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Research Article

Effectiveness of Virtual Reality Interactive Play for Children During Intravenous Placement: A Randomized Controlled Trial

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SUMMARY

Purpose: This study aimed to evaluate the effectiveness of an interactive virtual reality (VR) play intervention including instructional play and emotional catharsis play sessions in reducing children's pain and fear during intravenous placement.
Methods: A randomized controlled trial with parallel groups was conducted. The sample consisted of 134 hospitalized children aged 6–12 years (intervention group: $n = 69$; comparison group: $n = 65$). The intervention involved one immersive intravenous scene in VR before the actual intravenous placement and one emotional catharsis VR play after injection. The comparison group received an educational photo book about intravenous placement before receiving intravenous placement. The children and their caregivers rated their pain and fear by using the Wong–Baker FACES Pain Rating Scale and the Children's Fear Scale. The time required for successful intravenous insertion was also compared between the two groups.
Results: Children's pain ($p = .028$) and fear scores ($p = .004$) were significantly lower in the intervention group than in the comparison group. Their caregivers' pain and fear scores (both $p < .001$) were significantly lower in the intervention group. The time required for successful intravenous insertion did not differ significantly between the intervention and comparison groups.
Conclusions: The interactive play intervention with VR effectively reduced children's levels of pain and fear during the intravenous placement procedure. The results of this study can serve as a reference for the implementation of a feasible, child-friendly care practice for clinical intravenous placement in school-aged children.

Introduction

Invasive treatment is a stressful process for hospitalized children. An intravenous injection is a common invasive treatment [1]. Although school-aged children can communicate the location and intensity of pain verbally, they often exhibit muscle tightening, body stiffness, fist clenching, painful stimulus avoidance, and procrastination during injection processes. They worry about displaying uncontrolled behaviors and attempt to appear brave to maintain control. If the child is not provided with an initial explanation of procedures or is provided with deceptive information, they can fear and distrust their medical care and medical caregivers and may not cooperate [2,3]. If a child's behavioral reaction during the injection process is intense, achieving a successful injection becomes difficult. Negative experiences with this medical process or unfamiliarity with the environment increases pain caused by intravenous injections and affects children's attitude toward future medical care, physical discomfort, and mental trauma [3].

Therapeutic play is a treatment in which games are designed with plans, goals, and skills in mind to understand the development, threatening life events, and internal conflicts of children who

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are ill, as an interventional care activity [4,5]. In therapeutic play, children inhabit the role of a third party to express their inner feelings; understand their inner worries, fears, and defense mechanisms; and deal with their concerns and anxieties. Medical staff members gain insight into children's needs and feelings in order to effectively implement health education about nursing interventions, medical treatment, and procedures [6]. Therapeutic play has three main forms, namely instructional, emotional outlet, and physiologically enhancing play [7].

Virtual reality (VR) is a computer-generated simulation that provides an immersive, multisensory, and three-dimensional environment in which a child can experience a changed sense of reality and concentrate on immersing themselves in it [8]. An immersive therapeutic play strategy that can be easily implemented can help alleviate the pain and fear of school-aged children receiving intravenous placement. Most studies on VR have applied the distraction principle to assist in reducing children's pain, fear, and anxiety by providing a comfortable environment for video watching [9–11] and interactive gaming [12,13]. Various VR programs have been extensively used for children and adolescents in intravenous placement or venipuncture [9–12,14,15]. In addition to distraction strategies, Wong et al. [15] used a hospital-based adventure story with cartoon characters for informative purposes. Eijlers et al. [16] asserted the need for further research on the effects of VR exposure as a preparation approach for medical procedures. This approach could be especially effective for children at a concrete operational stage who have the capacity for logical thinking [17]. In addition to providing instructional play before treatment, VR can minimize children's pain, fear, and anxiety during intravenous placement; improve their psychological construction, interpretation, and communication; and enhance their sense of control and participation in treatment. Following intravenous placement, immersive cathartic play can guide children in expressing their emotional feelings of the medical care process. Therefore, this study aimed to develop a VR play intervention, including instructional and emotional catharsis play sessions for hospitalized school-aged children undergoing intravenous placement, and examine the effectiveness of this strategy compared with an educational photo book about intravenous placement in reducing children's pain and fear during the procedure.

Specifically, we determined the effectiveness of the intervention on the basis of the following items:

Hypothesis 1. The intervention group with VR play intervention will have a lower pain score than the comparison group with educational book.

Hypothesis 2. The intervention group with VR play intervention will have a lower fear score than the comparison group with educational book.

Hypothesis 3. The intervention group with VR play intervention will take less time required than the comparison group with educational book.

Methods

Design and setting

A parallel, two-arm, multicenter, randomized controlled trial was conducted at the pediatric wards of two medical centers in northern and central Taiwan between June and September 2020. The study was registered with the ClinicalTrials.gov (NCT04558086).

Participants

We included children aged 6–12 years who were recommended to receive intravenous placement by a physician. We excluded children who had developmental delay, epilepsy, visual or hearing impairment, nearsightedness with more than 8.0 diopters or farsightedness with more than 5.0 diopters, or head trauma sustained in the past month; required blood transfusion and blood preparation; received two or more intravenous injections; were undergoing chemotherapy; had experienced VR-induced dizziness; or had a history of vertigo.

The G*Power 3.1.2 program was used to calculate the required sample size; the calculation revealed that for analysis of covariance (ANCOVA) with two groups, a minimum sample size of 128 was required to achieve a power level of 80.0%, an alpha level of 0.05, a medium Cohen's f effect size of 0.25, and a total of 8 covariates, including the children's age, gender, frequency of past intravenous injections, prior use or nonuse of VR, fear scores in pretest, caregiver's age and gender, and registered nurses' years of work experience. Assuming a 5.0% dropout rate, we recruited a total of 134 participants in this study.

Randomization

Allocation concealment was used to randomly assign the enrolled participants into two groups. A staff member not involved in the study used Random Allocation Software 2.0 for the block randomization of the two medical centers; the allocation results were placed in opaque, sealed envelopes, which the participants opened after they and their primary caregivers signed the consent forms.

Interventional instrument

The VR headset HTC Vive was used in this study. The head-mounted display device of the VR Cosmos helmet presented a multiangle view of the virtual world, allowing for a fully immersive experience for the participants. A detector captured the movement of the participants and interacted with the virtual environment. In addition, the wireless hand controller mirrored the participants' hand actions (e.g., grasp or aim) in the virtual world. A light sensor was affixed to the helmet and front end of the controller to locate the position of the controller in the three-dimensional space. The scenes and scripts of the interactive VR play were designed on the basis of clinical implementations of intravenous placement and a literature review (Table 1). We cooperated with the research team of the third author to develop the VR play entities.

Participants allocated to the intervention group underwent instructional and emotional catharsis play sessions executed in the VR environment. The instructional play consisted of one immersive intravenous scene in VR to inform the participants about the purpose and process of injection and what must be done prior to receiving actual intravenous placement. The interactive scene lasted approximately 5 min. The scene started from opening the treatment room, where the child could look around the setting with the handheld controller while listening to the purpose and explanation of intravenous placement procedures along with soft background music. Each participant was asked to stretch out their arm on a red pillow. They then watched the sequence of procedures that followed, namely the trying of a blue rubber band around their arm, disinfection and injection of the intravenous area, deposition of blood in a test tube, placement of a sticker on the needle, and connection of the needle with the long fluid tube. Finally, a rabbit

Table 1 *Design for Virtual Reality Interactive Play.*

Virtual reality interactive play	Instructional play	Emotional catharsis play
Purpose	To inform the participants about the purpose and process of injection and what must be done prior to receiving actual intravenous placement	To forger the feeling of pain and fear of intravenous placement, and relaxation
Content	Immersive intravenous scene	Interactive play
Intervention timing	Before injection	Post injection
Time taken	5 min	5 min
Background music	Soft music	Brisk and relaxing rhythmical music

and two figures representing bacteria entered into the room and announced that a game in which participants must eradicate the bacteria after completing the intravenous placement. The instructional play scene is illustrated in Figure 1.

The postinjection emotional catharsis play session began with an interactive VR scene in which figures representing bacteria were running and jumping in the treatment room, with brisk but relaxing rhythmical music. The rabbit said the following: "Welcome back, little warrior! You were really brave just now. There are a lot of bad bacteria here making our body sick; let's destroy them!" Each participant held a hand controller with the non-injected hand to play for 5 min. Finally, the rabbit clapped its hands and said the following: "You are really amazing. You can make us healthy by stopping the bacteria!" The scene of the emotional catharsis play is also illustrated in Figure 1.

Participants allocated to the comparison group were provided with an educational photo book on intravenous placement entitled *Detective Conan: The Truth about Needles* developed by Hsieh et al. [18] before receiving intravenous placement. The main content of the book outlines the aim of intravenous placement, sensory and procedural information, and care considerations for hospitalized school-aged children.

Tools

Wong–Baker FACES pain rating scale

One of the primary tools in this study was pain. The degrees of pain experienced by the children and reported by their primary caregivers were measured using the Wong–Baker FACES pain rating scale (WBFPS) [1]. The scale contains six cartoon faces with pain ratings of 0–10, with 0 representing 'no pain' and 10 representing 'excruciating pain'. The internal reliability coefficients for the WBFPS were determined to be 0.82–0.92, and the test–retest reliability was 0.90 [19]. The children and primary caregivers were asked to select the faces that best described the pain levels experienced by the children who received intravenous injections; the pain levels were subsequently converted into numerical values [1,19,20].

Children's fear scale

Similarly, the degrees of fear experienced by the children and their primary caregivers were measured using the Children's Fear Scale (CFS) [21]. The scale consists of five cartoon faces with fear ratings of 0–4, with 0 representing 'no fear' and 4 representing 'extreme fear'. The CFS was also determined to have satisfactory reliability and validity. The children and their primary caregivers were asked to select the faces that best described the fear levels of the children who received intravenous injection; the fear levels were subsequently converted into numerical values [21–23].

The time required for successful intravenous insertion

The time required for successful intravenous insertion in this study was defined that began the moment the participants were fitted with the tourniquets and the injection sites determined and ended when the venous catheters (No. 24) were inserted and blood returned to the return blood cavities.

Data collection

All participants and their primary caregivers were provided with an explanation of the study's objectives and their questions

Figure 1. The scenes of instructional play (left) and emotional catharsis play (right) sessions.

were answered by the first author. After signing a consent form, they completed demographic information form. The participants completed the CFS, and a NT$ 200 voucher was gifted to their primary caregiver. After opening the sealed envelopes, the participants were assigned to either the intervention group or the comparison group. The intervention group received VR interactive play, and the comparison group received the educational photo book about intravenous placement. During intravenous injections by the primary care nurses, the time required for successful intravenous insertion was calculated by the first author. After the completion of intravenous placement in the comparison group or after the emotional catharsis play in the intervention group, the participants and their primary caregivers were requested to complete the WBFPS and CFS. The participants in the comparison group were then invited to play the emotional catharsis game.

The study design, procedure, and reporting followed the CONSORT recommendations on randomized controlled trials [24]. All instruments used for data collection were demonstrated to have psychometric adequacy. We further examined the content validity to verify the relevance, accuracy, and suitability of the VR play scenes and scripts. As part of the two-round content verification, five experts were invited to rate the play content from 1 ('the content is very inappropriate and must be deleted') to 5 ('the content is very appropriate and must be retained'). Next, we invited two students from each of the following grades to experience the use and operation of the VR play: 1–2, 3–4, and 5–6. Based on the purpose and process of the intravenous placement in the VR play, the students were requested to rate the content from 1 ('do not understand at all') to 4 ('fully understand'). The content validity index in the second round was 0.90 for the experts and 0.96 for the students.

Ethical considerations

Ethical approval for this trial was obtained from the institutional review boards of two participating medical centers in Taiwan (108163-F & 200129). All included patients and their caregivers provided signed informed consent. The participants were permitted to withdraw from the study at any time without prejudice.

Data analysis

Descriptive statistics are presented as mean and standard deviation or as number and percentage for categorical variables. The significance of differences between the intervention and comparison groups at baseline and the time required for successful intravenous insertion were analyzed using the Student's *t* test for continuous variables or Fisher's exact test for categorical variables. ANCOVA was used to compare the levels of pain and fear between the two groups, after adjustment for the covariates. All analyses were performed using the Statistical Package for Social Science (version 22.0; IBM, Armonk, NY, USA). For all participants, a *p* value of <.05 was considered statistically significant.

Results

The flowchart of participant recruitment is illustrated in Figure 2. We initially assessed 179 participants for eligibility and randomized 134 (74.9%) of them. Of the randomized participants, 69 participants were allocated to the intervention group and 65 participants were allocated to the comparison group, and all of them completed the clinical trial. As presented in Table 2, before the interventions, the two groups were comparable in terms of baseline characteristics. The average age of the participants was 10.01 years (±1.71), and over half of the participants were girls (80; 59.7%). The majority were hospitalized for endocrine examination (116; 86.6%). Moreover, a quarter of the participants (34; 25.4%) had never received intravenous injection before. Over half of the participants (73; 54.5%) had no previous VR experience. The average age of the primary caregivers was 43.57 years (±5.72), and most of these caregivers were mothers (104; 77.6%). The average age of the nurses who executed the intravenous injections was 28.62 years (±5.61), and their average work experience was 6.58 (±5.41) years. The two groups did not differ significantly in demographic or clinical characteristics, except for prior use or nonuse of VR and caregivers' age. The intervention group had significantly fewer participants who had used VR than did the comparison group (34.8% vs. 56.9%, $p = .015$). The average age of the caregivers in the intervention group was significantly younger than that of those in the comparison group (42.28 ± 4.61 vs. 44.94 ± 6.45 years, $p = .007$). No adverse events occurred during the trial. Moreover, no patient experienced VR sickness, seizures, discomfort, or infection-related events related to the VR experience.

Analysis of pain intensity

As presented in Table 3, the degrees of pain (1.33 ± 1.60 vs. 2.06 ± 2.00, $p = .028$) experienced by the children who received

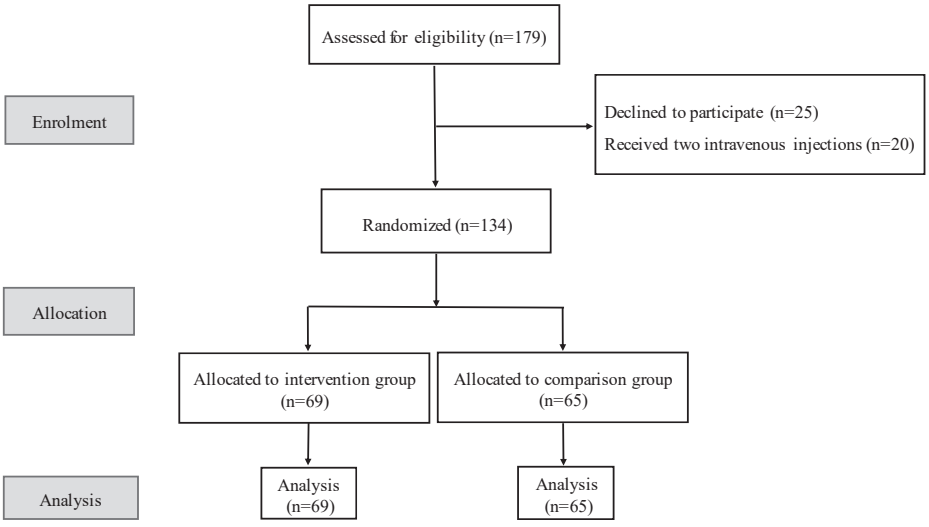

Figure 2. Participant Flowchart.

Table 2 *Baseline Demographic and Clinical Characteristics of Participants (N = 134).*

Variable	Intervention group ($n = 69$) Mean ± *SD*/*n* (%)	Comparison group ($n = 65$) Mean ± *SD*/*n* (%)	*p*
Child			
Age	9.81 ± 1.70	10.22 ± 1.70	.172
Male	32 (46.4)	22 (33.8)	.139
Reason for admission, endocrine examination	56 (81.2)	60 (92.3)	.077
Times of past intravenous injection received	1.55 ± 1.33	1.71 ± 1.65	.544
Have used virtual reality	24 (34.8)	37 (56.9)	.015
Caregiver			
Age	42.28 ± 4.61	44.94 ± 6.45	.007
Relationship, mother	55 (79.7)	49 (75.4)	.679
Nurse			
Age	29.04 ± 6.28	28.17 ± 4.79	.365
Registered nurse working years	6.79 ± 5.83	6.37 ± 4.95	.657

Note: Student's *t*-test or Fisher's exact test; *SD*, standard deviation.

intravenous injections were significantly lower in the intervention group than the comparison group, after adjustment for the children's age, gender, frequency of past intravenous injections, prior use or nonuse of VR, fear scores in pretest, caregiver's age and gender, and registered nurses' years of work experience. Additionally, the degrees of pain (1.13 ± 1.51 vs. 2.68 ± 1.74, $p < .001$) assessed by the primary caregivers were also significantly lower in the intervention group, after adjustment for the aforementioned covariates.

Analysis of fear intensity

As to the prior needle-related fear intensity in the pretest, the mean score of fear intensity in the intervention group (1.58 ± 1.27) was higher than that in the comparison group (1.38 ± 1.33). However, the fear perceived in the pretest by the two groups children differed non-significantly ($t = 0.870$) (Table 3). Similarly, the degrees of fear (0.36 ± 0.64 vs. 0.95 ± 0.96, $p < .001$) assessed by the primary caregivers were also significantly lower in the intervention group, after adjustment for the aforementioned covariates (Table 3). The degrees of fear experienced by the children who received intravenous injections were significantly lower in the intervention group compared with the comparison group, after adjustment for the children's age, sex, frequency of past intravenous injections, prior use or nonuse of VR, fear scores in pretest, caregiver's age and sex, and registered nurses' years of work experience (0.28 ± 0.54 vs 0.65 ± 0.94, $p = .004$).

Analysis of time required for successful intravenous insertion

The average seconds required for successful intravenous insertions were taken in the intervention group (51.89 ± 21.51) and in the comparison group (50.91 ± 16.29). Of all participants, five were excluded due to the external factors, including disinfecting for multiple times or finding blood vessels for a long time due to dirty or cold hands. The time required for successful intravenous insertion did not differ significantly between the two groups (Table 3).

Discussion

The main findings of the present study are that interactive play with VR intervention was effective and reduced children's pain and fear during intravenous placement. According to our review of the literature, this is the first randomized controlled trial to investigate the effects of both VR exposure and distraction in children during intravenous placement. The lack of other similar protocol studies means that comparing our results with those of other studies would be difficult. However, these results are consistent with those of studies that have examined the effects of similar concepts of therapeutic play, such as dramatic, instructional, or role-play sessions, on the pain, anxiety, and fear of school-aged children during needle-related procedures [25–29]. Silva et al. [3] employed the dramatic therapeutic play technique and evaluated the corresponding outcomes by using the Child Drawing: Hospital instrument; they did not observe a significant difference in the degree of anxiety between the intervention and control groups. Hsieh et al. [18] provided children with an educational photo book (the book used in our comparison group) about intravenous placement before the procedure, and patients watched their favorite music video during the procedure; they observed that fear intensity was

Table 3 *Main Study Outcomes (N = 134).*

Variable	Before IV placement Mean ± *SD*	After IV placement Mean ± *SD*	F	*p*
Pain score by child			5.00	.028
Intervention group ($n = 69$)		1.33 ± 1.60		
Comparison group ($n = 65$)		2.06 ± 2.00		
Pain score by caregiver			28.51	<.001
Intervention group ($n = 69$)		1.13 ± 1.51		
Comparison group ($n = 65$)		2.68 ± 1.74		
Fear score by child			8.53	.004
Intervention group ($n = 69$)	1.58 ± 1.27	0.28 ± 0.54		
Comparison group ($n = 65$)	1.38 ± 1.33	0.65 ± 0.94		
Fear score by caregiver			20.30	<.001
Intervention group ($n = 69$)		0.36 ± 0.64		
Comparison group ($n = 65$)		0.95 ± 0.96		
	Intervention group ($n = 66$) Mean ± *SD*	Comparison group ($n = 63$) Mean ± *SD*	*t*	
Time required for successful intravenous insertion, seconds ($n = 129$)[a]	51.89 ± 21.51	50.91 ± 16.29	0.29	.772

Note: Analysis of covariance or Student's *t*-test; *SD*, standard deviation; Adjusted for children's age, sex, frequency of past intravenous injections, prior use or nonuse of VR, fear scores in pretest, caregiver's age and sex, and registered nurses' years of work experience.
IV: intravenous
[a] Five participants were excluded due to the external factors.

significantly and effectively reduced but pain was not. This may reflect that a variety of VR devices have been developed rapidly in these years. The intervention process in this present study was highly accepted by the participants. The findings still revealed significant effects on children's pain and fear that we controlled for the prior use or nonuse of VR as one of covariates.

Previous interventional studies using VR for health education have mostly been executed in the context of children's surgical [30–35] and radiological exam preparations [36,37]. Koo et al. [38] conducted a meta-analysis of five studies and demonstrated the significant benefit of VR in reducing preoperative anxiety in children. Similar findings were reported for the preparation of school-aged children before chest X-ray and magnetic resonance imaging examinations: their anxiety was alleviated, and the use of general anesthetics was reduced [36,37]. Eijlers et al. [16] concluded that further research must be conducted on additional VR exposure strategies, apart from VR distraction strategies. Notably, in previous VR exposure designs, in addition to the first-person role designed by Ryu [34], third-person roles or cartoon characters as instructors were favored [30,31,35]. In the present study, we employed an interactive strategy for children to be completely immersed, from experiencing the treatment room settings to the process of intravenous placement. In addition, the immersive game of eradicating bacteria effectively reduced the degrees of pain and fear.

The time required for successful intravenous insertion did not differ significantly between the intervention and comparison groups. This finding is consistent with those of other studies on VR distraction strategies during intravenous placement, such as the use of a snow world [39], optional games [40], a rollercoaster application [41], and an under-the-ocean game [42]. However, Chen et al. [11] used four virtual environments (i.e., rollercoasters, space exploration, a wildlife park, and travel destinations) selected by school-aged children in an emergency department and revealed that the time required for successful intravenous insertion was significantly shorter in the VR group (53.50 ± 19.01 vs. 61.32 ± 25.78, $p = .046$). Many factors affect the time required for nurses to successfully achieve an intravenous injection, such as the preparation standards, the time it takes to search for a vein, and the cooperative state of the child. Because of the diversity of standard care groups, the preparation standards vary across hospitals and may include the participation of a child life specialist and the use of analgesics or local anesthesia. The VR intervention did not reduce or extend the time required for successful intravenous insertion and can still be used as a reference for clinical practice.

However, this study has some limitations. First, only 134 participants were recruited from two medical centers in northern and central Taiwan. Because of the Covid-19 pandemic, the rate of inpatient hospitalization for children has decreased. Most participants diagnosed in this study were hospitalized for endocrine examinations. Therefore, the results obtained from this small sample may not be generalizable to all hospitalized children or children with chronic illness. Second, this study used HTC Vive VR equipment with a high-end laptop, which provided an excellent immersive effect but must be set up in a fixed place. Wireless VR headsets may be more convenient to operate in future studies. Third, the interactive VR play intervention in our study included instructional and emotional catharsis play sessions; therefore, a comparison of the effects of these two play sessions on the pain and fear of school-aged children could not be performed. Future studies could compare the effects of a VR play intervention implemented at different time points, such as before, during, and after intravenous placement. Finally, we used only the WBFPS and CFS as subjective assessment tools; we did not perform an objective monitoring process to examine participants' pain and fear responses. Thus, future studies could include heart rate, respiratory rate, blood pressure, salivary cortisol, and other monitoring instruments to assess children's pain and fear during intravenous placement.

Conclusion

The VR interactive play intervention including instructional play and emotional catharsis play sessions is an effective method to decrease school-aged children's levels of pain and fear during intravenous placement procedure. In addition, the VR intervention does not extend the time required for successful intravenous insertion and could be used as a reference for clinical practice. This study validates VR interactive play as an age-appropriate, safe, and feasible intervention strategy that allows children to quickly immerse into a virtual environment from experiencing the treatment room settings to the process of intravenous placement. The results of this study can serve as a clinical reference for the implementation of a child-friendly care practice for intravenous placement in school-aged children.

Author contributions

All authors made substantial contributions. MFH, ICL, CYL, and CWC were responsible for the study conception and design. All authors participated in the data collection and analysis. MFH, YWW and CWC wrote the article with the input from all authors. YWW, ICL, CYL, FCL, PCL, and CWC supervised the study. All authors approved the final version for submission.

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Conflict of interest

The authors declare no potential conflicts of interest, real or perceived.

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