Cogitare Enfermagem

FREE COMMUNICATION

Buzzy® and Pikluc® in the relief of pediatric pain in intramuscular injection: randomized clinical trial protocol

HIGHLIGHTS

1. First clinical trial comparing Buzzy® and Pikluc® in pediatric pain.
2. Evaluation of the equivalence between different application times of Buzzy®.
3. Improvement of clinical nursing practice in intramuscular injections.

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ABSTRACT

Objective: Describe the protocol for a randomized clinical trial to verify the equivalence of positioning Buzzy® devices for 15 seconds or Pikluc® immediately before administering intramuscular injections for pain relief in children compared to Buzzy® positioned for 30 seconds before the procedure. **Method:** Controlled, open-label, equivalence randomized clinical trial protocol with three groups (Buzzy® 15 seconds, Pikluc® and Buzzy® 30 seconds), conducted in two Pediatric Emergency Departments in southern Brazil with children aged 1 to 11 years. The primary outcome is the pain score, while secondary outcomes include pain categorization and assessment of concurrent and non-concurrent behaviors. **Final considerations:** The protocol will allow for the evaluation of equivalence between the Buzzy® device applied for 15 seconds before and Pikluc® immediately before intramuscular injection in reducing pain in children, compared to Buzzy® for 30 seconds before the procedure.

KEYWORDS: Pediatric Nursing; Injections, Intramuscular; Biomedical Technology; Pain; Clinical Trial Protocol.

HOW TO REFERENCE THIS ARTICLE:
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 "insert year, month and day"];30:e96620en. Available from: https://doi.org/10.1590/ce.v30i0.96620en

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INTRODUCTION

Intramuscular injection is a procedure commonly performed by the nursing team during child care and is considered painful due to the mechanical trauma resulting from needle insertion and drug administration[1]. According to the International Association for the Study of Pain, pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage[2].

In this context, it is incumbent upon the nursing team to seek strategies to provide non-traumatic care that addresses physical aspects such as pain reduction and emotional aspects including the minimization of fear, anxiety, and stress experienced by the child[1]. Therefore, it is necessary to improve the use of non-pharmacological measures for pediatric pain management, especially during intramuscular injections. It should be noted that there are different resources available, such as the application of heat or cold, vibration, virtual reality, audiovisual distraction, and local pressure devices[3-4].

During intramuscular injections in children, the nursing team can use Buzzy®, a bee- or ladybug-shaped device that uses Oscilice® technology and delivers high-frequency vibration combined with a wing-shaped ice pack, which should be applied for at least 30 seconds before the procedure[5]. The combination of these stimuli generates different sensations and, consequently, there is a reduction in pain during needle insertion[5].

Another technology available to nurses is the Pikluc® local pressure device, consisting of small tips that sensitize the nerve endings in the area and divide the impact of needle insertion, helping to reduce pain by inhibiting the transmission of painful stimuli[4]. It should be noted that Pikluc® is a Brazilian product[4], easily accessible and with limited studies on its effectiveness. In addition, both Pikluc® and Buzzy® are based on the Gate Control Theory of Pain[6].

Although both devices offer benefits, Pikluc® can be used immediately before the procedure, without requiring a minimum time to be effective in reducing pain, and costs less than Buzzy®. However, the manufacturer of Buzzy® recommends using it for 30 to 60 seconds before the procedure to reduce pain[5]. Still on the use of Buzzy®, the literature presents different times: immediately before the procedure[7], 15 to 45 seconds[8], 30 to 60 seconds[9], 30 seconds[10-12], and 60 seconds[13-14].

Therefore, it is essential to test this time on a national scale, using 15 seconds as an intervention to reduce the duration of the procedure, making it less uncomfortable for the child while ensuring pain reduction. The 30-second time will be used as a control, as this is the minimum time recommended by the manufacturer of Buzzy®. Furthermore, Pikluc® will be tested due to the scarcity of studies with this device, as evidenced in a scoping review[15].

It should be noted that this protocol is unique in the national and international context, as it is the first to compare Pikluc® and different times of Buzzy®. In view of the above, this study aims to describe the protocol of a randomized clinical trial to verify the equivalence of positioning the Buzzy® device for 15 seconds or the Pikluc® immediately before administering intramuscular injections for pain relief in children compared to the Buzzy® positioned for 30 seconds before the procedure.

METHOD

This is a controlled, open-label, equivalence randomized clinical trial protocol (RCT) reported according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)[16] and Template for Intervention Description and Replication (TIDieR)[17]. This RCT is registered under number RBR-57m3wnw on the Brazilian Registry of Clinical Trials (ReBEC) platform. The RCT was conducted in two Pediatric Emergency Departments at two public hospitals in southern Brazil. The recruitment period has been completed, and data analysis is currently underway.

The population consisted of children aged between 1 and 11 years, divided into two strata, the first comprising children aged 1 to 3 years and the second comprising children aged 4 to 11 years. The sample was calculated to test the equivalence between three treatment groups, with 90% power and an alpha level of 0.05 (adjusted to 0.0167 by comparison using Bonferroni correction for three paired comparisons), using a one-sided test with equivalence margins of ±2.0 points, mean difference of 0 points, and standard deviation of 2.84 (pilot study data), resulting in 55 participants per group, totaling 165.

The children were randomly assigned, by stratified randomization, in blocks of nine to the groups: Intervention Group 1, Intervention Group 2, and Control Group. In Intervention Group 1, Buzzy® was applied for 15 seconds before intramuscular injection; in Intervention Group 2, Pikluc® was used immediately before the procedure; while in Control Group, Buzzy® was applied for 30 seconds before intramuscular injection. An external researcher prepared the randomization list in the RANDON Program (www.random.org) and stored it in opaque, sealed envelopes. The principal investigator opened the envelopes during the recruitment of the children, and they contained the randomization group assignments: A = Intervention Group 1, B = Intervention Group 2, and C = Control Group.

The study was conducted in four stages. In the first stage, the proposal was presented to the heads and nursing professionals of the Pediatric Emergency Departments, obtaining the consent of the institutions. The study was then submitted to and approved by the Research Ethics Committees of the participating institutions.

In the second stage, training was provided to nursing professionals during working hours and according to availability. The training included reading and signing the Free and Informed Consent Form; completing a sociodemographic and educational questionnaire; participating in a interactive lecture to present the research protocol and the Buzzy® (Figure 1A) and Pikluc® (Figure 1B) devices; and low-fidelity simulation with intramuscular injection administration in a doll. Throughout the process, nursing professionals were allowed to clarify doubts and, as new professionals joined the nursing team, they were invited to participate in the research. Those who accepted received the appropriate training.

In the third stage, the research protocol "Buzzy® 30s, Buzzy® 15s, and Pikluc® - BBP" (Appendix A), based on the recommendations for use of the Buzzy®[5] and Pikluc®[4] devices and specialized literature[18-19], was tested in a pilot study with 60 children. After evaluation, no adjustments to the protocol were necessary.

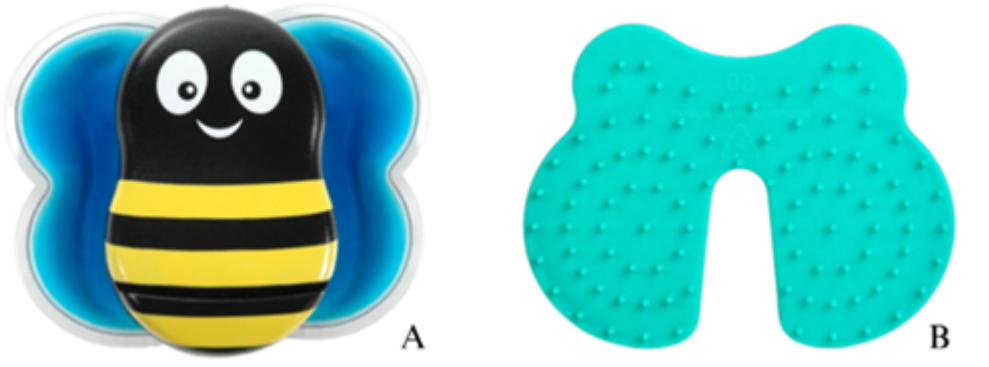

Figure 1. Buzzy® and Pikluc® devices. Florianópolis, SC, Brasil, 2024
Source: Buzzy® (2024)[5]; Adapted from Likluc (2024)[4]

The fourth stage consisted of collecting data from the RCT (recruitment of participants), according to the BBP research protocol (Appendix A). Thus, the steps of the protocol were summarized as follows: children indicated for intramuscular injection, after undergoing screening and medical consultation, who met the eligibility criteria (Figure 2), verified with their caregivers, were invited to participate in the study accompanied by their caregiver. After acceptance, the researcher led the participant to an empty office (if no office was available, the procedure room was used), explained the objectives, advantages, and limitations of participating in the research, the stages of data collection, and answered any questions, providing the Free and Informed Consent Form for reading and signature by those caregivers.

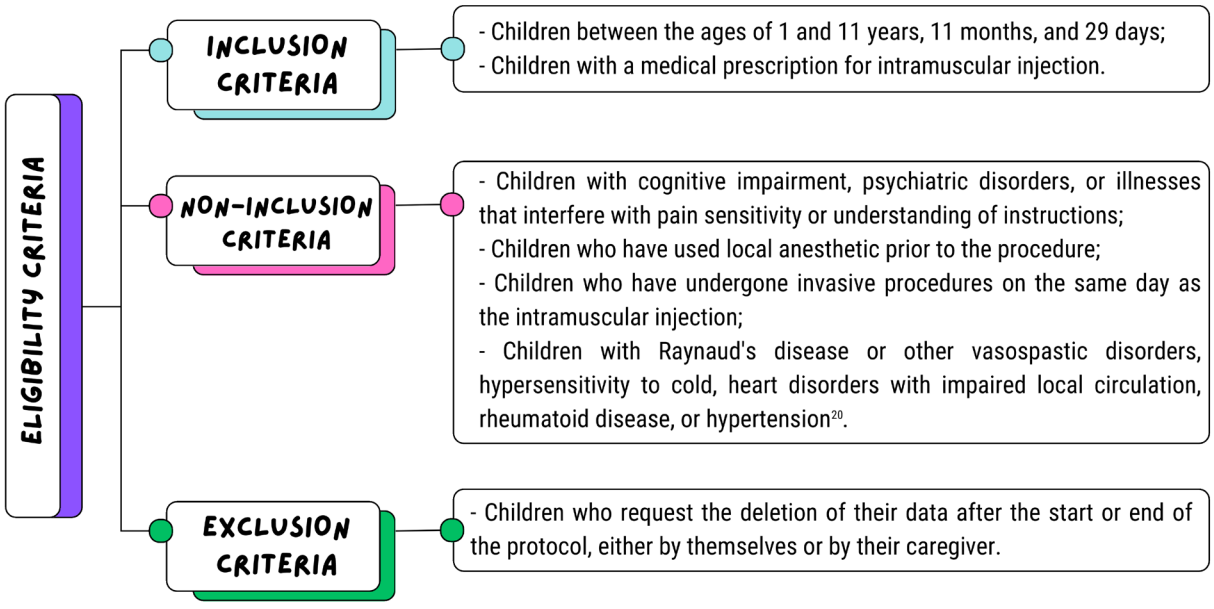

Figure 2. Eligibility criteria for participants. Florianópolis, SC, Brasil, 2024
Source: The authors (2024).

Subsequently, the randomization envelope was opened, indicating which group the child would be assigned to: Intervention Group 1 (Buzzy® for 15 seconds), Intervention Group 2 (Pikluc®) or Control Group (Buzzy® for 30 seconds). Next, the Free and Informed Assent Form was read and signed for children over 4 years of age. For children between

1 and 3 years of age, only the Free and Informed Consent Form was signed by their caregivers. Then, the researcher filled in the characterization data for the child and their caregiver. Next, an Instructional Therapeutic Play session was conducted, in which the steps for administering the intramuscular injection and using the Buzzy® or Pikluc® device were explained, depending on the child's randomization group. The Instructional Therapeutic Play is recommended for children aged 4 years and older; for children aged 1 to 3 years, the session was designed to explain the procedure to caregivers. During the Instructional Therapeutic Play session, children aged 4 years and older and their caregivers had the opportunity to ask questions and, if they wished, have the procedure performed on a doll.

After the Instructional Therapeutic Play session, the child and caregiver were taken to the procedure room, where the intramuscular injection was administered by the unit's nursing professional with the aid of the Buzzy® or Pikluc® device, according to the child's randomization group. The primary and secondary outcome data were collected, the child was praised, the researcher thanked them for participating in the study, and data collection was completed.

It should be noted that the initial approach for presenting the research, inviting participation, reading and signing the Free and Informed Consent Form and/or Free and Informed Assent Form, in addition to filling out the instrument with sociodemographic and clinical information, took approximately seven to ten minutes. The Instructional Therapeutic Play session, used to present the Buzzy® or Pikluc® devices and simulate intramuscular injection, lasted between seven and twelve minutes. The procedure itself, including the evaluation of the outcomes, took about five minutes. The variables used in the study are shown in Figure 3.

The primary outcome was pain associated with intramuscular injection in children, assessed by the researcher in children aged 1 to 3 years using the Face, Legs, Activity, Cry, Consolability Scale (FLACC)[21], and by self-report in children aged 4 to 11 years using the Faces Pain Scale - Revised (FPS-R)[21]. The secondary outcomes were: 1) Pain assessment in children aged 4 to 11 years, performed by the caregivers and the researcher, using the FPS-R[21] scale; 2) Categorization of pain reported by the child[21-22]; 3) Assessment of concurrent and non-concurrent behaviors, based on selected variables from the Observation Scale of Behavioral Distress (OSBD)[23]. Concurrent behaviors are those that hinder, prevent, or delay the procedure, while non-concurrent behaviors facilitate or do not hinder its execution[23-24]. The concurrent behaviors evaluated in this study were: attacking the professional, whining, crying, showing nervousness, shouting, moving around until immobilized, and protesting. Non-concurrent behaviors included: assisting with the procedure, speaking, responding verbally during the procedure, and requesting information[23-24].

The data were entered and will be analyzed using the Statistical Package for the Social Sciences (SPSS®) version 29.0. For the primary analysis, a bilateral design will be used to test equivalence between groups. Pain scores will be analyzed by linear regression, considering the group (three levels: Buzzy® 15 seconds, Pikluc® and Buzzy® 30 seconds) as a fixed effect by stratum. The results will be presented as mean score differences and confidence intervals (CIs) of 98.33% (adjusted by the Bonferroni method from 95% for three paired comparisons).

Intervention variable
Evaluation of the equivalence of the Buzzy® device positioned for 15 seconds before intramuscular injection and Pikluc® immediately before this procedure.
Control variable
Position the Buzzy® for 30 seconds before intramuscular injection.
Demographic variables
Age, gender, education level, and skin color of the child.
Clinical variables
Body Mass Index (BMI) and nutritional status.
Behavioral variables
Concurrent behaviors: attacks the professional, whines, cries, shows nervousness, screams, moves around until immobilized, and protests. **Non-concurrent behaviors:** assists with the procedure, speaks, responds verbally during the procedure, and asks for information.
Variables related to intramuscular injection
Medication, dose, needle gauge, application site, and position of the child.
Primary outcome variable
Pain score for children aged 1 to 3 years using the FLACC scale (researcher assessment). Pain score in children aged 4 to 11 years using the FPS-R scale (self-reported).
Secondary outcome variables
Pain score for children aged 4 to 11 years using the FPS-R scale (assessment by caregiver and researcher). Categorization of pain in children, according to the FLACC and FPS-R scales. Assessment of concurrent and non-concurrent behaviors according to variables from the OSBD scale.
Characterization variables of those caregivers
Age, gender, degree of kinship, education level, and occupation.
Characterization variables of nursing professionals
Professional category, age, gender, length of training, length of experience in pediatrics, and length of experience at the institution.

Figure 3. Study variables. Florianópolis, SC, Brasil, 2024
Source: The authors (2024).

For secondary outcomes, pain assessments performed by the researcher and caregivers (children aged 4 to 11 years) will be analyzed by linear regression, similar to the primary outcome. Pain categorization will be analyzed using logistic regression, with a significance level of $\alpha = 0.025$ (0.05/2), and the results will be presented as an odds ratio with a 95% CI. Pain levels by age group will be analyzed using mixed linear models, with a significance level of $\alpha = 0.025$ (0.05/2). For behavioral outcomes, two categories will be analyzed using mixed logistic regression: a) Concurrent behaviors, with $\alpha = 0.007$ (0.05/7); b) Non-concurrent behaviors, with $\alpha = 0.0125$ (0.05/4). Both results will be presented as odds ratios with 95% CIs.

This study complied with the standards established by Resolution No. 466, dated December 12, 2012, of the National Health Council of the Ministry of Health, which provides guidelines and standards regulating research involving human subjects[25]. Furthermore, the researchers declare that they are aware of and comply with the requirements established by the General Data Protection Law, Law No. 13,709, of August 14, 2018[26], and that all measures have been taken to ensure the secrecy, confidentiality, and privacy of the data.

The physical data generated in this study was stored in file folders, and virtual data was downloaded to an external hard drive, deleting all records from any virtual platform, shared environment, or cloud. After the research is completed, the raw and analyzed data, data collection instruments, Free and Informed Consent Forms, and Free and Informed Assent Forms of each participant will remain under the responsibility of the supervising professor, stored in a locked cabinet in the Nursing Department of the Federal University of Santa Catarina for five years to ensure their security and validity. After this period, the data will be destroyed.

The study was approved by the Research Ethics Committee of the Federal University of Santa Catarina under opinion number: 5,901,237, and by the Research Ethics Committee of the Joana de Gusmão Children's Hospital under opinion number: 6,036,546. It should be noted that at the end of the research, the results obtained will be disseminated through the publication of articles in national and/or international journals, presentation of abstracts at scientific events, posters on the research group's social networks, and feedback to the units participating in the study.

FINAL CONSIDERATIONS

The results of this RCT are expected to contribute to the field of nursing by: 1) Determine whether the Buzzy® and Pikluc® devices are equivalent in reducing pain associated with intramuscular injections in children; 2) Evaluate the equivalence between different application times of the Buzzy®; 3) Identify the most appropriate technology for each age group studied; 4) Provide evidence on the level of pain in each group analyzed; 5) Compare self-reported pain levels and those assessed by caregivers and the researcher; 6) Evaluate the impact of the devices on children's behavior during intramuscular injection.

ACKNOWLEDGEMENTS

Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brazil (CAPES) - Finance Code 001 - Doctorate Scholarship, process no. 88887.666427/2022-00. National Council for Scientific and Technological Development - Brazil (CNPq) - Research Productivity Grant, process no. 309565/2022-7. CNPq - Call No. 14/2023 - Support for International Scientific, Technological, and Innovation Research Projects, process No. 441879/2023-3.

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APPENDIX A

RESEARCH PROTOCOL"BUZZY® 30s, BUZZY® 15s AND PIKLUC® - BBP"

(continue)

Stage	Group	Activity
1	Everyone	Welcome the child and their caregiver when they arrive at the nursing station, after they have undergone screening and a medical consultation with a prescription for an intramuscular injection.
2	Everyone	Check whether the child meets the inclusion criteria. If so, talk to the child and their caregiver to invite them to participate in the research.
3	Everyone	Take the child and their caregiver to an empty consultation room (if no consultation room is available, use the procedure room) and explain the objectives of the study, the advantages and disadvantages of participating in the research, the stages of data collection, and answer any questions they may have.
4	Everyone	Upon acceptance, deliver the Free and Informed Consent Form to the caregiver party for reading and signing, in two copies, one for the researcher and one for the participant.
5	Everyone	Open the randomization envelope to indicate which group the child will be assigned to.
6	Everyone	Deliver the Free and Informed Assent Form for children over 4 years of age for reading and signing, in two copies, one for the researcher and one for the participant. It should be noted that for children between 1 and 3 years, 11 months, and 29 days of age, only the Free and Informed Consent Form must be signed by their legal caregivers.
7	Everyone	Fill in the details about the child and their caregiver.
8	Intervention Group 1	Prepare the child and their caregiver for the procedure through an Instructional Therapeutic Play session, explaining the steps involved in administering the intramuscular injection and using the Buzzy® device positioned for 15 seconds before the procedure.
8	Intervention Group 2	Prepare the child and their caregiver for the procedure through an Instructional Therapeutic Play session, explaining the steps involved in administering the intramuscular injection and using the Pikluc® device positioned immediately before the procedure.
8	Control Group	Prepare the child and their caregiver for the procedure through an Instructional Therapeutic Play session, explaining the steps involved in administering the intramuscular injection and using the Buzzy® device positioned for 30 seconds before the procedure.
8	Everyone	It should be noted that Instructional Therapeutic Play is recommended for children aged 4 years and older. For children aged 1 to 3 years, 11 months, and 29 days, the session will be intended for caregivers.
9	Everyone	Sanitize your hands and put on Personal Protective Equipment to simulate the intramuscular injection during the Instructional Therapeutic Play session.
10	Intervention Group 1 Control Group	Pick up the pre-prepared Instructional Therapeutic Play session kit, consisting of: doll, tray, procedure gloves, syringe, needle, gauze, cotton wool, Alcoholic Chlorhexidine > 0.5% or 70% Isopropyl Alcohol, micropore tape, and Buzzy® device.

RESEARCH PROTOCOL"BUZZY® 30s, BUZZY® 15s AND PIKLUC® - BBP"

(continue)

Stage	Group	Activity
10	Intervention Group 2	Pick up the pre-prepared Instructional Therapeutic Play session kit, consisting of: doll, tray, procedure gloves, syringe, needle, gauze, cotton wool, Alcoholic Chlorhexidine > 0.5% or 70% Isopropyl Alcohol, micropore tape, and Pikluc® device.
11	Everyone	Explain to the child and caregiver that the materials must be returned at the end of the Instructional Therapeutic Play session.
12	Everyone	Introduce the doll to the child and the caregiver by telling a story that explains why the intramuscular injection is being given. Use language appropriate for the child's age group, and the storyline should be similar to your situation.
13	Everyone	Allow the child and caregiver to handle the materials.
14	Everyone	Ask the child and caregiver for help in performing the procedure on the doll.
15	Intervention Group 1	Simulate intramuscular injection administration on the doll, using the Buzzy® device positioned for 15 seconds before the procedure.
15	Intervention Group 2	Simulate intramuscular injection administration on the doll, with the aid of the Pikluc® device positioned immediately before the procedure.
15	Control Group	Simulate intramuscular injection administration on the doll, using the Buzzy® device positioned for 30 seconds before the procedure.
16	Everyone	Check the prescription, paying attention to the characteristics of the medication to be administered, as well as the dose.
17	Everyone	Check the indicated anatomical region, avoiding areas that are hard, painful, scarred, spots, bruises, and/or lesions.
18	Everyone	Position the doll, taking into account the site of administration.
19	Everyone	If it is in the Vastus Lateralis muscle: ask the doll to position itself for the procedure, in a supine position, lying on its side or sitting, maintaining a comfortable and safe position. The doll may, at the child's discretion, remain on their lap, provided that the location for the procedure is convenient for the researcher. Palpate the region until you find the greater trochanter and knee joints, divide the vertical distance between these two landmarks into three, and inject the needle into the middle third.
19	Everyone	If it is in the Ventrogluteal muscle: ask the doll to position itself for the procedure, supine, lying on its back, on its side, or on its stomach, maintaining a comfortable and safe position. The doll may, at the child's discretion, remain on their lap, provided that the location for the procedure is convenient for the researcher. The region should be palpated until the greater trochanter is found, the anterior superior iliac tubercle (found by flexing the thigh over the hip and measuring 1 to 2 cm above the crease that forms in the groin) and the posterior iliac crest; place the palm of the hand on the greater trochanter, the index finger on the anterior superior iliac tubercle, and the middle finger along the iliac crest as far posteriorly as possible; inject the needle into the center of the V formed by the fingers.

RESEARCH PROTOCOL"BUZZY® 30s, BUZZY® 15s AND PIKLUC® - BBP"

(continue)

Stage	Group	Activity
19	Everyone	If it is in the Deltoid muscle: ask the doll to position herself for the procedure, either sitting or lying on her side with her elbow flexed, maintaining a comfortable and safe position. The doll may, at the child's discretion, remain on their lap, provided that the location for the procedure is convenient for the researcher. The acromial process should be located and the injection administered only into the upper third of the muscle, which begins approximately 2 fingers' width from the acromion.
20	Everyone	Assess the need for restraint of the doll, together with the child. If so, physical restraint will be used by the caregiver, if necessary.
21	Everyone	Clean the injection site with cotton wool soaked in Chlorhexidine Alcoholic Solution > 0.5% or 70% Isopropyl Alcohol.
22	Intervention Group 1	With your non-dominant hand, turn on the Buzzy® device and place it against the skin of the wrist, at the site indicated for needle insertion, according to the measurement/location established previously. Leave Buzzy® on for 15 seconds. Move the Buzzy® about 4 cm above the needle insertion site. Repeat the cleaning of the injection site.
22	Intervention Group 2	With your non-dominant hand, place Pikluc® immediately against the skin of the doll where the injection will be given.
22	Control Group	With your non-dominant hand, turn on the Buzzy® device and place it against the skin of the wrist, at the site indicated for needle insertion, according to the measurement/location established previously. Leave Buzzy® to work for 30 seconds. Move the Buzzy® about 4 cm above the needle insertion site. Repeat the cleaning of the injection site.
23	Everyone	Request the doll, if it is more comfortable and possible, breathe deeply.
24	Everyone	With your dominant hand, insert the needle into the indicated location according to the previously established measurement/location, at a right angle of 90°, and aspirate. If no venous return is identified, inject the medication in a continuous motion. Remove the needle in one firm motion.
25	Intervention Group 1	Move the Buzzy® device over the needle insertion site. Allow the Buzzy® device to work for 15 seconds. Remove the Buzzy® device.
25	Intervention Group 2	Remove the Pikluc® device.
25	Control Group	Move the Buzzy® device over the needle insertion site. Allow the Buzzy® device to work for 30 seconds. Remove the Buzzy® device.
26	Everyone	Lightly compress dry cotton onto the area and apply pressure, but do not massage. Place the gauze with micropore tape. Disregard the syringe and the needle in the sharps collection box. Let go of the doll.
27	Everyone	Thank the doll for participating and for her courage.
28	Everyone	Ask the child and the caregiver about any questions they may have. Clarify them, if necessary. Ask the child and caregiver if they wish to perform the procedure on the doll. Encourage and praise the participation of the child and the caregiver. Store the Instructional Therapeutic Play session material and sanitize it afterwards.
29	Everyone	Sanitize your hands, end the Instructional Therapeutic Play session, and direct the child and their caregiver to the procedure room for the intramuscular injection.

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(continue)

Stage	Group	Activity
30	Everyone	Record the child's weight and height on the medical record form. It should be noted that these data are verified during the screening of the child and that the devices used for weighing and measuring will be those available in the sector.
31	Everyone	Inform the responsible professional that the child has completed the Instructional Therapeutic Play session and the randomization group. The professional will begin the procedure.
32	Everyone	Check the prescription, paying attention to the characteristics of the medication to be administered, as well as the dose.
33	Everyone	Check the indicated anatomical region, avoiding areas that are hard, painful, scarred, spots, bruises, and/or lesions.
34	Everyone	Position the child, taking into account the site of administration.
35	Everyone	If it is in the Vastus Lateralis muscle: ask the child to position themselves or ask the caregiver to position them for the procedure, in a supine position, lying on their side or sitting, maintaining a comfortable and safe position. The child may, at the discretion of the caregiver, remain on their lap, provided that the location for the procedure is convenient for the nursing professional. Palpate the region until you find the greater trochanter and knee joints, divide the vertical distance between these two landmarks into three, and inject the needle into the middle third.
35	Everyone	If it is in the Ventrogluteal muscle: ask the child to position themselves or ask the caregiver to position them for the procedure, in a supine position, lying on their side or face down, maintaining a comfortable and safe position. The child may, at the discretion of the caregiver, remain on their lap, provided that the location for the procedure is convenient for the nursing professional. The area should be palpated until the greater trochanter, the anterior superior iliac tubercle (found with the thigh flexed over the hip and measuring 1 to 2 cm above the crease that forms in the groin) and the posterior iliac crest; place the palm of the hand on the greater trochanter, the index finger on the anterior superior iliac tubercle, and the middle finger along the iliac crest as far posteriorly as possible; inject the needle into the center of the V formed by the fingers.
35	Everyone	If it is in the Deltoid muscle: ask the child to position themselves or ask the caregiver to position them for the procedure, in a sitting or lateral decubitus position with the elbow flexed, maintaining a comfortable and safe position. The child may, at the discretion of the caregiver, remain on their lap, provided that the location for the procedure is convenient for the nursing professional. The acromial process should be located and the injection administered only into the upper third of the muscle, which begins approximately 2 fingers' width from the acromion.
36	Everyone	Assess the need to restrain the child, together with the caregiver for them. If so, physical restraint will be performed by the nursing professional, with assistance from the caregiver, if necessary.
37	Everyone	Clean the injection site with cotton wool soaked in Chlorhexidine Alcoholic Solution > 0.5% or 70% Isopropyl Alcohol.
38	Intervention Group 1	With your non-dominant hand, turn on the Buzzy® device and place it against the child's skin at the site indicated for needle insertion, according to the measurement/location established previously. Leave Buzzy® on for 15 seconds. Move the Buzzy® about 4 cm above the needle insertion site. Repeat the cleaning of the injection site.

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(conclusion)

Stage	Group	Activity
38	Intervention Group 2	With your non-dominant hand, place Pikluc® immediately against the child's skin where the injection will be given.
38	Control Group	With your non-dominant hand, turn on the Buzzy® device and place it against the child's skin at the site indicated for needle insertion, according to the measurement/location established previously. Leave Buzzy® on for 30 seconds. Move the Buzzy® about 4 cm above the needle insertion site. Repeat the cleaning of the injection site.
39	Everyone	Ask the child, if comfortable and possible, to breathe deeply.
40	Everyone	With your dominant hand, insert the needle into the indicated location according to the previously established measurement/location, at a right angle of 90°, and aspirate. If no venous return is identified, inject the medication in a continuous motion. Remove the needle in one firm motion.
41	Intervention Group 1	Move the Buzzy® device over the needle insertion site. Allow the Buzzy® device to work for 15 seconds. Remove the Buzzy® device.
41	Intervention Group 2	Remove the Pikluc® device.
41	Control Group	Move the Buzzy® device over the needle insertion site. Allow the Buzzy® device to work for 30 seconds. Remove the Buzzy® device.
42	Everyone	Lightly compress dry cotton onto the area and apply pressure, but do not massage. Place the gauze with micropore tape.
43	Everyone	Dispose of syringes and needles in a sharps container. Let go of the child.
44	Everyone	Praise the child for their behavior during the procedure.
45	Everyone	The researcher should: observe the child during the procedure and record their perception of the intensity of pain during the intramuscular injection. For children aged 1 to 3 years, 11 months, and 29 days, the Face, Legs, Activity, Cry, Consolability (FLACC) scale will be used, and for children aged 4 to 11 years, 11 months, and 29 days, the Faces Pain Scale - Revised (FPS-R) will be used. Assess behavioral variables (aggression toward the professional, whining, crying, nervousness, shouting, moving until immobilization, protesting, assisting in the procedure, talking, responding verbally during the procedure, and requesting information) derived from the adapted Observation Scale of Behavior Distress (OSBD).
46	Everyone	After the procedure, ask children aged 4 to 11 years, 11 months, and 29 days about their perception of pain felt during the procedure using the FPS-R Scale.
47	Everyone	After the procedure, ask the caregiver for the child (over 4 years of age) about their perception of the pain felt by the child during the intramuscular injection using the FPS-R scale.
48	Everyone	Thank the child and their caregiver for participating in the research and finish collecting the data.
49	Control Group Intervention Group 1	Sanitize the Buzzy® device with Alcoholic Chlorhexidine > 0.5% or 70% Isopropyl Alcohol and sanitize your hands.
49	Intervention Group 2	Sanitize the Pikluc® device with Alcoholic Chlorhexidine > 0.5% or 70% Isopropyl Alcohol and sanitize your hands.

Received: 21/08/2024
Approved: 06/03/2025
Associate editor: Dra. Claudia Nery Teixeira Palombo

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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 TL, Bitencourt AS, de Moura SST, Silva BSM, 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.

ISSN 2176-9133