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Efficacy of Virtual Reality vs. Tablet Games for Pain and Anxiety in Children Undergoing Bone Pins Removal: Randomised Clinical Trial

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ABSTRACT

Aims: To verify the efficacy of virtual reality compared to tablet games for pain and anxiety management in children undergoing percutaneous bone pin and/or suture removal procedures.

Design: Randomised clinical trial using two parallel groups: (1) virtual reality or (2) tablet game.

Methods: Three-center, randomised pragmatic clinical trial, using a parallel design with two groups (experimental group: immersive virtual reality; active comparator: tablet games). Children aged 6–17 requiring percutaneous pins and/or sutures were recruited between 2020 and 2022 from three outpatient orthopaedic clinics in paediatric hospitals. Pain was measured with the Numerical Rating Scale and anxiety with the Child Fear Scale before and immediately after the procedure.

Results: A total of 188 participants were assigned to either the virtual reality group (96 participants) or the tablet group (92 participants). At the first assessment, there was no noticeable difference between the two groups in terms of pain or anxiety levels. However, further analysis revealed that participants aged 13 and older in the virtual reality group experienced significantly lower anxiety.

Conclusion: Virtual reality was not more efficacious than games on a tablet for pain and anxiety of children undergoing removal of bone pins or sutures. However, virtual reality demonstrated a benefit in reducing anxiety for teenagers, particularly those aged 13-older.

Abbreviations: CFS, Child Fear Scale; CHU, Centre Hospitalier Universitaire (eng.); CONSORT, Consolidated Standards of Reporting Trials; HMD, Head Mounted Device; ITT, Intent to Treat; M, Mean; MedDRA, Medical Dictionary for Regulator Activities; NRS, Numerical Rating Scale; PT, Preferred Term; REDCap, Research Electronic Data Capture; SD, Standard Deviation; SOC, System Organ Classification; URCA, Unité de Recherche Clinique Appliquée (eng.); VAS, Visual Analog Scale; VR, Virtual Reality.

Implication for the Professional and/or Patient Care: Virtual reality games provide an immersive, non-pharmacological alternative of for anxiety management of teenagers during pins and/or sutures removal.

Impact: This study showed that a virtual reality game may help reduce anxiety during pins and/or sutures removal procedures in patients aged 13 years and older.

Reporting Method: We adhered to the CONSORT checklist for reporting results.

Patient or Public Contribution: A patient partner reviewed the study design, methods and final manuscript.

Trial Registration: NCT03680625

1 | Introduction

Percutaneous pinning is a technique used in orthopaedic surgery to stabilise an unstable fracture by inserting percutaneous bone pins (or Kirschner wires). In some cases, sutures are also required to facilitate wound healing. Both pins and sutures are typically removed in outpatient orthopaedic clinics during follow-up appointments. These procedures, considered quick and mildly painful, are usually performed with little to no analgesia. However, several studies have shown that children often experience moderate to severe pain during the removal of pins and/or sutures (Bigdeli Shamloo et al. 2018). Pain and anxiety in children undergoing these procedures are frequently underestimated by caregivers (Dulai et al. 2016). Given the known negative effect of children's past painful experiences on their long-term health trajectories (McMurtry et al. 2015), managing pain management for these procedures is crucial.

Multiple studies have examined pain and analgesia during percutaneous wire removal from bones. For example, Lim et al. (2014) compared over-the-counter medications including acetaminophen, ibuprofen, and placebo. No statistically significant or clinical difference was observed among the groups. Anxiety and fear, previously identified as potential challenges, may have confounded their results. Alternatively, Dulai et al. (2016) compared topical liposomal lidocaine to a placebo during bone pin removal. No statistically significant difference was found in pain scores ($p = 0.81$) measured with a 10 cm visual analog scale (VAS). However, their study confirmed that children do indeed experience moderate pain (Mean (M) = 3.03 cm Standard Deviation (SD) = 2.69 cm). In our pilot study, procedural pain experienced by children during pin and/or suture removal was considered moderate to severe (M = 4.8, SD = 3.1; Numerical Rating Scale, 0–10) and their fear was considered low to moderate (M = 1.8, SD = 1.4; Child Fear Scale, 0–4). Other studies have shown similar results, with pain levels being rated as moderate to severe M = 4.9/10 SD 3.1 (Bigdeli Shamloo et al. 2018). Given the nature of the procedure, the use of narcotics or full procedural sedation would exceed analgesic requirements and introduce additional challenges, such as extended monitoring and longer clinic visits, making narcotics unsuitable for routine use (Dulai et al. 2016; Sorenson and Hennrikus 2015; Templeton et al. 2010). Templeton et al. (2010) also examined the effect of oral midazolam on procedural anxiety during pin removal, but no significant difference was observed compared to placebo.

In recent years, non-pharmacological methods have emerged for pain management during bone pin or suture removal such as distraction techniques by a hospital child life specialist (Sorenson and Hennrikus 2015). Distractions are often reported anecdotally in the paediatric orthopaedic setting but have not been tested in a randomised controlled trial before. Distractions could be highly promising as they can be cheap, easy to use, and simple to implement with very few side effects depending on the method chosen. Effective distraction techniques such as bubble blowing, music, guided imagery, toys, or video games, have been proven effective for pain management in children undergoing needle-related procedures (Birnie et al. 2014). Within the last two decades, an increasing number of studies have examined the use of interactive and immersive distractions, such as virtual reality (VR), for procedural pain management (Tas et al. 2022). Such distractions work by captivating the child's attention in the game, inhibiting their perception of painful stimuli.

VR is a distraction tool that immerses the user in a computer-generated world that stimulates different senses (Hoffman et al. 2014). Pain reduction using VR has already shown promising results in children (Dascal et al. 2017; Tas et al. 2022). As well, anxiety and distress may be managed using VR during painful procedures, such as venipuncture, wound care, chemotherapy, and dental procedures (Dumoulin et al. 2019; Gold and Mahrer 2018; Wiederhold et al. 2014). Recently, studies have also examined the effectiveness of VR on pain and anxiety in children during painful procedures, such as phlebotomy, and have shown a positive effect on both (Dumoulin et al. 2019; Gold and Mahrer 2018). The use of VR as a distraction during painful procedures enhanced parents and healthcare professionals/phlebotomists' satisfaction (Dumoulin et al. 2019; Gold and Mahrer 2018). Moreover, the accessibility of VR worldwide is becoming increasingly important, which may favour a more positive, humanistic approach to procedural anxiety and pain management.

While VR has often been discussed as a distraction technique, emerging evidence suggests that its pain-relieving effects may involve more than just distraction. Mechanisms beyond distraction, such as immersive sensory engagement and modulation of pain perception through changes in brain activity, are also believed to play a role (Hoffman et al. 2007; Jain et al. 2024; Maddox et al. 2024). Studies have shown that the immersive nature of VR can activate neural pathways that inhibit the perception of pain, similar to the effects of opioid analgesics (Hoffman et al. 2007). Furthermore, the effectiveness of VR in managing pain may be influenced by features such as interactivity and the sense of presence in the virtual environment (Jain et al. 2024). These findings highlight the potential of VR as a multifaceted tool for pain management in children undergoing painful or stressful procedures.

Evidence suggests that reducing procedural pain and distress in the short term will have better long-term outcomes and

Summary

- What is already known
  - Percutaneous pin and suture removal in children is commonly performed with minimal or no analgesia, often leading to moderate to severe pain. While pharmacological interventions have shown limited efficacy, non-pharmacological methods like distraction techniques, including Virtual Reality, have demonstrated potential for pain and anxiety management in paediatric procedures. However, research on the effectiveness of VR during bone pins and suture removal remains limited, with mixed findings from previous studies.
- What this paper adds
  - This clinical trial demonstrates that both virtual reality and tablet-based interventions are safe for managing procedural pain and anxiety in children undergoing bone pinor suture removal. It also highlights the importance of age-specific responses, showing that teenagers may experience greater anxiety reduction with virtual reality, informing tailored approaches to management of paediatric medical procedures.
- Implications for policy/practice
  - The findings offer valuable insights for optimising non-pharmacological pain management strategies, enhancing patient experiences, and informing best practices in paediatric orthopaedic care worldwide. Our study provides practical insights into the feasibility and challenges of integrating Virtual Reality into clinical settings, including cost and training considerations, supporting evidence-based policy decisions for non-pharmacological pain management.

long-lasting effects on future pain perception and health trajectories (McMurtry et al. 2015). The effect of the pain extends beyond the duration of the painful procedures per se. How children remember these experiences can have long-lasting effects (Noel et al. 2017). Children are at risk of developing pain problems and avoiding medical care (Noel et al. 2017). Moreover, when children and their parents experience preprocedural anxiety and distress coupled with heightened pain levels, they are more likely to form negatively skewed memories of painful procedures and the healthcare environment (Fischer et al. 2019; Noel et al. 2017, 2019). Reducing the recollection of pain from past experiences in children (i.e., they remember less pain compared to an earlier report) may lead to lower levels of pain and distress in future experiences (Noel et al. 2017). Moreover, a study conducted by Cohen et al. (2001) showed that children undergoing vaccine injections who received pain and distress interventions (e.g., distraction and topical anaesthetic) reported better protection against the formation of negatively biased memories.

A similar study published in 2024 tested the use of VR in the context of bone pin removal for procedural pain and anxiety management. The clinical trial developed by Fabricant et al. (2024) compared three main groups with a small sample size: VR gaming simulation ($n = 37$), VR goggles with a noninteractive video ($n = 36$), or a tablet computer with the same noninteractive video ($n = 40$). The study results showed no statistical significant differences between the use of VR and other distraction techniques (Fabricant et al. 2024).

This study holds significant international relevance as percutaneous pinning is a widely used orthopaedic procedure across diverse healthcare systems worldwide. Pain and anxiety management during pin and suture removal in children remains an underrecognized yet critical challenge, with implications for long-term health outcomes. Given the increasing accessibility of non-pharmacological interventions such as VR, identifying effective, scalable, and cost-efficient pain management strategies is crucial for improving paediatric care globally. This research contributes to the growing body of evidence supporting innovative approaches to procedural pain relief, with the potential for widespread implementation across various cultural and clinical settings.

2 | The Study

2.1 | Aims

The aim of this pragmatic randomised clinical trial was to verify the efficacy of immersive VR distraction compared to non-immersive tablet game for pain and anxiety management in children undergoing percutaneous bone pin or suture removal.

2.2 | Primary Objective (Primary Multiple Outcomes)

Verify whether immersive VR distraction is superior to a tablet game for procedural pain and anxiety management in children during percutaneous bone pin and/or suture removal procedures.

2.3 | Secondary Objectives

a. Compare the occurrence of side effects between the VR immersive distraction and non-immersive tablet groups.

b. Compare healthcare professionals' satisfaction levels between the VR immersive distraction and non-immersive tablet groups.

c. Compare children and parents' satisfaction levels between the VR immersive distraction and non-immersive tablet groups.

d. Compare the requirement for rescue analgesia between the VR immersive distraction and non-immersive tablet groups.

e. Compare the use of co-interventions (any additional measures performed by healthcare professionals or parents to aid in managing the child's pain or anxiety, such as verbal reassurance or additional distractions) in each group.

f. Compare overall procedural time between the VR immersive distraction and non-immersive tablet groups.

3 | Methods

3.1 | Design

A three-center, randomised pragmatic clinical trial was conducted using a parallel design with two groups: (1) experimental group (immersive VR) and (2) tablet games comparator. Participants were randomised in a 1:1 ratio.

3.2 | Study Setting and Sampling

Convenience sampling techniques were used to recruit participants in orthopaedic outpatient clinics at three paediatric hospitals in Montreal (Canada): CHU Sainte-Justine Hospital, Montreal Children's Hospital, and Shriners Hospital for Children-Canada between 2020 and 2022. Eligible patients and their accompanying parent/legal guardian, scheduled for a follow-up appointment for percutaneous bone pin and/or suture removal, were approached in the clinic by a member of the research team. They were introduced to and informed about the study, and their consent for participation was obtained.

The planned sample size ($n = 188$) was determined based on data from our pilot study, a within-subject study design with 20 children from 7 to 17 years old, in which we measured pain through a verbal numerical rating scale (0–10) and anxiety through the Children Fear Scale (0–4) during painful medical procedures (Le May et al. 2021). To achieve 80% power to reject the null hypothesis of equal means, assuming a mean difference for pain of 1.5 (SD = 3.3) and a 2.5% significance level in a two-tailed *t*-test, each group should have 94 participants. To achieve similar statistical parameters for a mean difference in anxiety of 0.7 (SD = 1.3), 67 participants would have been required in each group. There was no attrition to account for based on our pilot study (Le May et al. 2021). A Bonferroni correction has been used to account for multiple comparisons.

3.3 | Inclusion and Exclusion Criteria

Children were eligible to participate if they were: (1) aged between 6 to 17 years; (2) undergoing percutaneous bone pin and/or suture removal; and (3) accompanied by a parent or legal guardian.

Children were excluded if they: (1) had a cognitive impairment that would prevent them from playing a VR game; (2) had a diagnosis of epilepsy or any other condition that would prevent them from playing a VR game; or (3) could not be in a sitting or semi-upright sitting position (Fowler's position) during the procedure, as the VR game required at least a 30° angle for head tracking. If the participant received analgesics (e.g., acetaminophen, ibuprofen) or anxiolytics (e.g., benzodiazepines) 24 h prior to the procedure, they were not excluded but the medications' name, dosage, and time of administration were reported in the data collection form.

3.4 | Randomization

Participants were allocated to either group in a 1:1 ratio using a stratified permuted block randomisation with random permutation block sizes of 4 and 6, with randomly selected block sizes. Stratification was done at the site level. Only an independent biostatistician from the Unité de recherche clinique appliquée (URCA) of the CHU Sainte-Justine had access to the randomisation list. To avoid selection bias, REDCap (Research Electronic Data Capture), a secure website specialising in computerised database management, was used to conceal allocation prior to participant recruitment. Outcome assessors were blinded to group assignments to ensure the validity of the findings.

3.5 | Study Interventions

3.5.1 | Experimental Intervention

Participants in this group used a wireless, head-mounted device (HMD) helmet (Oculus Quest) while undergoing bone pin and/or suture removal. The game used in the intervention, DREAM (Paperplane Therapeutics, see https://paperplanetherapeutics.com/products/healthcare), was developed for therapeutic purposes. DREAM is a "point and shoot" game with an "on rail" mechanic where participants, floating on a gimbal from island to island, can throw balls at balloons and trolls. The game combines an easy to use, immersive experience with an environment optimised to reduce cybersickness. The DREAM game was approved for use in a paediatric population by a team of healthcare professionals based on expert consensus through a usability focus groups with clinicians working with children and VR game design experts. There was consensus about the non-aggressive elements of game, and speed of navigation to reduce motion sickness, fast learning curve and easiness for children to learn the game. The game was tested during the pilot study. Participants could begin playing the game 5 min before the beginning of the procedure to familiarise themselves with the gameplay.

3.5.2 | Tablet Game Comparator

Patients in this group were offered a tablet to play a non-immersive video game while they underwent bone pin or suture removal. The tablet offered a selection of age-appropriate games, thoughtfully curated and supplied by our research team to ensure an engaging and supportive experience. This choice was made based on ethics committee recommendations, which required an active control group rather than a no-intervention group. Moreover, the tablet game, used as an active comparator, aligns with the study's objective of evaluating non-pharmacological pain management strategies by leveraging distraction, a shared mechanism with virtual reality. Tablets are not routinely available to children in clinical settings, and while some parents occasionally brought their own, this was not a common practice. To enhance engagement, we asked children about their preferred games, which were then downloaded and provided through research funds. The child could choose from these options and begin playing 5 min before the procedure. The

term 'tablet game' is consistently used throughout the manuscript to ensure clarity.

3.6 | Study Timepoints

This study had two timepoints (T0) and (T1). T0 corresponds to Baseline (5 min before the procedure) and T1 corresponds to immediately after the procedure.

3.7 | Instruments

3.7.1 | Primary Outcomes

Pain intensity was assessed using the Numerical Rating Scale (NRS) (Price et al. 1994). The NRS is a self-reported, 11-point scale ranging from 0 (no pain) to 10 (worst pain ever felt). Participants were asked to indicate the pain intensity felt at the moment. This scale has an established validity and reliability with children from 6 to 17 years of age (Bailey et al. 2010; Castarlenas et al. 2017; Miró et al. 2009; Tsze et al. 2018). Pain intensity was measured at (T0) and (T1).

The level of anxiety was assessed with the Child Fear Scale (CFS), a self-reported measure of anxiety in children (McMurtry et al. 2011). The scale is composed of 5 faces ranging from 0 (no fear) to 4 (extremely fearful). Participants were asked to select the face that best represents how they felt during the procedure. Validity and reliability have only been established for children aged from 5 to 10 years (Kuttner and LePage 1989), but the CFS has previously been used with children ranging from 8 to 18 years old during painful medical procedures (Stoltz and Manworren 2017). The level of anxiety was measured at (T0) and (T1).

3.7.2 | Secondary Outcomes

1. Occurrence of side effects was documented from the beginning to the end of the procedure and evaluated with a checklist.
2. Healthcare professional's satisfaction level with the intervention was compared between groups (T1) using a 7-item tailored Likert-type scale including four choices: "Strongly disagree", "Disagree", "Agree" and "Strongly agree". The items were: (1) How many times did you attend a procedure in which virtual reality has been used? (2) Virtual reality helped the child control their anxiety/fear. (3) Virtual reality interfered with the flow of the proceedings. (4) Virtual reality allowed the child to cooperate better during the procedure. (5) I would reuse virtual reality for other medical procedures in children. (6) The virtual reality device was adapted to the environment of the procedure room. (7) The concept of using virtual reality during medical procedures is an idea worth developing.
3. Parents' and children's satisfaction levels were compared between groups (T1) using a verbal numerical rating scale (0–10) to answer the following question, recommended by PedIMMPACT: 'Considering pain relief, side effects, physical recovery, and emotional recovery, how satisfied were you with the treatments you/your child received for pain?' (McGrath et al. 2008).
4. Requirement for rescue medication was compared between groups and documented (yes/no).
5. Co-interventions by parents or healthcare professionals (any additional measures performed by healthcare professionals or parents to aid in managing the child's pain or anxiety, such as verbal reassurance or additional distractions) were compared between groups and documented.
6. Procedural time (time needed for the orthopaedic procedure) was documented in minutes and compared between groups.

3.8 | Data Collection

Data was collected by research staff at three timepoints: Before the procedure and the VR intervention (T0) and immediately after the procedure (T1). Demographic and clinical characteristics were collected via parent reports and hospital chart review at T0. The informed consent, assent of the child, and baseline data collection (T0) required about 15 min. Once consent was obtained, a member of the research team accessed REDCAP to determine the allocation of participants to the experimental or active control group 5 min before the start of the procedure. This measure was used to prevent observer bias, as blinding was impossible given the nature of the interventions. Demographic and clinical characteristics were assessed with parent reports and hospital chart review. Study interventions and removal of pins and/or sutures lasted about 20 min. Data collection immediately after the procedure (T1) required about 15 min. Data were collected on paper forms and then transferred into REDCap, a web application designed for constructing and overseeing online surveys and databases, by a member of the data management team at URCA. Data were also reviewed by a data manager for possible errors.

3.9 | Data Analysis

Analyses were conducted using the SAS version 9.4 (SAS Institute Inc., Cary, NC). An Intent to Treat (ITT) approach was used to assess the efficacy. Because few missing data were expected, the population data set for the primary outcome corresponds to the randomised population and was restricted to patients assessed for the primary outcome. No imputation was performed for missing data. To account for the two primary outcomes (dual primary endpoints), a Bonferroni correction was applied, and the p-value was set at 0.025 (two-sided). We confirmed normal distribution for pain and anxiety scores before using parametric tests. In cases where data were not normally distributed, appropriate non-parametric tests (Mann–Whitney U test) were used. No adjustments were made for the multiple secondary outcomes and subgroup analyses ($p = 0.05$) because these results are not considered decisional.

Participants characteristics of each group were summarised using means and standard deviations for continuous variables and frequencies and percentages for categorical variables. For primary outcomes, mean anxiety and pain scores after the

intervention (T1) were compared using an ANCOVA model adjusted for pre-intervention scores (T0). Subgroup analyses were done for sex/gender and age groups (6–12 years, 13–17 years). Chi-Square, Fisher Exact test, *t*-test, and Wilcoxon test were used for group comparisons on secondary outcomes. Effect sizes were calculated for the primary outcomes as well as for comparisons between groups on age and sex/gender. Side effects and adverse events were reported using the MedDRA (Medical Dictionary for Regulatory Activities) terminology and their proportions were compared between groups using Preferred Term (PT) and System Organ Classification (SOC) categories.

4 | Patient Partner Contributions

One of the co-authors of the current paper (KC) was implicated from the conception of the study as a partner patient. She reviewed the study design, methods, results and final manuscript and presentations.

4.1 | Ethical Considerations

This trial was approved with the latest approval date on May 19th, 2022, by the Research and Ethics Board of the CHU Sainte-Justine, Shriners *Hospital for Children-Canada*, and Montreal Children Hospital; approval numbers MEO-21-2019-5486 and MP-21-2019-2030 respectively. The trial was registered on clinicaltrials.gov prior to patient recruitment (NCT03680625). Upon enrollment, children were assigned codes to use on data collection forms to ensure their confidentiality.

5 | Results

5.1 | Characteristics of the Participants

A total of 188 children were recruited to participate in this multicentric, pragmatic randomised clinical trial from June 2019 to October 2022. Of the 188 participants, 96 were randomised to the VR group and 92 to the tablet group. The sample included more boys (60.6%; $n = 114$) than girls and the mean age was similar in each group (10.4 ± 3.4 years old in the VR group and 10.3 ± 3.2 years old in the tablet group). The most common procedure was bone pin removal (85.11%; $n = 160$). Characteristics of the participants are shown in Table 1. The recruitment flow chart is presented in Figure 1.

5.2 | Primary Multiple Outcomes

Following are the results regarding the primary multiple outcomes on pain and anxiety as well as adjusted mean differences on these outcomes.

TABLE 1 | Patients Characteristics.

Characteristics	Virtual reality ($n = 96$)	Tablet ($n = 92$)
Age (years), mean ± SD	10.4 ± 3.4	10.3 ± 3.2
Sex, *n* (%)		
Female	42 (43.8)	32 (34.8)
Male	54 (56.3)	60 (65.2)
Previous hospitalisation, *n* (%)		
Yes	39 (40.6)	29 (31.5)
No	56 (58.3)	61 (66.3.)
Missing	1 (1.0)	2 (2.2)
Previous experience of procedural pain excluding vaccination, *n* (%)		
Yes	58 (60.4)	44 (47.8)
No	38 (39.6)	45 (48.9)
Missing	—	3 (3.3)
Medical and surgical history, *n* (%)		
Yes	41 (42.7)	38 (41.3)
No	54 (56.3)	51 (55.4)
Missing	1 (1.0)	3 (3.3)
Procedures, *n* (%)[a]		
Removal of sutures	38 (39.6)	37 (40.2)
Removal of bone pins	83 (86.5)	77 (83.7)

Abbreviation: SD = Standard deviation.
[a]Some patients could have more than one procedure.

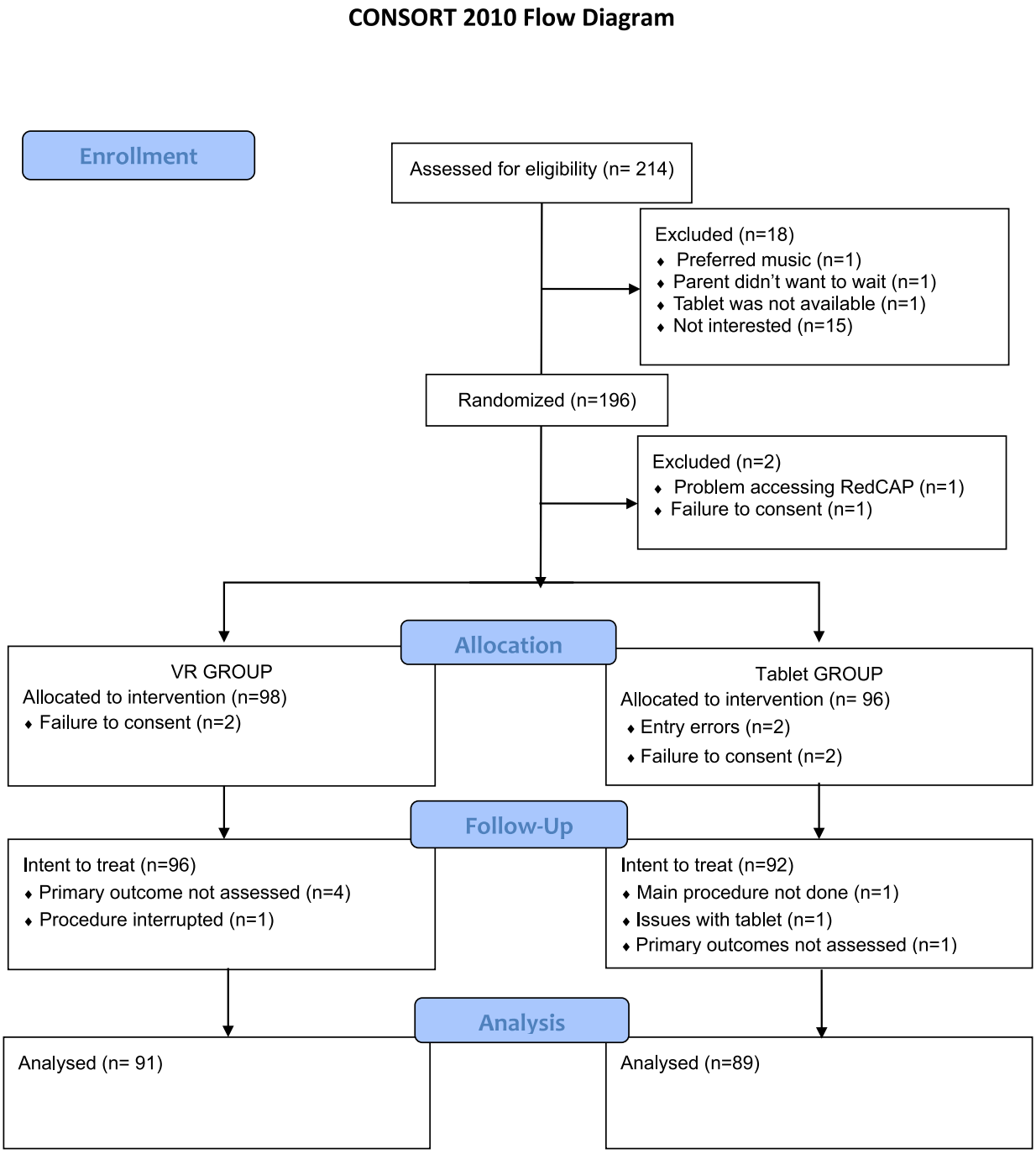

FIGURE 1 | Study Flow Diagram.

5.2.1 | Pain

The mean (±SD) procedural pain scores between the VR and Tablet groups at T1 were respectively: 3.7±3.1 and 3.7±2.8, $p=0.90$.

5.2.2 | Anxiety

The mean (±SD) procedural anxiety scores between the VR and Tablet groups at T1 were respectively: 1.2±1.3 and 1.3±1.5, $p=0.69$.

5.2.3 | Mean Differences on Pain and Anxiety

Results from the ANCOVA analysis on the adjusted mean differences on pain and anxiety, as well as confidence intervals and effect sizes, are presented in Table 2.

5.3 | Subgroup Analyses on Primary Outcomes

Primary multiple outcomes were also analysed through subgroup analyses based on age group and sex/gender. We merged the sex and gender variables since all children provided the same information regarding their sex and gender. Tables 3 and 4 present results of these analyses.

5.3.1 | Age

There was a statistical significant difference between groups on the mean anxiety score in the group of children aged 13–17 years ($p = 0.028$) with a moderate effect size. No significant difference was observed in mean anxiety in the group of children aged 6–12 years ($p = 0.42$). No significant difference was observed in mean pain score between the groups of children aged 6–12 years ($p = 0.65$) and 13–17 years ($p = 0.32$). Effect sizes were low on these last comparisons.

5.3.2 | Sex/Gender

There was no significant difference observed between boys and girls in both groups regarding the mean pain score (Boys: $p = 0.60$; Girls: $p = 0.50$) or the mean anxiety score (Boys: $p = 0.58$; Girls: $p = 0.77$). Effect sizes were also low in these comparisons.

5.4 | Secondary Outcomes

5.4.1 | *Side* Effects/*Adverse Events*

Only one child reported side effects (dizziness) in the VR group (but the child still completed the VR session) compared to three children (dizziness, nausea) in the tablet group. No serious adverse events were reported in both groups.

TABLE 2 | ANCOVA on mean difference between groups for pain and anxiety at T1.

	Mean difference	97.5% CI[a]	Adjusted[b] mean difference	97.5% CI	*p*[c]	Effect-size
Pain	0.03	(−0.97; 1.02)	0.06	(−0.93; 1.04)	0.90	0.02
Anxiety	−0.09	(−0.55; 0.38)	−0.08	(−0.53; 0.37)	0.69	0.06

[a]Confidence interval.
[b]Adjusted for baseline value (pre-intervention).
[c]*p*-value significant at 0.025 (Bonferroni correction applied).

TABLE 3 | Subgroup Analysis—Scores on Pain according to sex and age.

	Adjusted mean difference	95% CI	*p**	*p* for interaction	Effect-size
Sex (*n*)				0.58	
Male (109)	0.35	(−1.0; 1.7)	0.60		0.11
Female (72)	−0.35	(−1.9; 1.2)	0.50		0.12
Age (years; *n*)				0.61	
6–12 (135)	0.2	(−1.1; 1.4)	0.65		0.05
13+ (48)	−0.35	(−1.8; 1.1)	0.32		0.16

*Significant at $p < 0.05$.

TABLE 4 | Subgroup Analysis–Scores on Anxiety according to sex and age.

	Adjusted mean difference	95% CI	*p**	*p* for interaction	Effect-Size
Sex (*n*)				0.52	
Male (109)	−0.25	(−0.8; 0.3)	0.58		0.18
Female (72)	0.15	(−0.6; 0.9)	0.77		0.11
Age (years; *n*)				0.025*	
6–12 (135)	0.15	(−0.4; 0.7)	0.42		0.11
13+ (48)	−0.8	(−1.6; 0.0)	0.028*		0.67

*Significant at $p < 0.05$.

5.4.2 | Healthcare Professionals' Satisfaction

Results showed significant differences in the mean satisfaction level of healthcare professionals regarding: 1- VR benefits for patients' anxiety management ($p = 0.009$) and 2- Their desire to reuse this procedure for future interventions ($p = 0.023$).

5.4.3 | Parents' and Children's Satisfaction

Mean satisfaction of parents in the VR group was significantly higher (9.2 ± 1.2) than in the tablet group (8.6 ± 1.9), $p = 0.015$. There was no significant difference between both study groups on the mean satisfaction of children with the intervention received ($p = 0.20$).

5.4.4 | Rescue Medication

Rescue medication was needed only for one child in the tablet group.

5.4.5 | Co-Interventions

Some co-interventions were observed in addition to the VR headset ($n = 4$, 4.2%) or the tablet ($n = 8$, 8.7%), which included mainly parent reassurance and parent holding hands.

5.4.6 | Procedural Time

Mean procedural time was 3.8 ± 4.0 min and 3.0 ± 3.4 min in the VR and tablet groups, respectively. There was no significant difference in procedural time between groups ($p = 0.10$).

6 | Discussion

In this multi-centric pragmatic randomised clinical trial on the efficacy of immersive VR intervention over a game on a tablet for pain and anxiety management of children undergoing bone pin or/and suture removal, we did not find any significant differences between groups on the primary multiple outcomes of pain and anxiety. A similar clinical trial conducted by Fabricant et al. (2024) found that both VR and tablet-based distractions were not significantly different in reducing procedural pain and anxiety in an orthopaedic setting. The authors specified that the fit of VR headsets varied among participants, especially younger children (< 6 years), which was a limitation, potentially compromising the immersive experience (Fabricant et al. 2024). Some participants also reported the VR video as slightly blurry, which might have affected the results (Fabricant et al. 2024). Additionally, according to the authors, the lack of subgroup analyses by age and sex/gender further limits the generalisability of the findings, as certain demographics might benefit differently from the interventions (Fabricant et al. 2024). In our study, subgroup analyses by age group showed that older children experienced lower pain levels (though not statistically significant) when using VR, suggesting a potential age-related benefit of VR over the tablet game comparator. This could suggest a potential age-related benefit of VR, but this finding requires careful interpretation given the results of other studies. For example, Jones et al. (2024) found that age did not significantly influence the effectiveness of VR for pain alleviation during paediatric burn care, indicating that VR's efficacy might be independent of age for certain populations and types of procedures. These findings highlight the need for more age-stratified research across different clinical settings to determine the role of age in VR's effectiveness. In our study, the age-stratified analysis showed a significant reduction in mean anxiety scores in children over the age of 13 years, suggesting that older children may respond differently to VR interventions. This finding aligns with other studies, using VR, that have reported lower anxiety levels for older children during painful and stressful procedures (Jivraj et al. 2020; Richey et al. 2022).

Moreover, considering pain levels, our results differ from those of a previous study that has found significant differences in pain outcomes when using VR distraction techniques during outpatient procedures in paediatric orthopaedics (Richey et al. 2022). However, our study directly compared VR to another active distraction technique (tablet game), which may have led to the similar pain management effects observed. The comparable outcomes may be partly due to the lower baseline levels of pain and anxiety prior to and during the procedure. Conversely, we did not find any differences in pain or anxiety when stratified by gender/sex. This finding is consistent with previous literature that reports minimal sex/gender differences in response to different distraction techniques (Jivraj et al. 2020; Richey et al. 2022; Shepherd et al. 2022).

Our study's findings revealed a slight but not significant reduction in anxiety levels immediately following the procedure for participants in the VR group. These results align with a comparable investigation assessing the effectiveness of VR in diminishing anxiety levels among children undergoing cast removals (Jivraj et al. 2020). In addition, recent systematic reviews have shown the links between anxiety levels and pain perception, associating the use of VR as having potential anxiolytic effects that can promote analgesia (Eijlers et al. 2019; Tas et al. 2022).

Furthermore, side effects were minimal in both groups, indicating that study interventions seem safe options for paediatric patients. Congruent with our findings, a comprehensive examination of literature highlighted that most studies on VR have reported only negligible side effects (Addab et al. 2022). This finding reinforces the safety of VR and underscores the reliability of both interventions as viable options for paediatric medical procedures. The assurance of minimal adverse side effects contributes to the overall positive outlook on the use of these interventions, supporting the continued exploration and application of VR in paediatric healthcare settings.

Healthcare professionals and parents expressed greater satisfaction with VR compared to a game on a tablet. Healthcare professionals reported significantly higher satisfaction with the VR intervention, particularly regarding patients' pain and anxiety management and willingness to reuse VR. These findings are similar to other studies (Richey et al. 2022; Jivraj et al. 2020; Shepherd et al. 2022; Burkhart et al. 2023), suggesting that healthcare professionals perceived VR as a more effective tool

for managing procedural pain and anxiety, which may influence its adoption in clinical settings.

In terms of satisfaction from parents and children, only parents' satisfaction was significantly higher in the VR group. This discrepancy may be due to parents' perceptions of novel technology being more effective or engaging for their children (Burkhart et al. 2023).

Finally, a study by Chen et al. (2024), who conducted a systematic review and meta-analysis on the effects of VR on pain and anxiety during children's circumcision, found that VR significantly reduced both pain and anxiety levels. While circumcision procedures differ from percutaneous bone pin and/or suture removal in terms of invasiveness and anxiety levels, their findings support the broader potential of VR as an effective intervention in paediatric pain management. These results further suggest that VR can be utilised across a range of medical procedures with varying levels of pain and anxiety, reinforcing its applicability in paediatric care.

6.1 | Strengths and Limitations of the Work

This randomised trial was designed to minimise selection biases. While the randomization procedure was not stratified by age group, the subgroups of interest were balanced through randomization. Additionally, as is the case with all subgroup analyses, these are exploratory by nature, and their limitations are acknowledged as such. However, selection biases will affect the study results only if there are quantitative or qualitative interactions between the unknown factors and the interventions (differential bias). If such differential bias is observed, it generally goes against the null hypothesis, suggesting that the intervention has an effect. For instance, potential selection bias might arise if children from higher socioeconomic backgrounds are overrepresented due to better access to advanced medical facilities offering VR treatments. If these children also have different responses to VR due to factors like previous experience or coping styles, this could lead to differential bias. Moreover, unmeasured confounding variables, such as the specific nature of the medical procedure or the individual coping styles of children, could influence both the exposure (VR intervention) and outcome (pain management) variables. These factors could have potentially confounded the observed associations. For example, children who are naturally more tolerant of pain or who had previous positive experiences with VR might respond more favourably, skewing the results. Another key limitation of this study is the lack of data on socio-demographic factors, such as socioeconomic background and prior exposure to technology, which could influence subgroup responses and the overall effectiveness of the interventions. We also did not account for engagement levels or perceived procedural severity, which may have influenced the different responses to VR across age groups.

Furthermore, this trial used an active control, thus a game on a tablet. The decision to use this type of control was highly recommended by the reviewers of the grant submitted to fund this study and also strongly suggested by the Ethical and Review Board of one of the study sites. As it was not considered ethical to refrain from using an active control knowing that VR had shown an effect in the pilot phase and also based on the fact that all the study sites have already implemented distraction tool boxes and for some sites employed child life specialists trained to distract children during painful procedures, we apprehended that there would be a possibility that the mean differences and effect sizes would be small because of this methodological decision.

Addressing these limitations in future studies would be critical for advancing our understanding of the studied phenomenon and informing evidence-based interventions in clinical practice.

6.2 | Recommendations for Future Research

Future research should focus on understanding the mechanisms behind why older children respond differently to these interventions and exploring long-term outcomes related to pain and anxiety management. Additionally, examining the cost-effectiveness of VR compared to traditional methods could provide valuable information for healthcare decision makers.

6.3 | Implications for Policy and Practice

The utilisation of VR games and tablet games as non-pharmacological interventions for pain and anxiety management during procedures, such as bone pin removal, has significant implications for healthcare policy and practice. Policymakers should consider incorporating both VR and tablet game technologies into healthcare settings as a standard component of patient care, recognising its potential to enhance patient comfort and reduce reliance on pharmacological interventions. Given that this study did not find VR to be superior to tablet-based interventions, resource allocation should prioritise the cost-effectiveness and feasibility of introducing these interventions into routine care. This may involve ensuring that tablet games, which are already widely available in many clinical settings, continue to be utilised effectively, while also exploring the introduction of VR technology where resources allow.

Additionally, healthcare practitioners should receive training on integrating both VR and tablet gaming into clinical practice, including selecting appropriate VR experiences for different patient populations and ensuring patient safety during VR sessions. Furthermore, healthcare facilities should establish protocols for the safe and ethical use of these technologies, addressing issues such as patient consent, privacy, and infection control.

The use of both VR and tablet game offers a promising solution in healthcare by providing an immersive, non-pharmacological alternative for managing pain and anxiety during procedures like pin and/or suture removal. By immerging patients into captivating virtual environments, both technologies effectively distract them from the discomfort and anxiety, which can significantly reduce the perception of pain. The interactive nature of both interventions engages patients both mentally and physically, enhancing the patient experience while potentially reducing reliance on traditional pain medications and minimising potential side effects.

Healthcare providers should actively assess patient preferences for both VR and tablet game interventions and offer them as part of a comprehensive pain and anxiety management plan. Collaborative decision making between healthcare providers and patients regarding the use of these technologies can enhance patient satisfaction and engagement with their care. Moreover, healthcare professionals should continuously evaluate the effectiveness of both interventions in reducing pain and anxiety and improving patient outcomes, contributing to the evidence base for integrating VR and tablet games into clinical practice.

7 | Conclusion

This study demonstrated that both VR and tablet-based interventions are safe in managing procedural pain and anxiety in children, but without showing significant differences in efficacy on the primary outcomes. The preference by healthcare professionals and parents for VR suggests a potential for increased use in clinical settings, though patient satisfaction did not significantly differ between interventions. The efficacy of VR on decreasing anxiety with teenagers underscores its impact and highlights its potential in addressing the unique needs of this age group within paediatric healthcare settings. Future research should explore specific scenarios where VR might offer unique benefits and assess the cost-effectiveness of implementing VR technology more broadly in routine paediatric care.

Author Contributions

The initial manuscript was drafted by Sylvie Le May, Mathilde Hupin Debeurme, Julien Gardner, Khadidja Chougui, Thierry Ducruet, Omar Ledjiar, Melanie Noel, Estelle Guingo and Argerie Tsimicalis. Sylvie Le May, Raissa Passos dos Santos, Estelle Guingo, Julien Gardner and Nicole Hung were involved in drafting the revised manuscript. The final draft was approved by all authors prior to publication. All authors agreed to be accountable for all aspects of the work.

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Conflicts of Interest

Only one of the co-authors has conflicts of interest to disclose. Stéphane Bouchard is president and part owner of In Virtuo, a company that distributes virtual environments (not for pain distraction), and conflicts of interest are managed under UQO's conflicts of interest policy.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Peer Review

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