Effectiveness of virtual reality on pain during peripheral catheterization in children: a pilot randomized trial

Efetividade da realidade virtual na dor durante a cateterização periférica em crianças: piloto de ensaio clínico randômico

Efectividad de la realidad virtual en el dolor durante la cateterización periférica en niños: ensayo clínico aleatorizado

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Abstract

Objective: To assess the feasibility of conducting a randomized clinical trial to evaluate the effectiveness of virtual reality on pain perception in children undergoing peripheral intravenous insertion, compared to traditional clinical method.

Methods: A pilot randomized clinical trial involved two groups: intervention with virtual reality and control with traditional clinical method during peripheral catheterization. Participants were children aged 4-14 years, who were clinically stable, conscious, and undergoing elective procedures. The feasibility outcomes included eligibility, recruitment, protocol fidelity, retention, missing data, and children's satisfaction. Pain perception was the secondary outcome, measured using the Faces Pain Scale – Revised.

Results: A total of 50 children were randomized into an intervention group (n=24) and a control group (n=26). Feasibility outcomes were largely achieved, although retention was suboptimal. Virtual reality had no significant effect on reported pain.

Conclusion: Virtual reality was feasible, well-tolerated, and appreciated by children, but a larger clinical trial is necessary.

Keywords
Pediatric nursing; Virtual reality; Pain; Catheterization; Peripheral; Pilot projects

Resumo

Objetivo: verificar a viabilidade de conduzir um ensaio clínico randômico sobre a efetividade da realidade virtual na percepção da dor em crianças submetidas à inserção intravenosa periférica, em comparação ao método clínico tradicional.

Métodos: Piloto de ensaio clínico randômico, com dois grupos: intervenção com realidade virtual e controle com método clínico tradicional durante a cateterização periférica. Os participantes foram crianças de 4 a 14 anos, clinicamente estáveis, conscientes e submetidas a procedimentos eletivos. Os desfechos de viabilidade incluíram elegibilidade, recrutamento, aderência ao protocolo, retenção, dados ausentes e satisfação das crianças. A percepção da dor foi o desfecho secundário, medido usando a Escala de Dor Facial – Revisada.

Resultados: Um total de 50 crianças foram randomizadas no grupo de intervenção (n = 24) e no grupo controle (n = 26). Os desfechos de viabilidade foram, em grande parte, alcançados, embora a retenção tenha sido subótima. A realidade virtual não teve efeito significativo sobre a dor relatada.

Conclusão: A realidade virtual foi viável, bem tolerada e apreciada pelas crianças, mas é necessário um ensaio clínico maior.

Descritores
Enfermagem pediátrica; Realidade virtual; Dor; Cateterização; Periférica; Projetos-piloto

Resumen

Objetivo: Verificar la viabilidad de realizar un ensayo clínico sobre la efectividad de la realidad virtual en la percepción del dolor en niños sometidos a la inserción intravenosa periférica, en comparación con el método clínico tradicional.

Métodos: Piloto de ensayo clínico aleatorizado con dos grupos: intervención con realidad virtual y control con el método clínico tradicional durante la cateterización periférica. Los participantes eran niños de entre 4 y 14 años,

Descriptores
Enfermería pediátrica; Realidad virtual; Dolor; Cateterización; Periférica; Proyectos piloto

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clínicamente estables, conscientes y sometidos a procedimientos electivos. Los resultados de viabilidad incluyeron la elegibilidad, el reclutamiento, la fidelidad al protocolo, la retención, los datos faltantes y la satisfacción de los niños. La percepción del dolor fue el resultado secundario, medido mediante la Escala de Dolor Facial Revisada.
Resultados: Se aleatorizó a un total de 50 niños en un grupo de intervención (n = 24) y un grupo de control (n = 26). Se lograron en gran medida los resultados de viabilidad, aunque la retención fue subóptima. La realidad virtual no tuvo un efecto significativo sobre el dolor referido.
Conclusión: La realidad virtual fue viable, bien tolerada y apreciada por los niños, pero es necesario realizar un ensayo clínico más amplio.

Brazilian Registry of Clinical Trials (Registro Brasileiro de Ensaios Clínicos – REBEC): RBR-6254jmy

Introduction

Peripheral intravenous catheters (PIVC) insertion is an invasive procedure that, despite its benefits, can cause pain, suffering, and stress for children.[1] In the emergency care, the literature has demonstrated that PIVC insertion pain is underestimated,[2,3] with healthcare providers focusing on technical aspects rather than children's experience. Due to this, children receiving emergency care face a heightened risk of physical pain and psychological distress from poorly managed needle procedures.[4] The literature further demonstrates that pain associated with PIVC insertion is under-treated, especially in infants, children with cognitive challenges and in low-income nations.[5] In this manner, professionals may undervalue a child's sensitivity to pain, potentially resulting in physical and emotional harm[6] and at times resorting to outdated techniques such as restraint.[2]

A consequence of not managing procedural pain are long-term avoidance of healthcare and fear of needles and traumatic memories. Common interventions for procedural pain management include local anesthesia, behavioral interventions like distraction.[1,6-8]

Regarding local anesthetics, they have been consistently employed in several countries,[2,6] and are endorsed by the Infusion Nurses Society.[1] However, although local anesthetics are available in developing countries like Brazil, their underuse is linked to the absence of institutional protocols, limiting nurses' autonomy in evidence-based procedural pain management.

Among procedural pain care practices, the utilization of Virtual Reality appears to be advantageous because it reduces the sensation of pain and added benefit of alleviating the fear associated with the procedure, as it entails the use of virtual reality goggles from the preparation to the procedure.[2] Virtual reality reduces pain perception by acting as a distraction,[8] redirecting the child's attention away from the painful stimulus and toward an immersive environment. This mechanism limits the brain's ability to process pain, as attention is focused elsewhere.[8,9] An experimental study[8] with using functional magnetic resonance imaging in adults confirmed reduced pain scores and decreased activity in brain areas related to pain, supporting the biological plausibility of virtual reality. Still, pain perception in children remains subjective and influenced by biological, psychological, and social factors.[10]

Systematic reviews have explored on effectiveness of virtual reality an its various pain procedures applications. Notably, these studies have predominantly been conducted in developed countries.[11-13] This technology may be even more beneficial in countries that do not routinely use drugs for procedural pain relief. However, there is less evidence on virtual reality use in PIVC insertion worldwide countries,[11-13] and no evidence in the context of Brazilian healthcare. Research results from randomized clinical trials (RCTs) on the efficacy of virtual reality for PIVC insertion pain in children remain inconclusive and the evidence is considered low to very low certainty regarding the efficacy of this intervention compared to no distraction or distraction other than virtual reality.[14-16] Therefore, well-designed, large, high-quality future RCTs are needed.[11-13]

Conducting this study in Brazil is relevant given the limited use of pharmacological pain management in children. Pilot studies are essential to test the feasibility of RCTs on a smaller scale,[14] helping to refine methodology, reduce sampling errors, and assess the practical use of virtual reality in emergency settings for PIVC insertion.

The objective of this trial was to assess the feasibility of conducting a RCT to evaluate the effectiveness of virtual reality on pain perception in children undergoing peripheral intravenous insertion, compared to traditional clinical method.

Methods

This is a single-center, parallel, open-label, RCT pilot study, and its reporting followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines[15] with 2 groups: virtual reality was implemented in the intervention group, whereas in the control group, the traditional clinical method was used.

The study took place in the Emergency Department of a children's hospital in Brazil and included all genders, clinically stable, conscious children aged 4 to 14 years who required elective peripheral intravenous catheter (PIVC) insertion. Exclusion criteria were cognitive deficits, conditions affecting pain sensitivity (e.g., neural tube defects), need for contact precautions, seizure history, severe dehydration. The pilot sample included 50 children, as recommended for pilot studies.[14]

The study stages included: proposal presentation, training of data collectors and PIVC inserters, and data collection. Following ethical guidelines, children were excluded if they removed the virtual reality glasses early, felt unwell, did not complete the questionnaire or pain scale, or requested data withdrawal.

The children were allocated to the study, divided into intervention and control. Block randomization (block size = 4) was adopted to allocate participants to either the intervention or control group. The randomization sequences were stratified based on age groups, specifically children aged 4 to 8 and 9 to 14. That is, children from 4 years old up to 8 years, 11 months, and 29 days, and children from 9 years old up to 14 years, 11 months, and 29 days. The randomization was performed using a table generated by the RANDOM program (www.random.org). An external researcher created the randomization. The information containing randomization was placed in a sealed envelope, opened only when the participant accepted. This study was not blinded due to the impossibility of concealing the use of the virtual reality.

The nursing staff received training conducted by the principal researcher, covering pediatric vascular anatomy, venous access assessment, management of difficult intravenous access using Difficulty Intravenous Access Score (DIVA),[16] PIVC insertion techniques, the research protocol, and strategies to prepare children and families for the procedure. The insertion procedure was standardized based on international guidelines[1] and hospital policy, with a visual protocol displayed in the medication room to ensure consistency.

Before the intervention, all children were prepared for the PIVC procedure. Those aged 4–8 participated in therapeutic play and could practice on a doll, while those aged 9–14 received an instructional booklet titled "It's Time to Take My Vein: What Do I Do?"[17] All children also had the opportunity to handle the virtual reality goggles during this preparation.

The hospital's nursing staff performed PIVC insertions following these steps: inspection of the insertion area, tourniquet applied 5 to 12 cm above the site, vein palpation and visualization, cleansing with 70% alcohol swabs for 30 seconds, skin stabilization 3 to 5 cm below the site, Gentle needle insertion and advancement of the polyurethane catheter into the vein until successful placement. The tourniquet was removed, and the dressing applied with transparent film or microporous adhesive tape®. The clinician's hands were washed before and after the procedure. Success was defined as achieving intravenous access on the first attempt, with full blood reflux, easy flushing with 1–10 mL of saline, and no signs of complications like infiltration or hematoma.[18]

The intervention involved preparing a video with a smartphone adapted to a headset and virtual reality goggles, placing a surgical cap on the child to prevent cross-contamination, and using the 3D video *"Ocean World: Underwater"* to position the child comfortably in dorsal decubitus. The video, featuring marine scenes with a relaxing melody, was selected to minimize nausea and dizziness,[19] as it did not provide a full panoramic view (360° content). The video link is available upon request.

The video lasted for 3 minutes and was repeated until the procedure was finished, wich took 259 seconds (M: 114.16; standard deviation [SD]: 59.61), deemed the maximum amount of time. Despite using headphones, the virtual reality was not fully immersive, allowing interaction between the child and researchers or caregivers. The video minimized child movement to reduce the risk of nausea and prevent sudden movements during the PIVC insertion. This stage took place in a private room with only the child, caregivers, the professional, and the researcher present.

The control group, referred to as the Traditional Clinical Method, was observed during the PIVC insertion without any intervention, and data were collected for comparison with the intervention group. The procedure was identical for both groups; however, the intervention group used virtual reality, while the control group did not receive any different technique.

This pilot was conducted between September and December 2021, by the principal researcher, who is a PhD student and a nurse. The intervention was conducted individually and face-to-face by the researchers. The data collection ended once the previously calculated sample size was reached.

Data were collected on a paper-based form, tabulated using the Microsoft Excel® tool, and analyzed using IBM SPSS® (version 29). Demographic characteristics were collected before the intervention commenced. Demographic and clinical data were collected to describe the sample.

Children were continuously observed during the procedure, which was divided into two phases: Time A (inspection) and Time B (insertion). Behavioral responses were recorded using the Observation Scale of Behavioral Distress (OSBD),[20] including information seeking, verbal resistance, verbal fear, verbal pain, emotional support, cry, yell, flail, rigidity, refusal position, restraint, and nervous behavior.

Time A was measured from the moment the professional applied the tourniquet to the child for vessel selection to the moment the catheter was inserted into the child's skin, corresponding to the inspection period. Time B was measured from the moment the professional inserted the catheter into the skin and ended after the first fixation of the catheter. The children's behavioral reactions were observed and recorded during these two distinct moments.

If more than one attempt was necessary, the time was restarted, and the time of all the inspections was counted and added up. The insertion time was counted only on the successful attempt. Thus, the child was evaluated according to its behavior at the time of clinical inspection of the vein and at the time of insertion when there was effectively tissue damage to the patient's skin.

After completing the peripheral intravenous catheterization, data collectors asked the nurses about variables related to the DIVA Score,[16] such as vein visibility and palpability, history of prematurity, and skin tone. The nursing staff assessed the DIVA score[16] prospectively to guide vein selection prior to insertion, while data collection occurred only afterward to avoid influencing the clinical evaluation or the procedure.

Primary outcomes: Feasibility criteria and limits were determined based on criteria used in previous pilot trials in vascular access,[21,22] eligibility (>80% of screened patients meeting all inclusion and no exclusion criteria); recruitment (>80% of eligible patients providing informed consent); protocol fidelity (>90% randomized patients receiving allocated intervention); retention (<5% of recruited patients lost to follow-up or withdrawing consent); missing data (<5% of total clinical outcome data unable to be collected); and, children satisfaction at glasses removal (>80% kept wearing glasses until the end of the intervention).

Secondary outcome: Pain report in children undergoing PIVC insertion measured by the FPS-R scale score (FPS-R).[23] The scale characterizes pain on a numerical scale ranging from 0 to 10, where 0 represents the absence of pain and higher numbers indicate increasing levels of pain.

Data analysis: Categorical variables were described through absolute frequency distribution. In the univariate analysis, to verify the association between the exposure variables and the primary outcome, the Relative Risks (RR) and their respective 95% Confidence Intervals (CI) and 5% significance level (p-value≤0.05) were estimated, using Pearson's X2 or Fisher's Exact tests. The OpenEpi Tool and the IBM SPSS® (version 29) were used for statistical analysis.

For the sample calculation, it was considered absence of pain or pain through the FPS-R scale.[22] It was considered absence of pain only when the child reported 0. Pain outcomes of the two comparison groups were used to estimate the minimum sample size, using the OpenEpi Tool (https://www.openepi.com/Menu/OE_Menu.htm). A significance level of 5% and a study power of 80% were considered, and an effect size of 1.5.

Ethical approvals were obtained from the Research Ethics Committee of the Hospital Regional Hans Dieter Schmidt/SES/SC (CAAE 51948421.2.0000.5363). The study was registered in The Brazilian Registry of Clinical Trials (Registro Brasileiro de Ensaios Clínicos, REBEC) database, with the following primary identifier

RBR-6254jmy. Children, caregivers, and professionals were informed about the study before its start. Written consent was obtained from the all participants.

Results

Fifty-eight children were evaluated for eligibility. Of these, four did not meet the inclusion criteria, thus, 26 children were allocated to the control and 28 to the intervention. The sample was being finalized when the minimum sample was reached without considering the losses in the process, being 54 randomized and 50 included in the sample, 24 in the intervention and 26 in the control, with 4 losses in the research follow-up (Figure 1). The recruitment was concluded when the sample of 50 was reached. Four children were lost from the intervention, two due to puncture failure after three attempts of PIVC insertion, being medicated with intramuscular medication and two children because they requested removal of the virtual reality googles.

The predominant diagnosis in both groups was acute gastroenteritis 13(26%), followed by headache 11(24%) and abdominal pain 5(10%). In the intervention, the most frequent diagnosis of acute gastroenteritis 9(37%), headache 4(16%) and abdominal pain 4(16%). In the control, there was more occurrence in the diagnosis of headache 7(26.9%), acute gastroenteritis 4(15.4%) and asthma attack 3(11.5%).

Demographic characteristics were homogeneous between the two groups (Table 1). The sample was composed mostly of girls, median age 9 years, who were normothermic, who did not use analgesics before PIVC, who had tortuous veins and were classified according to DIVA as not difficult to cannulate. PIVC insertion was mostly performed with the 24 Gauge catheter and established on the first attempt.

Of the 58 children screened, 54 met eligibility criteria with 93% eligible (Table 2). Informed consent was obtained from 53 of the 54 eligible children (98%), reaching the eligibility and recruitment criteria. Four participants were lost to follow up, with two being due to PIVC insertion failure and two due to glasses withdrawn (7%), therefore retention criteria were not met. For the protocol fidelity criteria, all randomized patients received allocated interventions. All data for the clinical outcome could be collected, hence the missing data criteria were met. Children's satisfaction with the glasses met the feasibility criteria with 92% in the intervention wearing glasses until the intervention's end.

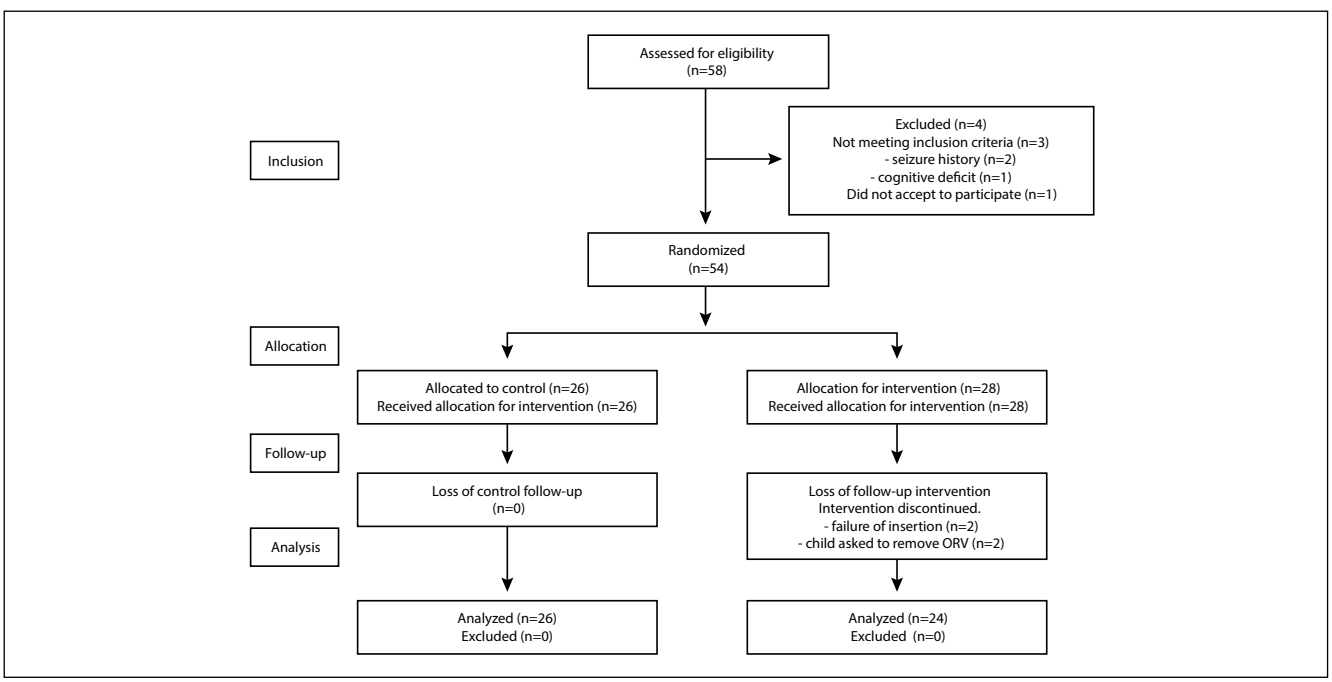

Figure 1. Flowchart illustrating the participant selection process from recruitment to data

Table 1. Sociodemographic and clinical characterization of the children in the intervention and control groups (n=50)

Variables	Intervention n(%) n=24	Control n(%) n=26
Sex		
Female	13(54.2)	12(46.2)
Male	11(45.8)	14(53.8)
Used painkiller today		
Yes	8(33.3)	14(53.8)
No	16(66.7)	12 (46.8)
Age in months (mediana +IQ*)	115 (38.8)	112.96 (44.1)
Temperature (mediana +IQ*)	36.6 (1.08)	36.73 (0.82)
Vein shape on hit attempt		
Crocked	7(29.2)	10(38.5)
Straight	17(70.8)	16(61.5)
DIVA rating in the attempt to get it right		
Easy intravenous access	21(87.5)	25(92.2)
Difficult intravenous access	3(12.5)	1(3.8)
Catheter size		
22 Gauge	3(12.5)	4(15.4)
24 Gauge	21(87.5)	22(54.6)
Number of attempts		
1	17(70.8)	21(80.8)
2 or more	7(29.2)	5(19.2)

IQ - Interquartile Range

Table 2. Protocol feasibility outcomes

Feasibility criteria	Predetermined threshold	Result (%)
Eligibility	>80% of screened children eligible	93
Recruitment	>80% eligible children consented	98
Protocol fidelity	>90% randomized patients receiving allocated intervention	100
Retention	<5% patients lost to follow-up	7
Missing data	<5% of primary clinical outcome data missing	0
Children´s satisfaction	>80% kept wearing glasses until the end	92

The use of virtual reality did not influence the report of pain, with 13 (54.2%) reporting pain in the intervention group and 18 (69.2%) in the control group, with no statistical difference between groups (Pearson's $\chi^2 = 0.273$, RR = 0.70, CI = 0.33–1.40). However, the intervention showed a lower report of pain. Based on the frequency of pain reports in the two comparison groups, a minimum sample size of 352 children was estimated for the RCT. In addition, as a modification from this pilot to the main study, it was observed the need to time the inspection time from the beginning of the clinical evaluation, not only after placing the tourniquet on the child. No harm or adverse effects were reported in this pilot.

Discussion

The study confirmed the feasibility and safety of using virtual reality during PIVC insertion in children in Brazilian emergency settings. The study successfully met the criteria for eligibility, recruitment, protocol fidelity, data collection, and children's satisfaction. Virtual reality was well-tolerated and appreciated. However, retention was limited due to difficulties with PIVC insertion, which often led to a change in the administration route before the procedure could be completed. This issue was related to the procedure itself, not to the use of virtual reality. The study suggests additional training in PIVC insertion or reconsidering failure as an exclusion criterion.

As expected in a pilot feasibility trial, the study showed no significant difference in pain reporting using virtual reality. Although, this technology is promising, and has been documented by several studies as a possible distraction to pain in other populations and settings.[11-13,23,24]

Moreover, two children in the study requested withdrawal of virtual reality because they were apprehensive about PIVC insertion, corroborating the findings of study,[2] then they could watch the procedure demonstrating that immersive experience could be not suitable for all children.[2] This highlights the need for individualized care, with the child's cooperation being indispensable for the distraction to be successful.

As a feasibility study, this pilot confirmed that virtual reality can be a viable non-pharmacological option for pain management, but larger studies are needed to confirm its effectiveness and generalizability. The sample of 50 children helped refine estimates for calculating the ideal sample size[14] for a future, well-powered RCT to better assess virtual reality's impact on pain reports during PIVC insertion in children.

Beyond informing future sample size calculations, the pilot allowed adjustments to the timekeeping instrument and research protocol to enhance clarity and feasibility. The videos were well accepted by children of all ages, and all experimental procedures were successfully implemented.

In the emergency context, assisting children during elective procedures could be beneficial. The literature in emergency care[2,3,5] indicates that pain associated with procedures is often inadequately man-

aged, however, there are opportunities to mitigate pain during invasive procedures, in situations where is no imminent risk of death. This pilot study showcased the feasibility of employing virtual reality in medication and observation rooms, underlining its potential positive impact. No harm or adverse effects were reported, likely because the selected video avoided full panoramic view, reducing the risk of cybersickness.[19]

Finally, the use of virtual reality in this research is particularly relevant in resource-limited settings, as it relies on free videos available on online platforms and should be tested in such environments to ensure its feasibility. Non-pharmacological methods for pain management, which do not require a medical prescription, provide straightforward training for healthcare teams, enabling greater autonomy in childcare. Additionally, the appeal of virtual reality to children, which stimulates their imagination, makes it especially beneficial during painful procedures for this population.

This study has limitations, including the wide age range and varying developmental levels of the participants, which may have influenced pain perception and reporting. To address these differences, we implemented age stratification during data analysis. Additionally, the four-year gap between data collection and publication may affect which may affect the timeliness of the findings. For future research, we suggest incorporating complementary pain assessment methods alongside scales like the FPS-R. These could include physiological measures (e.g., heart rate, blood pressure, respiratory rate, and salivary cortisol levels) as well as behavioral observations of pain expression.

Conclusion

This pilot study demonstrated the feasibility of using an virtual reality distraction was feasible, tolerated, and appreciated by children. The ability of virtual reality to distract the child into an imaginary world has the potential to reduce pain associated with invasive procedures. The need for a larger RCT to evaluate the effectiveness of virtual reality during PIVC insertion is reinforced, with the pediatric population directly benefiting from the proof of this non-pharmacological method for pain relief.

Contributors

Rocha PFA, Rocha PK, and Santos LM declare having contributed to the conception of the study. Rocha PFA declares having contributed to data collection. Rocha PFA, Rocha PK, Santos LM, Ullman A, and Bitencourt AS declare having contributed to data analysis and interpretation. Rocha PFA, Rocha PK, Santos LM, Ullman A, and Plummer K declare having contributed to the discussion of results. Rocha PFA, Rocha PK, Santos LM, Ullman A, Plummer K, Bitencourt AS, Souza S, and Silva TL declare having contributed to drafting and/or critical revision of the manuscript. Rocha PFA, Rocha PK, Santos LM, Ullman A, Plummer K, Bitencourt AS, Souza S, and Silva TL declare having approved the final version to be published.

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