The Journal of Pediatrics

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The Journal of Pediatrics 2019; **20**: 160–167.e4

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Printed in Australia by
Elsevier Australia
475 Victoria Avenue
Chatswood NSW 2067 Australia
ABN 70 001 002 357

Virtual Reality for Pediatric Needle Procedural Pain: Two Randomized Clinical Trials

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Objective To assess the efficacy and safety of a virtual reality distraction for needle pain in 2 common hospital settings: the emergency department (ED) and outpatient pathology (ie, outpatient laboratory). The control was standard of care (SOC) practice.

Study design In 2 clinical trials, we randomized children aged 4-11 years undergoing venous needle procedures to virtual reality or SOC at 2 tertiary Australian hospitals. In the first study, we enrolled children in the ED requiring intravenous cannulation or venipuncture. In the second, we enrolled children in outpatient pathology requiring venipuncture. In the ED, 64 children were assigned to virtual reality and 59 to SOC. In pathology, 63 children were assigned to virtual reality and 68 to SOC; 2 children withdrew assent in the SOC arm, leaving 66. The primary endpoint was change from baseline pain between virtual reality and SOC on child-rated Faces Pain Scale-Revised.

Results In the ED, there was no change in pain from baseline with SOC, whereas virtual reality produced a significant reduction in pain (between-group difference, −1.78; 95% CI, −3.24 to −0.317; $P = .018$). In pathology, both groups experienced an increase in pain from baseline, but this was significantly less in the virtual reality group (between-group difference, −1.39; 95% CI, −2.68 to −0.11; $P = .034$). Across both studies, 10 participants experienced minor adverse events, equally distributed between virtual reality/SOC; none required pharmacotherapy.

Conclusions In children aged 4-11 years of age undergoing intravenous cannulation or venipuncture, virtual reality was efficacious in decreasing pain and was safe. *(J Pediatr 2019;209:160-7)*.

Trial registration Australia and New Zealand Clinical Trial Registry: ACTRN12617000285358p

Pediatric needle procedures, predominantly venipuncture and intravenous cannulation, are the most common cause of pain in US children's hospitals.[1,2] Despite the repeated identification of pediatric needle pain as a priority, this remains undermanaged.[3-7]

The recommended approach to pediatric procedural pain integrates psychological, physical, and pharmacological elements.[6,8] However, the commonplace strategies of topical local anesthetic or coolant preparations target only nociception.[2] These strategies do not address anxiety, a key driver of noncooperation, which encumbers needle procedure performance.[9] Nonpharmacological interventions to ameliorate anxiety are thus central to facilitate needle interventions, but are inconsistently applied.[1,2,6]

Virtual reality is an interactive, 3-dimensional, computer-simulated environment accessed through a head-mounted device, precluding the real-world view. We postulated that virtual reality distraction would be a useful nonpharmacological intervention in hospital-based needle procedures for pediatric patients.

ED	Emergency department
FPS-R	Faces Pain Scale-Revised
MCID	Minimally clinically important difference
SOC	Standard of care

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Supported by the Australian Federal Government Department of Industry,Innovation and Science (ICG000042). The study funder and supporting bodies had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or decision to submit the manuscript for publication. E.C. and P.L. hold shares in Smileyscope Pty Ltd holding intellectual property arising from this study, which includes a patent entitled "virtual reality apparatus." The other authors declare no conflicts of interest.

Portions of this study were presented at the Australian Health Informatics Conference, July 30, 2018, Sydney, Australia; the Australasian College for Emergency Medicine Annual Scientific Meeting, November 21, 2018; and The Australian Pain Society on April 7, 2019 in the Gold Coast, Australia.

https://doi.org/10.1016/j.jpeds.2019.02.034

Methods

To determine the efficacy of a virtual reality distraction for needle procedures for pediatric patients, we performed 2 concurrent, randomized, controlled trials. Aiming to maximize representativeness, we sampled 2 hospital-based populations in whom needle procedures are commonly performed and in whom distraction might be used. We assigned participants 1:1 to virtual reality or standard of care (SOC) in the emergency department (ED) or outpatient pathology (ie, outpatient laboratory). The SOC arm was intended to reflect routine practice in our tertiary pediatric institutions. Participants were recruited at 2 pediatric referral hospitals in Melbourne, Australia (Monash Children's Hospital and Royal Children's Hospital). We report along CONSORT guidelines,[10] incorporating relevant elements from the nonpharmacological[11] extension.

Two authors developed a virtual reality sequence based on their clinical practice, with iterative input from child life therapy, medical, pathology, and nursing staff. In brief, the sequence is an interactive underwater adventure beginning with relaxation and progressing to marine scenes (**Figure 1** and **Video** [available at www.jpeds.com]). The child interacted with the environment (eg, virtual fish) through gaze-based tracking. A short version was used for venipuncture and a longer sequence for intravenous cannulation. Content was played on a Google Pixel XL/Google Daydream (Google, Mountain View, California) and built in Unity.

Ethics approval was granted by Monash Health HREC (HREC/17/MonH/15), and the study was prospectively registered on the Australia and New Zealand Clinical Trial Registry (ACTRN12617000285358p). The trial was conducted in accordance with the Australian National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007)[12] and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95). Ethics approval was not granted for future individual participant data sharing.

Participants, Randomization, and Procedures

Eligible participants were opportunistically identified. Participants were aged 4-11 years, required venipuncture or intravenous cannulation for any indication, and had sufficient English ability to complete study instruments. Exclusion criteria were critical medical illnesses or deteriorating clinical status, medical conditions that precluded virtual reality use or study instrument completion, and the inability to consent/assent. All children gave assent and caregivers/legal guardians provided written consent. There was no participation payment.

Systemic analgesia and topical anesthetic were given at treating clinician's discretion. Baseline data were collected as close to immediately before the needle procedure as possible. After baseline data collection,[13] allocation was revealed, with prior concealment by opaque envelope. Simple randomization sequences stratified by site[14] were generated in advance by computerized randomized number generator (random.org).

Figure 1. Screenshot of the virtual reality aquatic environment. Depicted are fish, coral, and a central visual effect that appears when the child directs their gaze at fish.

If randomized to virtual reality, the virtual reality headset was introduced and the appropriate virtual reality sequence was played. Blinding was not feasible. In the SOC arm, clinicians were instructed to perform the needle procedure as they usually would. Because both sites were tertiary children's hospitals with existing protocols for the minimization of procedural pain and distress, standard care involved age-appropriate distraction, such as child-life therapy, toys, books, and electronic devices. These distractions were allowed at the clinician's discretion. Standardized distractions were not mandated because this would not reflect clinical practice in all patients. Postprocedural measures were taken immediately after the procedure.

Data Collection

The primary outcome was change in baseline pain between virtual reality and SOC. We used the child-rated Faces Pain Scale-Revised (FPS-R),[15] a well-established psychometric measure[16] with values from 0 to 10 that is recommended by the Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (PedIMMPACT) for children aged 4-12 years.[17]

Secondary outcomes included change in child-rated anxiety (visual analogue thermometer,[18] 0-10), caregiver's rating of their child's distress (visual analogue scale, 0-10), the need for restraint (number of people restricting movement, excluding those only performing comfort positioning), number of needle attempts and success, the child's withdrawal of their arm, and the need for procedural sedation.

Procedural data included proceduralist-judged Difficult Intravenous Access Score (scores ≥4 indicating difficult access),[19] proceduralist-rated skill, the adequate

application of topical local anesthetic (4% amethocaine >30 minutes prior), and procedural duration (tourniquet application to cutaneous barrier dressing completion time). Caregivers and proceduralists could write free-text comments. Children were prompted for feedback by standardized open-ended questions with responses transcribed verbatim. Adverse events and their treatment(s) were recorded.

There were 2 changes to the original study protocol. One prespecified secondary outcome (subjective risk of needlestick injury) was not recorded because it lacked validity. Procedural duration was redefined as above during statistical analysis as the a priori definition of procedure room entry/exit time did not accurately reflect actual needle procedural time.

Data Analyses

Using G*Power 3.1.9.2[20] with 80% power and a 2-sided alpha of 0.05, a sample size of 114 per setting was required to detect a 1.75-point difference with a SD of 3.3, based on a venipuncture trial[21] and a large hospital sample.[1] Allowing for contingencies, we targeted 120 patients per setting.

An independent statistician performed statistical analysis with SPSS 24.0 (SPSS, Inc, Chicago, Illinois) and R (The R Foundation, Vienna, Austria). Data were analyzed on an intention-to-treat basis. A *t* test was used for normally distributed data (presented as mean difference and 95% CI), the Mann-Whitney *U* test for nonparametric data (shown as medians), and the Fisher exact test for categorical data, with a 2-sided alpha of 0.05. No multiple comparison adjustments were made.[22]

Pain and anxiety are also represented as percentage change from mean group baseline and are illustrative only. They were not used in statistical analysis and are presented as mean only because the percentage change transformation alters the variable's distribution.[23]

Because change from baseline measures were used for the primary outcome measure, a post hoc multivariable linear regression model was constructed to examine the effect of virtual reality after controlling for baseline pain and other variables. The model was constructed from clinically important variables.[23,24] A second model, requested during review, investigated the effects of virtual reality vs any distraction, intravenous cannulation vs venipuncture, and study site.

Qualitative data were analyzed to understand the patient, caregiver, and proceduralist perspectives. Grounded theory and inductive thematic analysis[25] were applied to identify, code, and categorize organized data. Because categorization biases proportions, feedback-specific proportions are not given.

Results

Recruitment occurred between July 13, 2017 and February 15, 2018, and was concluded after adequate enrollment. In the ED study, 123 participants were randomized: 59 to SOC and 64 to virtual reality (**Figure 2**; available at www.jpeds.com). In the pathology study, 131 participants were randomized: 68 to SOC and 63 to virtual reality. Two children, both in the pathology SOC group, withdrew assent after randomization, leaving 66 in the pathology SOC arm.

In both the ED and pathology groups, baseline characteristics were balanced between virtual reality and SOC groups (**Table I** and **Table II** [available at www.jpeds.com]). In both procedural settings, the median age was approximately 8 years and there was a male preponderance.

In the ED, most patients underwent intravenous cannula insertion (**Table III**). Topical local anesthetic use was high. In the SOC group, distraction was used in 43 patients (73%), with electronic media (television, video, phones, tablets) in 32. Children with difficult venous access were rare (n = 2 each in virtual reality and SOC). Nearly all

Table I. Baseline patient characteristics

	ED		Outpatient (pathology)	
Characteristics	**SOC (n = 59)**	**Virtual reality (n = 64)**	**SOC (n = 66)**	**Virtual reality (n = 63)**
Age, years	8.2 (5.8-10.6)	7.9 (6.4-9.9)	7.4 (5.8-9.1)	8.2 (6.3-10.3)
Sex				
Female	27 (46)	29 (45)	30 (46)	25 (40)
Male	32 (54)	35 (55)	36 (55)	38 (60)
Topical local anesthetic	50 (85)	57 (89)	9 (14)	8 (13)
Baseline FPS-R score*	4 (1-6)	4 (2-6)	0 (0-2)	0 (0-2)
Baseline visual analogue thermometer anxiety score†	5 (2-8)	6 (4-8)	5 (2-7)	5 (1-7)
Previously had this procedure	31 (53)	37 (58)	54 (82)	54 (86)
Distraction				
None	16 (27)	N/A	9 (14)	N/A
Television/video	20 (34)		47 (71)	
Phone/tablet	12 (20)		8 (12)	
Child life therapy	6 (10)		1 (2)	
Toy/book	4 (7)		Nil	
Count/find objects	1 (2)		1 (2)	

N/A, Not applicable.
Data are number (%) or median (IQR).
Percentages may not add to 100 owing to rounding.
*Child-rated FPS-R.[15]
†Child-rated anxiety, visual analogue thermometer.

Table III. Procedural and postprocedural characteristics

Characteristic	ED		Outpatient (pathology)	
	SOC (n = 59)	Virtual reality (n = 64)	SOC (n = 66)	Virtual reality (n = 63)
Procedure				
Venipuncture	12 (20)	11 (17)	66	63
Intravenous cannulation	47 (80)	53 (83)	Nil	Nil
Number of needle attempts				
1	45 (76)	47 (73)	60 (91)	61 (97)
2	10 (17)	14 (22)	6 (9)	2 (3)
≥3	4 (7)	3 (5)	Nil	Nil
Number of people required to restrain child				
0	13 (22)	14 (22)	10 (15)	19 (30)
1	17 (29)	39 (61)	12 (18)	32 (51)
2	25 (42)	9 (14)	42 (64)	11 (18)
≥3	4 (7)	2 (3)	2 (3)	1 (2)
Change in FPS-R score from baseline*	0.39 (−1.45 to 0.67)	−1.39 (−2.42 to −0.36)	2.76 (1.79 to 3.72)	1.37 (0.50 to 2.23)
Change in visual analogue thermometer anxiety score from baseline†	−0.46 (−1.36 to 0.45)	−2.2 (−3.20 to −1.20)	0.17 (−0.79 to 1.12)	−1.40 (−2.25 to −0.54)
Caregiver's rating of child's distress, visual analogue Scale‡	4 [1-8]	1 [0-5]	4.5 [0.75-8]	2 [0-5]

Data are number (%), mean (95% CI), or median [IQR].
*Child-rated FPS-R.[15]
†Child-rated anxiety on visual analogue thermometer.
‡Parent-rated child distress on visual analogue scale. Percentages may not add to 100 owing to rounding.

proceduralists rated themselves competent or above (**Table IV**; available at www.jpeds.com).

In pathology, all children underwent venipuncture. Topical local anesthetic application was much less common than in the ED and difficult venous access was rare. The SOC arm used distraction in 57 individuals (86%), with electronic media in 55. All proceduralists rated themselves competent or above.

In the ED, with regard to the primary endpoint of change from baseline pain, virtual reality decreased pain in comparison with the SOC group (between-group difference, −1.78; 95% CI, −3.24 to −0.32; P = .018; **Figure 3**). From baseline, children assigned to SOC had no change in FPS-R (0.39; 95% CI, −0.67 to 1.45; P = .47). However, the virtual reality group had a significant reduction in pain (−1.39; 95% CI, −2.42 to −0.36; P = .009). Expressed as percentage change from group mean, the FPS-R increased by an average of 10% in the SOC group but decreased by −31% in the virtual reality group.

In pathology, with regard to the primary endpoint, the virtual reality group exhibited a much smaller increase in pain from baseline in comparison with SOC (between-group difference, −1.39; 95% CI, −2.68 to −0.11; P = .034; **Figure 3**). From baseline, pain increased in both the SOC group (2.76; 95% CI, 1.79-3.72; P < .001) and the virtual reality group (1.37; 95% CI, 0.50-2.23; P = .003). Expressed as percentage change from group mean, pain scores increased by an average of 190% in the SOC group and 130% in the virtual reality group.

In the ED, the virtual reality group reported a decrease in postprocedure anxiety in comparison with SOC (between-group difference, −1.75; 95% CI, −3.09 to

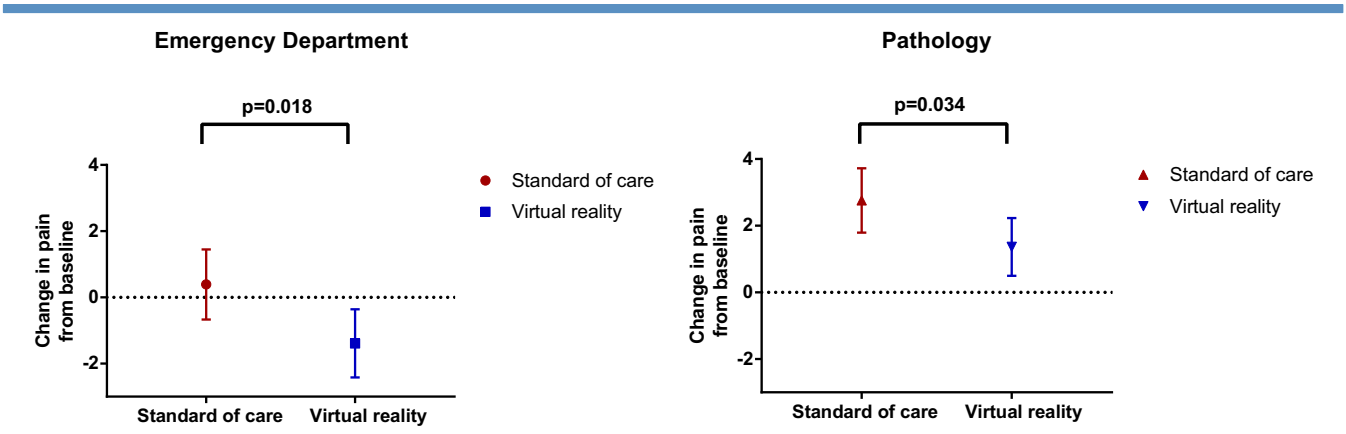

Figure 3. Change from baseline pain on child-rated FPS-R. Data are group mean ± 95% CI. In ED (left), there was no change in pain from baseline with SOC, whereas virtual reality produced a significant reduction in pain (P = .018). In pathology (right), both groups experienced an increase in pain from baseline, but this was significantly less in the virtual reality group (P = .034).

−0.40; $P = .011$). From baseline, self-rated anxiety did not change in the SOC group (0.46; 95% CI, −0.45 to 1.36; $P = .32$), but decreased significantly in the virtual reality group (−2.2; 95% CI, −3.20 to −1.20; $P < .001$). Expressed as percentage change from group mean, anxiety changed by an average of −8% in the SOC group and −37% in the virtual reality group.

In pathology, the virtual reality group also reported a greater change in postprocedure anxiety than SOC (between group difference, −1.56; 95% CI, −2.84 to −0.29; $P = .016$). From baseline, those assigned to SOC had no change in anxiety (0.17; 95% CI, −0.79 to 1.12; $P = .73$), however, those assigned to virtual reality had less anxiety (−1.40; 95% CI, −2.25 to −0.54; $P = .002$). Expressed as percentage change from group mean, anxiety increased by an average of 4% in the SOC group and decreased by −31% in those allocated to virtual reality.

When caregivers rated their child's distress, in comparison with SOC, the virtual reality group were assessed as exhibiting less median distress in both ED (SOC, 4.0; virtual reality, 1.0; $P = .020$) and pathology (SOC, 4.5; virtual reality, 2.0; $P = .004$).

In the ED, virtual reality decreased the proportion of children requiring 2 or more people for restraint (SOC, 49%; virtual reality, 17%), reflected in a greater proportion of procedures achieved with no restraint or single-person restraint (SOC, 51%; virtual reality, 83%; $P < .001$). In pathology, the proportion of children requiring 2 or more people for restraint was decreased with virtual reality (SOC, 67%; virtual reality, 19%), because more procedures were performed with no restraint or single-person restraint (SOC, 33%; virtual reality, 81%; $P < .001$).

In the ED, after initial needle procedure failure, escalation to pharmacological means was required twice in the SOC group (nitrous oxide and midazolam once each), and once in the virtual reality group (nitrous oxide). Pharmacological sedation was not used in pathology.

First needle success rate was high, and there was no difference with or without virtual reality in ED (SOC, 76%; virtual reality, 73%; $P = .84$) or pathology (SOC, 91%; virtual reality, 97%; $P = .27$). Virtual reality did not significantly alter the median procedural time (minutes:seconds) in either setting (ED: SOC, 9:00; virtual reality, 7:08 [$P = .12$]; pathology: SOC, 4:55; virtual reality, 5:06 [$P = .84$]).

Adverse effects were rare and minor. None required pharmacotherapy. In ED, 4 SOC patients had adverse effects (dizziness, nausea, headache, vomiting), but there were no adverse effects in the virtual reality arm ($P = .05$). In pathology, 3 patients had side effects in each group (SOC: nausea, vomiting, headache; virtual reality: nausea, headache). Fourteen children (22%) in the ED and 9 in pathology (14%) removed their headset at some point. Virtual reality was resumed by most, but permanently removed by 2 children in the ED and 4 children in pathology.

Multivariable linear regression explored postprocedural pain using predictors of baseline pain, age, sex, topical local anesthetic, prior needle exposure, and virtual reality. This analysis confirmed that virtual reality significantly decreased pain in both the ED (−1.34 units; $P = .03$) and pathology (−1.46 units; $P = .013$) after adjustment for baseline pain and other variables. A higher baseline FPS-R was associated with greater postprocedural pain in both settings (ED, $P = .005$; pathology, $P = .002$). Older age was associated with less pain in pathology ($P = .04$), but not in the ED ($P = .06$). Sex was not associated with a difference in pain (ED, $P = .72$; pathology, $P = .92$), nor was topical local anesthetic (ED, $P = .16$; pathology, $P = .06$).

The second model added variables to the original model. It compared virtual reality use vs "any distraction," intravenous cannulation vs venipuncture, and study site. In the ED, using virtual reality reduced pain in comparison with non virtual reality interventions (−1.57 units; $P = .016$) and there was no difference in pain between venipuncture and intravenous cannulation ($P = .79$) or study site ($P = .058$). In pathology, virtual reality also reduced pain when compared with any distraction (−1.34 units; $P = .019$), and study site did not contribute (pathology, $P = .052$). No predictors differed from the first model. Restricting the model to compare specific distractions (eg, television/video or tablet/phone) with virtual reality resulted in insufficient statistical power to draw conclusions.

Qualitative feedback was provided by at least 1 participant in most procedures in the ED (82/123 [67%]) and pathology (74/129 [57%]; **Table V**; available at www.jpeds.com). Three themes emerged.

First, respondents found virtual reality provided distraction, reducing child pain and distress. For example, P175 (child): "I felt the needle but was too distracted by virtual reality to care," and P67 (caregiver): "Very impressed that he said that he felt no pain at all." Second, virtual reality supported the procedure, resulting in "calm" or "still" children. P146 (proceduralist): "Spent a lot of time calming her down last time. She was much better this time [with virtual reality]." Third, suggestions for improvement were given: future content, greater preprocedural virtual reality preparation, and headset fitting issues. P25 (child): "More of the curly tailed fish please," and P53 (proceduralist): "Headset slipped down a bit."

Almost all children assigned to virtual reality wanted it for future needle procedures (ED, 60/64 [94%]; pathology, 57/63 [90%]). The majority of caregivers (ED, 52/56 [93%]; pathology, 51/55 [93%]) and proceduralists (ED, 49/57 [86%]; pathology, 48/55 [87%]) would recommend or consider using virtual reality in the future.

Discussion

Virtual reality reduced pain, anxiety, and distress in comparison with SOC in both ED and pathology, supported by the finding that fewer people were required to restrain children. Benefits were consistent in qualitative and quantitative analyses. Adverse effects were rare and minor.

Suboptimal childhood pain management is associated with acute and long-term physical and psychological ramifications, including conditioned pain hypersensitivity, needle phobia, and health care avoidance.[5,26] Children rate needles the second-most painful health care experience after their primary pathology,[7] and caregivers rate needles as one of the most distressing parts of health care.[27] Unmanaged pain is frequent, with 50%-60% of children reporting significant pain and anxiety.[4]

Prior reviews[28,29] and meta-analyses[30,31] suggested that virtual reality may be useful for pain. Primary studies, however, examined discrete populations, were generally small, highly heterogenous, originated from the psychology literature, and the risk of guideline-assessed bias was generally high.[29,31,32] Applying a pragmatic[33] ethos to 2 common hospital-based settings, we enrolled a clinically broad sample of children. Given the subjectivity of pain, we strove for validity, using quantitative and qualitative data and a dual-setting design. We studied children aged 4-11 years, a younger group than previously studied,[34-37] and one that is developmentally important—needle phobia has a median onset age of 5.5 years.[38]

Various strategies exist for needle pain. Nociception-directed choices include topical local anesthetic[39] and a proprietary cooled vibration device.[40] However, these methods do not control apprehension.[9] Although we detected no benefit for local anesthetic in linear regression, this post hoc analysis had limited power because most children in the ED received local anesthetic and the converse was true in pathology.

Systematic reviews of distraction-based therapies confirm efficacy for pain and distress, with low-technology options (eg, blowing bubbles, books), less effective than high-technology ones (eg, television, virtual reality).[41,42] Our a priori aim was to compare virtual reality with clinician-directed SOC (ie, current practice) for hospital-based needle procedures, and we found virtual reality advantageous in this comparison. In the SOC group, distraction interventions were customized by the clinician. Post-hoc linear regression suggested that virtual reality had greater pain benefit than this "any distraction" group, but unfortunately there was insufficient power to compare virtual reality with specific nonvirtual reality distractions. This factor should be explored in future studies.

Needle pain studies using different virtual reality sequences to ours indicate no effect,[34,35] raising the possibility that content may have an effect distinct to virtual reality itself. Indeed, the largest prior study of virtual reality in outpatient phlebotomy reported a mean difference of −0.3 in the self-rated FPS-R between virtual reality and SOC in individuals aged 10-21 years.[37] We saw a greater reduction in mean FPS-R in the outpatient phlebotomy group (−1.39; 95% CI, −2.68 to −0.11; $P = .034$), which may indicate content-specific effects, or could be from confounders such as age.

The effect of virtual reality was greater at younger ages, concordant with prior investigations associating younger age and greater needle pain.[3] Younger children are less able to control fear or respond to reassurance and are, therefore, optimal candidates for distraction.[9] Taken together, virtual reality may be a useful needle pain distraction option, particularly for younger children.

Pediatric pain management position statements emphasize 3 relevant non-negotiables: positional measures, local anesthetic, and age-appropriate distraction.[6] Although we found virtual reality efficacious as a distraction measure, it cannot replace the other non-negotiables.

Virtual reality may not be appropriate for every child. A minority of children assigned to virtual reality (ED, 4/64 [6%]; pathology, 6/63 [10%]) did not want virtual reality for their next needle. In addition, a few patients reported virtual reality was unengaging or were too apprehensive to engage with virtual reality. Although virtual reality could be useful for many patients, cooperation is necessary for any distraction to be successful. Despite best practices, inevitably, a small proportion of children will require restraint and/or sedation and approaches should be individualized.

In the ED and pathology, virtual reality had a favorable effect on pain. By occupying a proportion of an individual's finite and limited attentional capacity, virtual reality is hypothesized to decrease the cognitive resources available to focus on pain and anxiety.[43] Functional magnetic resonance imaging with virtual reality use demonstrates modulation of pain control systems including the anterior cingulate cortex, providing biological plausibility.[44]

The magnitude of changes in self-rated pain requires consideration. In the ED, virtual reality reduced pain by −1.78 units (95% CI, −3.24 to −0.32) in comparison with SOC. In pathology, virtual reality reduced pain by −1.39 units (95% CI, −2.68 to −0.11). Differences fall between intervals on a scale with 2-point intervals, and occur in addition to clinically important baseline pain in the ED. To our knowledge, no minimally clinically important difference (MCID) is definitively established for pediatric needle pain.

A pain MCID is "often sought after, but elusive,"[45] varying according to scale, population, procedure, and statistical methodology.[46-48] Investigators have used different instruments in pediatric populations to estimate MCID in existing pain.[49-52] Three major problems limit applicability. First, MCID studies did not impose an additional painful and anxiety-provoking stimulus (ie, needle). Second, they do not examine outpatients. Third, children were up to 5 years older.[49] We saw an absolute change in FPS-R, which falls below that which some would consider minimally clinically important,[51,52] but exceeds thresholds set by others.[49,50] Using percentage change criteria, pain reductions meet Tsze's[52] MCID in the ED group, and exceed the ideally clinically important change threshold in pathology. Our qualitative data also support meaningful pain reduction in at least a subset of patients.

This study has limitations. First, virtual reality is not blindable. The major purpose of blinding is to eliminate subjectivity,[53] yet pain and anxiety are inherently subjective. Observational pain scores were impractical because they

usually include a facial scale measure and virtual reality obscures the face.[17] Overall, it seems unlikely that results are solely due to expectation influencing report.

Second, analyses were conducted without multiplicity adjustment. We report prespecified main outcome data with *P* values and CISs as suggested to facilitate interpretation.[22,54] Importantly, the effects of virtual reality were consistent across the ED and pathology (2 trials), with qualitative data supporting quantitative results. In aggregate, this suggests results are reliable and valid rather than false positives.

Third, these results may not be generalizable to children outside tertiary centers. There were few patients with severe needle phobias or severe developmental issues. However, patients enrolled mirrored a typical population for whom activity-based distractions would be considered.

The virtual reality intervention used was safe and effective in children aged 4-11 years, decreasing needle pain, anxiety, distress and the need for restraint in 2 hospital-based settings. Future research could evaluate other pediatric needle contexts including ward inpatients, vaccination, finger pricks, repeated procedures, examine the role of specific content, and compare virtual reality with other distractions. ■

We thank the patients, their caregivers, and the staff of our institutions.

Submitted for publication Nov 5, 2018; last revision received Jan 29, 2019; accepted Feb 26, 2019.

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Data Statement

Data sharing statement available at www.jpeds.com.

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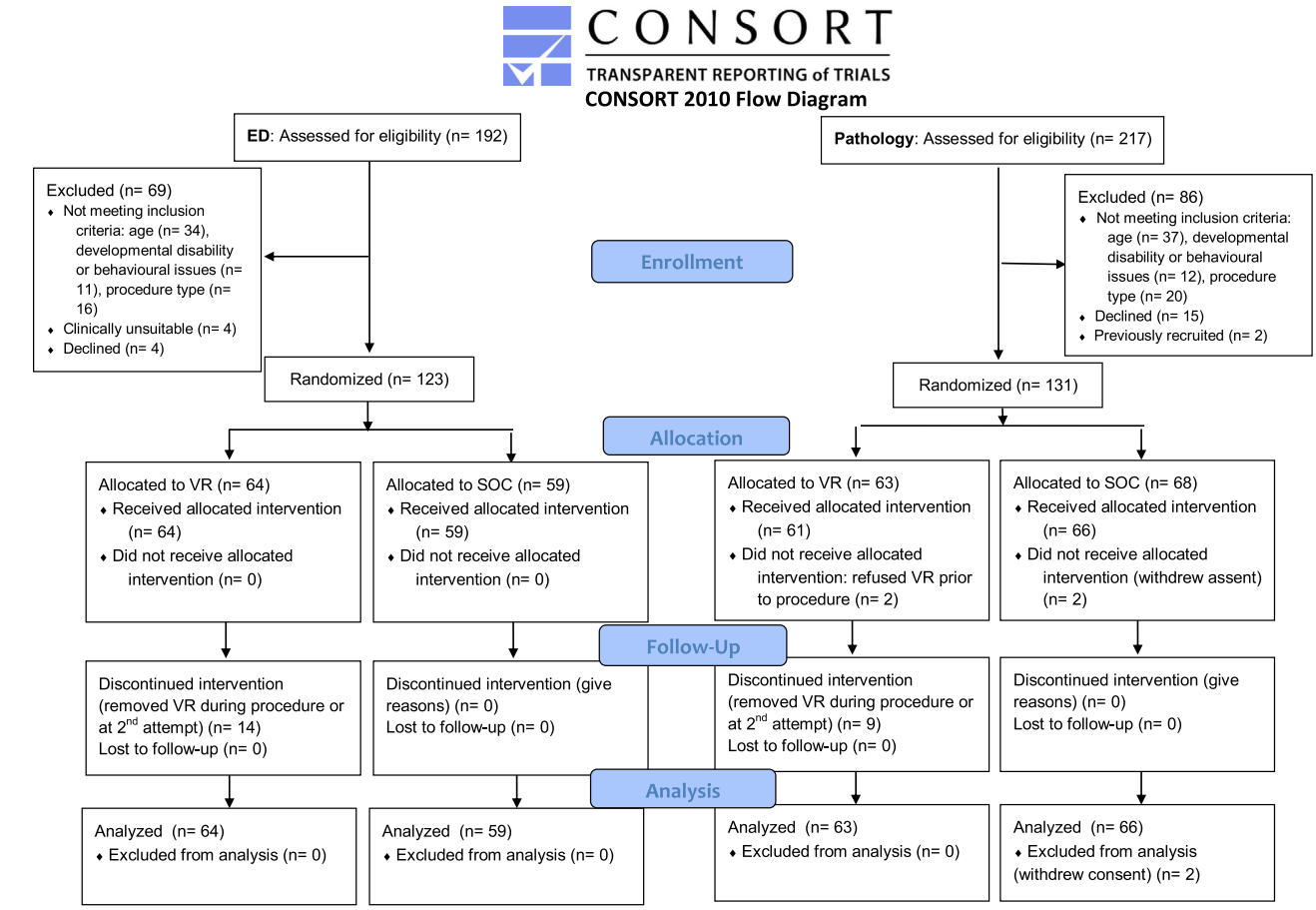

Figure 2. CONSORT diagram.

Table II. Baseline characteristics

Characteristic	ED		Outpatient (pathology)	
	SOC (n = 59)	Virtual reality (n = 64)	SOC (n = 66)	Virtual reality (n = 63)
Indication: diagnostic or treatment				
Diagnostic	35	33	N/A	N/A
Treatment	8	19		
Both	16	12		
Previous virtual reality exposure	19 (32)	19 (30)	15 (22)	16 (25)
Baseline systemic analgesia				
None	32	41	64	63
Paracetamol	19	19		1
NSAID	9	7		
Opioid	3	3		
Presenting complaint				
Abdominal pain	18 (31)	18 (28)	N/A	N/A
Musculoskeletal including trauma	8 (14)	4 (6)		
Infective	18 (31)	19 (30)		
Other	15 (25)	23 (36)		
DIVA score ≥4	2 (3)	2 (3)	1 (2)	1 (1)
Language other than English spoken at home	14 (24)	12 (19)	14 (21)	18 (29)
Severe caregiver-rated needle phobia	5 (9)	11 (17)	12 (18)	9 (14)
Any developmental concern	2 (3)	5 (8)	10 (15)	10 (16)

DIVA, proceduralist rated difficult intravenous access score[19]; *N/A*, not applicable; *NSAID*, nonsteroidal anti-inflammatory drug.
Data are number (%).
Baseline systemic analgesia: patients may have received >1 medication. Percentages may not add to 100 owing to rounding.

Table IV. Procedural characteristics

Characteristics	ED		Outpatient (pathology)	
	SOC (n = 59)	Virtual reality (n = 64)	SOC (n = 66)	Virtual reality (n = 63)
Proceduralist self-rated skill				
Novice	Nil	2 (3)	Nil	Nil
Advanced beginner	Nil	3 (5)	Nil	Nil
Competent	20 (34)	19 (30)	5 (8)	4 (6)
Proficient	27 (46)	30 (47)	16 (24)	23 (37)
Expert	12 (20)	10 (16)	44 (67)	36 (57)
Removed headset				
Temporary	N/A	12 (19)	N/A	5 (8)
Permanent		2 (3)		4 (6)
Withdrew limb	17 (29)	10 (16)	15 (23)	8 (13)
Need to call for further personnel	7 (12)	6 (9)	4 (6)	5 (8)
Comfort positioning	5 (9)	5 (8)	42 (64)	40 (64)
Procedural time, min:sec	9:00 (6:11-15:00)	7:08 (5:47-11:30)	4:55 (3:28-6:56)	5:06 (3:55-6:46)
Need for sedation	2 (3)	1 (2)	Nil	Nil

Data are number (%) or median (IQR). Percentages may not add to 100 owing to rounding.

Table V. Qualitative data

Participants*	Setting	Group	Feedback	Subtheme (+/−)*
Theme 1: virtual reality provides distraction, and decreases pain and distress				
P4 (Proc)	ED	Virtual reality	Enjoyable for patient. Well tolerated. Quality distraction. Fun.	Distract (+)
P11 (Carer)	ED	Virtual reality	Huge difference compared to usual: had many blood tests for nephritis recently and this was the best he's been.	Support (+)
P12 (Proc)	ED	Virtual reality	Worth a try: she was distracted but got upset. Would recommend.	Distract (+)
P13 (Proc)	ED	Virtual reality	Patient normally distressed with this procedure but with the virtual reality the patient was a completely different child.	Distress (+)
P22 (Proc)	ED	Virtual reality	Good distraction, patient was compliant.	Distract (+)
P24 (Carer)	ED	Virtual reality	I believe she wouldn't have even needed anesthetic cream with virtual reality.	Pain (+)
P32 (Proc)	ED	Virtual reality	Excellent distraction! Initial discomfort felt by patient when mask put on which increased his anxiety. Once this was sorted out, he settled quickly.	Distract (+)
P34 (Proc)	ED	Virtual reality	Patient was entranced and very distracted.	Distract (+)
P41 (Proc)	ED	Virtual reality	Great distraction technique.	Distract (+)
P53 (Child)	Pathology	Virtual reality	I did not know when the needle went in.	Pain (+)
P54 (Proc)	Pathology	Virtual reality	Did not use virtual reality, too anxious and new to patient.	Anxiety (−)
P66 (Carer)	Pathology	Virtual reality	I think this is a great idea. My daughter was really scared about the idea of bloods being taken. But with being distracted it helped so much and the ladies were fabulous.	Distract (+)
P67 (Carer)	ED	Virtual reality	Very impressed that he said that he felt no pain at all.	Pain (+)
P73 (Proc)	ED	Virtual reality	Patient would have been more distressed without virtual reality.	Distress (+)
P107 (Carer)	Pathology	Virtual reality	Any tools to distract the kids from focusing on the injection/needle is always beneficial. Virtual reality was wonderful, I'm a huge advocate.	Distract (+)
P112 (Carer)	Pathology	Virtual reality	Keeps kids' attention and kids relaxed.	Distract (+)
P114 (Child)	Pathology	Virtual reality	Didn't notice needle go in.	Pain (+)
P116 (Carer)	Pathology	SOC	A tool like that would be so useful-even when he's anxious in the car, it could be something positive to talk about and look forwards to.	Anxiety (+)
P149 (Proc)	Pathology	Virtual reality	Worked really well for him. He was very distressed secondary to previous bad experience.	Anxiety (+)
P161 (Child)	ED	Virtual reality	Didn't feel anything at all.	Pain (+)
P164 (Carer)	Pathology	Virtual reality	Didn't really work because the video was not engaging for this particular patient.	Distract (−)
P171 (Child)	Pathology	Virtual reality	I felt the needle but was to distracted by virtual reality to care.	Pain (+)
P192 (Child)	Pathology	Virtual reality	That was so fun! I would really like it next time please.	Distract (+)
P196 (Carer)	ED	SOC	Would have really helped his anxiety to be distracted by virtual reality.	Distract (+)
P202 (Carer)	Pathology	Virtual reality	Much less distressed than usual. I think it would have helped my son from ages 5-6.	Distress (+)
P206 (Child)	Pathology	SOC	I'd like to think of the needle as a fish nibble next time.	Anxiety (+)
P215 (Proc)	ED	Virtual reality	Great, very helpful distraction for procedures.	Distract (+)
P237 (Carer)	ED	Virtual reality	That's a very effective and interesting method for children to decrease their anxiety of injection.	Anxiety (+)
P239 (Carer)	Pathology	Virtual reality	Had 300 needles, first time he had not cried.	Distress (+)
P245 (Child)	ED	Virtual reality	Has Playstation virtual reality at home so this wasn't that exciting.	Distract (−)
P249 (Child)	Pathology	Virtual reality	Didn't hurt this time.	Pain (+)
P250 (Carer)	Pathology	SOC	Virtual reality would have worked well for him - he really liked it.	Distract (+)
P254 (Proc)	ED	Virtual reality	Great distraction so far. Problem may persist with extremely anxious patients, but great for everyone else.	Distract (+) Anxiety (−)
Theme 2: virtual reality supports keeping the child still and calm				
P1 (Proc)	ED	Virtual reality	Keeps them calm.	Calm (+)
P12 (Proc)	ED	Virtual reality	Increased distress if pain and patient can't see cause.	Blocking (−)
P23 (Proc)	ED	Virtual reality	It's great, [patient] was distressed for about 2 seconds then was completely calm.	Calm (+)
P24 (Proc)	ED	Virtual reality	A calm child is great.	Calm (+)
P27 (Proc)	ED	Virtual reality	Calm, well distracted.	Calm (+)
P37 (Proc)	ED	Virtual reality	Provided good distraction and entertainment; allowed child to not visualize needle, calming the patient.	Calm (+), Block (+)
P53 (Carer)	Pathology	Virtual reality	Thank you, it was really good. Anything helps.	Support (+)
P68 (Carer)	Pathology	Virtual reality	Made the experience much easier. Last time we had to hold her down.	Still (+)
P87 (Carer)	Pathology	SOC	He wouldn't get scared if he couldn't see the needle.	Block (+)
P91 (Carer)	ED	Virtual reality	Stopped my child crying and moving arms around.	Still (+)
P108 (Carer)	Pathology	Virtual reality	Great idea. Patient was completely relaxed throughout the whole procedure.	Calm (+)
P109 (Proc)	Pathology	Virtual reality	Have taken blood from this little girl before. Felt this child was much calmer than last time.	Calm (+)
P120 (Carer)	Pathology	Virtual reality	He fainted last time. They helped him a lot.	Support (+)
P133 (Carer)	Pathology	Virtual reality	From a mum who's child has regular blood tests and autism, this was amazing.	Support (+)
P146 (Proc)	Pathology	Virtual reality	Spent a lot of time calming her down last time. She was much better this time.	Calm (+)
P162 (Carer)	ED	Virtual reality	He always wants to see needle procedures going in as it makes him more calm.	Calm (−), Block (−)
P171 (Carer)	Pathology	SOC	Great idea, I wish she could have used it during the needle. It would be great to block the view.	Block (+)
P200 (Carer)	Pathology	Virtual reality	Highly recommended - he was very calm!	Calm (+)
P207 (Carer)	ED	SOC	I think this would have helped distract him from watching and seeing what was being done.	Support (+)
P230 (Carer)	Pathology	Virtual reality	Usually needs 3 people to hold him down.	Calm (+)

(*continued*)

Table V. Continued

Participants*	Setting	Group	Feedback	Subtheme (+/−)*
Theme 3: Feedback and suggestions on how to improve the virtual reality experience				
P1 (Child)	ED	Virtual reality	I'd like to see starfish and more dolphins.	Content
P25 (Child)	ED	Virtual reality	More of the curly tailed fish please.	Content
P32 (Proc)	ED	Virtual reality	Please ensure mask is comfortable.	Headset (−)
P52 (Carer)	Pathology	Virtual reality	I would recommend time to process needle procedure and using headset prior to needle. Especially for children with autism.	Prepare (−)
P53 (Child)	Pathology	Virtual reality	Headset slipped down a bit.	Headset (−)
P60 (Carer)	Pathology	Virtual reality	Better if gave child a game he was familiar with.	Content (−)
P61 (Carer)	Pathology	Virtual reality	Improve the weight of the headset. More user friendly for spectacle-wearers.	Headset (−)
P63 (Proc)	ED	Virtual reality	Aids distraction. Virtual reality would be more inclusive if in other languages.	Content
P85 (Proc)	ED	Virtual reality	Warn doctor of timing of story to match procedure.	Prepare (−)
P86 (Child)	ED	Virtual reality	Adding plot twist would help.	Content
P118 (Carer)	Pathology	Virtual reality	Spend time prepping kids about goggles.	Prepare (−)
P131 (Proc)	Pathology	Virtual reality	Seemed to be shocked when needle inserted. I would warn earlier in future maybe.	Prepare (−)
P156 (Proc)	ED	Virtual reality	Patient commented "got bored" of video. Perhaps provide greater age-appropriate context.	Content (−)
P160 (Proc)	ED	Virtual reality	Goggles too big and didn't seem to fit.	Headset (−)
P173 (Carer)	Pathology	Virtual reality	Something more relevant to older kids.	Content
P205 (Carer)	Pathology	Virtual reality	Add more modes or choices.	Content
P228 (Carer)	Pathology	Virtual reality	Would be better if she got to watch it longer before the blood test. We were rushed at pathology and didn't get to try it beforehand.	Prepare (−)
P247 (Proc)	Pathology	Virtual reality	Would have been better if he knew what to expect. First blood test.	Prepare (−)
P253 (Carer)	ED	Virtual reality	Thought it was great but that he would have probably preferred something with more action.	Content

Carer, Caregiver; *Proc*, proceduralist.
*(+): positive polarity feedback, (-): negative polarity feedback.

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