

RESEARCH ARTICLE

A randomized controlled trial on virtual reality distraction during venous cannulation in young children

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Abstract

Background and Objectives: Pain management in children is often inadequate, and the single most common painful procedure in children who are hospitalized is needle procedures. Virtual reality (VR) has been shown to decrease anxiety and pain in children undergoing painful procedures primarily in children from the age of 7 years. Our aim for this study is to investigate patient satisfaction and pain reduction by using a three-dimensional VR interactive game as a distraction in 4–7 years old children during venous cannulation.

Methods: In this randomized clinical trial, we enrolled 106 children aged 4–7 years who were scheduled for venous cannulation. Patients assigned to the control group were adherent to standard of care, including topical numbing cream, positioning, and distraction in this group by games of choice on a tablet/smartphone. In the study group, children were adherent to standard of care and were distracted by an interactive VR game. Primary outcomes were patient satisfaction and the procedural pain assessed by using Wong–Baker Faces Pain Rating Scale; secondary outcomes were the procedural time and any adverse events.

Results: We found an overall high level of patient satisfaction with our regime of topical numbing cream, positioning, and distraction. The primary outcome of pain during the procedure was median 20 mm (IQR 0–40) and 20 mm (IQR 0–55) (Wong–Baker 0–100 mm) in the VR group and the control group, respectively (difference: 0 mm, 95% CI: 0–20, $p = .19$). No significant difference was found in procedural times. The number of adverse effects was low, with no significant difference between the two groups.

Conclusions: VR distraction is an acceptable form of distraction for children 4–7 years old when combined with topical numbing cream and positioning during preoperative venous cannulation. No difference was found between VR- and smartphone/tablet distraction.

KEYWORDS

children, distraction, procedural pain

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Editorial Comment

This paper confirms that virtual reality is a suitable distraction tool in pre-school children undergoing an anxiety producing and potentially painful procedure. An accompanying editorial discusses the value and role of virtual reality in the pre-anesthesia environment.

1 | BACKGROUND

Pain experiences in hospitalized children are neglected and undertreated.¹⁻³ The single most common painful procedure in children is needle procedures.³ Fear of pain can increase the overall pain experience, but also evoke pain that would not necessarily otherwise be experienced and enhance the experience of pain in future procedures.⁴ Most often pharmacological and nonpharmacological interventions are used together for optimal pain management.⁴⁻⁹ The most common psychological interventions used for needle-related procedural pain and distress in children is distraction.⁴⁻⁹ When using distraction children's senses become disengaged from the nociceptive stimulus. An effective distractor should be immersive, through a high level of engagement and stimulating as many senses as possible.¹⁰ An example of such a distractor is immersive virtual reality (VR), where both the sense of sight and hearing are activated at the same time. Randomized controlled trials have examined the effects of VR as a pain and anxiety-reducing intervention in different contexts and patient groups. Research suggests that VR has a reducing effect on pain and anxiety compared to standard treatment or other distraction.¹¹⁻¹⁹ Most VR studies only included children older than 7 years. However, children under 7 years might also benefit from using VR as distraction during needle puncture procedures as documented by Chan et al who included children aged 4-11 years in their study.¹⁹ There is, however, a lack of VR studies focusing only on the younger children.

Thus, the aim of our trial was to examine the effects of VR on the pain ratings of children aged 4-7 years during venous cannulation before induction of anesthesia. We hypothesized that distraction with VR compared with smartphone or tablet would reduce pain ratings in children aged 4-7 years old during venous cannulation.

2 | MATERIALS AND METHODS

2.1 | General study design

This is a multicenter randomized, observer blinded clinical trial enrolling children scheduled for venous cannulation. The patients were admitted for a preoperative venous cannulation at four university hospitals in Denmark. Patients were eligible when being between 4 and 7 years old and Danish speaking. Time period for data collection was March-October 2021.

We adhered to the Consolidated Standards of Reporting Trials statement (CONSORT), and the trial was approved by the Danish Data Protection Agency. Data protection rules were complied. Data from the patient record were *not* collected in this trial. Data were

entered into an Excel spreadsheet and stored on a secured hospital server. Before writing the protocol, we systematically searched PubMed for relevant references.

The National Committee on Biomedical Research Ethics waived the need for review of the project. Danish Medicines Agency was not involved due to study design (no medicine involved) since our VR gear was not considered a medical device. Patient anonymity was carefully protected. Informed consent from the parents after oral and written information was sought and granted for all enrolled children.

2.2 | Exclusion criteria

Exclusion criteria included an American Society of Anesthesiologists classification score of >2; not understanding Danish; treatment with sedatives within the previous 3 h; cognitive impairment; psychiatric diagnosis; headache, dizziness, recent head injury, epilepsy, and other conditions in which application of VR goggles was judged to be potentially harmful; and failure to correctly provide a topical anesthetic (lidocaine and prilocaine [eutectic mixture of local anesthetics (EMLA)] or tetracaine (Ametop)) before the venous cannulation.

2.3 | Trial conduct

A computer-generated randomization list (Research Randomizer 2, www.randomizer.org) was created for the two groups. After consent was obtained the children were assigned to the intervention by opening of sealed, opaque, consecutive numbered envelopes. Children were assigned in the order they were enrolled. The trial started with distraction according to randomization, and the invasive procedure started within minutes, maximally after 5 min. All children, regardless of intervention group, were adherent to our mandatory standard of care (SOC): topical numbing cream, positioning, and distraction.

2.4 | Blinding

Fifteen minutes after the procedure a post anesthesia care unit (PACU) nurse interviewed the child, noting efficacy and any side effects of the intervention. The nurse who was blinded to the randomization (i.e., way of distraction) noted if the child thought the distraction was fun and for a future needle procedure would choose it again, the pain score and the satisfaction with the distraction modus estimated by the parents using a Numeric Rating Scale (NRS). Finally, the procedure time and any adverse effects were noted.

2.5 | Control group

Patients assigned to the control group were distracted by an experienced nurse anesthetist or anesthesiologist by use of a smartphone or a tablet. During the procedure, the child played a two-dimensional game of his or her own choice.

2.6 | VR group

Patients assigned to the VR group were distracted by VR. Patients engaged with the VR game named *Freddy-the-Frog*, a three-dimensional (3D) interactive game made in cooperation with a professional VR company (Khora Virtual Reality Denmark, Copenhagen, Denmark) and custom-made for the needle procedures scenario. The patients used the Oculus Go VR goggles holding a controller in the hand not assigned for the procedure. We made a short introduction after which the child was able to start the game requiring no further training. An assistant was present but no special training in VR is needed for operating our VR gear. The game has been designed as a peaceful and nonthreatening universe displaying a cozy room with a desk, a fireplace, a bookshelf and an armchair in which *Freddy-the-Frog* is sleeping. The child wakes him up and Freddy goes to a stage in the room, where he encourages the child to look down and see that (s)he has a magic wand in his/her hand. Freddy then explains that he will blow soap bubbles towards the child and if the child touches the bubble with the wand it will fly into a magic

hat and transform. The scenario is kept neutral and becomes uninteresting behind the patient, to avoid the patient from turning his or her torso making venous puncture difficult for the clinician.

2.7 | Outcomes

To evaluate the efficacy of VR, we chose two primary outcomes: child satisfaction and pain score. Child satisfaction was assessed by whether the child would use VR again for a future needle procedure. Pain was assessed by the Wong–Baker pain scale. The Wong–Baker faces pain rating scale is validated for self-reporting pain assessment in children in this age group, which is considered superior to observational scoring or parental scoring.²⁰ Secondary outcomes were procedural time, parent satisfaction and any adverse events. Safety issues and serious immediate adverse outcomes (e.g., nausea, vomiting, dizziness, or claustrophobia after use of VR) were evaluated during the follow-up period of 15 min.

2.8 | Statistical analysis

With a type 1 error rate of 5% and 120 children, we achieved a power of 98% to detect or discard a difference of 15 mm (SD 20). The distribution of the data was assessed by inspecting qq-plots and histograms, which suggested the data to be non-normally distributed. All analyses were by the intention-to-treat principle. Analyses of continuous

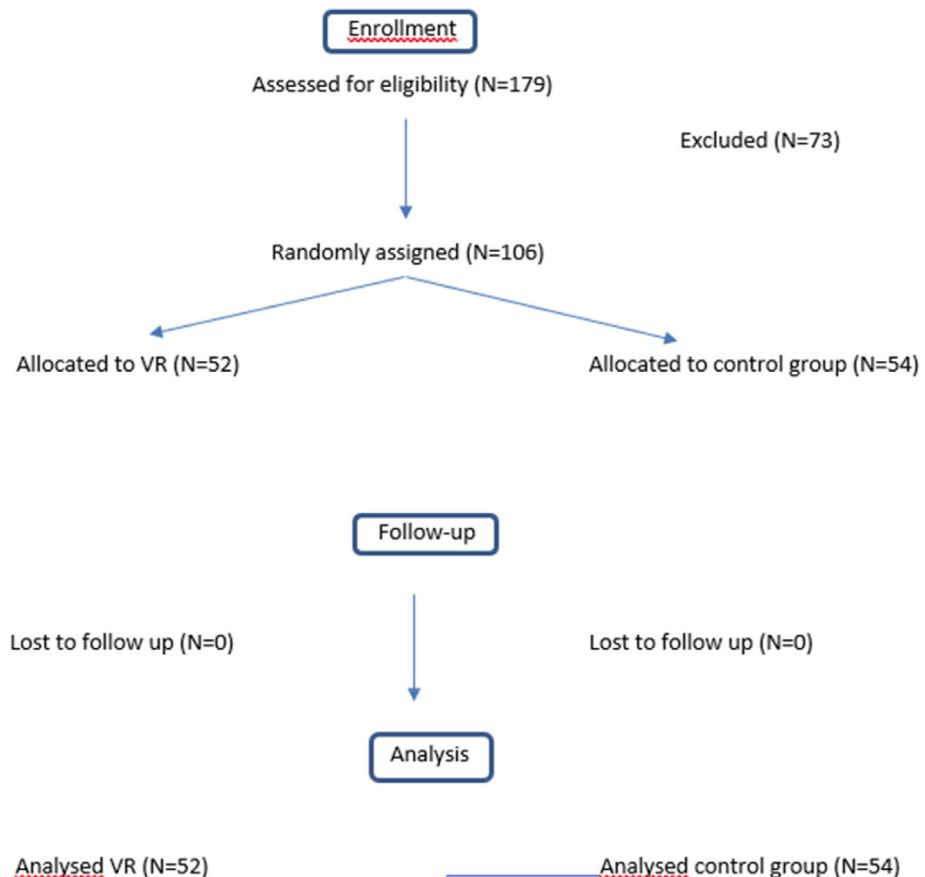


FIGURE 1 CONSORT diagram

Analysed VR (N=52)

Analysed control group (N=54)

outcome were performed using the nonparametric van Elteren test to adjust for site. Differences were calculated using the Hodges-Lehmann estimator. All continuous outcomes were also analyzed using parametric tests. All binary outcomes were analyzed with logistic regression adjusted for site. A p value $<.05$ was considered statistically significant. Stata statistical software version 16.1 was used for all analyses.

2.9 | Results

One hundred seventy-nine children who fulfilled the inclusion criteria were approached, 73 declined to participate. Due to the COVID-19 pandemic, inclusion was slow at a single site and we decided to stop the trial prematurely. In total, 106 children were included (Figure 1). Characteristics of children allocated to either the VR or the control group are shown in Table 1; the two groups were roughly equivalent on relevant variables.

The primary outcome of pain during the procedure were median 20 mm (IQR 0–40) and 20 mm (IQR 0–55) in the VR group and the control group, respectively (difference: 0 mm, 95%CI: 0–20, $p = .19$). Eighty percent in the VR group and 82% in the control group would use the same distraction again for procedural pain (1.15 [0.41–3.26], $p = .79$).

The secondary outcomes are seen in Table 2. We found a high level of parent satisfaction in using the distraction with our custom-

made 3D VR interactive game or smartphone/tablet with no difference between groups.

The success rates (Table 3) were 73% and 85% (OR: 0.44, 95%CI: 0.16–1.19, $p = .11$) in the VR group and the control group, respectively. Unsuccessful procedures due to anxiety and lack of cooperation were seen more often in the VR group. The procedural times in the two groups were equal, with a mean time of around 2 min from tourniquet to dressing application. Adverse effects were few, with no significant differences between the two groups.

We found no evidence of difference in treatment effect according to trial site or age. Similar results were found using parametric tests compared with nonparametric tests.

3 | DISCUSSION

In this large multicenter randomized trial we confirm the efficacy of our regime using numbing cream, comfort positioning and distraction: Median pain scores during venous cannulation were acceptable (20 mm/100 mm), procedure time was 2 min, side-effects were negligible and child and parent satisfaction high (80–90%).

We were not able to find any difference in our prime outcome pain and patient satisfaction between the two groups despite research suggesting that VR has a reducing effect on pain and anxiety compared to standard treatment or other distraction.^{11–19} Also, in a recent review published in 2021 the benefits of using VR were shown in significant reduced pain scores.¹¹ Most studies with small sample sizes were found to be unclear about risk of selection bias and to have a high risk of performance and detection bias.⁶ Also, from an ethical point we decided to use numbing cream and comfort positioning as part of the standard-of-care in both study groups, both interventions

TABLE 1 Demographics

	VR	Control
Sex, M/F, n (%)	36 (69%)/16 (31%)	44 (81%)/10 (19%)
Age, mean (SD), y	5.9 (1.4)	5.8 (1.4)

TABLE 2 Outcomes

	VR ($n = 52$)	Control ($n = 54$)	Difference (95%CI)	p value
Pain, median (IQR), mm	20 (0–40)	20 (0–55)	0 (0 to 20)	.19
Use again children, n (%)	36 (82)	39 (80)	1.15 (0.41 to 3.26)	.79
Time, median (IQR), s	120 (60–165)	110 (60–180)	0 (–25 to 20)	.72
Parent satisfaction, median (IQR), mm	90 (80–100)	100 (70–100)	0 (0 to 0)	.88
Use again parents, n (%)	40 (91)	47 (96)	0.43 (0.07 to 2.53)	.35
Fun children, n (%)	38 (86)	45 (92)	0.55 (0.14 to 2.14)	.39

	VR	Control	Difference	p value
Success, n (%)	38 (73)	46 (85)	0.44 (0.16 to 1.19)	.11
Reasons for not successful				
• Anxiety, n (%)	5 (13)	1 (2)		
• Nausea, n (%)	0 (0)	1 (2)		
• Dizziness, n (%)	0 (0)	1 (2)		
• Lack of cooperation, n (%)	4 (11)	0 (0)		
• Impossible cannulation, n (%)	5 (14)	6 (13)		

TABLE 3 Success rate

are evidence-based measures for pain reduction during pediatric needle procedures. By implementing these measures of pain reduction our hypothesis is that it could mask the pain reduction efficacy of VR in our study.

Venous cannulation is still experienced as painful and distressing for children and adolescents.¹⁻³ Therefore, continuous search for measures to diminish the pain experience is required. In our clinic, we have implemented a standard-of-care regime for improving the procedural experience, including distraction. Psychological interventions for pain and distress reduction have been recommended in systematic reviews.⁴⁻⁸ VR distraction as a modulator of pain experience has been examined in experimental settings by using functional MRI and has revealed a neural correlate of pain modulation comparable with other types of distraction.²¹ Our trial was focusing on distraction for reducing pain and improving satisfaction associated with venous cannulation in children aged 4-7 years. This age group was chosen because fear of needles is greatest in children, especially younger children.^{22,23} In a meta-analysis from 2019 there was a considerable variation in the fear of needles by age ($I^2 = 99.9\%$, $\tau^2 = 0.08$). Fear of needles was greatest in children, especially younger children (60%–80% below the age of 10).²² In a recent study, we documented higher satisfaction when using VR versus standard care as part of a multimodal approach for management of procedural pain in children aged 7-16 years.¹⁷ The aim of the current study was to examine the effects of VR on the pain ratings of children aged 4-7 years during venous cannulation. In the study by Chan in children aged 4-11 years undergoing intravenous cannulation or venipuncture, virtual reality was efficacious in decreasing pain.¹⁴ In our trial more children in the VR group compared with the control group (smartphone or tablet) showed anxiety and lack of cooperation as a reason for failed venous cannulation.

The VR software (*Freddy-the-Frog*) in the current trial was developed in cooperation with a professional VR company and was customized for the needle procedure scenario, creating a game with an age-appropriate level of immersion. VR equipment is increasingly accessible because of lower costs and straightforward functionality. Most children are confident with two-dimensional and 3D computer gaming in everyday life. We found a small number of children not able to cooperate utilizing VR goggles. We found no overall difference in success rate according to age, but we believe to have reached the lower age limit by the age of 4 years for introducing VR as a distraction tool.

This trial has numerous strengths. First, the trial was pragmatic, observer blinded, multicentered and enrolling a relatively high number of children. Second, we used an evidence-based practice of topical anesthesia and positioning for all children. This led to low pain scores for all children, regardless of intervention group, which may have made it difficult to detect any possible true effect of VR (low assay sensitivity).

The trial has limitations as well. First, we chose pain during the procedure as the primary outcome as a measure of distraction. Pain may not be an ideal measure of distraction; however, no better outcome exists, in our opinion. We could have chosen “work conditions” assessed by the phlebotomist; however, this would have unblinded the trial further. Second, in the control group the children were

allowed the distraction on a smartphone/tablet of their own choosing. This may have affected the result by giving the children in the control group a higher sense of control. Third, the trial was stopped prematurely. This was due to the COVID-19 pandemic slowing the inclusion at one site. Stopping a trial prematurely increases the risk of both type 1 and 2 errors.

4 | CONCLUSION

This trial is the first large multicenter trial to introduce VR distraction during needle procedures in young children and shows an overall high success rate, low pain scores and high user satisfaction in this age group. We did not find any difference in patient satisfaction and pain score comparing VR with smartphone or tablet in children aged 4-7 years old during venous cannulation.

The regime consisting of topical numbing cream, comfort positioning and distraction is recommended for pain and anxiety reduction during iv cannulation prior to anesthesia.

CONFLICT OF INTEREST

No author has direct or indirect conflicts of interest.

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How to cite this article: Thybo KH, Friis SM, Aagaard G, et al. A randomized controlled trial on virtual reality distraction during venous cannulation in young children. *Acta Anaesthesiol Scand*. 2022;66(9):1077-1082. doi:[10.1111/aas.14120](https://doi.org/10.1111/aas.14120)