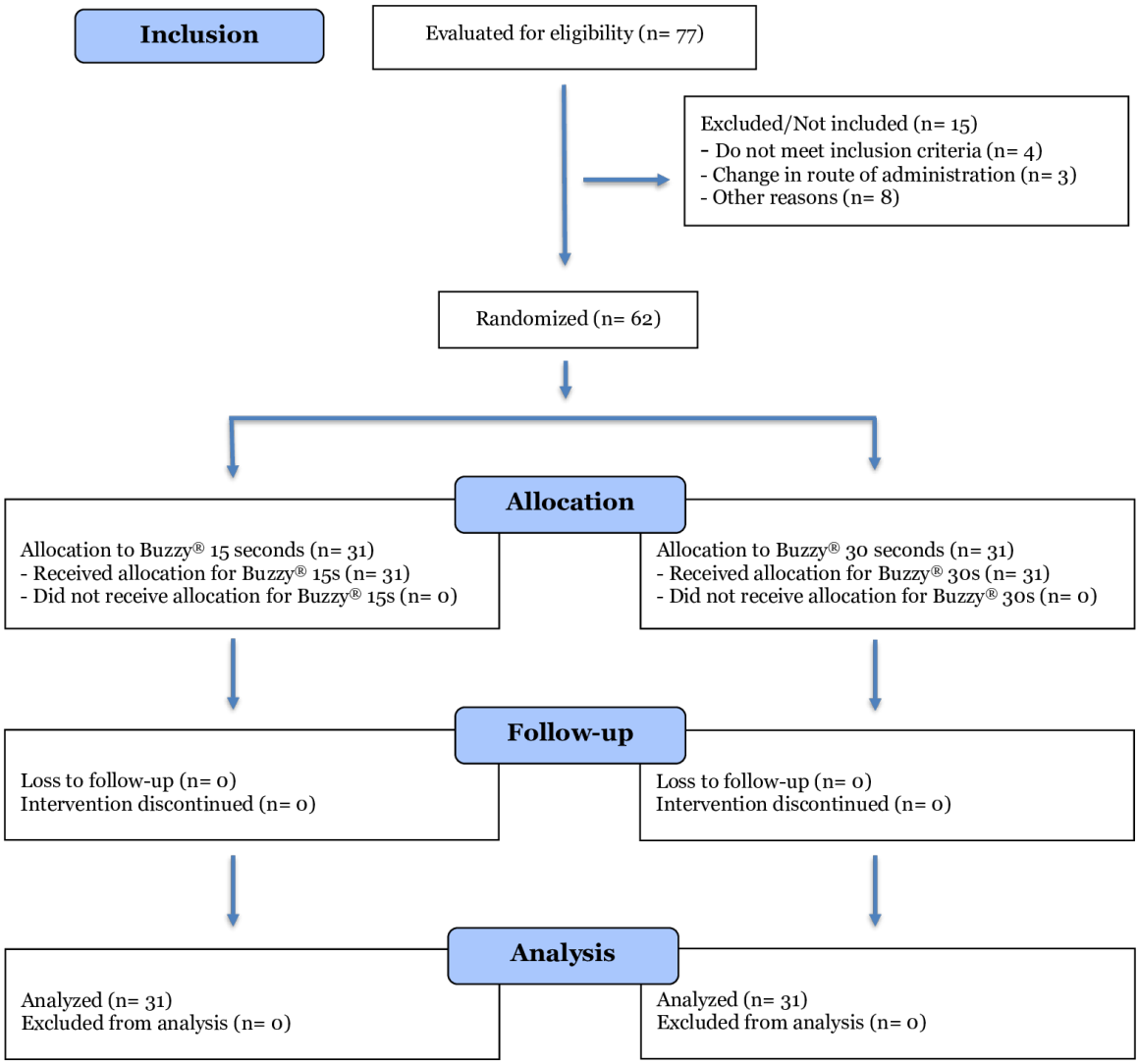

Figure 1. Flow diagram of the study stages. Florianópolis, SC, Brazil, 2024

Source: Adapted from CONSORT (2010)[9].

Table 1. Sociodemographic characteristics of the children and guardians. Florianópolis, SC, Brazil, 2024

(continue)

Variables	Experimental Group n (%)	Control Group n (%)
CHILD		
Gender		
Female	16 (51.6)	12 (38.7)
Male	15 (48.4)	19 (61.3)
Age		
1 year	14 (45.2)	10 (32.3)
2 years	8 (25.8)	12 (38.7)
3 years	9 (29.0)	9 (29.0)
Education		
Daycare	25 (80.6)	20 (64.5)
Early childhood education	1 (3.2)	0 (0)
Does not attend	5 (16.1)	11 (35.5)

Table 1. Sociodemographic characteristics of the children and guardians. Florianópolis, SC, Brazil, 2024

(conclusion)

Variables	Experimental Group n (%)	Control Group n (%)
CHILD		
Skin color		
White	18 (58.1)	15 (48.4)
Brown	12 (38.7)	13 (41.9)
Black	1 (3.2)	3 (9.7)
Nutritive condition		
Eutrophic	15 (48.4)	16 (51.6)
Thin or severely thin	5 (16.2)	7 (22.6)
At risk of overweight or overweight	7 (22.6)	7 (22.6)
Obesity or severe obesity	4 (12.9)	1 (3.2)
GUARDIANS		
Gender		
Female	29 (93.5)	27 (87.1)
Male	2 (6.5)	4 (12.9)
Degree of kinship with the child		
Mother/Father	30 (96.8)	29 (93.5)
Others	1 (3.2)	2 (6.5)
Age, mean ± SD	28.9 ± 7.0	30.3 ± 10.3
Education		
Complete or incomplete elementary education	3 (9.7)	6 (19.3)
Complete or incomplete high school education	19 (61.3)	15 (48.4)
Complete or incomplete higher education	9 (29.0)	10 (32.3)

Legend: n = number; SD = standard deviation.

Source: The authors (2024).

Regarding pain, a difference was found between the mean of the experimental group and control group of 0.17 for the control group (Experimental Group = 4.35 ± 1.2; Control Group = 4.52 ± 1.0). Regarding the degree of pain, the experimental group reported more instances of mild discomfort (n= 10, 32.3%), compared to the control group (n= 4, 12.9%); regarding moderate pain, the experimental group reported 20 instances (64.5%) compared to 27 (87.1%) from the control group.

When associating pain with the variables related to the procedure, it was found that there was no statistically significant relationship between the variables, thus indicating that the dose of the medication, needle gauge, position, and injection administration region are not associated with the child experiencing different levels of pain (Table 2).

Regarding behavior, it was observed that the child, when experiencing moderate pain or severe discomfort, expresses crying during the intramuscular injection (p= 0.08; RR = 0.74; CI= 0.5525, 0.9961). However, regardless of the type of pain, whether minor discomfort or moderate pain or severe discomfort, the behavior with the least association was whining (p= 0.08; RR= 0.73; CI= 0.5357, 0.9952), meaning there is a tendency for the child to exhibit such behavior regardless of the pain level. The behavior "moves until immobilization" did not show a statistically significant relationship, but it stood out among other behaviors, as it was found that its frequency in both the experimental

group (n= 18, 85.7%) and the control group (n= 23, 95.8%) was higher when moderate pain or severe discomfort was observed (Table 3).

Table 2. Association between pain level and intramuscular injection procedure in children. Florianópolis, SC, Brazil, 2024

Procedure variables and pain level	Experimental Group n (%)	Control Group n (%)	p-value	RR	CI
Medication dose					
0 to 2 mL					
Mild discomfort	10 (32.3)	4 (17.4)	0.35	0.82	0.6033, 1.115
Moderate pain or severe discomfort	21 (67.7)	19 (82.6)			
Needle gauge					
0.60 mm x 25 mm					
Mild discomfort	10 (33.3)	4 (13.8)	0.14*	0.77	0.5776, 1.035
Moderate pain or severe discomfort	20 (66.7)	25 (86.2)			
Others					
Moderate pain or severe discomfort	1 (100)	2 (100)	0.75*	0.83	0.2294, 3.028
Position					
Prone position					
Mild discomfort	9 (30.0)	4 (13.3)	0.21	0.80	0.6147, 1.061
Moderate pain or severe discomfort	21 (70.0)	26 (86.7)			
Supine position					
Mild discomfort	1 (100)	0 (0)	1.0*	0.5	0.03982,6.278
Moderate pain or severe discomfort	0 (0)	1 (100)			
Region					
Ventrogluteal muscle					
Mild discomfort	8 (27.6)	4 (13.3)	0.30	0.83	0.6411, 1.089
Moderate pain or severe discomfort	21 (72.4)	26 (86.7)			
Lateral vastus muscle					
Mild discomfort	2 (100)	0 (0)	1.0*	0.3	0.01966, 4.577
Moderate pain or severe discomfort	0 (0)	1 (100)			

Legend: RR = Risk Ratio; CI = Confidence Interval; n = number; * = Fisher's Exact.
Source: The authors (2024).

Table 3. Association between pain level and children's behaviors during intramuscular injection procedure. Florianópolis, SC, Brazil, 2024

(continue)

Behavioral variables and pain level	Experimental Group n (%)	Control Group n (%)	p-value	RR	CI
Crying					
Yes					
Mild discomfort	8 (32.0)	2 (8.3)	0.08	0.74	0.5525, 0.9961
Moderate pain or severe discomfort	17 (68.0)	22 (91.7)			
No					
Mild discomfort	2 (33.3)	2 (28.6)	1.0	0.93	0.4477, 1.946
Moderate pain or severe discomfort	4 (66.7)	5 (71.4)			

Table 3. Association between pain level and children's behaviors during intramuscular injection procedure. Florianópolis, SC, Brazil, 2024

(conclusion)

Behavioral variables and pain level	Experimental Group n (%)	Control Group n (%)	p-value	RR	CI
Whine					
Yes					
Mild discomfort	2 (28.6)	2 (25.0)	1.0	0.95	0.5144, 1.763
Moderate pain or severe discomfort	5 (71.4)	6 (75.0)			
No					
Mild discomfort	8 (33.3)	2 (8.7)	0.08	0.73	0.5357, 0.9952
Moderate pain or severe discomfort	16 (66.7)	21 (91.3)			
Screaming					
Yes					
Mild discomfort	0 (0)	0 (0)	1.0*	1.0	0.5462, 1.831
Moderate pain or severe discomfort	3 (100)	3 (100)			
No					
Mild discomfort	10 (35.7)	4 (14.3)	0.12	0.75	0.5475, 1.027
Moderate pain or severe discomfort	18 (64.3)	24 (85.7)			
Moves until immobilization					
Yes					
Mild discomfort	3 (14.3)	1 (4.2)	0.50	0.89	0.7371, 1.085
Moderate pain or severe discomfort	18 (85.7)	23 (95.8)			
No					
Mild discomfort	7 (70.0)	3 (42.9)	0.53	0.52	0.1673, 1.647
Moderate pain or severe discomfort	3 (30.0)	4 (57.1)			

Legend: RR = Risk Ratio; CI = Confidence Interval; n = number; * = Fisher's Exact.
Source: The authors (2024).

It is noteworthy that 28 nursing technicians participated in the research, of which 21 (75.0%) were female, with an average age of 39.6 years (± 9.5). Still, 17 (60.7%) technicians had been working in Pediatrics for up to ten years, and 19 (67.9%) had been working in the hospital where the data collection was conducted for up to ten years.

DISCUSSION

The sample of this study was predominantly composed of male children, a finding similar to the results of a documentary research conducted in an Emergency Room in the far south of Brazil[15]. The higher frequency of boys in urgent and emergency care may be associated with behavioral differences between the sexes, with boys generally being more prone to exposure to risky situations and activities requiring greater physical mobility. In contrast, girls tend to be subject to greater surveillance and protection by caregivers[15], which may reduce the occurrence of situations that require emergency care.

It was observed that the children were predominantly accompanied by women, reinforcing the centrality of the maternal figure in child care. This finding is in line with a study that points to the mother as the main caregiver of the child[16] in the hospital context, including support during clinical procedures. The majority presence of women as companions may be attributed to traditional sociocultural constructs that assign mothers the role of primary caregivers, while fathers are often delegated the role of financial support and less involvement in direct care practices[16].

Regarding the pain experienced by the children, it was observed that the experimental group, in which the Buzzy® was positioned for 15 seconds before the intramuscular injection, showed a higher proportion of cases classified as minor discomfort and a lower occurrence of moderate pain compared to the control group, which used the Buzzy® for 30 seconds. These findings align with the study that applied the Buzzy® immediately before the injection and observed lower pain scores in the intervention group[17]. However, it differs from research that used the device for 30 seconds before the procedure and found a significant reduction in pain compared to the control group[18].

The better performance of the experimental group in this study may be related to the shorter waiting time between the positioning of the device and the administration of the injection. Reducing the interval between stimulus and procedure may enhance the distracting effect and limit the anticipation time of pain, which, in turn, is directly associated with increased pain perception in children.

In this sense, applying the Buzzy® for shorter periods proves to be a viable strategy, capable of providing immediate relief and reducing anticipatory stress. Moreover, the practical impact of this finding should be highlighted, as even applying it for 15 seconds can be feasible in emergency contexts, where time is a critical resource and executing quick and effective interventions is essential for pediatric care.

To minimize pain, irritation, and the risk of tissue injury, it is recommended that injectable solutions have a pH as close to physiological as possible (approximately 7.4)[19]. In the present study, the most frequently used medications were ondansetron, with a pH of 4.6, and dipyrone, whose pH can vary between 4.0 and 7.0[20-21]. Most children received ondansetron, either alone or in combination with dipyrone. The use of these medications may have contributed to higher pain scores, as the administration of solutions far from physiological pH is associated with greater discomfort/pain during intramuscular administration. This factor may have acted as a potential pain modifier, regardless of the application time of the Buzzy® device, and should be considered in the interpretation of the results.

Variables such as medication dose and needle gauge have a limited impact on pain intensity, which may suggest that pain perception is related to the situation the child was subjected to, an unfamiliar environment, and emotional issues[22], and not exclusively related to the procedure itself.

Moreover, a trend was identified between pain intensity and the presence of crying and the absence of whimpering, demonstrating the importance of considering the child's behavior as an indicator of pain level. Children who did not cry or whimper reported lower perceived pain intensity; the use of Buzzy® may have helped distract them from the procedure.

The results of this study indicate that the Buzzy® device positioned for 15 seconds before the intramuscular injection is a promising tool, as despite not having a statistical difference, it was found that pain scores were lower in the experimental group, indicating

that the 15-second timing has a similar effect to the 30-second positioning. Thus, by using the Buzzy® for 15 seconds, the procedure becomes faster, causing less stress for the child and consequently less pain.

Additionally, it is recommended to conduct other clinical trials with larger and varied samples in different care contexts, aiming to contribute to consolidating the effectiveness of the Buzzy® device in different populations and clinical situations. The incorporation of the Buzzy® device into nursing practice reaffirms the commitment that the nursing team has to promote less painful, more specialized care for the pediatric population based on scientific evidence.

Among the limitations identified in this study, it is noteworthy that data collection was conducted exclusively in two units, which restricts the possibility of generalizing the findings to other contexts or populations. Furthermore, the research was conducted in an emergency room, a place that, by its very nature, tends to be stressful for children.

CONCLUSION

Although no statistically significant difference was identified between the positioning times of the Buzzy® device (15 versus 30 seconds), the results showed that children in the experimental group had lower pain scores and a lower frequency of cases classified as moderate or severe pain. These findings indicate that applying the Buzzy® for 15 seconds may perform similarly to the conventionally recommended time, suggesting a comparable clinical effect between the two tested times. It is emphasized that such evidence strengthens the applicability of the Buzzy® device for 15 seconds before the procedure as a viable non-pharmacological strategy for pain management in pediatrics.

FUNDING

This study was conducted with support from the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brazil (CAPES) - Funding Code 001 - Doctoral Scholarship, process no. 88887.666427/2022-00. Research supported by the Conselho Nacional de Desenvolvimento Científico e Tecnológico - Brazil (CNPq) - Call no. 14/2023 - Support for International Scientific, Technological, and Innovation Research Projects, process no. 441879/2023-3.

REFERENCES

1. Raja SN, Carr DB, Cohen M, Finnerup NB, Flor H, Gibson S, et al. The revised International Association for the Study of Pain definition of pain: concepts, challenges, and compromises. Pain [Internet]. 2020 [cited 2025 May 12];161(9):1976-82. Available from: https://doi.org/10.1097/j.pain.0000000000001939

2. Faccioli SC, Tacla MTGM, Rossetto EG, Collet N. The management of pediatric pain and the perception of the nursing team in light of the Social Communication Model of Pain. BrJP [Internet]. 2020 [cited 2025 May 12];3(1):37-41. Available from: https://doi.org/10.5935/2595-0118.20200009

3. Jesus MC, Trindade CS, Lopes J, Ramos AL. Intramuscular Administration of Medication in Paediatrics: integrative literature review. RIASE [Internet]. 2020 [cited 2025 May 15];6(1):2038-53. Available from: http://dx.doi.org/10.24902/r.riase.2020.6(1).310.2117-2133

4. Kurt A, Dinç F, Akkoç B. Effect of the Helfer skin tap technique on pain, anxiety, and fear in children undergoing intramuscular injection: an open-label randomized controlled study. Arch Pediatr [Internet]. 2024 [cited 2025 Apr 12];31(2):148-54. Available from: https://doi.org/10.1016/j.arcped.2023.10.008

5. Jin F, Wang X, Qi M, Zhang W, Zhang Y. Effectiveness and safety of Buzzy device in needle-related procedures for children under twelve years of age: A systematic review and meta-analysis. Medicine [Internet]. 2024 [cited 2025 May 16];103(15):e37522. Available from: https://doi.org/10.1097/MD.0000000000037522

6. Buzzy Medical [Internet]. [place unknown]: Buzzy Medical; 2024 [cited 2025 Apr 14]. O que é o Buzzy;[about 3 screens]. Available from: https://buzzy4shots.com.br/pages/o-que-e-o-buzzy

7. Melzack R, Wall PD. Pain mechanisms: a new theory. Science [Internet]. 1965 [cited 2025 Apr 17];150(3699):971-9. Available from: https://doi.org/10.1126/science.150.3699.971

8. Düzkaya DS, Uysal G, Şiktaş Ö, Karakul A, Açikgöz A. Effects of the Helfer skin tap technique and Buzzy® application on the levels of pain and fear experienced by children during vaccination: a randomized controlled trial. J Pediatr Nurs [Internet]. 2024 [cited 2025 Apr 19];79:e278-e284. Available from: https://doi.org/10.1016/j.pedn.2024.10.037

9. Schulz KF, Altman DG, Moher D; The CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Med [Internet]. 2010 [cited 2025 Jun 24];8:18. Available from: https://doi.org/10.1186/1741-7015-8-18

10. Leventhal LC, Bianchi RC, de Oliveira SMJV. Clinical trial comparing three types of cryotherapy in non-pregnant women. Rev Esc Enferm USP [Internet]. 2010 [cited 2025 May 18];44(2):337-43. Available from: https://doi.org/10.1590/S0080-62342010000200014

11. Moura JWS, Silva TL, Bitencourt AS, de Moura SST, Silva BSM, dos Santos LM, et al. Buzzy® and Pikluc® in the relief of pediatric pain in intramuscular injection: randomized clinical trial protocol. Cogitare Enferm [Internet]. 2025 [cited 2025 Jun 2];30:e96620en. Available from: https://doi.org/10.1590/ce.v30i0.96620en

12. da Silva FC, Thuler LCS. Cross-cultural adaptation and translation of two pain assessment tools in children and adolescents. J Pediatr [Internet]. 2008 [cited 2025 Apr 10];84(4):344-9. Available from: https://doi.org/10.1590/S0021-75572008000400010

13. Costa Júnior AL. Análise de comportamentos de crianças expostas à punção venosa para quimioterapia [thesis]. Brasília: Instituto de Psicologia, Universidade de Brasília; 2001. 280 f.

14. Ministério da Saúde (BR). Resolução Nº 466, de 12 de dezembro de 2012. Aprova as diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. Diário Oficial da União [Internet]. 2013 Jun 13 [cited 2025 Jun 22];150(112 Seção 1):59-62. Available from: https://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=13/06/2013&jornal=1&pagina=59&totalArquivos=140

15. da Silva BR, Robalo EC, Gabatz RIB, Couto GR, Cruz VD, de Moraes CL. Perfil de crianças atendidas em um serviço de urgência e emergência no sul do Brasil. J Nurs Health [Internet]. 2021 [cited 2025 Apr 10];11(1):e2111118981. Available from: https://doi.org/10.15210/jonah.v11i1.18981

16. Rodrigues JIB, Fernandes SMGC, Marques GFS. Preocupações e necessidades dos pais de crianças hospitalizadas. Saude Soc [Internet]. 2020 [cited 2025 Apr 12];29(2):e190395. Available from: https://doi.org/10.1590/S0104-12902020190395

17. Şahiner NC, Ínal S, Akbay AS. The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children. J Perianesth Nurs [Internet]. 2015 [cited 2025 May 21];30(3):228-35. Available from: https://doi.org/10.1016/j.jopan.2014.05.011

18. Sapçi E, Kocamaz EB, Gungormus Z. Effects of applying external cold and vibration to children during vaccination on pain, fear and anxiety. Complement Ther Med [Internet]. 2021 [cited 2025 May 22];58:102688. Available from: https://doi.org/10.1016/j.ctim.2021.102688

19. Usach I, Martinez R, Festini T, Peris JE. Subcutaneous Injection of Drugs: Literature Review of Factors

Influencing Pain Sensation at the Injection Site. Adv Ther [Internet]. 2019 [cited 2025 May 29];36:2986-96. Available from: https://doi.org/10.1007/s12325-019-01101-6

20. Simpson KH, Hicks FM. Clinical pharmacokinetics of ondansetron. A review. J Pharm Pharmacol [Internet]. 1996 [cited 2025 May 30];48(8):774-81. Available from: https://doi.org/10.1111/j.2042-7158.1996.tb03973.x

21. da Silva LD, Camerini FG. Analisys of intravenous medication administration in sentinel network hospital. Texto Contexto Enferm [Internet]. 2012 [cited 2025 May 30];21(3):633-41. Available from: https://doi.org/10.1590/S0104-07072012000300019

22. Rezende AF, Vitorino AM, Piran CMG, Shibukawa BMC, Oliveira LM, Higarashi IH, et al. Percepção da criança sobre a hospitalização: revisão integrativa. Rev Feridas [Internet]. 2022 [cited 2025 Apr 15];10(54):1959-64. Available from: https://doi.org/10.36489/feridas.2022v10i54p1959-1964

Received: 25/06/2025
Approved: 18/09/2025
Associate editor: Dra. Luciana de Alcantara Nogueira

Corresponding author:
Jefferson Wildes da Silva Moura
Universidade Federal de Santa Catarina
Rua Delfino Conti, S/N – Trindade, Florianópolis, SC, Brasil.
E-mail: jefferson.wsmoura@gmail.com

Role of Authors:
Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work - **Moura JWS, dos Santos LM, Rocha PK.** Drafting the work or revising it critically for important intellectual content - **Moura JWS, Silva GF, Silva TL, Rodrigues PA, Alves TF, dos Santos LM, Rocha PK.** Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved - **Moura JWS, Rocha PK.** All authors approved the final version of the text.

Conflicts of interest:
The authors have no conflicts of interest to declare.

Data availability:
The authors declare that the data can be made available upon request to the corresponding author.

ISSN 2176-9133