Experience report

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Instructional Therapeutic Play in preparing children and their caregivers for clinical research: an experience report

Brinquedo Terapêutico Instrucional no preparo de crianças e seus responsáveis em pesquisa clínica: relato de experiência

Juguete Terapéutico Instruccional en la preparación de niños y cuidadores en investigación clínica: informe de experiencia

ABSTRACT
Objective: To report on the experience of using Instructional Therapeutic Play in preparing children and caregivers for procedures related to clinical research protocols. **Method:** Experience report on Instructional Therapeutic Play sessions conducted by researchers, involving children and their caregivers during participation in clinical research approved by Research Ethics Committees. **Results:** A total of 420 children and their caregivers participated, with a predominance of males (52.1%). The Instructional Therapeutic Play facilitated understanding of the clinical research protocol, promoted greater acceptance and cooperation on the part of the children, and reduced resistance to procedures and minimized feelings of fear and anxiety. **Final considerations:** The Instructional Therapeutic Play proved useful in establishing communication between researchers and research participants, facilitated the presentation of the protocol and the devices and technologies involved in clinical research, and contributed to the ethical conduct of research in Pediatrics.
Descriptors: Play and playthings; Child; Caregivers; Nursing research; Pediatric nursing.

RESUMO
Objetivo: Relatar a experiência do uso do Brinquedo Terapêutico Instrucional no preparo de crianças e responsáveis para a realização de procedimentos vinculados a protocolos de pesquisas clínicas. **Método:** Relato de experiência sobre sessões de Brinquedo Terapêutico Instrucional, conduzidas pelos pesquisadores, envolvendo crianças e seus responsáveis durante participação em pesquisas clínicas aprovadas por Comitês de Ética em Pesquisa. **Resultados:** Participaram 420 crianças e seus responsáveis, com predomínio do sexo masculino (52,1%). O Brinquedo Terapêutico Instrucional favoreceu a compreensão do protocolo da pesquisa clínica, promoveu maior aceitação e cooperação por parte das crianças, além de reduzir a resistência aos procedimentos e minimizar sentimentos de medo e ansiedade. **Considerações finais:** O Brinquedo Terapêutico Instrucional mostrou-se útil no estabelecimento da comunicação entre os pesquisadores e os participantes da pesquisa, facilitou a apresentação do protocolo e dos dispositivos e tecnologias envolvidos nas pesquisas clínicas e contribuiu para a condução ética da pesquisa na Pediatria.
Descritores: Brincadeiras e brinquedos; Criança; Cuidadores; Pesquisa em enfermagem; Enfermagem pediátrica.

RESUMEN
Objetivo: Informar la experiencia del uso del Juguete Terapéutico Instruccional en la preparación de niños y cuidadores para la realización de procedimientos vinculados a protocolos de investigaciones clínicas. **Método:** Informe de experiencia sobre sesiones con Juguete Terapéutico Instruccional, conducidas por los investigadores, que involucraron a niños y sus cuidadores durante la participación en ensayos clínicos aprobados por Comités de Ética en Investigación. **Resultados:** Participaron 420 niños y sus cuidadores, con predominio del sexo masculino (52,1%). El Juguete Terapéutico Instruccional favoreció la comprensión del protocolo de investigación clínica, promovió una mayor aceptación y cooperación por parte de los niños, además de reducir la resistencia a los procedimientos y minimizar sentimientos de miedo y ansiedad. **Consideraciones finales:** El Juguete Terapéutico Instruccional demostró ser útil para establecer la comunicación entre los investigadores y los participantes del estudio; facilitó la presentación del protocolo y de los dispositivos y tecnologías involucrados en las investigaciones clínicas y contribuyó a la conducción ética de la investigación en Pediatría.
Descriptores: Juego e implementos de juego; Niño; Cuidadores; Investigación en enfermería; Enfermería pediátrica.

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INTRODUCTION

Therapeutic Play (TP) is a care technology available to the nursing team to promote comprehensive and specialized care for the child[1], being suitable for clarifying doubts and expressing feelings[2]. Furthermore, it contributes to relieving anxiety arising from threatening or atypical experiences for the age[3], which may be experienced in the hospital environment.

In Brazil, the practice of using TP in nursing care has been supported by the Federal Nursing Council (Conselho Federal de Enfermagem, Cofen) since 2004, through Resolution No. 295/2004, which authorizes its use by nurses[4]. This Resolution was revoked and amended in 2017 by Resolution No. 546/2017, which expanded the use of TP to the nursing team and required it to be prescribed and supervised by a nurse[5].

TP can be categorized into three modalities: a) Dramatic Therapeutic Play (DTP); b) Instructional Therapeutic Play (ITP); and c) Therapeutic Play Enhancing Physiological Functions[3]. Among these categories, ITP is ideal for preparing the child for hospitalization and/or the performance of therapeutic procedures, contributing to the child's understanding and, consequently, cooperation[2].

ITP can be used in various scenarios involving the health-disease process. In Pediatric Emergency, for example, it has been employed in promoting comprehensive care and preparing children for painful procedures[2,6]. This scenario is important for atraumatic care for both the child and their caregiver[2].

A qualitative study conducted in an inpatient unit of a Pediatric Hospital in Rio de Janeiro, which has 46 beds and serves children between 29 days and 12 years of age, with a team of 12 nurses and seven nursing technicians, found that ITP made the child less stressed and calmer, contributing to better acceptance of the procedure, as well as minimizing pain and discomfort resulting from the intervention[7].

A phenomenological study conducted in a hospital in the interior of São Paulo, which evaluated the family's perspective on the ITP, found that the strategy contributed to the child's concrete understanding of the procedures and, although crying persisted, there was a change in aggressive behaviors directed at the nursing staff. Furthermore, families reinforced the importance of incorporating ITP into the care offered to the child[2].

In the context of clinical research, the Research, Technology and Innovation Laboratory in Child and Adolescent Health (GEPESCA) has been using devices and technologies that are sometimes unknown to the child and their caregiver in its research, to improve the care provided. In this context, the ITP allows researchers to explain the importance, benefits, and limitations of the devices and technologies for both clinical practice and research, as well as demonstrating, step by step, the procedure to be performed, and the clinical research protocol for both the intervention and control groups. Furthermore, the ITP session allows the child and their caregiver to handle hospital materials, perform the procedure on a low-fidelity simulator (such as dolls), and clarify doubts and concerns about the procedure and/or research protocol.

Based on the above, this study aims to report on the experience of using Instructional Therapeutic Play in preparing children and caregivers for procedures related to clinical research protocols.

METHOD

This is a descriptive study, of the experience report type, derived from pilot randomized clinical trials (RCTs) and/or RCTs that used Buzzy®, Pikluc®, Virtual Reality (VR) goggles, SecurAcath®, and Cyanoacrylate Glue during the conduct of clinical research protocols in Pediatrics.

These studies were developed as Undergraduate Final Projects, Master's Dissertations, or Doctoral Theses in the field of Nursing, linked to GEPESCA at the Federal University of Santa Catarina. The ITP was used in these studies to introduce the devices or technologies to the children and their caregivers, as well as to prepare the children for the procedure in both the intervention and control groups, as reported. It is noteworthy that the application of the ITP was part of the protocol of each of these studies.

The study settings included two Children's Hospitals, the Pediatric Emergency Unit of a University Hospital, two Primary Health Care Units, and two Vaccination Clinics. The hospital units involved were Emergency Room, Urgent Care, Pediatric Oncology, and Surgical Center. All the aforementioned settings are located in the Southern region of Brazil, and the study period took place between February 2022 and May 2025.

The ITP sessions were conducted by researchers, with the collaboration of nursing academics and/or scientific initiation scholarship students. Children and adolescents aged between zero and 14 years participated in the sessions, together with their respective caregivers. It is worth noting that ITP is recommended for children aged 4 years and older; thus, when they were younger than 4 years old, the session was directed at their caregivers, while for the others, the activity contemplated the binomial child/caregiver.

Following the presentation of the research, acceptance for participation, and ethical procedures, the ITP session followed sequential steps: presentation of the low-fidelity simulator (doll) and its clinical history; explanation of the devices or technologies used in the study; evaluation and positioning of the simulator with the assistance of the child and/or caregiver; performance of the procedure, according to protocol; provision of post-procedure care, when applicable; opportunity for the child and/or caregiver to handle the materials; performance of the procedure by the child and/or caregiver, if they wished; clarification of doubts; and closing of the ITP session with praise and referral to the professional in the sector responsible for performing the procedure on the child.

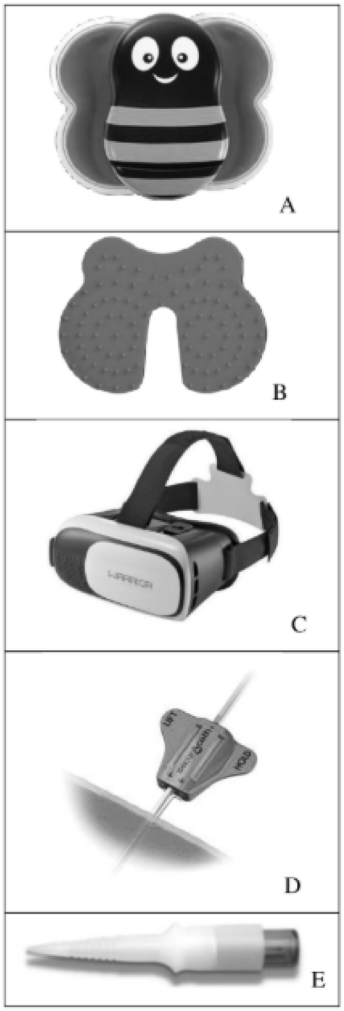
To record and organize observations from the ITP sessions, a specific instrument was developed that included questions about research identification, location, period, and responsible parties; sample characterization; simulated procedure; materials used; average session time; and impressions about the use of ITP in preparing the child and caregivers for participation in the clinical research. The researchers responsible for the studies completed this instrument, which allowed for the systematic organization of the data and the analysis of the findings presented in this experience report.

Since this is an experience report, review by the Research Ethics Committee (REC) was not required. However, all the research mentioned was submitted for evaluation and received ethical approval from the RECs of the participating institutions.

RESULTS AND DISCUSSION

This experience report covered ITP sessions that prepared children and caregivers for the use of Buzzy® (Figure 1A) or Pikluc® (Figure 1B) devices during intramuscular injection administration; VR goggles (Figure 1C) during vaccination or peripheral intravenous catheterization (PIC); and SecurAcath® (Figure 1D) and Cyanoacrylate Glue (Figure 1E) during the insertion of Peripherally Inserted Central Catheters (PICC).

Figure 1. Devices and technologies used in clinical research



Sources: Buzzy®, 2025[8]; Adapted from Likluc®, 2025[9]; Palimontes, 2025[10]; Adapted from SecurAcath®, 2025[11]; Adapted from H. B. Fuller Medical Adhesive Technologies, 2025[12].

After the research presentation, acceptance of the invitation to participate, and completion of ethical procedures, the child was invited to play, and the ITP session began. First, the low-fidelity simulator, that is, the doll, was presented to the participants, and its clinical history was narrated, similar to the child's history (Figure 2). Furthermore, the importance of performing the procedure for promoting or restoring the simulator's health was explained. Subsequently, the devices or technologies used in the study were presented, according to the randomization group, and how they could contribute to providing atraumatic care was explained.

Figure 2. Introduction of the doll and its clinical history.

Source: Personal Collection, 2025.

Next, the anatomical region of the simulator was evaluated and, depending on the procedure to be performed, the appropriate area was chosen. According to the region and the procedure, the simulator was positioned, and the child and/or caregiver were invited to assist in positioning the simulator. In the context of intramuscular injection, vaccination, and PIC, the child and/or caregiver assisted by holding the simulator, as is usual in real procedures, since this prevents spontaneous movement of the child during the procedure. In the context of PICC, the pharmacological measures used during catheterization and how the sedation process occurs in the simulator were presented.

Subsequently, the area was disinfected and the procedure was conducted on the simulator, in accordance with the research protocol and the randomization group to which the child was assigned. After completing the procedure on the simulator, the area was compressed with dry cotton, and a dressing was applied in the case of intramuscular injection and vaccination. In cases of intravenous therapy, the catheter was secured and covered. Next, the child and/or caregiver were asked about their desire to perform the procedure on the simulator, handle the materials involved in the procedure, and clarify any possible doubts (Figure 3). Finally, the child and caregiver were praised for their participation, the session was concluded, the materials were collected, and both were referred to the professional in the sector responsible for performing the procedure on the child.

Figure 3. Child handling a doll during an ITP session

Source: Personal Collection, 2025.

A total of 420 children and their caregivers participated in the ITP sessions. Among the participating children, males predominated (n = 219; 52.1%). Regarding the procedures performed (n = 421; 100%), 220 were intramuscular injections (52.3%); 136 were PICs (32.3%); 50 were vaccines (11.9%); and 15 were PICCs (3.5%); linked to five different studies. It is worth noting that the study related to PICC lines began in January 2025 and is ongoing, currently in the participant recruitment phase. In all studies, interest was found among children and/or their caregivers in using the tested devices and technologies, aiming at managing pain associated with hospital procedures such as intramuscular injections and PIC, and preventing PICC displacement.

The ITP session provided a safe environment for children and their caregivers to express fears and anxieties stemming from previous and current experiences. Furthermore, aspects related to the importance of the procedure and its mechanism of action were addressed, contributing to a reinterpretation of the current experience. It is emphasized that the adequate and educational preparation provided by the ITP to the children and their caregivers allowed them to understand the procedure and the devices and technologies involved in the research. This understanding fostered greater cooperation, less resistance to the procedure, and a significant reduction in emotional aspects such as fear, anxiety, and insecurity, feelings frequently present due to a lack of adequate information for the child, especially in hospi-

tal settings and regarding painful procedures.

With the use of ITP, it became possible to clearly show what would happen, explain that the procedure could hurt, what the child might feel, and, most importantly, why the procedure was necessary. The specialized preparation allowed the child to face the procedure with more confidence. In this context, ITP proved fundamental in reducing stress and fear, avoiding desperate situations, such as the child being taken "by force", crying, screaming, or in total disorientation about what was to come. Furthermore, through the ITP session, it was possible to bring the child and their caregiver closer to the healthcare team, contributing to the establishment of a better relationship between those involved, as well as offering atraumatic care – in addition to showing both the importance of participating in research and the need for such research for safer clinical practice.

The scenario presented aligns with findings in the literature, which highlight the benefits of ITP for both pediatric patients and their caregivers, as well as for the multidisciplinary team, since the use of ITP minimizes suffering and strengthens the bond between those involved[2,7]. Furthermore, predictability is an important factor in pediatric behavior, since children tend to prefer familiar situations because it provides a sense of security. This logic applies to the context of ITP, insofar as, by knowing what will happen, the child feels more prepared and confident, reducing stress and the need for physical restraint.

Furthermore, it is important to delve into the child's world during the application of the ITP, as infants naturally possess a great deal of imagination[13,14]. Therefore, the success of ITP depends not only on execution but also on adherence to the actual procedure, since the child tends to internalize the demonstrated steps and expects them to be followed as explained.

Furthermore, a recurring argument among professionals is the perception that ITP demands excessive time in care, a complaint observed in study settings and reported in the literature[7]. However, this research observed that ITP sessions lasted an average of ten minutes, depending on the complexity of the procedure, the study protocol, and the questions asked by the children and caregivers, both related to the research and the procedure. It is believed that this shorter duration offers atraumatic care for the child and, consequently, is less stressful for the caregiver and the professional performing the procedure, potentially even reducing the time spent on the procedure itself.

In the context of clinical research, ITP helped researchers explain the research procedure and protocol playfully, creating a welcoming environment for the children and their caregivers. Furthermore, the use of ITP made participation in the research more attractive and brought benefits to the participants, especially to the control group, which did not receive the device or technology tested during their procedure, permeating their participation with ethical and respectful care. This is aligned with Resolution No. 41 of the National Council for the Rights of Children and Adolescents, which emphasizes the right of hospitalized children and adolescents not to feel pain, when there are means to avoid it[15], since ITP contributes to the reduction of pain associated with the procedure[7].

Furthermore, it is noteworthy that not all children and/or caregivers reported prior contact with the devices or technologies used in the studies. Therefore, the session with the ITP proved fundamental in promo-

ting initial contact and enabling familiarization with the devices or technologies tested, fostering greater acceptance and participation in the research. This approach reinforced respect for essential ethical principles in research with human subjects, especially in Pediatrics, such as autonomy, assent from children older than 4 years, and consent from their caregivers. Therefore, the ITP was a strategy to improve participant receptiveness, contributing to the success of the studies.

This research had some limitations, including: the absence of a specific room or consulting room for conducting the ITP session, which had to be carried out in spare consulting rooms or in the procedure room itself; and high demand in the emergency room on some days, requiring greater agility from the researchers.

This study reinforces the importance of ITP and the possibility of its inclusion in clinical research protocols, as well as its use as a facilitator for the use of new technologies in child care, in addition to Nursing care practice. Furthermore, it corroborates the demystification of the idea that units such as the Pediatric Emergency Room are not suitable for conducting ITP due to limited time with the child and their caregiver, reinforcing the importance of including respectful practices with children in this setting, whenever clinical conditions allow.

Furthermore, the use of ITP as a technology to explain research protocols to children significantly contributes to reflections on the ethical conduct of clinical studies in Pediatrics. By providing a playful and safe environment, ITP promotes understanding of procedures and encourages dialogue, respecting the child's right to information and active participation in decisions involving their care.

Recognizing children as subjects of rights implies ensuring not only the consent of legal caregivers, but also free, informed assent appropriate to the child's age and developmental level. This practice reinforces the principles of autonomy, beneficence, and justice in research involving vulnerable populations.

FINAL CONSIDERATIONS

The ITP has proven to be a valuable technology for researchers, facilitating communication and promoting the presentation of devices and technologies used in RCT pilots and/or RCTs, as well as preparing the child and their caregivers for the procedures and understanding of the research protocol. This approach respects the fundamental ethical principles governing research with human subjects, especially with vulnerable populations such as the pediatric population, by ensuring a welcoming and appropriate environment for providing information and obtaining informed assent from the child.

The experience with ITP broadened the researchers' awareness of the need to integrate strategies that promote active listening, respect for the child's progressive autonomy, and specialized care. Furthermore, the potential of ITP as an ethical and methodological tool to foster the qualified participation of children in clinical research is evident, pointing the way to improving investigative practices and developing future studies that consolidate its application in the context of pediatric research.

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