Southern California CSU DNP Consortium

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EFFECT OF VIRTUAL REALITY DISTRACTION ON CHILDREN’S ANXIETY AND PAIN PERCEPTIONS DURING CAST AND PIN REMOVAL

A DOCTORAL PROJECT

Submitted in Partial Fulfillment of the Requirements

For the degree of

DOCTOR OF NURSING PRACTICE

By

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ABSTRACT

Background:Anticipatory pain and anxiety related to children’s fear of the unknown aspects of procedures and their association with a prior incident leading to fracture care may impact future healthcare interventions. Purpose: The overarching goals of this project were to optimize orthopedic care by decreasing children’s perceptions of pain and anxiety during a percutaneous bone pin removal and/or cast procedure and increase the child’s and parent’s overall satisfaction with the experience. Therefore, the purpose of this Doctor of Nursing Practice (DNP) Quality Improvement (QI) project was to develop, implement, and evaluate the effectiveness of virtual reality (VR) protocol for use with pediatric orthopedic patients undergoing a cast or percutaneous bone pin removal procedure. Methods: This evidence-based quality improvement project used the Plan, Do, Study, Act (PDSA) Framework. Participants received care at an outpatient pediatric orthopedic clinic in a Southern California magnet children’s hospital and included a convenience sample of 30 children ages 7-18 years, with no neurologic deficits, hearing impairment, or vertigo. Children’s perceptions of pain and anxiety related to the procedures and the children’s and parent’s overall satisfaction with the VR distraction technology were the four outcomes measured. The clinic’s registered nurses used the Wong-Baker Faces Pain Rating Scale (WBFPRS) and the Child Fear Scale (CFS) anxiety level to assess the child’s pre-and post-procedural pain and anxiety levels. Child and parent satisfaction surveys were used to assess overall satisfaction with the VR distraction experience. Results: Thirty-seven children were asked to participate in the VR experience until a sample size of 30 was obtained. Only one of the 30 children reported pain pre-procedure; she reported a level 2 pain score and was scheduled for pin removal. A total of three children reported pain post-procedure: the same child who underwent a pin removal and two others who described their pain as arm stiffness noted after the cast removal. Reduction of anxiety levels post-procedure was statistically significant (p<.001). Twenty-nine (96.67%) children reported they would use VR again. Similarly, twenty-nine (96.67%) parents agreed or strongly agreed they would use VR again if their child had to undergo similar procedures. Conclusion: VR distraction effectively reduced children’s perceptions of anxiety during cast and/or percutaneous pin removal. Parents and their children overwhelmingly rated VR as an effective distraction technique when used for cast or pin removal procedures. Development of guidelines for the use of VR, as well as enhanced teamwork and interdisciplinary collaboration, were essential to the success of this project. Future studies should focus on using VR as a distraction technique to reduce anxiety and pain for children undergoing other brief medical procedures in ambulatory centers.

*Keywords*: virtual reality; pediatrics; orthopedics; child; anxiety; pain; perception; distraction technique; cast removal; percutaneous bone pin removal

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**Background**

Children report fear and distress during medical procedures, which may contribute to an intensified cycle of pain and anxiety (Dumoulin et al., 2019). Children’s experience and their management of anticipatory pain and anxiety vary widely. A child’s inability to manage pain and anxiety can lead to trauma. Medical procedures can not only cause discomfort in children but can also be associated with negative experiences that may impact appropriate healthcare interventions in the future (Eijlers et al., 2019).

Pain and anxiety related to medical procedures are subjective experiences with clinical and economic implications. Research suggests using an intensive interdisciplinary team approach to treat pain can decrease the pain response and result in fewer missed days of school and work (Zernikow et al., 2018). Achieving adequate management of pain and anxiety in the pediatric patient population requires comprehensive knowledge of assessment and intervention strategies. Psychological support during medical procedures, such as distractions, is suggested as a SOC (Dumoulin et al., 2019). Gerçeker,et al., (2020) reported there are evidence-based non-pharmacologic distraction strategies that can effectively reduce pain and anxiety during medical procedures (Dumoulin et al., 2019; Gerçeker et al., 2021; Gold & Mahrer, 2018; Koç Özkan & Polat, 2020; Semerci et al., 2021; & Walter-Larsen et al., 2019).

Research on virtual reality (VR) has demonstrated its effectiveness as a distraction technique to decrease children’s perceptions of pain and anxiety during medical procedures (Gerçeker et al., 2021). VR is a 3-dimensional computer simulation platform accessed through a head mount device, immersing the subject in a virtual world view (Chan et al., 2019).

Children with orthopedic fractures are frequently seen in emergency department visits (Naranje et al., 2016). Fractures occur throughout childhood and adolescence at a rate of 180 per 1000 children, or one in every five children (Naranje et al., 2016). Most fractures are treated on an outpatient basis. Annually, approximately 1,000 pediatric patients are treated for orthopedic fractures and cared for by a pediatric orthopedic group at the project facility. Many of these fractures require casting, and 10%-15% may need surgery for percutaneous bone pin removal procedures (Le May et al., 2021).

Furthermore, patient distress challenges the treatment team when performing a procedure on a distraught child. This may delay the procedure or require rescheduling, which can negatively influence the parents' perception of their child’s experience. A child’s inability to manage their anxiety can create a negative experience, which can adversely impact the child’s overall quality of life, and the child may also become fearful of returning to the clinic for follow-up visits (Jivraj et al., 2020).

**Problem Statement**

Currently, in the project facility, VR is inconsistently used as a distraction technique to decrease anxiety and the perceptions of pain for children who undergo cast and/or pin removal. Research has shown that using VR is a noninvasive strategy that can alleviate pain and anxiety, resulting in increased patient and parent satisfaction (Dunn et al., 2019). In the project setting where this author works as a nurse practitioner (NP), there is no established VR protocol specific to its use in the pediatric orthopedic outpatient setting during percutaneous bone pin and or cast removal. Therefore, the author was granted permission to pursue an evidence-based project to determine whether this intervention should become a standard of care (SOC) for families of all children who met established criteria.

**Purpose Statement**

The project's goals were to optimize orthopedic care by decreasing children’s perceptions of pain and anxiety during a percutaneous bone pin removal and/or cast procedure and increase the child’s and parent’s overall satisfaction with the experience. Therefore, the purpose of this Doctor of Nursing Practice project was to develop, implement, and evaluate the effectiveness of a VR protocol for use with pediatric orthopedic patients undergoing a cast or percutaneous bone pin removal procedure.

The following seven objectives are identified to achieve these goals:

1. Develop a VR protocol to implement a distraction technique to decrease perceptions of pain and anxiety based on a thorough review of the literature on this topic and consultation with a child life specialist in the project hospital setting.
2. Review and select tools to assess pain and anxiety in children and ascertain parent and/or caregiver and child satisfaction with the VR experience.
3. Develop a VR protocol and resource materials, including a procedure checklist for implementing the VR protocol, a parent pamphlet, and assent/consent forms.
4. Obtain protocol approval by medical and administrative staff.
5. Educate nurses, orthopedic surgeons, and cast technicians about using the VR protocol.
6. Implementation of the VR experience for three weeks.
7. Analyze the data and provide a summary report to disseminate the findings.

**Supporting Framework**

The conceptual framework guiding this project was the Plan-Study-Do-Act (PDSA). This quality improvement (QI) framework was used to improve assessment and management in the clinical setting by applying the scientific method. The Institute for Healthcare Improvement’s (IHI, 2021) Model for Improvement (MFI) developed by W. Edwards Deming directs an approach incorporating three questions that focus on rapid improvement attempts. First, the aim is focused on determining what is to be accomplished. Secondly, the investigator will need to identify a change that will be an improvement. Third, the investigator will need to review the findings, summarize what was learned, and compare the results. These basic questions influence improvement and the PDSA cycle (Langley et al., 2009).

The PDSA is commonly used in healthcare for QI and involves four steps. The first step is to identify the purpose and tasks that will be assigned, which are the predictors of the outcomes. The PDSA cycle visualizes how the framework builds, influences, and demonstrates essential steps to enable an improvement. Appendix A contains a representation of the PDSA cycle that illustrates the individual components of PDSA that the author incorporated as essential features for this project.

**Application of Plan-Do-Study-Act**

In this framework, individuals and teams select an intervention, test, and implement a change applying the PDSA cycle (Institution for Healthcare Improvement [IHI], 2021). To determine if the aim was accomplished, quality must be created in the design stage (Institution for Healthcare Improvement [IHI], 2021). Therefore, improvements begin with a strategic plan.

***Plan***

The first phase begins with developing the *Plan,* which involves identifying when, how, and where the plan will be executed (Provost & Murray, 2011). The primary stakeholders were the child life specialist, and outpatient registered nurses (RN), orthopedic surgeons, clinic administrators, and cast technicians in the involvement process. During this phase, ongoing planning, consultation, and discussions with the team were essential.

**Gather Information.** An objective of this project was to develop a protocol for VR as a distraction technique during the percutaneous bone pin and/or cast removal procedure. The author conducted an extensive review of literature on children’s perceptions of pain and anxiety and the effectiveness of VR as a distraction technique during pin and/or cast removal and other outpatient procedures. Research noted children who are not cooperative in a medical procedure might require anesthesia which adds a potential risk of side effects (Mallineni & Yiu, 2016). With VR as a nonpharmacologic intervention, research has demonstrated that parents and staff observed less pain and anxiety in children during medical procedures (Le May et al., 2021).

**Interdisciplinary Collaboration in the Development and Evaluation of the Protocol.** One child life specialist coordinated use of VR as a distraction technique and intervention across all the pediatric specialties in the project’s outpatient setting. Gathering information from the child life and pediatric orthopedic departments was essential to collaborate and create an interdisciplinary team with RNs, orthopedic surgeons, clinic administrators, and cast technicians. Based on best practices reported in the literature, a VR protocol was developed, implemented, and evaluated based on identified outcome measures. A meeting was held with stakeholders to review the protocol's benefits and discern the project's feasibility. There was a discussion about all the protocol components with a consensus agreed upon by the participants to proceed.

**Development of a Protocol**. Before this project, there was no formal protocol for the use of VR in the pediatric orthopedic outpatient clinic setting, and some children were not provided the opportunity to use this distraction technique due to scheduling issues. A literature review was essential to apply evidence-based research to implement the VR intervention. A review of the research suggested the development of a project protocol focused on participants between the ages seven and 18, who are neurologically intact, have no cognitive impairment, no history of motion sickness, headaches, dizziness, and can sit up greater than 30 degrees (Jivraj et al., 2020; Le May et al., 2021). The following were the essential components addressed in the protocol:

**Child and Family Participation**. An instructional pamphlet was developed by child life specialist and author and given to the child and family member or caregiver to explain the VR procedure and experience as a distraction strategy during the orthopedic procedure. The child’s pain and anxiety levels were assessed pre-procedure and post-procedure. The author developed a parent and child informational survey to determine eligibility and a post-procedure satisfaction survey. Wong-Baker FACES Pain Rating Scale (WBFPRS), and Child Fear Scale (CFS) scales were utilized to collect outcome data. Instructions were given to the clinic nurses on administering these two tools.

**Role of Child Life Specialists, Healthcare Providers, and Nurses*.*** The protocol outlined expectations and responsibilities of the child life specialist, healthcare providers, and clinic RNs as to the implementation of the VR experience. For example, the child life specialist distributed the informational pamphlet, and the nurses assessed for pain and anxiety using the WBFPRS and CFS instruments. Other healthcare providers were instructed to provide comforting words to the parents and child using the VR and pin and cast removal experiences.

**Staff Education.** A lesson plan was developed, and the author provided a PowerPoint presentation. The staff included child life specialist, nurses, orthopedic surgeons, cast technicians, and clinic assistants.

***Do***

The next phase is the *Do* in the PDSA cycle, which is the test of change, executing the plan (Langley et al., 2009). The proposed change includes activities to implement VR utilization protocol during percutaneous bone pin and/or cast removal in the pediatric orthopedic outpatient setting. This proposal was submitted to the Institutional Review Board (IRB) as a QI study. During the 12 weeks, there will be two phases: Phase 1 - Education and training of the staff, nurses, and orthopedic surgeons by the author and child life specialist, including a PowerPoint presentation to describe the VR protocol. Phase 2 - Implementation of the VR protocol as part of SOC and data collection. Key elements of the protocol included educating the children and parents, providing the VR experience pamphlet, answering their questions, collecting pre-intervention data, implementing the VR distraction during cast or pin removal, and collecting post-outcome measures.

***Study***

The *Study* phase involves gathering the data and analyzing the results (Langley et al., 2009). The goal of this phase was to evaluate the effectiveness of VR as a distraction technique. The data collected via the surveys and questionnaires during the *Do* phase were analyzed using appropriate statistical methods. The author reviewed the statistical findings, and a report was presented to the stakeholders.

***Act***

The *Act* phase in the PDSA cycle involves identifying what was learned and what will be polished in the next cycle (Langley et al., 2009). During this phase, assessment predictions will be evaluated (Langley et al., 2009). After the author analyzed the data, a summary report was shared with the team to educate and obtain feedback. The stakeholders’ review of the report, the project findings, and the author’s recommendations will influence further decision making, such as refinement of the protocol or offering VR distraction as a SOC during cast and pin removal for all patients who meet established criteria. This report and subsequent stakeholder discussions completed the first PDSA cycle and will determine whether this nonpharmacologic intervention will be adapted, adopted, or aborted.

**Review of Literature**

**Background**

The purpose of this project was to provide an evidence-based literature review to support the effectiveness of VR as a distraction technique to reduce procedural pain and anxiety during brief medical procedures in the pediatric population. The PICO question was, “Is VR an effective distraction technique during brief outpatient orthopedic procedures with the pediatric population?”

**Search Methods**

A literature review was conducted to provide an overview of anxiety and pain in children and investigate key factors associated with using VR as a distraction technique to decrease children’s anxiety and perceptions of pain during medical procedures conducted in ambulatory healthcare settings. The following databases were searched for publications: CINAHL, Pubmed, Psychoinfo, and Google Scholar. Boolean operators further narrowed search topics by including “AND” and “NOT.” MeSH terms used in combination of these terms included: virtual reality, distraction, pain, anxiety, procedure, efficacy, children and not adults, surgery, chronic pain, and VR glasses, as shown in the PRISMA flow diagram (Appendix B).

All research articles were screened for inclusion and exclusion criteria. The inclusion criteria included: English language and peer-reviewed articles published from January 2016 through March 2021. To accomplish the literature review, the focused content areas included VR efficacy during brief pediatric medical procedures, children’s perceptions of pain, anxiety, and parental or child/adolescent satisfaction using VR as a distraction tool. Eight peer-reviewed journal publications were selected for review, as shown in Appendix B. This section summarizes the research findings of the eight studies and concludes with recommendations for VR efficacy and implementation in the clinical setting.

**An Overview of Pain and Anxiety in Children**

***Pain***

Pain is a subjective experience influenced by an individual’s society, culture, and environmental factors (Koç Özkan & Polat, 2020). Pediatric medical procedures may be painful and result in anxiety and fear. When pain experiences begin at a young age and are poorly managed, there are associated negative and long-term consequences that can continue into adulthood, affect pain awareness, and result in increased physical complaints and disturbances in growth and development (Arane et al., 2017). Children with inadequate pain control may also delay future medical care (Short et al., 2017). Early childhood painful experiences associated with medical procedures may cause reluctance to participate in future medical care during adulthood.

In treating pain, common pediatric pharmacologic analgesia includes over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDS) (Nuelle et al., 2020). For intense pain, medication management may include opioid therapy, which is known to have a high tolerance and dependence risk (Arane et al., 2017). Adverse effects are possible with opioid use, including nausea, constipation, respiratory depression, and cognitive impairment (Arane et al., 2017). With brief procedures conducted in the outpatient department, topical cream is used to decrease pain during venipuncture (Dumoulin et al., 2019; Gerçeker et al., 2021). Cast and bone pin removal procedures are considered brief procedures that are not as painful as other procedures conducted in the outpatient setting. However, children undergoing unfamiliar procedures may believe they are painful, leading to heightened awareness and misperceptions of potential pain that create a distressing environment (Gerçeker et al., 2021).

The assessment of pain in children is the “fifth vital sign” (Birnie et al., 2019). In 1983, Wong and Baker developed the WBFPRS to help children effectively communicate about their pain (Birnie et al., 2019; Garra et al., 2010). WBFPRS is a pain scale commonly used in children over 3 years and adolescence to monitor and improve pain management (Appendix C). Researchers have used this scale to determine the efficacy of pain management interventions. The scale allows the patient to self-report and identifies the level of pain. Garra et al. (2010) conducted a prospective, observational study of children ages eight to 17 who presented to a pediatric emergency department with acute pain. A total of 120 patients were assessed. These researchers compared the WBFPRS to the validated visual analog scale (VAS) and found a correlation of r=0.90; 95% confidence interval [CI] = 0.86 to 0.93). Establishing a baseline pain level in children and determining post-intervention pain levels allows the healthcare team to evaluate the effectiveness of interventions to eliminate or minimize the discomfort of common procedures such as percutaneous bone pin removal.

Nonpharmacological methods to decrease children’s pain are categorized as behavioral, physical, or cognitive/behavioral interventions (Koç Özkan & Polat, 2020; Short et al., 2017). The first essential strategy focuses on behavioral techniques such as parental teaching or procedural preparation. The second type of intervention involves physical techniques such as positioning for comfort, deep breathing, massage, or cold application (Koç Özkan & Polat, 2020). The third type of strategy includes cognitive or behavioral methods, including distraction techniques such as listening to music, using VR goggles, and software programs that create a simulated experience or calming environment (Koç Özkan & Polat, 2020). Distraction methods help to redirect children to focus from the painful medical procedure to a visual experience with VR, which may reduce the child’s perception of pain and anxiety.

***Anxiety and Fear***

Anxiety and fear are negative emotions that arise when there is a threat in a life situation. Children commonly experience these emotions during medical procedures, which may be viewed as a threat to the body. The fear of what will happen during an unfamiliar procedure may escalate and result in a heightened perception that the procedure will be a painful event (McMurtry et al., 2011). Exposure to strangers, such as the healthcare team and anticipation of the unknown before a medical procedure can also increase the child’s level of anxiety.

The Children’s Fear Scale (CFS) is commonly used to assess anxiety and fear (McMurtry et al., 2011). The CFS is based on the Faces Anxiety Scale (FAS), developed to measure anxiety or fear in adults in the intensive care unit (McKinley et al., 2003). The CFS instructions for use were adapted from those of the FAS to align with age and fear-related appropriate vocabulary (McMurtry et al., 2011). Appendix D contains a copy of the FAS and instructions for its use. There is no gold standard for assessing procedural anxiety or fear in the pediatric population. While the CFS is not fully validated, McMurtry et al. (2011) found the CFS to have moderate interrater reliability (rs=.51, p<.001) and test-retest reliability (rs=.76, p<.001) for measuring children’s fear during venipuncture.

Common pediatric orthopedic outpatient procedures such as cast removal or splint application are painless but may cause anxiety in children (Jivraj et al., 2020). The equipment, buzzing noise of the saw, and the unfamiliar procedures involved in cast removal may induce fear and anxiety in the child. Inadequate management of anxiety may create a stressful situation for the child, parent, and the healthcare team. It may also delay the time to complete the brief procedure if the child cannot cooperate.

**VR as an Effective Distraction Tool**

Eight randomized controlled trials (RCT) were selected as relevant to the framework of the project. Seven of the eight studies looked at the effectiveness of VR and the reduction of pain in children (Dumoulin et al., 2019; Gerçeker et al., 2020; Gerçeker et al., 2021 Gold & Mahrer, 2018; Koç Özkan & Polat, 2020; Semerci et al., 2021; & Walter-Larsen et al., 2019). Five of the RCTs (Dumoulin et al., 2019; Gerçeker et al., 2020; Gerçeker et al., 2021; Gold & Mahrer, 2018; Koç Özkan & Polat, 2020) investigated both anxiety and pain, while one RCT only investigated anxiety (Jivraj et al., 2020). Five RCTs examined VR experience satisfaction (Dumoulin et al., 2019; Gerçeker et al., 2020; Gold & Mahrer, 2018; Jivraj et al., 2020; & Walter et al., 2019). Of these five RCTs studies, three examined both parent and child satisfaction (Dumoulin et al., 2019; Gerçeker et al., 2020; Gold & Mahrer, 2018), while two investigated only children’s satisfaction with their VR experience (Jivraj et al., 2020; Walter-Larsen et al., 2019). Each of these RCTs provided valuable findings to use in developing a project’s VR protocol. Each of the articles is discussed related to the effect of VR distraction on children’s level of pain and anxiety during outpatient medical procedures and parent or child satisfaction with the VR experience.

**Pain, Anxiety, and Satisfaction**

Seven RCTs reviewed for this project investigated the efficacy of VR distraction in reducing children’s pain level during outpatient procedures. Dumoulin et al. (2019) studied the use of VR distraction during needle insertion procedures in 59 children between the ages of eight to 17 years, with a mean age of 13.37, who was admitted to a children’s hospital emergency department. This convenience sample was randomized into the experimental group that used VR as a distraction mode, with the control groups assigned to watching television or SOC distraction by a child life specialist. The authors created two visual analog scales (VAS) to measure pain intensity and anticipatory anxiety pre and immediately post-procedure. Dumoulin et al. (2019) reported that VR distraction was an effective way to distract children during medical procedures; however, the results were not statistically significant (p=0.08) in the reduction of pain intensity scores between the two groups. Their study did not assess for anxiety; however, they reported increased satisfaction by the children (p < 0.01) and no statistical difference in parent satisfaction. Limitations in the study include the wide age range and a single setting, the emergency department, which is an uncontrolled setting that can impact the reliability of using VR as an intervention by staff. In addition, only 75% of the patients requested to use a topical pharmacologic anesthetic agent that may have affected their level and reports of pain.

Gerçeker et al. (2021) studied VR efficacy in 42 participants between the ages of six to 17 years undergoing procedures in a pediatric hematology setting. Children were randomized into an experimental group receiving VR as a distraction technique and a standard care group during port needle-related procedures. Children’s pain levels were measured after the procedure using the WBFPRS. Anxiety and fear scales used included Children’s Anxiety Meter (CAM) and CFS, respectively. There were statistically significant differences (p< .001) in reduced levels of pain (2.4 ±1.8, and 5.3 ±1.8), fear (0.8 ± 0.9 and 2.0 ±1.0), and anxiety (2.9 ±2.0 and 5.4 ± 2.0) scores in the VR group compared to the control group. This study did not assess child or parent satisfaction. Limitations noted were that participants had prior experiences with needle-related procedures, and a wide range of ages and developmental stages can influence children’s perception of pain, fear, and anxiety.

In Gold and Mahrer’s (2018) RCT, VR efficacy was investigated in a sample of 143 children and youth randomized into a control or VR group. The sample included children between the ages of 10 to 21 years who were scheduled for a routine blood draw in an outpatient pediatric phlebotomy setting. Patients and caregivers assessed pain and anxiety in addition to satisfaction in the VR and SOC groups. Additionally, the phlebotomists’ responses were evaluated post-procedure regarding their perception of patient pain, anxiety, and cooperation, as well as whether the phlebotomist would use VR with future patients (Gold & Mahrer, 2018). The study findings demonstrated patients in the VR group experienced significantly less procedural pain as measured by the pain VAS (p=.001), Pain Color Analogue Scale (p<.001), and Faces Pain Scale-Revised (p<.001). Patients in the VR group also had significantly lower anxiety VAS scores (p<.001) and Facial Affective Score (p<.001) compared with SOC scores. The authors reported that children who had high anxiety sensitivity showed greater benefit from the use of VR in comparison to those children with low anxiety sensitivity (p<.001) (Gold & Mahrer, 2018). Phlebotomists, patients, and caregivers reported high levels of satisfaction regarding the feasibility and utility of VR. Limitations in this study included the wide age range of participants, lack of blinding of study personnel, and phlebotomist assessment of participants during the procedure, which may have impacted the results. It is also possible that there may have been unintentional inaccuracies in the phlebotomists’ reports of patient experiences.

A comparison of the use of VR, a kaleidoscope, and SOC was investigated by Koç Özkan and Polat (2020). Their study investigated perceptions of pain and anxiety in 135 participants between the ages of four to 10 years during routine health visits that required a venipuncture procedure. WBFPRS and VAS were used to assess pain, while CFS was used to assess anxiety. Koç Özkan and Polat (2020) found statistically significant differences in pain (1.97 ±1.2 and 2.95 ±1.9; p =.000) and anxiety (0.43±0.5 and 0.93±0.8, p=.000) scores when comparing the VR group with the kaleidoscope and SOC groups. Limitations in this study included not using a double-blind method as researchers and nurses were aware of children’s groups. In addition, participant or parent satisfaction was not addressed.

Gerçeker et al. (2020) compared to pain, fear, and anxiety levels in children during blood draws at a hospital. There were 136 participants between the ages of five to 12 years divided into three groups: two VR groups using different visual and audio theme software programs, either a rollercoaster or ocean rift environment and a third SOC group. There were 136 participants between the ages of five to 12 years. The WBPFRS was used to assess pain, CFS assessed the level of fear, and CAM measured anxiety. The researchers reported statistically significant differences in pain scores as self-reported by children and in parent and nurse assessment scores of children’s pain levels comparing the two types of intervention – VR and SOC (p=.000). Significant differences were noted in fear and anxiety scores in both VR groups after blood draws (p<.05).

Semerci et al. (2021) investigated the effect of VR distraction on pain during venous port access in 71 pediatric oncology participants between the ages of seven and 18, who were randomly assigned to a VR intervention group or control group. After the procedure, participants reported their pain level using the WBFPRS. Results showed significant differences in the VR intervention group compared to the control group (2.34 ± 2.76 versus 5.03 ± 3.35; p<.001). The study’s generalizability is limited as a nurse and a pediatric oncology assistant performed the venous port access procedures at a single hospital. Although parents were present in the SOC group, there were no topical medications used to reduce pain during the procedure in either group, as topical anesthetics are not routinely used for venous port access in Turkey. Participant and parent satisfaction were not addressed in this study.

Walter-Larsen et al. (2019) conducted a study in a university teaching hospital anesthesia department with 64 children between the ages of seven to 16 years undergoing needle procedures. They were randomized into two groups, the experimental VR group, and the control SOC group. There was no significant reduction in VAS pain scores when comparing VR and SOC groups undergoing intravenous catheter placement in the preoperative setting. However, the study found high satisfaction levels, with 100% of participants who used VR stating they would request it for future procedures. There was no difference in pain scores or procedure times in both groups. Limitations of this study were that it included more males than females (88.1% versus 11.9%), a wide age range, and anxiety was not assessed, which may impact results when children obtained venous cannulation before anesthesia.

Jivraj et al. (2020) studied VR use in reducing anxiety during cast removal in 90 participants aged four to 18. Anxiety was assessed during the procedure using the Children’s Emotional Manifestation Scale (CEMS). The Short State Anxiety Inventory Scale (SSAIS) was used to measure anxiety immediately before and after the cast removal. Given the wide age range of participants’ psychosocial development, the researcher stratified the groups according to age: four to seven years, eight to 12 years, and 13-18 years. Findings revealed a lower baseline level of anxiety in the older patients in the eight to 12-year-old and 13 to18 year-old-groups. However, all groups still experienced a significant reduction in patient anxiety in the VR group during the cast removal (p=0.03) and post-procedure (p=0.01). Patient satisfaction scores indicated that 90% of patients would use VR again. Jivraj et al.’s (2020) research was the first study to use VR distraction in a pediatric orthopedic outpatient setting. The wide age range may have influenced the degree of children’s anxiety at baseline, understanding of VR equipment uses, and VR understanding by participants. Pain levels were not assessed in this study. Including this variable may have led to a better understanding of the overall VR experience. The researcher noted that the intraprocedural anxiety assessment was time-consuming in a busy outpatient clinic.

**Summary**

VR is an advanced technology that produces an immersive simulated 3-dimensional virtual environment. The equipment incorporates a head-mounted display and a thick pair of goggles. The effectiveness of redirecting a patient’s attention from the feared stimulus or symptom toward a more interesting stimulus is demonstrated in VR experiences. As a result, the perception of pain and anxiety is decreased.

Brief medical procedures may cause pain and anxiety that affect future healthcare adherence to follow-up clinic visits or cause avoidance or delayed care. The literature review supported VR as an effective distraction technique to reduce perceptions of pain and anxiety in children undergoing minor procedures in outpatient settings. The literature strongly supports the efficacy of VR as a strategy to reduce perceptions of pain and anxiety in children and reports high levels of parental satisfaction with its use. It has been demonstrated to be an efficacious and safe distraction intervention for children undergoing procedures in various specialty healthcare settings and departments such as hematology-oncology, orthopedic center, burn center, and emergency medicine (Chan et al., 2019; Das et al., 2005; Dumoulin et al., 2019; Dunn et al., 2019; Jivraj et al., 2020; Semerci et al., 2021).

**Methods**

The purpose of this QI project was to develop, implement, and evaluate the effectiveness of the VR protocol for pediatric orthopedic patients undergoing a cast or percutaneous bone pin removal procedure. Effectiveness was measured using four outcome measures: children’s perceptions of pain and anxiety related to the procedures and children’s and parent’s overall satisfaction with this distraction technology. The PDSA model guided the process for this QI project. This section describes the QI design, setting, sample population, ethical considerations, measurement instruments, and procedures. This section addresses pre and post-procedure measures used to evaluate VR efficacy in reducing children’s pain and anxiety and the post-procedure measure of satisfaction with the VR experience. The analysis and evaluation plan is also outlined.

**Project Design**

This QI project involved the collection of data pre- and post-implementation of a VR distraction experience during a common orthopedic procedure. It focused on children’s perceptions of pain and anxiety and overall satisfaction and the effect of VR distraction on children’s pain and anxiety levels during cast and/or pin removal in one pediatric orthopedic outpatient clinic. The Starlight VR program was chosen for the project as it has an established history as a VR platform that has been used successfully in children’s hospitals. It offered a variety of video games and scenery to help distract children during difficult medical procedures or assist them in relaxing. The platform has been used in the inpatient units at the project hospital and sporadically in the hospital’s outpatient clinic area.

**Setting**

The setting for this project was a pediatric orthopedic outpatient clinic in a magnet children’s hospital serving patients in Southern California. The children’s hospital serves approximately 1000 pediatric patients annually who require fracture care that includes casting and cast and percutaneous bone pin removal. Approximately 15 children are seen weekly in the outpatient setting for cast and pin removal procedures conducted in examination rooms decorated in a child and teen-friendly manner.

**Participants**

Parents whose children were returning for follow-up fracture care and who required cast or bone pin removal procedures were approached by the child life specialist to participate in the project. Inclusion criteria included children ages seven to 18 years old and English speaking and whose parents were also English speaking. Exclusion criteria included participants with known cognitive, visual, or hearing impairment, history of seizures, or children who did not give their assent or their parent or legal guardian declined to consent. Children could also withdraw from the VR intervention if they experienced unfavorable or unintended signs or symptoms associated with the equipment. Additionally, a child would have been withdrawn from the project if consent or assent had been withdrawn or if the healthcare team believed the child was unable to continue; however, this did not occur. Approximately 30 children were selected using a convenience sample of pediatric clinic patients.

**Ethical Considerations**

Approval of this QI project was granted by the IRB at both the project site and California State University Long Beach. Ethical considerations for this project included parental consent and child assent. Children ages seven and older were also required to give their assent to participate in the VR distraction technique. Copies of the recruitment script, the parental consent and child assent forms, and the institutional approvals are located in Appendices E, F, and G, respectively. Enrolled patients were assigned a unique code, and data collected on the outcome measures were stored in an Excel file on a secured password computer.

**Development of Protocol and Instructional Materials**

The author conducted an extensive literature review of children’s perceptions of pain and anxiety and the effectiveness of VR as a distraction technique during brief medical procedures. The literature provided key elements on which the framework of the VR protocol was based. In addition, a child life specialist employed in the setting with expertise in VR distraction techniques provided consultation in developing the protocol. The VR protocol was submitted for review and approval to the chair of pediatric orthopedic surgery and the director of the child life department. As needed, they edited the author’s work related to the specific requirements of the pediatric orthopedic and child life departments and approved the final version of the protocol (Appendix H).

Instructional materials were developed by the author and the child life specialist. Four key components included the child and parent VR pamphlet, equipment use instructions, and video instructions (Appendix I).

**Stakeholder Education**

Education of orthopedic surgeons, RNs, cast technicians, and administrators regarding VR protocol was an important component of the successful implementation of this intervention. These stakeholders were given an in-service education regarding the VR protocol as a distraction technique. The author and child life specialist assigned to this project developed training materials and conducted a fifteen-minute educational session for stakeholders (Appendix J). Before initiating the pilot project, the VR PowerPoint presentation was made available to all stakeholders.

**Measures**

***Data Measures***

Before the procedure, demographic information was collected on age, gender, and relationship to the child (Appendix K). The author, child life specialist, and/or RNs collected the pain and anxiety ratings and the VR satisfaction survey at the end of the procedure before the parent and child left the examination room. The surveys were secured in a locked office in the department

***Wong-Baker Faces Pain Rating Scale***

The WBFPRS (Appendix C) was used to assess children’s self-reported pain. The tool was developed for use by children aged three and older to rate the severity of their pain on a numeric scale ranging from zero to ten, with zero being no pain and ten the worst pain. This scale has been validated in children between three to 18 years old and demonstrated strong reliability in rating children’s pain (Wong & Baker, 1988). The WBFPRS has been utilized in pediatric hospitals throughout the United States as a primary pain assessment tool and is a reliable and valid measure of acute pain. Validity and reliability agreement between VAS and WBFPRS was demonstrated in the assessment of acute pain in a study of children seen in the emergency department, r=0.90; confidence interval [CI} = 0.86 to 0.93 (Garra et al., 2010).

The clinic’s RNs documented the child’s reported pain level on the project VR data form using the WBFPRS tool. The RN asked the child to identify their pain level immediately before the VR headset placement. Immediately after the headset was removed, the child was asked to rate their pain.

***Child Fear Scale***

The CFS is a self-reported measure of fear adapted specifically for use in children from the adult Face Anxiety Scale (McMurtry et al., 2021). This scale is a one-item self-report that measures anxiety-related fear in children. This tool consists of drawings depicting five faces representing various pictorial adaptations of fear. The five faces are given a numerical score, ranging from zero (no look of facial fear/anxiety noted) through four (depiction of an extremely fearful/anxious facial look). The order of faces demonstrates no fear on the left and extreme fear on the right faces with a zero-to-four-point scale (Appendix D).

The child was asked by the clinic nurse to rate their level of anxiety after providing a pain rating and immediately before VR headset placement. Immediately after the headset was removed, the child was asked to rate their level of anxiety after providing their pain rating. The nurse recorded the child’s response indicating the level of anxiety pre-procedure and post-procedure. This scale was demonstrated to be a valid and reliable measure of anxiety related to fear in two RCTs. Gerçeker et al. (2020) studied the effect of VR in children from age five-12 years who underwent blood draw. Another study involved the effect of VR in children from age six-17 years underwent porta-catheter access(Gerçeker et al., 2021).

***Child and Parent Satisfaction Survey***

Following the procedure, the child and parent or guardian completed the author-developed satisfaction survey. Parents received instruction to answer three questions related to their overall satisfaction with their child’s VR experience using a Likert five-point scale (Appendix L). The children's survey assessed five areas related to their satisfaction with the VR experience in reducing their pain and anxiety levels. The choices represented a modified Likert scale that a child would understand. This project’s author developed both self-report tools that were reviewed by an expert panel for agreement and consensus.

**Project Protocol and Procedures**

The project protocol involved four steps: reading a script to potential participants, discussing the informational brochure given to the parents, instructing the child and family members on the VR experience steps, and collecting pain, anxiety, ad satisfaction data. Parents of eligible children were approached at the orthopedic outpatient clinic by the child life specialist and/or author, who provided an overview of the purpose of the project using a written script describing the Starlight VR experience. Children who provided assent and parents who provided consent were educated with the VR procedure pamphlet and introduced to the Starlight Xperience Software and VR goggles by the author or child life specialist. The VR headset played an immersive, interactive scene chosen by the child life specialist to ensure maximum interest or by the child to ensure maximum interest. There were a variety of VR software programs of various lengths with or without controllers that the child could select from to view. The child life specialist and the author reviewed the materials and answered questions the parent and child had about the VR experience.

The third part of the protocol included the role of the child life specialist when the child was in the examination room. She ensured the equipment was used appropriately and the child understood how to work the controller after providing instructions about how to use and adjust the controller. The procedures are outlined in part three of the protocol.

The fourth part of the protocol involved the collection of data. The RNs assessed the pain and anxiety pre-procedure level using the measurement tools. The VR intervention began 30 seconds before starting the procedure and lasted about two to three minutes until the procedure was complete. The parent or guardian was present throughout the procedure. Immediately following the procedure, the RN asked and recorded the pain and anxiety levels and handed the child and parent or guardian the VR satisfaction survey. The child life specialist was responsible for collecting the paper and pencil forms that contained the pain and anxiety rating scores and post-satisfaction surveys and secured them in a locked area of the department. The only identifying information on the three forms was a de-identified patient number matched with the child’s medical record number. The author secured the data forms and de-identified the patient form number.

**Data Collection and Analysis**

The data analysis plan involved using descriptive and inferential statistics using the Intellectus software program. The clinical impact of VR on the pain and anxiety levels among children undergoing pin and/or cast removal was analyzed using paired t-tests. Descriptive statistics, including mean, standardized deviation, and percentages, were used to describe thedemographic data that included age, gender, and history of pediatric orthopedic fractures within the past year, procedure type-cast or pin removal, and if the mother, father, or guardian was present during the procedure. Satisfaction scores of parent and child were analyzed using descriptive statistics.

**Results**

Demographic and post-procedure child and parent satisfaction descriptive statistics are presented, as are the results of a two-tailed paired t-tests analysis of pre- and post-WBFPRS and CFS assessments scores. Recruitment occurred between March 21, 2022, and April 8, 2022. The author sought permission from 37 parents and their children to participate in this quality improvement program. Because six children preferred a different distraction modality, they were not included in this project. A seventh child, an adolescent, preferred to watch the procedure without using VR distraction and was also not included.

**Demographics**

A convenience sample of 30 children and parents participated in the project. The average age of the children was 10.10 years (SD 2.29), with a range of ages from seven to 14 years, and 70% (n=21) of the participants were male. Ninety percent (n=27) of the orthopedic procedures were cast removals, with 10% (n=3) involving percutaneous pin removals. Mothers represented most of the parents (n=23, 76.67%) present during the VR experience.

**Pain Assessment**

The RNs used the WBFPRS and asked the child to point at the face that identified the child’s pain level with facial representations corresponding to a scale of 0 to 10. One child who had a pin removal procedure reported a pre-procedure pain score of 2. The other 29 participants reported no pain pre-procedure. Post-procedure, three of the 30 reported pain. The child who reported pain pre-procedure also reported pain (level 2) after the pin removal. The other two described their pain as stiffness after their casts were removed that was unrelated to the procedure. A two-tailed paired t-test was performed with no statistical difference between children's pre- and post-pain assessment (t=1.44; p=1.61) (Table 1 and Figure 1, Appendix M).

**Anxiety Assessment**

Anxiety was assessed by the RNs using the CFS with pictures representing the fear scale scores of 0 to 4. The t-test findings demonstrated a significant statistical difference in fear levels from pre- to post-VR experience (t=5.52; p<.001). The patient population's pre- and post-procedure anxiety assessments are displayed in Table 2, Figure 2, Appendix M.

**Parent and Child Satisfaction with VR Distraction**

The post-procedure child and parent satisfaction scores are displayed in Appendix M. Parents were asked whether they would use VR again for their child. Most parents reported a high level of satisfaction and would have their child use VR again in the future. Five (16.67%) answered they agreed (n=5), and 80% (n=24) indicated they strongly agreed they would use VR distraction again (Table 3, Appendix M). One parent’s responses to the satisfaction survey did not match the parent’s written comments about the VR experience. The parent wrote the child’s experience was “great”; however, the responses to the survey queries were negative. It may have been that the parent was confused by the scoring rubric

Similarly, there was a high level of satisfaction among the children with using the VR distraction experience. When asked whether VR helped the child feel less anxious during the procedure, 86.7% (N=26) reported it helped a lot, and 13.3% (N=4) responded a little. Twenty-nine (96.8%) children indicated they would use VR again for future medical procedures. The patient survey results are displayed in Table 4, Appendix M.

**Discussion**

The purpose of the quality improvement project was to develop, implement, and evaluate the effectiveness of a VR protocol for use with pediatric orthopedic patients undergoing a cast or percutaneous bone pin removal procedure. The PDSA cycle guided all phases of the project to achieve its objectives. A convenience sample was selected and offered the VR experience to decrease their pain and anxiety during the removal procedure. The data demonstrated that there was overwhelmingly positive support from parents and their children for the use of VR as a distraction strategy. The pain scores revealed no improvement as 29 children reported no pain at the start of the procedure, and 27 reported no pain at its conclusion. The anxiety scales were significantly improved with the use of VR. The results demonstrated in this study– lower anxiety scores - were similar to those of Jivraj et al. (2020), who saw significantly decreased anxiety during cast removal.

Pediatric healthcare providers seeing children in clinic visits for cast removal would not expect children to report pain before or after the procedure as cast removal is not considered a painful experience per se. However, children may have preconceived notions that cast and pin removal is painful. The results of this study were consistent with this assumption, as 29 out of the 30 participants reported no pain before the procedure, and 27 reported no pain after their procedure. Two children reported pain and described their pain as stiffness after the removal of the cast.

The Gerçeker et al. (2020) VR study demonstrated a significant reduction in pain scores following a venipuncture procedure, which is often associated with pain, especially for children, unlike cast removal, which is not painful per se. Jivraj’s study (2020) on the effect of VR only assessed anxiety and not pain during cast removal; however, he did recommend that future studies in this area should also assess pain as an outcome measure. Jivraj et al. (2020) did not study percutaneous pin removal, which may be associated with pain during this brief procedure. Therefore this project included an assessment of pain in addition to anxiety assessment in children undergoing either cast or percutaneous pin removal procedures.

All of the VR studies reviewed for this project (Gerçeker et al., 2020, Gerçeker et al., 2021; Gold & Mahrer, 2018; Koç Özkan & Polat, 2020;) discussed the reduction of anxiety, which was also an outcome measure of this study. The significant reduction in anxiety scores seen in this project was consistent with the results of the research studies reviewed for this project that used the VR experience as an intervention strategy (Gerçeker et al., 2020, Gerçeker et al., 2021; Gold & Mahrer, 2018; Koç Özkan & Polat, 2020).

Of note, the VR protocol helped identify appropriate candidates for VR distraction and established the procedure for instructing parents and children about using the equipment. Education about selecting children and VR procedures has implications for future training of RNs, Nurse Practitioners, and other healthcare providers who may need to step in and use the VR equipment if a child life specialist is unavailable. There was enthusiastic buy-in from the orthopedic surgeons, RNs, orthopedic cast technicians, and staff, and no reports of delays in the time allotment for these procedures.

**Recommendations**

The recommendation was made to the stakeholder group that a child life specialist be available Monday through Friday versus three days a week to provide the VR experience for all eligible pediatric patients. The project findings supported that the VR experience should be consistently used and its utilization expanded and offered to children in other ambulatory outpatient settings where brief minor procedures are performed. The author recommended that RNs be trained to use the VR equipment and provide additional support if multiple procedures occur simultaneously and the child life specialist is working with another child. Based on the positive response from the children and parents, arrangements were made to purchase Oculus VR systems for adolescents. With this purchase, an additional wide range of age-appropriate adolescent distraction videos will be available for selection by the older pediatric population.

Similar to the findings of Jivraj et al. (2020) related to using VR with cast removal, this study also demonstrated VR as an effective distraction technique in reducing anxiety levels. The results are in line with other studies in

volving its use in pediatric subspecialty clinics, such as hematology-oncology, and in caring for patients undergoing procedures related to burn care management and venipuncture (Gerçeker et al., 2020, Gerçeker et al., 2021; Gold & Mahrer 2018; Koç Özkan & Polat, 2020).

Two children did report post-cast removal pain scores of two and characterized their pain as stiffness; one child undergoing pin removal had a score of two pre and post on the WBFPS. To best evaluate the effect of VR as a distraction technique, this author recommends that future studies on this subject should have the pediatric participants assess their pain and anxiety levels using the pain and anxiety tools before, during, and after the procedure. A future study should involve pediatric subjects undergoing pin removal as this project only had three subjects. One wonders whether their pain scores may be higher during or after the procedure. Further explorations should assess, and document organizational issues related to the use of VR, such as its effect on workflow and time management.

Parents and their children’s responses were overwhelmingly positive when asked if they would request to use VR as a distraction technique during future medical procedures. Future studies should evaluate the perceptions of the healthcare team about the feasibility of using VR as a distraction technique and its impact related to time constraints and efficiency in a high workflow pediatric orthopedic clinic.

**Implications**

Nonpharmacological approaches are used in the hospital and ambulatory settings to decrease anxiety and pain experienced by children. VR is gaining acceptance as an effective intervention during minor procedures associated with pain or anxiety, or both. Stakeholders – nurse practitioners, RNs, orthopedic surgeons, child life specialist, and orthopedic cast technician - involved in this project have enthusiastically embraced its use based on their verbal feedback. They have advocated for VR to be added as another distraction tool for children and adolescents undergoing selective procedures in outpatient clinic settings beyond the orthopedic clinic. Based on the success of this project and the findings of the other studies in the literature review, VR distraction is an effective intervention that can be used in numerous outpatient settings during brief procedures to reduce patient anxiety.

**Limitations**

Limitations of this QI project were the lack of a control group and a convenience sample limited to 30 patients, of whom only three had percutaneous pin removals. Other limitations included English-speaking children and parents, whereas the project setting services many Hispanic patients. By asking the participants to complete the satisfaction survey in the procedure room, there may have been social-desirability response bias knowing that they would hand their surveys back to the author or the child life specialist. Only one child life specialist trained in VR distraction limited the opportunity to offer VR when more than one child was having the removal procedure at the same time in the clinic.

**Conclusions**

Interprofessional collaboration among the RNs, child life specialist, and orthopedic surgeons was strengthened during all phases of this project. Their committed partnership was essential for its success. There were no comments voiced to the project author or child life specialist about problems with the VR distraction intervention extending the time for or delaying the procedure. The anxiety levels of children ages 7 to 14 who participated in this project were significantly reduced, which supports the effectiveness of VR distraction during cast removal. None of the 27 children undergoing cast removal reported pain before the procedure; two reported pain described as stiffness after cast removal. There were only three subjects undergoing pin removal. This group of children should be more closely studied to compare their pain and anxiety scores to determine if the two procedures differ in pain and anxiety responses. Parent and child satisfaction responses supported using VR as an effective distraction technique for reducing participant anxiety levels during cast and pin removal. Finally, the family-centered approach required for VR engaged parents and children in a positive experience that significantly lowered the child’s level of anxiety.

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**Appendix A**

**PDSA Cycle**

Diagram

Description automatically generated

Note. *The Model for Improvement was developed by W. Edwards Deming and directs an approach to incorporate three questions that focus on rapid improvement attempts (IHI, 2021).*

**Appendix B**

**PRISMA Flow Chart**

Studies included in quantitative synthesis  
(n =8)

Records excluded  
(n = 15)

Records screened  
(n = 30)

Records after duplicates removed  
(n =295 )

## Identification

## Eligibility

## Included

## Screening

Records identified through database searching  
(n = 30 )

Additional records identified through other sources  
(n =349 )

Studies included in qualitative synthesis  
(n = 0 )

Full-text articles assessed for eligibility  
(n =15 )

Full-text articles excluded, with reasons  
(n = 7)

Not adults related articles

Not chronic pain related articles

Not surgery articles

Not VR glasses related articles

**Appendix C**

Diagram

Description automatically generated

**Appendix D**

**Children’s Fear Scale (CFS; McMurtry et al., 2011)**

Shape

Description automatically generated

**Children’s Fear Scale (CFS; McMurtry et al., 2011)** and Author Permission to Use

**Instructions for Children:** “These faces are showing different amounts of being scared. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [point to the last face on the right]. Have a look at these faces and choose the one that shows how scared you were during [the needle].”

**Score the chosen face from 0 to 4.**

Sources: Please cite the CFS Initial Validation Study: McMurtry, C.M., Noel, M., Chambers, C.T., McGrath, P.J. (2011). Children’s fear during procedural pain: Preliminary investigation of the Children’s Fear Scale. Health Psychology, Advanced Access Online. Adapted from the (adult) Faces Anxiety Scale: McKinley, S., Coote, K., & Stein-Parbury, J. S. (2003). Development and testing of a faces scale for the assessment of anxiety in critically ill patients. Journal of Advanced Nursing, 41, 73-79. For more information: contact C. Meghan McMurtry at [cmcmurtr@uoguelph.ca](mailto:cmcmurtr@uoguelph.ca)

**Appendix E**

**Script: Virtual Reality Goggles for Cast and Pin Removal**

We are seeking permission from parents who may wish to have their child participate in a virtual reality distraction technique during the child’s cast or pin removal. We are studying children’s perceptions during this experience and parent’s and children’s perceptions of its benefit.

We are using virtual reality goggles during procedures such as cast removal and pin removal to help your child by creating an entertaining distraction that tries to help decrease their fear, anxiety and pain during the procedure.

Your child is able to see a virtual environment while blocking out their vision of the procedure while it is performed. The goggles are safe to use, though some patients may experience nausea or dizziness while using them. If your child has a seizure disorder, your child should not participate in this activity. Instead, we will find other means of distraction such as books or bubbles with our child life specialists.

Our child life specialist will present your child with two different virtual environments to choose from while they wear the goggles. They will spend a few minutes getting used to the VR environment. We then perform the procedure once they are comfortable. Once the procedure is completed, we will remove the goggles.

Your child will be asked to rate his/her level of pain and anxiety before the procedure starts and immediately afterwards. Both you and your child will complete a brief questionnaire about the Virtual Reality Experience.

If you would like your child to participate, I will provide you with a parent consent form and a child/teen assent form to sign.

After signing the consent forms, a pamphlet will be given to you with more information about the experience.

Thank you for considering this request to have your child participate in the Virtual Reality experience during their cast or pin removal.

Do you wish to be given the consent forms to read and sign if you so wish.

\_\_\_\_ YES \_\_\_\_ NO

If yes, provide the consent and, if signed, the pamphlet

**Appendix F**

**Parental Consent Form**

You have the option to take part in a Quality Improvement Project. Your participation is voluntary. The goals of this form are to give information about what is expected of you and your child in the study if you choose to take part and to help you decide if you want to be in the study.

We are seeking permission from you for your child to participate in a virtual reality (VR) distraction technique during your child’s cast or pin removal procedure. We are studying children’s perceptions during this experience and parent’s and children’s perceptions of its benefit.

We are using virtual reality (VR) goggles during procedures such as cast removal and pin removal to help your child by creating an entertaining distraction that tries to help decrease their fear, anxiety, and pain during the procedure.

Your child will see a virtual environment while blocking out your child’s vision of the procedure while it is performed. The VR goggles are safe to use, though some patients may experience nausea or dizziness while using them. If your child has a history of motion sickness, headaches, dizziness, or seizure disorder, your child should not participate in this activity. Instead, we will find other means of distraction such as books or bubbles with our child life specialists.

Our child life specialist will present your child with two different virtual environments to choose from while your child wears the goggles. They will spend a few minutes getting used to the VR environment. The child life specialist will then perform the procedure once you are comfortable. Once the procedure is completed, we will remove the goggles.

The Registered Nurse will ask your child to rate his/her level of pain and anxiety before the procedure starts and immediately afterwards. Both you and your child will complete a brief questionnaire about the Virtual Reality Experience.

If you wish your child to participate in this Virtual Reality (VR) experience, please let the nurse know, and the child life specialist will provide you with more information on the VR activity. You will be asked to complete a brief questionnaire about your child’s experience, your satisfaction, and evaluate this experience as a parent.

If you wish to not participate or to stop the VR experience at any time, it will not affect your child’s care. You and your child will not lose any benefits or be penalized if you choose this option. The child life specialist will have an alternate distraction technique available for your child.

XXX Hospital COVID-19 protocols are followed at all times during your and your child’s participation in the study.

Thank you for considering this request to have your child participate in the Virtual Reality experience during their cast or pin removal and completing the parental satisfaction questionnaire.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date and time

**Child Assent**

We are doing this project to help kids like you when they are having their cast or pin removed.

Important things for you to know…

* You can decide if you want to take part-be a volunteer.
* You can say “No” or you can say “Yes.”
* No one will be upset if you say “No.”
* If you say “Yes” you can always say “No” later.
* You can say “No” at any time.
* We would still take good care of you no matter what you decide.
* Your parent will be with you.

We want to learn if wearing head goggles and watching a sea life or outer space video scene, helps you relax while your cast or pin is removed.

The child life specialist will show you and your parent a video of a child in our clinic using goggles while watching a video and having his pin removed.

The child life specialist will help you put the goggles on and show you how to use the video equipment.

The Registered Nurse will ask you some questions before and after the procedure.

After the video is finish, you will be given a piece of paper with some questions, to let us know what it was like for you.

If you feel dizzy or want to stop the video at any time let the nurse of your parent know.

Write your name below if you want to use the goggles and video that will be used for this project.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Write your name here, child

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date and Time

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date and Time

**Appendix G**

**HUMAN RESEARCH PROTECTIONS PROGRAM**

**DETERMINATION OF ACTIVITY NOT REQUIRING IRB REVIEW QUALITY IMPROVEMENT**

**Approval Effective:** January 25, 2022

**MHS Project No.:** 242-22

**Title:** Effect of Virtual Reality Distraction on Children's Anxiety and Pain Perceptions

During Cast and Pin Removal

**Principal Investigator:** Carol Cunningham, MSN, FNP-C, RN

A designated member of the Human Research Protections Program has reviewed the above-indicated application for *Activity Not Requiring IRB Review* and determined the proposed activity meets the criteria for a Quality or Performance Improvement Project.

Quality improvement activities implementing a practice to improve the quality of patient care within XX and collecting patient or provider data for clinical, practical, or administrative purposes must be maintained consistent with applicable rules, regulations, and XX policy related to Quality Improvement. This includes relevant procedures outlined in HRP SOP 303, *Activity Not Requiring IRB Review.*

You are responsible for notifying XX Research Administration prior to implementing changes to the proposed activity as this may affect project determination(s) and status.

When preparing manuscripts of ‘Quality Improvement’ projects for publication or presentation, the submitter should avoid using terminology such as “researched”, “investigation”, or “discovered”. These all suggest that research was conducted and revealed ‘generalizable information’, rather than quality improvement activities designed to improve local processes of care.

Before submitting for publication or presentation, please submit a copy of the manuscript to HRP Office at XX.

Should you require further assistance with this matter, please contact XX.

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Sincerely,



5. Maintain your research records as detailed in the protocol.

6. If you would like to continue this research after this one-year period, please submit an Annual

Check-in Form, and when applicable, updated IRB Application and all relevant project documents to

the CSULB IRB one month prior to your project expiration date of March 18, 2023.

Should you have any questions about the conduct of your research under this protocol, particularly about

providing informed consent and unexpected contingencies, please do not hesitate to contact the IRB

Office via email, IRB@csulb.edu, or call (562) 985-8147. Please specify your project title and reference

number in all correspondence with this committee. We wish you the best of success in your research.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within California State

University, Long Beach Institutional Review Board's records.

1250 Bellflower Blvd., Long Beach, CA 90840

Ph. (562) 985-8147 Fax. (562) 985-8665**Appendix H**

**Virtual Reality Study Protocol**

1. Establish eligibility of patients for enrollment:

Children between 7-18 years of age

Neurologically intact, no cognitive impairment.

No history of motion sickness, headaches, dizziness or seizure disorder

Able to sit >30 degrees.

2. Present Starlight VR brochure and information on study to patient and parents: Child life can show video of patient using VR goggles during pin removal. Explain the Wong-Baker FACESE Pain Rating Scale and Child Fear Scale to patient and parent. Explain goal of study to use VR to decrease the child’s pain and anxiety during the cast or pin removal

3. Nurse to secure pre-procedure WBFPRS and CFS scores

4. Child life specialist will then present the VR goggles and explain their use. The VR program will be selected and the child will begin use of the VR goggles just prior to the procedure start. Once acclimated to the VR, the cast or pin removal will be performed by the appropriate member of the clinical team.

5. Upon completion of the procedure, the VR goggles will be removed.

6. Post-procedure WBFPRS and CFS scores will be obtained by the Registered Nurse (RN). The author, RN, the child life specialist, or cast technician will give the parent/caregiver and child the satisfaction questionnaires to complete before leaving the examination room.

7. Storage of questionnaires will be in a locked Office of Child Life Department and Pediatric Orthopedic Surgery Department at XX

**Appendix I**

**Starlight Xperience Pamphlet for Parent and Child**

The child life specialist performs the following steps to provide the virtual reality (VR) experience. This is done two minutes prior to the beginning of the procedure, and after the physician explains the procedure to child and parent.

1. The patient is given the VR controller to hold in their hands.
2. The headset is placed on the individual with assistance from the child life specialist.
3. The child life specialist turns on goggles by holding down the power button on the right side of the goggles, lights will flash, and the controller will automatically turn on.
4. If necessary, the child life specialist will adjust the goggles at the request of the child. Loosening the headset is achieved by turning the wheel to the left while the patient holds the goggles on their face so the child can find where the picture is clear. Then tightening by turning wheel to the right.
5. If still unclear, the child life specialist will hold the circle button under the goggles (left side) to adjust the distance from the child’s eyes.
6. The child life specialist gives instructions about the controller. There are 4 buttons which include the following: Touchpad: swipe or click to interact; App: game menu, pause, or go back; Daydream: access main menu, dashboard, and settings. Holding it down re-centers the headset & controller; and Volume.
7. The child is instructed to use touchpad to view apps, point, and click to launch.
8. Virtual reality experience continues until the procedure is completed or the child requests to have it stopped.
9. To exit and turn off the software program, press and hold the power button down. The light will flash, then turn off.
10. Maintenance of the VR equipment requires cleaning, using alcohol wipes on the outer plastic and foam areas after each use. Do not use alcohol wipes on the front of the camera, eye lens, and P-sensor (located in between the lens).
11. Charging-Charger contains two ports, one for the headset (located on the left side) and one for the controller (located on the bottom). Headset light will turn orange, controller light will pulse white.

Games:

* Apps for lying down/without controller: Pebbles the Penguin, Space Pups, Asteroid Miner
  + Uses head to steer/jump/aim
  + Use to re-center orientation when lying down
  + Pebbles The Penguin: control penguin sliding down a mountain, never ends
  + Space Pups: a music game, control an astronaut puppy, never ends
  + Asteroid Miner: mine colorful asteroids, never ends
* Apps with controller
  + Passive Experience
    - Invasion!: alien invasion greeted by a cute and heroic bunny
    - Asteroids!: aliens in outer space
    - Ocean Rift: explore underwater world, can use controller to swim around
  + Casual
    - Hello Mars: Mars landing sequence, control a rover, & shuttle landing
    - Wonderglade: carnival mini-games (basketball, mini-golf, racing)
    - LEGO Brickheadz Builder VR: play LEGO characters, objectives
  + Puzzle
    - Bait!: catch fish, objectives
    - Along Together: guide a child through an environment
    - Flutter VR: butterflies, objectives, reading
    - Makorama VR: navigate a robot through 3D puzzles
  + Educational
    - BBC Earth: Life in VR: explore ocean, underwater tour
    - Expeditions: 14 expeditions for a self-guided tour
    - Google Street view: needs Internet, visit points of interest
  + Relaxation
    - Mindfulness-Aurora: narration, sync breathing with the world
* Left-handed: Press  to open Dashboard, click Settings (cog wheel), click Switch to left handed.

**Appendix J**

**Stakeholder Educational Materials**

**Training and Education for Stakeholders**

Learning Objectives

* Understand the VR protocol
* Review the script
* Review the WBFS and CFS, satisfaction surveys
* Data collection

**Review the VR protocol**

1. Establish eligibility of patients for enrollment:

* Children between 7-18 years of age
* Neurologically intact, no cognitive impairment.
* No history of motion sickness, headaches, dizziness or seizure disorder
* Able to sit >30 degrees

2. Present Starlight VR handout and information on study to patient and parents

* Child Life specialist can show video of patient using VR goggles during pin removal.
* Explain the Wong-Baker FACESE Pain Rating Scale and Child Fear Scale to patient and parent
* Explain goal of study to use VR to decrease the child’s pain and anxiety during the cast or pin removal
* If parent/guardian indicates willingness to participate, provide parent/guardian with the consent form and child with the assent form. Allow the parent and child privacy to read and sign in private.
* Collect the forms when signed. If the parent/guardian or child declines, thank them for considering the project.

3. Nurse to secure pre-procedure WBFPRS and CFS scores

4. Child Life specialist will then present the VR goggles and explain their use. The VR program will be selected and the child will begin use of the VR goggles just prior to the procedure start. Once acclimated to the VR, the cast or pin removal will be performed by the appropriate member of the clinical team.

5. Upon completion of the procedure, the VR goggles will be removed.

6. Post-procedure WBFPRS and CFS scores will be obtained by the Registered Nurse (RN). The author, RN, the child life specialist, or cast technician will give the parent/caregiver and child the satisfaction questionnaires to complete before leaving the examination room.

7. Storage of questionnaires will be in a locked Office of Child Life Department and Pediatric Orthopedic Surgery Department

**Request for Participation Script to be Read to the Parent**

We are seeking permission from parents who may wish to have their child participate in a virtual reality distraction technique during the child’s cast or pin removal. We are studying children’s perceptions during this experience and parent’s and children’s perceptions of its benefit.

We are using virtual reality goggles during procedures such as cast removal and pin removal to help your child by creating an entertaining distraction that tries to help decrease their fear, anxiety and pain during the procedure.

Your child is able to see a virtual environment while blocking out their vision of the procedure while it is performed. The goggles are safe to use, though some patients may experience nausea or dizziness while using them. If your child has a seizure disorder, your child should not participate in this activity. Instead, we will find other means of distraction such as books or bubbles with our child life specialists.

Our child life specialist will present your child with two different virtual environments to choose from while they wear the goggles. They will spend a few minutes getting used to the VR environment. We then perform the procedure once they are comfortable. Once the procedure is completed, we will remove the goggles.

Your child will be asked to rate his/her level of pain and anxiety before the procedure starts and immediately afterwards. Both you and your child will complete a brief questionnaire about the Virtual Reality Experience.

If you wish your child to participate in this Virtual Reality experience, please let the nurse know, and I will provide you with more information on the VR activity.

Thank you for considering this request to have your child participate in the Virtual Reality experience during their cast or pin removal.

**Appendix K**

**Demographic Information**

**Child Life Specialist or Registered Nurse to Complete:**

Patient age recorded in years: \_\_\_\_\_\_\_\_

Patient gender: \_\_\_\_\_\_\_\_\_\_\_\_

1= male

2=female

Relationship to child:

Mom: \_\_\_\_

Dad: \_\_\_\_\_

Other: \_\_\_\_

VR scenery: \_\_\_\_\_\_\_\_

Cast removal: \_\_\_\_\_\_\_

Pin removal: \_\_\_\_\_\_\_\_

**Appendix L**

**Child Post Satisfaction Survey   
with VR Experience in Reducing Pain and Anxiety**

Please complete after the procedure. Completion of the survey constitutes agreement to participate. Please do not put your name or identifier on this survey.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **1. When you were using VR did you feel pain?** | No pain | Little pain | Pain | Lots of Pain | Comments |
| **2. When you were using VR did you feel anxious?** | No anxiety | Little anxious | Anxious | Lots of Anxiety | Comments: |
| **3. Virtual Reality (VR) helped to reduce my pain during the procedure** | Yes, it helped a lot | Yes, it helped a little | Not really | Not at all | Comments: |
| **4. Virtual Reality (VR) helped me feel less anxious during the procedure** | Yes, it helped a lot | Yes, it helped a little | Not really | Not at all | Comments: |
| **5. I would use VR again in the future for a brief medical procedure** | Yes | No | Maybe | Unsure | Comments: |

**Parent Post Satisfaction Survey with VR Experience in Reducing Pain and Anxiety**

Please complete after the procedure. Completion of the survey constitutes agreement to participate. Please do not put your name or identifier on this survey.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1. Virtual Reality helped reduce my child’s perception of pain during the procedure** | Strongly disagree | Neither disagree nor agree (Neutral) | Agreed | Strongly Agree |
| **2. Virtual Reality helped reduce my child’s perception of anxiety during the procedure** | Strongly disagree | Neither disagree nor agree (Neutral) | Agreed | Strongly Agree |
| **3. I would have my child use VR again in the future for a brief medical procedure** | Strongly  Disagree | Neither disagree nor agree (Neutral) | Agreed | Strongly Agree |

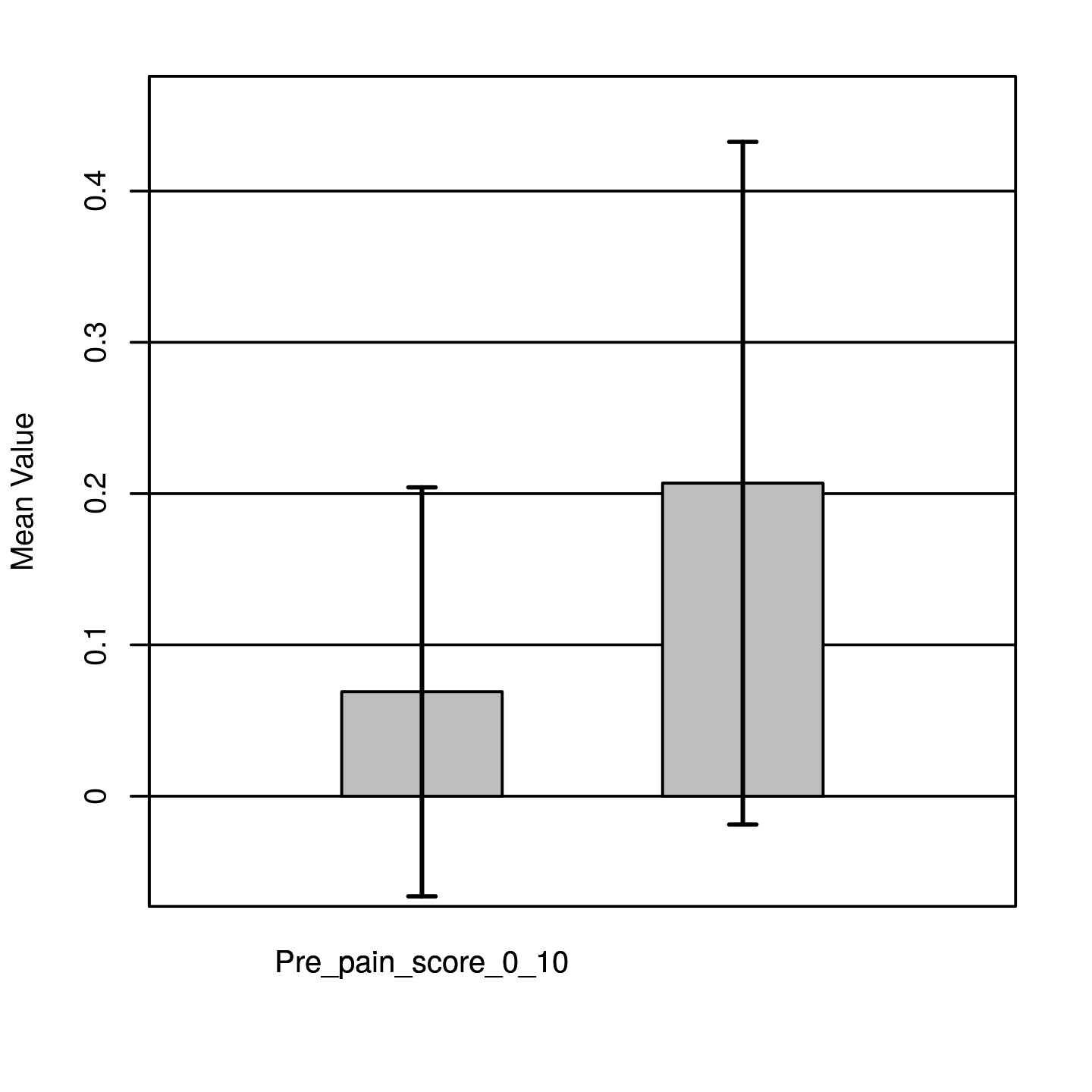
**Appendix M**

**Data Analysis and Results**

*Table 1. Two-Tailed Paired Samples t-Test for the Difference Between Pre-pain score 0-10 and Post-pain score 0-10*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Pre-pain score 0-10 | | Post pain score 0-10 | |  |  |  |
| *M* | *SD* | *M* | *SD* | *t* | *p* | *d* |
| 0.07 | 0.37 | 0.21 | 0.62 | -1.44 | .161 | 0.27 |
| *Note.* N = 30 | | | | | | |

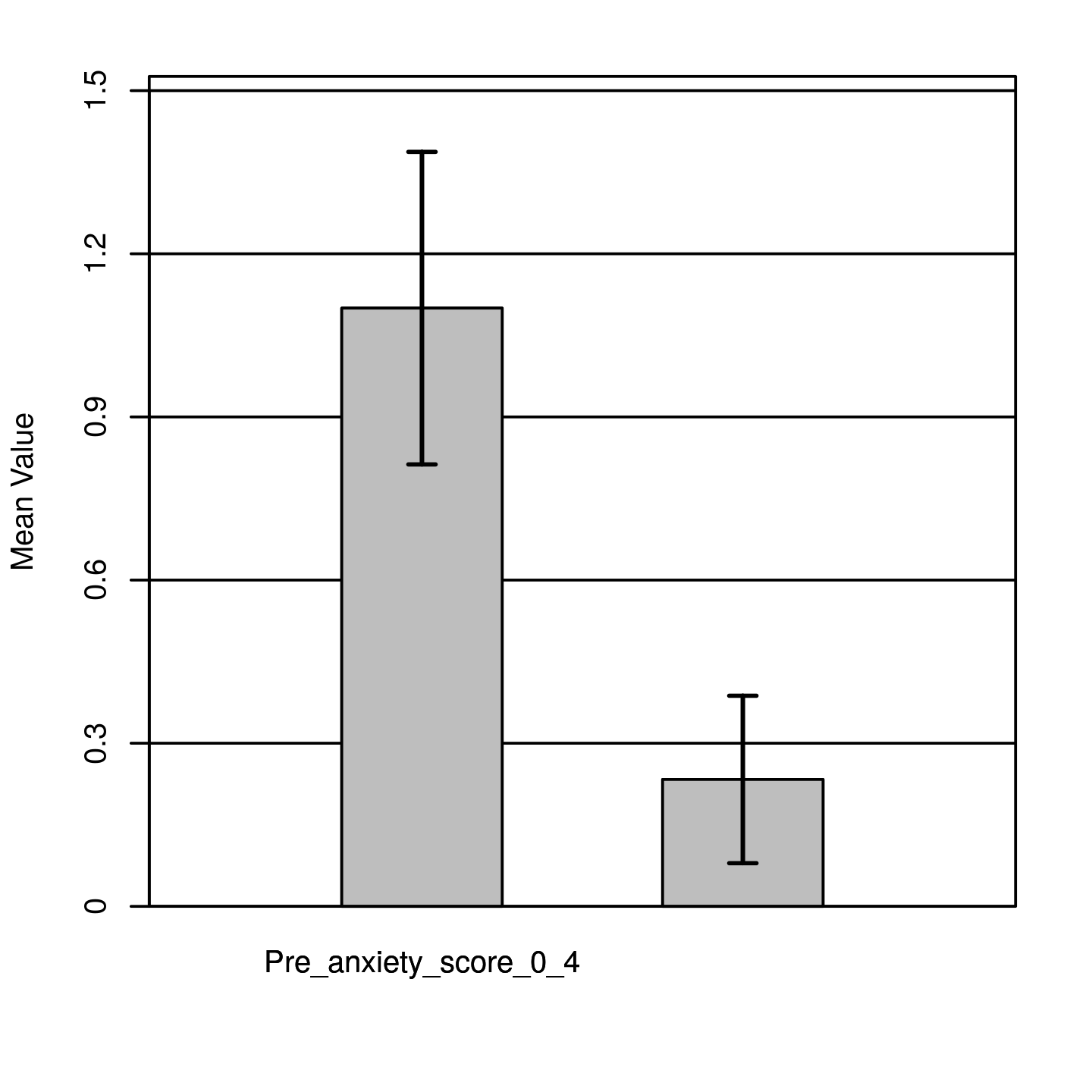
*Figure 1. The means of Pre-pain score 0-10 and Post-pain score 0-10 with 95.00% CI Error Bars*



*Table 2. Two-Tailed Paired Samples t-Test for the Difference Between Pre-anxiety score and Post-anxiety scores (0-4)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Pre-anxiety score 0-4 | | Post anxiety score 0-4 | |  |  |  |
| *M* | *SD* | *M* | *SD* | *t* | *p* | *d* |
| 1.10 | 0.80 | 0.23 | 0.43 | 5.52 | < .001 | 1.01 |
| *Note.* N = 30. Degrees of Freedom for the *t*-statistic = 29. *d* represents Cohen's *d.* | | | | | | |

*Figure 2. The means of Pre-anxiety score0-4 and Post anxiety score 0-4 with 95.00% CI Error Bars*



*Table 3.* *Parents Perceptions of the Benefits of the VR Experience During Procedure*

|  |  |  |
| --- | --- | --- |
| Variable | *n* | *%* |
| VR reduced child’s perception of pain |  |  |
| Strongly disagree | 1 | 3.33 |
| Neither disagree nor agree (neutral) | 2 | 6.67 |
| Agreed | 5 | 16.67 |
| Strongly Agreed | 22 | 73.33 |
|  |  |  |
| VR helped reduce child’s perception of anxiety during procedure |  |  |
| Strongly disagree | 1 | 3.33 |
| Agreed | 9 | 30.00 |
| Strongly Agreed | 20 | 66.67 |
|  |  |  |
| Would use VR again for child |  |  |
| Strongly disagree | 1 | 3.33 |
| Agreed | 5 | 16.67 |
| Strongly agreed | 24 | 80.00 |
|  |  |  |
|  | | |

*Table 4 Children’s Perceptions of the Benefits of the VR Experience During Procedure*

|  |  |  |
| --- | --- | --- |
| Variable | *n* | *%* |
| When you were using VR did you feel pain? |  |  |
| No | 25 | 83.33 |
| Yes, a little pain | 5 | 16.67 |
|  |  |  |
| When you were using VR did you feel anxious? |  |  |
| No | 16 | 53.33 |
| Yes, a little anxious | 12 | 40.00 |
| Lots of anxiety | 2 | 6.67 |
|  |  |  |
| VR helped to reduce my pain during the procedure |  |  |
| Yes, it helped a lot | 22 | 73.33 |
| Yes, it helped a little | 6 | 20.00 |
| Not Really | 1 | 3.33 |
| Missing\* | 1 | 3.33 |
| VR helped me feel less anxious during the procedure |  |  |
| Yes, it helped a lot | 26 | 86.67 |
| Yes, it helped a little | 4 | 13.33 |
|  |  |  |
| I would use VR again in the future for brief medical procedures |  |  |
| Yes | 29 | 96.67 |
| Maybe | 1 | 3.33 |
|  |  |  |
| *VR=Virtual Reality, \* Comments= child did not have pain to begin with.* | | |

|  |
| --- |
|  |