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Uses of Immersive Virtual Reality Distraction as an adjunct to anesthesia to decrease levels of pain in patients experiencing acute procedural pain: An Evidence-Based Educational Module

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Uses of Immersive Virtual Reality Distraction as an adjunct to anesthesia to decrease levels of pain in patients experiencing acute procedural pain: An Evidence-Based Educational Module

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Abstract

Background: Virtual reality (VR) is a relatively new technology that has garnered medical researchers' attention. VR is a computer-generated depiction of an immersive environment that can be viewed through a headset.[1] This multi-sensory immersion provided by VR hypothetically distracts the patient from pain and can reduce pain levels in patients experiencing pain.

Objectives: The purpose of this study is to improve anesthesia provider knowledge on the value of virtual reality and its effects as a distraction to reduce pain levels. A literature review including primary research studies addresses the PICO question: "Can immersive virtual reality be used as an adjunct to anesthesia in patients ages 10 through 70 who are experiencing acute procedural pain compared to a pharmacological approach?" The literature review is used to provide the educational framework to improve provider knowledge. The overall objective is to increase awareness to improve healthcare outcomes for patients experiencing acute pain

Methodology: The primary methodology of the proposed project is to administer an online educational intervention to providers focusing on the benefits of the use of virtual reality as a distraction to reduce pain levels in patients experiencing pain. Pre- and post-assessment surveys will be used to measure the improvement of provider knowledge before and after the intervention.

Results: 11,198 studies were identified, nine randomized control studies were included in the review. All nine studies were at high risk of bias in at least one domain. A total of 483 patients experiencing pain participated in the nine studies. Of the ten studies examined, eight of them showed a statically significant decrease in pain level reported than the standard of care. One study showed no difference.

Conclusion: The data in this review suggests that VR may have a place in treating patients experiencing acute pain. The studies presented were heterogeneous. Further research is required to validate findings, establish optimal populations, settings, and determine the cost-efficacy of immersive virtual reality in the treatment of acute pain.

Keywords: Virtual reality, immersive virtual reality, acute pain treatment, distraction from pain, analgesia.

Introduction

The problem

Pain is considered a universal medical complaint by patients and can be caused by injury, disease, or an invasive medical procedure. Pain can induce stress, which causes a multitude of harmful side effects. Treating pain is complicated and is often treated pharmacologically. The pharmacological approach has significant disadvantages, including narrow therapeutic windows, the potential for abuse, cost, and detrimental side effects. Opioids are one example of a pharmacological approach to pain and include side effects such as hypotension and respiratory depression, leading to death if not monitored appropriately. Opioid use in the perioperative setting has put patients at risk for long-term opioid abuse[2]. The Centers for Disease Control and Prevention (CDC) reports that 70,237 Americans died from drug overdoses in 2017, of which 47,600 were opioid-related. In 2017, 11.1 million people reported ill-use of prescription opioid pain medications; nearly 900,000 people used heroin, and 2.1 million people suffered from an opioid use disorder.[3]

Healthcare organizations are researching different strategies to limit opioids in the clinical setting to curb this opioid crisis. Virtual reality (VR) is a relatively new technology that has garnered the attention of medical researchers. VR is a computer-generated depiction of an immersive environment that can be viewed through a headset.[1] This multi-sensory immersion provided by VR hypothetically distracts the patient from pain and can reduce pain levels in patients experiencing pain.

Background

A variety of non-pharmacological methods have been proven to decrease pain, including cognitive-behavior procedures, hypnosis, and distraction[4]. Distraction has been proven to possess considerable efficacy in treating pain. In 1996 a new technique of reducing pain using immersive virtual reality was created by Hunter Hoffman and David Patterson[5]. This method's idea was to create an illusion of going inside a virtual world and how it affected attentional resouces[5]. Humans have been found to have a limited amount of attentional capacity. A distraction that consumes a portion of the attentional capacity is said to leave less cognitive capacity for processing pain[4]. Pain perception has been found to have a vital psychological component. The brain's incoming pain signal can be interpreted as painful or not, depending on what the patient is thinking. If a patient in pain enters an immersive virtual world, the patient's focus changes from pain to exploring the virtual world. This change in focus is said to decrease the levels of pain experienced by the patient.[5]

Virtual reality allows users to immerse themselves inside a three-dimensional environment. A head-mounted display sits over the eyes with a motion tracker that tracks the head's motion. The image displayed changes according to the head's movement as if they are looking around a simulated environment. Headphones are placed over the ears to provide audio feedback to immerse the user altogether. The immersive virtual reality is said to distract the user and use a portion of the limited attentional capacity leaving less room for processing pain and theoretically decreasing pain levels in the user.

Virtual reality distraction also appears to modify how the brain processes incoming signals from pain receptors. Results using an MRI provide physiological evidence that virtual reality reduces the pain experienced by modulating the brain's response to painful peripheral simulation, modulating sensory and emotional aspects of pain processing[6].

Systematic Review Rationale

The idea of virtual reality as an alternative approach to pain control has been on the rise as technology has become more accessible. As of late, evidence of the effectiveness of virtual reality distraction for pain reduction came primarily from case materials and studies using a one-group pre-post design[4]. However, there has been a growing amount of controlled investigations of virtual reality's effectiveness for reducing pain. The purpose of this systematic review was to:

1. Determine the feasibility of the use of immersive virtual reality as a distraction to reduce pain levels in patients experiencing pain,
2. determine the relationship between Distraction and pain relief
3. contribute to the literature concerning ways to use immersive virtual reality as an opioid-sparing adjunct to anesthesia.

Objectives of the Systematic Review

Immersive virtual reality can be a multi-sensory distraction used to decrease levels of pain in users. This technique can be used as an adjunct to anesthesia with little to no side effects. The goal is to reduce the amount of sedation and opioids used in patients in the clinical setting. This review aims to examine the efficacy of VR as a distraction to reduce pain levels in patients experiencing pain. The question to be answered is:

1. Can immersive virtual reality be used as an adjunct to anesthesia in patients ages 10 through 70 who are experiencing acute procedural pain?

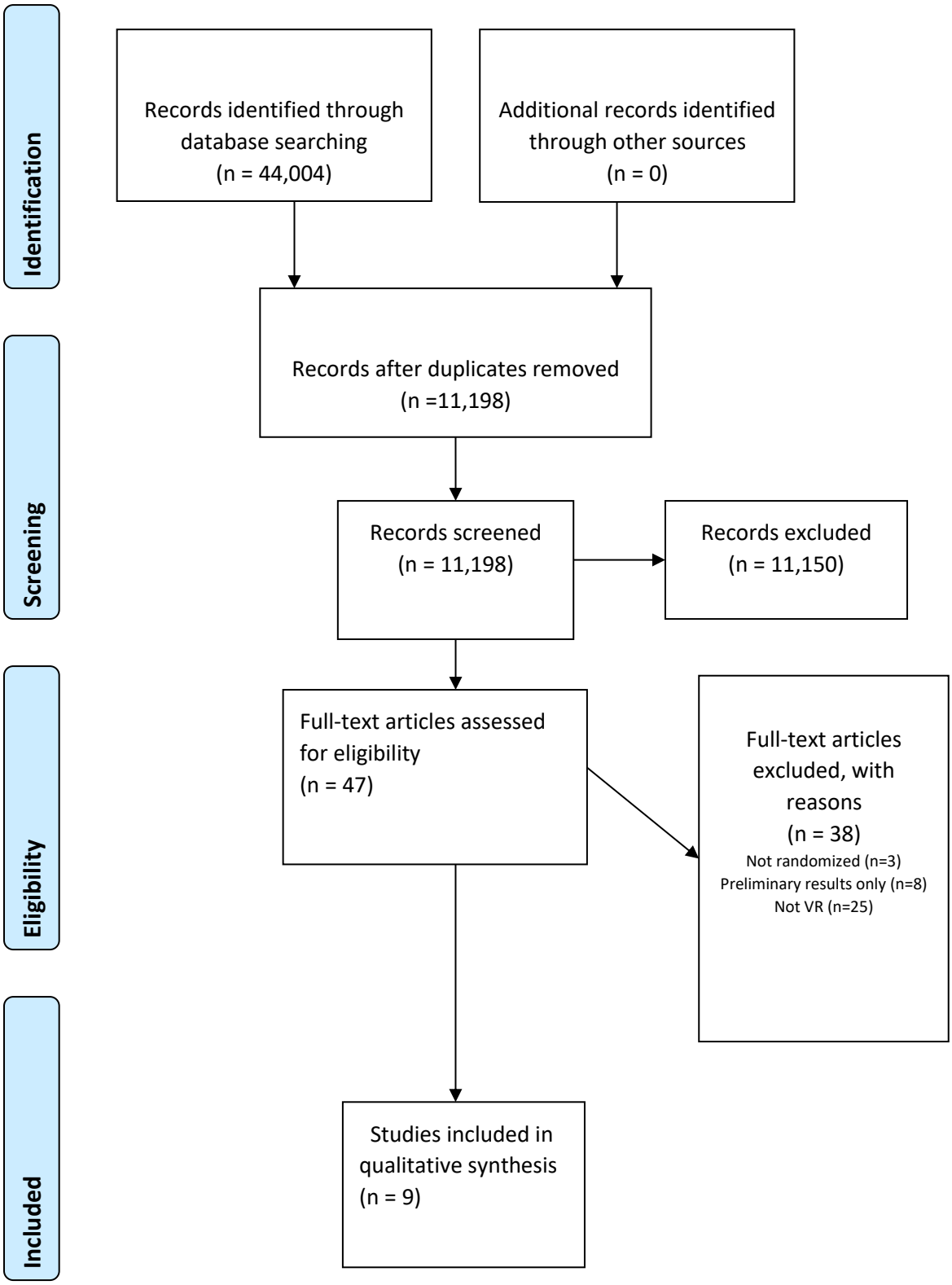
The goal is to create an educational module to help educate about the benefits of virtual reality as an adjunct for pain relief. A pre and post-test will be conducted to assess the efficacy of the educational module.

Methodology Systematic Review

Search Strategy and Sources

A PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) was used as a basis for reporting research. The PRISMA statement consists of a 27 item checklist and a four-phase diagram. The PRISMA goal is to aid researchers in reporting systematic reviews and meta-analyses with a focus on randomized trials[7]. PRISMA flow diagram can be viewed in figure 1.

Figure 1. PRISMA Flow Diagram



The databases used to located research included PubMed, CINAHL, Medline(ProQuest), the Cochrane Database of Systematic Reviews, and Google Scholar. The keywords and Boolean phrases used to search the databases were "virtual reality," "therapy," and "pain." Figure 1 includes the PRISMA flow diagram created to aid in the screening process.

Study Selection and Screening and Screening of Evidence

An exhaustive search of the databases was conducted, and the results are shown in Table 1. Pubmed resulted in 217 results, CINAHL 8,835 results, Medline (ProQuest) 50 results, The Cochrane 2 results, and Google Scholar 34,900 results. After duplicates were removed, 11,198 results were remaining. The records were then screened using the following inclusion criteria:

1. Studies involving the use of immersive virtual reality to treat acute pain
2. Studies that focused on the benefits of immersive virtual reality as a distraction to patients experiencing acute pain

The following exclusion criteria were applied:

1. Research reports that did not address primary research (e.g., opinion articles, editorials, literature reviews)
2. Research reports involving the uses of immersive virtual reality for treatments other than pain relief
3. Research reports focused on the prevention of pain

2. 11,150 articles were excluded. The remaining 47 articles were then screened for eligibility, and 38 were removed. The remaining nine items were included in the review and listed in the table

Table 2. Database Search Table

Database	**PubMed**	**CINAHL**	**Medline (ProQuest)**	**Cochrane**	**Google**
Boolean Phrase	"virtual reality," "therapy," "simulation," and "pain."	-	-	-	-
Search Results	**217**	**8,835**	**50**	**2**	**34,900**

Table 3. Inclusion and Exclusion Criteria

Inclusion	**Exclusion**
Population: • Patients experiencing pain • Patients ages 10-70 **Intervention:** • The use of virtual reality **Outcomes:** • The mean difference in self-related pain during the healthcare intervention with and without VR. • Only data relevant to pain scores with and without VR was extracted	**Population:** • patients younger than ten years and older than 70 years • patients complaining of chronic pain **Intervention:** • Not randomized • If the study included interventions other than VR

Type of study: • Research studies conducted from 20 to 2020 • RCTs	• Patients who didn't receive "virtual reality." **Category of research:** • Articles before 2000 • Articles that did not have full text • Articles that only listed preliminary results

Results

Study Characteristics

Study characteristics are detailed in Table 3. All 9 were randomized control trials (RCT), studying 483 participants. Five Studies were performed during dressing changes, three studies were performed during a procedure, and one was performed on patients experiencing pain. Studies were conducted in English-speaking countries. Eight of the studies were completed in the inpatient setting, and one was in an outpatient setting. Pain measurement instruments were heterogeneous but mainly employed a 100-point pain scale.

Pain Outcome measures

Overall, all but one[8] of the clinical trials included in this systematic review showed that the VR intervention decreased the pain experienced by both adult and pediatric patients with respect to the control conditions. Most studies[9-16] showed a reduction in different pain components, which were separately measured: a sensory component (worst pain and moderate

pain), an affective component (unpleasantness and bothersome), and a cognitive component (amount of time spent thinking about pain). These tools included different scales to rate pain, such as visual analog scales (VASs), graphic rating scales (GRS), visual analog thermometer (VAT), and numeric pain rating scale (NPRS). Other scales, specifically used for children/adolescents, included the Faces Pain Scale (FPS) and the Adolescent Pediatric Pain Tool word graphic rating scale (APPT-WGRS). Other less used complementary tools that could contribute to estimating pain included physiological measures, such as heart rate and oxygen saturation[14], and the evaluation of pharmacologic analgesic requirement.[14],[15] In one of the studies involving pediatric patients, in addition to the children's self-report measurements of the pain, also the nursing staff reported helpful information through interviews[14] or by using the Faces, Legs, Activity, Cry, and Consolability (FLACC) scale.[14]According to the nurses' observations, VR was helpful both in reducing pain and in increasing children's cooperation.[14]

Virtual Reality Hardware/Software

Most RCTs included in this review used conventional VR equipment, consisting of head-mounted devices (HMD) and motion tracking systems plus joysticks or other devices to interact with the virtual environment. The software used in three of the ten studies was called "Snow World" [8, 13, 15], and it was explicitly designed to reduce pain experienced by patients with burns as it depicts an icy, cool virtual environment. In Snow World, the user could adventure around in a frosty virtual environment and interact with objects such as snowballs using a joystick. The users also were immersed in spatialized sound and background music.[17] Hoffman 2000[11] used the software called "SpiderWorld." This program was initially created to overcome spider phobias but was used in early immersive VR research. Spiderworld placed the user in a virtual

kitchen and allowed the user to interact with their surroundings, such as touching a virtual spider and eating a virtual candy bar. [17]

Kipping[14] used off-the-shelf software targeting the pediatric population taking into account their age group and intellectual capabilities. Such programs included "Disney's Chicken Little" and "Need for Speed." These programs are games and are intended to engage the patient.

Two out of ten used the combination of a Samsung phone connected to Samsung goggles.[16, 18] The software chosen was called "Bear Blast." This multi-sensory game allowed the user to travel on a preset path through a colorful, vibrant, highly interactive environment filled with toy-like trees, mountains, rainbows, mushrooms, and bushes.[9] as they travel the trail, the user can control the direction of a continuously firing cannon, which interacts with items in the world and positively reinforces experimentation and activity.[9]

The studying conducted by Guo et al. [10] used a pair of ultra-high-resolution 3D glasses, headphones, a mouse, and a computer. The software utilized was a 3D film called "Afanda," which depicts a mysterious dream planet where users can reach out to touch a graceful scene.[10] The study conducted by JahaniScoorab et al. [12] utilized a non-interactive 3D Blu-ray player connected to a pair of video glasses and played a 3D film called "IMAX dolphin and Whales 3D 1080p"[12]

Risk of Bias

The nine studies' risk of bias was split into five domains (table 4); randomization, allocation concealment, detection bias, attrition bias, and selective reporting. All nine studies demonstrated a low risk of bias in one domain. None of the trials reported sufficient detail that their bias risk could be assessed across all domains. Five of the studies were considered low risk in selective reporting, and there was a high risk of bias, and two studies didn't supply ample

information to determine bias level. All the studies had short follow-up periods, which led to low attrition bias on the studies. Four out of the ten studies did not describe their allocation concealment in sufficient detail to be assed, while two of the studies explained their allocation concealment. Seven of the studies were considered a low risk of bias in the randomization domain. The majority of trials did not report sufficient detail for detection bias to be assessable, and two studies were considered low risk.

Table 4 Bias chart

	Randomization	**Allocation concealment**	**Detection bias**	**Attrition bias**	**Selective reporting**
Hoffman 2000[11]	-	-	?	+	-
Kipping 2012[14]	+	?	?	+	-
Gold2017[9]	+	+	?	+	?
Walker 2014[8]	+	?	?	+	?
Matheve 2020[19]	+	+	+	?	-
Spiegel 2019[16]	+	-	?	+	-
Guo2015[10]	?	?	?	+	+
JahaniShoorb 2015[12]	?	?	?	+	+
Jeffs 2014[13]	+	+	+	+	-
McSherry 2017[15]	+	+	?	?	+

Key: (-) high risk of bias; (+) low risk of bias; (?) unclear risk of bias

Summary of Evidence

Nine RCTs were selected for the systematic review, studying 483 male and female participants ranging from 10 to 70 years old. Of the ten chosen studies, five studies focused on reducing pain during wound care and dressing changes. One focused on reducing pain during venipuncture. Two studies looked at reducing pain during urologic procedures, and one examined reducing pain during physical therapy.

Wound care and dressing change

McSherry 2017[15] RCT included 18 participants ranging from ages 20-70 who were receiving wound care. The intervention had an immersive VR headset, and the control consisted of the standard of care for wound care. The number of patient requests for opioid administration during the procedure significantly decreased in the wound procedures with immersive VR than without immersive VR ($\chi 2 = 9.9$; df = 3; P = 0.02). Only 11% of the participants requested opioid administration during the wound procedure 2 or 3 times during the immersive VR procedures, but 60% of participants asked for opioid administration during the wound procedure 2 or 3 times when no IVR was used.[15]

In Jeffs 2104 [13] study, 28 patients ages 10-17 who received burns would care were randomly selected into three groups. One group used immersive VR, the second group used passive distraction, and the control group used standard of care.[13] The immersive VR group was the only group with an estimated decrease in pain perception from baseline pre-procedure pain to procedural pain reported.[13] Adolescents pretreated with opiate analgesics, and female adolescents reported more pain during wound care.[13]

Kipping's RCT evaluated 41 adolescents ages 11-17 years old who were receiving burns wound care.[14] The intervention used an immersive VR head-mounted display, and the control group had access to television, stories, music, and caregivers. The nursing staff reported a statistically significant reduction in pain scores during dressing removal and significantly fewer rescue doses of nitrous oxide given to those receiving immersive VR than those in the control group.[14]

Of The five RCTs examing 197 participants ranging from ages 10 to 73, all five showed statistically significant decreased pain levels during wound care in adult and pediatric patients with burns and other injuries using VR as a distraction compared to the control. The highlights of studies focusing on wound care and dressing change include a reduced amount of opioids used, reduced anesthetic rescue doses of nitrous oxide administered, and a statistically significant reduction in pain levels while using immersive VR.

Venipuncture and acute procedural pain

Gold 2018[9] RCT of 143 participants ages 11-17 years old receiving routine venipuncture. The intervention group used an immersive VR headset, and the control group used the current standard of care.[9] Findings showed that VR significantly reduced acute procedural pain during routine venipuncture and anxiety than the current standard of care.[9] A significant interaction between patient-reported anxiety sensitivity and treatment condition indicated that patients undergoing routine blood draws benefit more from VR intervention when they are more fearful of physiological sensations related to anxiety. Patients and caregivers in the VR intervention group also reported high levels of satisfaction with VR after the procedure.[9]

Immersive VR was shown to be well-liked by the patients, caregivers, and phlebotomists during routine venipuncture. The immersive VR transformed the venipuncture experience into a

less distressing, potentially pain-free experience. Immersive VR was especially beneficial in pediatric patients with high anxiety.[9]

Urologic procedure

JahaniShoorb 2015[12] conducted an RCT including 30 females ages 18-34 years old undergoing an episiotomy repair. The intervention group received treatment with VR (video glasses and local infiltration 5 ml solution of lidocaine 2%), and the control group only received local infiltration (5 ml solution of lidocaine 2%).[12] There were statistically significant differences between the pain score during episiotomy repair in both groups (P=0.038). Sixty percent of the non-VR group expressed severe pain during the skin repair, while the intervention group's severe pain was 20%.[12] Another exciting result from this study was a reduction in the perceived pain period during an episiotomy. Patients receiving VR stated that the perceived repair time was less than 46% of the actual time spent.[12] Immersive VR was also shown to be an effective non-pharmacological method to reduce pain during episiotomy repair.[12]

Walker 2014 study was an RCT including 45 male patients ages 18-70 who were referred for flexible cystoscopy. None of the measures for pain or anxiety showed improvement in the VR distraction group. The study was powered to detect a difference of 20% between the two groups. It was felt that a 20% difference in the responses likely indicated a clinically significant difference between the two groups.[8] While the study did not show a difference in pain levels between the control and intervention groups. The author admitted the subjects did not feel fully immersed in the VR environment.[8] for immersive VR to distract the patient from pain, the patient must feel fully immersed in the VR. The author implied the lack of immersion could’ve been from the current technology, and improvements in technology could lead to better outcomes and fuller immersion.[8]

Inpatient pain

The RCT conducted by Spiegel[16] examined 120 hospitalized patients with an average pain score of >3 out of 10 points. The intervention group included an immersive VR headset with a library of 21 VR experiences, and the control group viewed specialized television programming to promote health and wellness. In this study, the authors found that on-demand use of VR in a diverse group of hospitalized patients was well tolerated and resulted in statistically significant improvements in pain versus a control group exposed to an in-room "health and wellness" television channel.[16]

Limitations of the systematic Review

In this review, ten random control studies were examined with relatively small sample sizes. The majority of the studies focused on pain from wound care and dressing changes. VR is a non-blindable intervention that creates issues in bias assessment. Additional limitations include the study populations being heterogeneous and the hardware and software used in the VR intervention making it challenging to conclude.

Gaps in literature

Current studies show promise for the use of immersive VR in the reduction of pain levels in patients. Still, there are significant gaps in the existing literature that should be addressed: Are there patient characteristics, cultural influences, and environments that limit or enhance immersive VR? Can Immersive VR reduce pain while also decreasing opioid requirements? Are there usage patterns or engagement characteristics that predict enhanced response to VR?[16] Can the use of immersive VR lessen the length of stay of inpatients? Can the use of immersive VR

lead to healthcare cost reductions? For Immersive VR to evolve and implant itself in the standard of care, these questions need to be examined.

Quality Improvement Project

Methodology

Setting and Participants

To fulfill the goals of this quality improvement project, a pre-and post-test will be conducted that involves a specific group of study participants receiving an educational intervention on the use of immersive virtual reality to treat acute pain. The primary setting of this quality improvement project will be online. The primary participants include all certified registered nurse anesthetists (CRNAs) employed by Broward hospitals. The participants will be recruited voluntarily, and the anticipated sample size will be between 5-15 participants.

Description of Approach and Project Procedures

The primary methodology of the proposed project is to administer an online educational intervention to providers which focus on the benefits of immersive virtual reality for the treatment of pain in the acute setting. Participants will complete an online pre-assessment test evaluating their current knowledge and perceptions of immersive virtual reality. Participants will watch an educational video about the use of immersive virtual reality to treat pain. Provider education is essential in bridging gaps in knowledge and improving the quality of patient care delivered and subsequent healthcare outcomes. An online post-assessment test will be added to the end of the module to evaluate knowledge gained and any changes in perception regarding immersive virtual reality

The information obtained in the post-assessment survey will provide feedback regarding the influence of the educational intervention. The pre/post-testing offers relevant information regarding the effectiveness of the educational intervention and seeks to promote the increased utilization of immersive virtual reality to provide safer care to patients. Results will also demonstrate if further education is needed and if the program would benefit other providers.

Protection of Human Subjects

For this study, the recruitment population will include certified registered nurse anesthetists employed with ANESCO who work at the Broward hospital system, Florida. This population is significant because they directly provide care to patients experiencing acute care and thus benefit from the education provided to improve patient outcomes. Recruitment will be conducted via email invitation to all certified registered nurse anesthetists. Participation is voluntary, and there is no penalty if participants decide to withdraw from the QI project. There are no perceived risks to the study, and its only requirement is the time spent completing the educational module.

Data Collection

The primary instruments of data collection will include a pre-assessment and post-assessment questionnaire to determine the effects of the education intervention. Both assessments will be conducted using surveys consisting of approximately ten questions focusing on knowledge and practice using Qualtrics. The pre-test will assess knowledge and current perspectives on the educational material, while the post-test survey will determine if the participants gained knowledge from the intervention. The instrument reliability and validity will be measured in accordance with the intervention provided and its effectiveness for the participants. The data

collected will be confidential, and no subject identifiers will be recorded during any component of the study.

Data Management and Analysis Plan

The co-investigator for this project will be the DNP student who will be responsible for administering the survey. To evaluate the responses provided on the pre-test and post-test, Excel software will be used to determine if participants received any knowledge and potentially modify their practice in response to the educational tool. Question will be measured, and the answers recorded to identify the knowledge base before and after the intervention and the practical applications of the intervention. Through the statistical analysis, the study results will identify patterns used to determine the effectiveness of educational intervention and its impact on clinician practice. The co-investigator will store the collected data in a password-protected laptop computer.

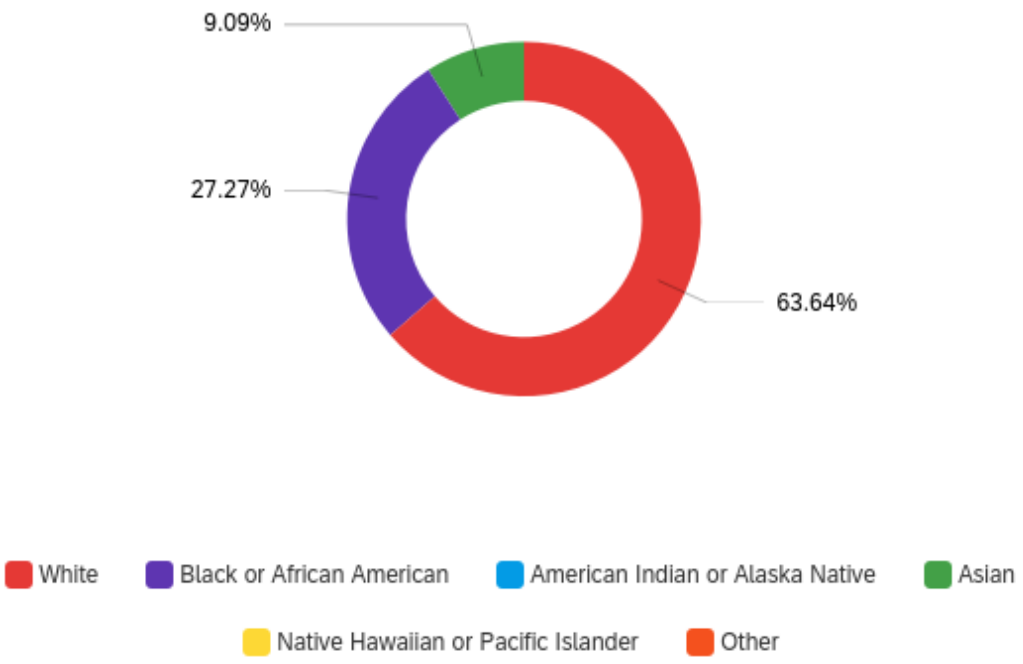
Results

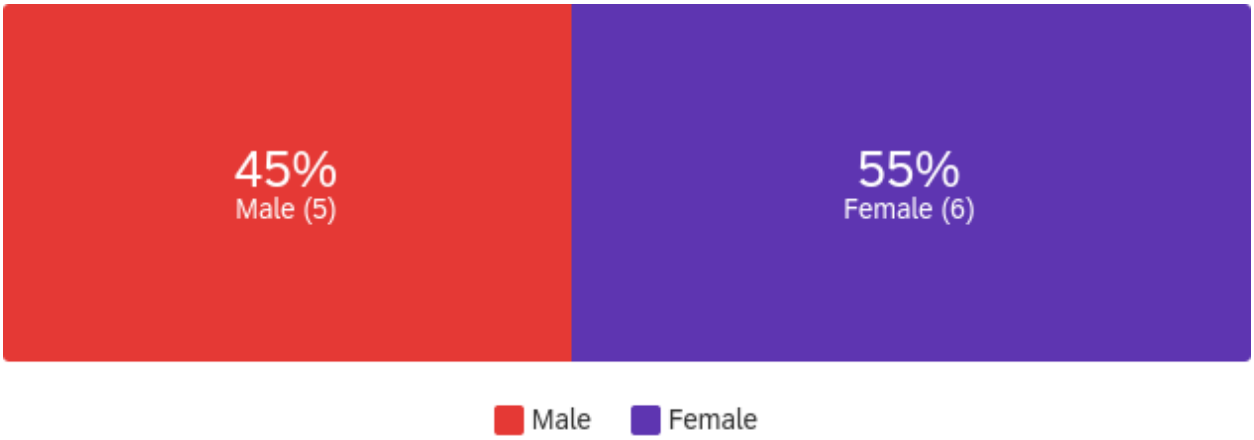
Pre-Test Participant Demographics

The pre-test demographics are shown in Table 5 below.

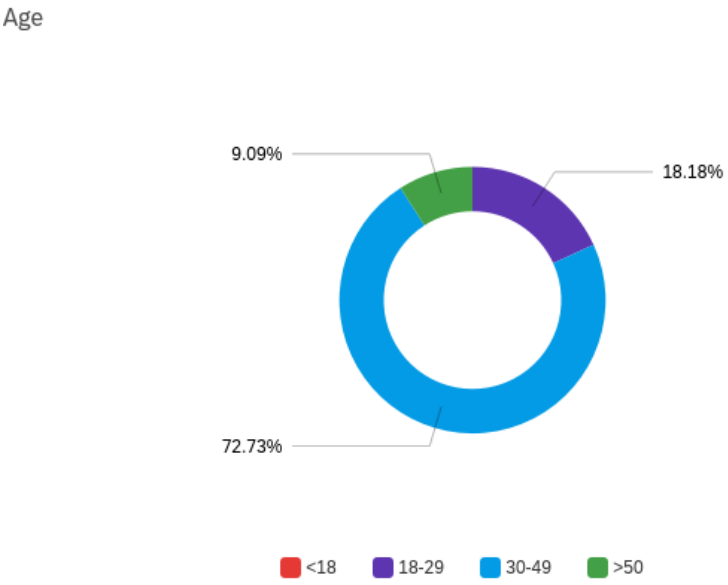
Table 5.

Pre-Test Participant Demographics





Participant's age:



There were 11 participants in the pretest demographics, female (n=6, 55%), as opposed to male (n=5, 45%). The participants were between the ages of 30 – 49 years old (n=8, 72%), and the remaining participants were as follows: 18 – 29 years old (n=2, 18%), >50 years old (n=1,

9%), The following ethnicities were represented: Caucasian (n=7, 63%), African American (n=3, 27%), Asian (n=1, 9%),and other (n=0, 0%).

Pre-Test Knowledge immersive virtual reality

Eleven participants completed the pre-test evaluating their current knowledge and perceptions about immersive virtual reality. Zero participants selected distraction as a way to treat pain. (80%) of participants believed that immersive virtual reality involved single sensory immersion. 45% of participants thought patients could not be distracted from pain, while 36% said maybe, and 18% said they believed patients being distracted could have reduced pain levels. 27% of participants correctly recognized the VAS pain scale. Only 27% of participants believed video games were included in immersive virtual reality, while the remainder thought it included board games, tic tac toe, or paper rock scissors.

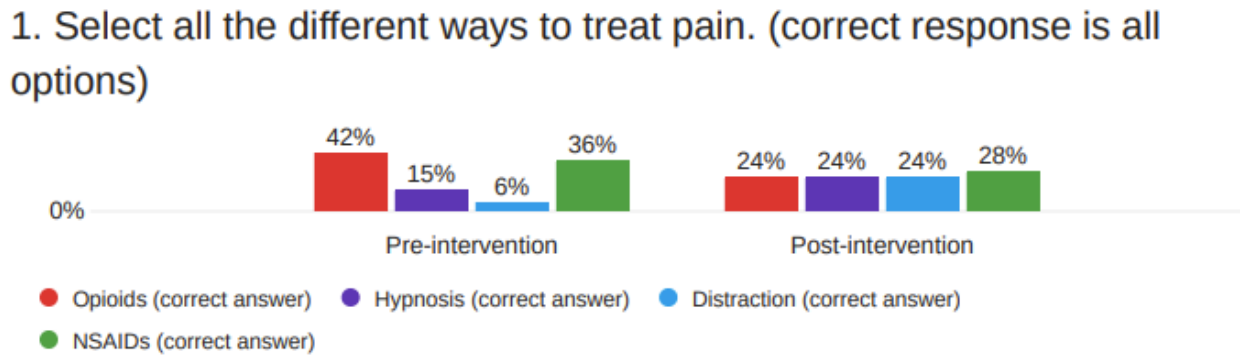
Over half the participants believed immersive virtual reality had been shown to reduce happiness. 27% of the participants correctly picked reduced anxiety with the treatment of immersive virtual reality. Over half the participants, 54%, selected hyperactive children respond best to immersive virtual reality compared to the 27% that correctly answered the question with anxious. 64% of participants believed patients receiving immersive virtual reality were “more” likely to request pain medications. The majority of the participants thought snow world was created for chemo patients compared to the correct answer of burn patients. The final question of the pre-test was, “If available at your facility, how likely are you to use immersive VR as an adjunct?” 72% of participants selected “Neither likely nor unlikely.”

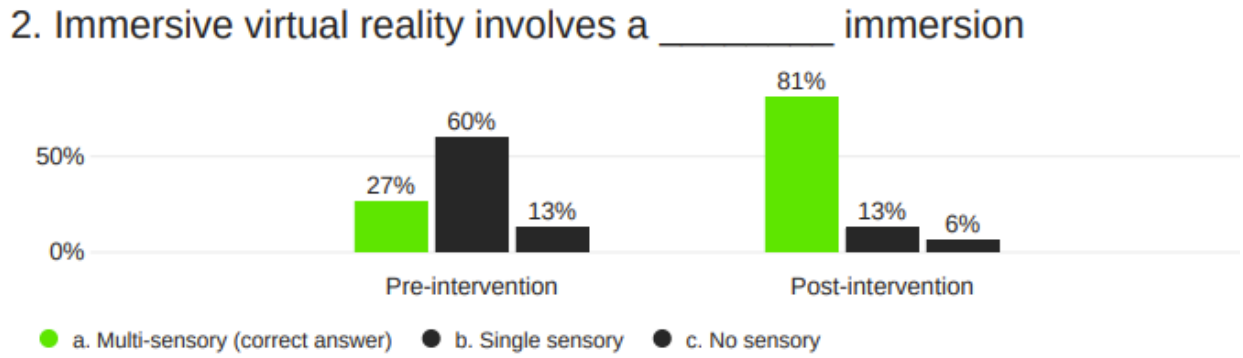
Post-Test Knowledge immersive virtual reality

All 11 participants completed the post-test evaluating their knowledge and perceptions about immersive virtual reality after receiving the intervention. On the first question on the post-test, all 11 participants selected distraction to treat pain compared to the pre-test, where zero picked it. 100% of participants selected "multi-sensory" the correct answer on the post-test compared to the zero participants who chose it on the pre-test. Following the intervention of the third question, all 11 participants selected the correct answer, agreeing that distraction can reduce the patient's pain level.

The VAS scale was 100% identified post-intervention compared to the 27% who identified it pre-intervention. All 11 participants correctly answered the 5th question post-intervention vs. the pre-intervention of 27%. Questions 6,7,8,9 all had the majority of participants selecting the correct answer post-intervention. On the final question, 54% of the participants selected "extremely likely" when asked if they would use immersive virtual reality as an adjunct at their facility compared to 0% pre-intervention. Knowledge increased in every question post-intervention.

Difference in Pre- and Post-Test Responses questions 1-3 (Knowledge About Immersive Virtual Reality)





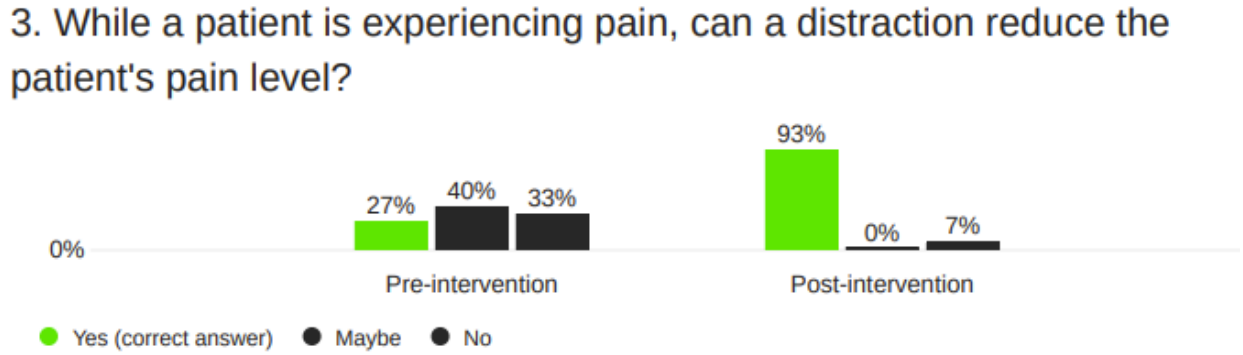
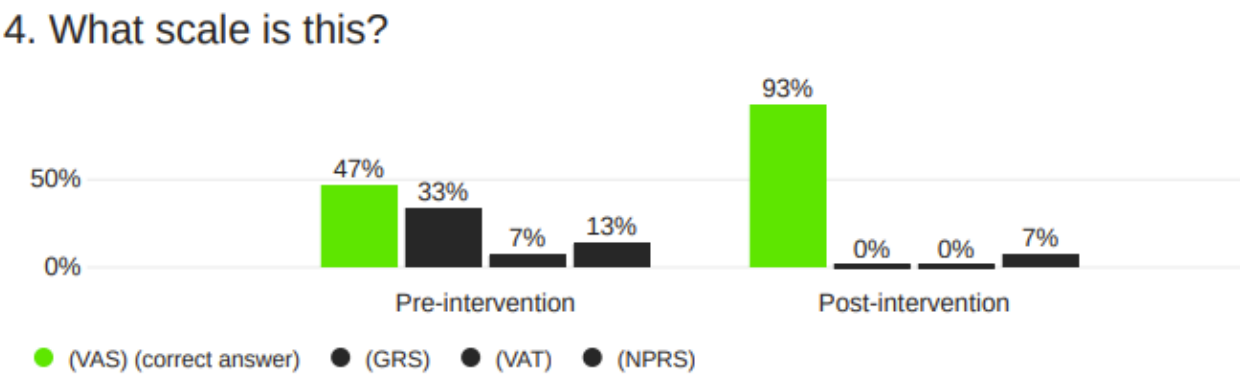
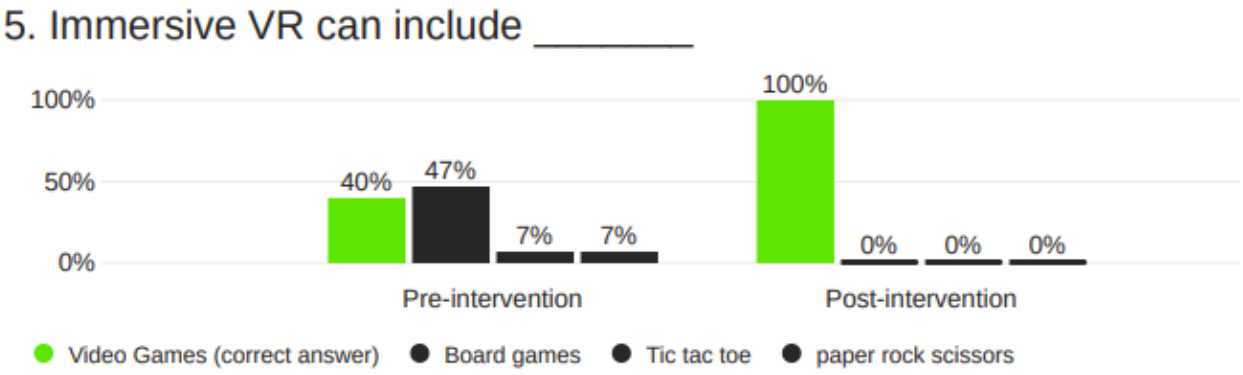


Table 4.

Difference in Pre- and Post-Test questions 4-6 (Knowledge About Immersive Virtual Reality)





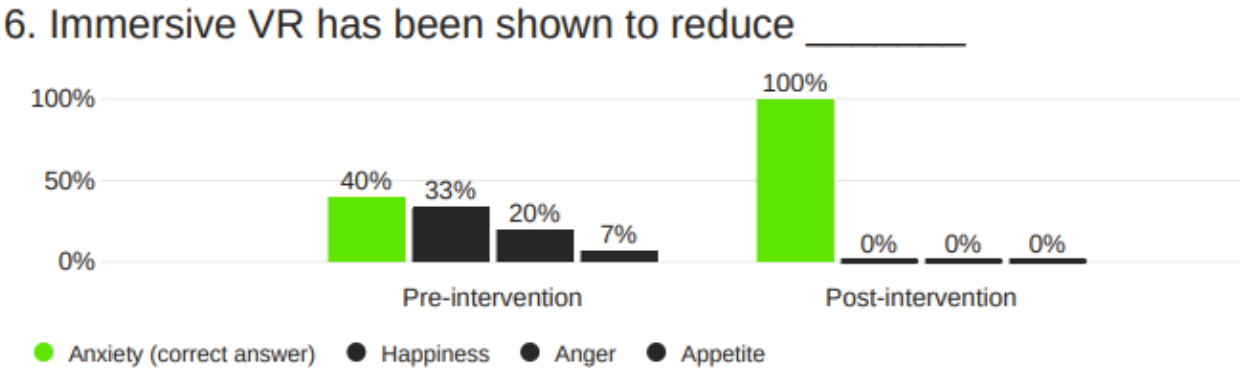
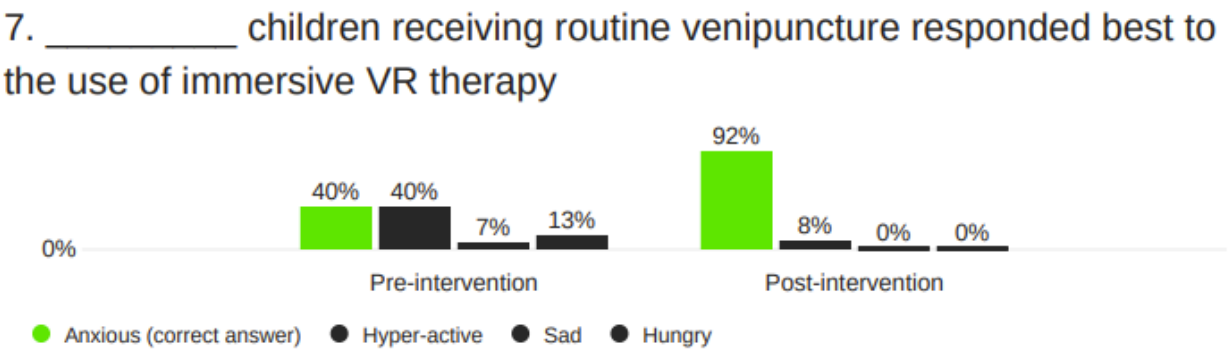
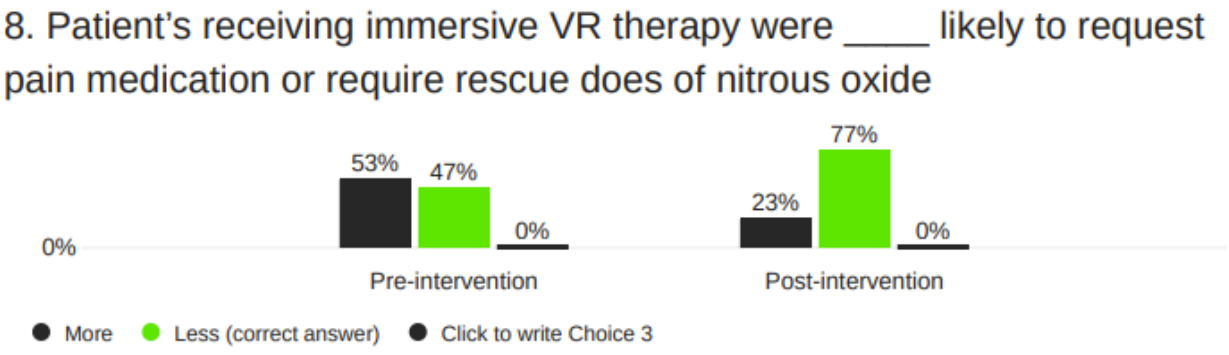
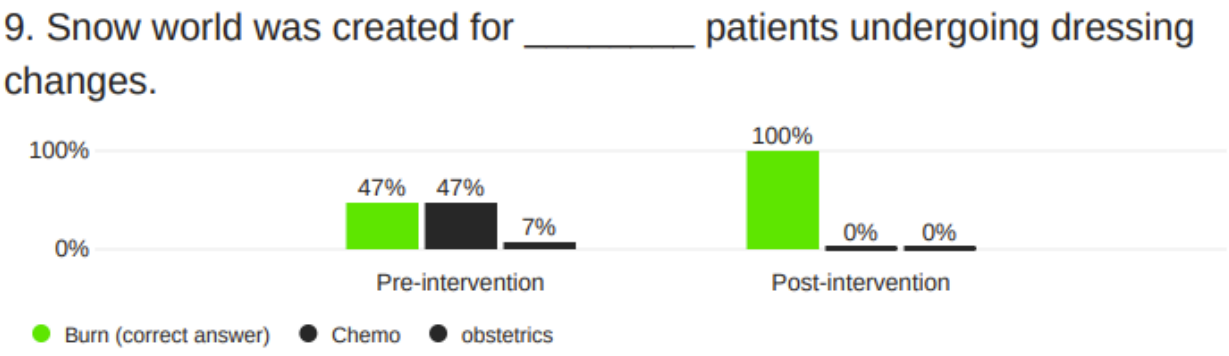


Table 5

Difference in Pre- and Post-Test questions 7-9 (Knowledge About Immersive Virtual Reality)



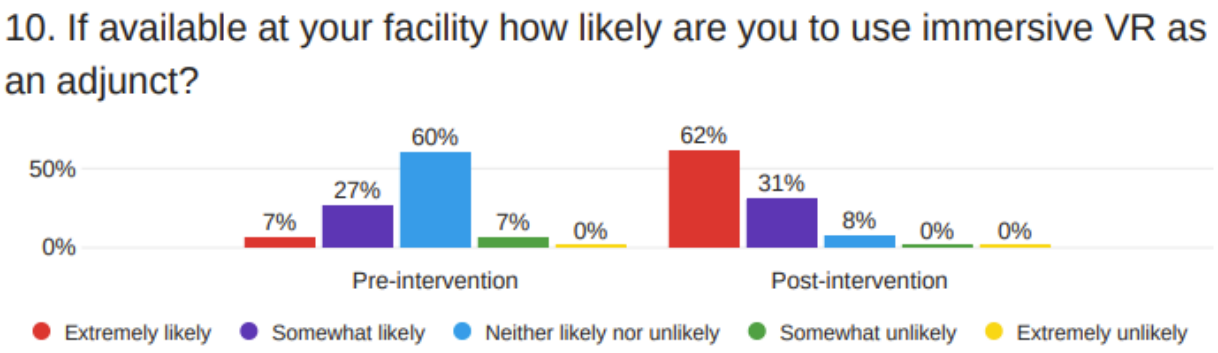




Conclusion of QI Project

Overall, the results show there was a gain in knowledge between pre-and post-test assessments. In every question, participants correctly picked the correct answer post-intervention. When asked, "If available at your facility, how likely are you to use immersive VR as an adjunct?" pre-intervention, 60% of the participants selected "neither likely nor unlikely." Whereas on the post-intervention, 62% of the participants selected "extremely likely." After participating in the educational module, participants showed increased interest and knowledge in immersive virtual reality.

There results of the QI project showed leaning in every question as well as an increase in perception pertaining to immersive VR. This project displays hope for the use of immersive VR as an adjunct to anesthesia to decrease levels of pain in patients experiencing acute procedural pain. There is still more research that needs to be done and further integration into the public health sector to be fully embraced as an adjunct to anesthesia.



Limitations of QI project

Limitations of the QI project include a small sample size. The survey was deployed to all certified registered nurse anesthetists at the Broward hospital system via email, but participation was low. Larger sample size would have increased the strength and reliability of the study. The delivery method of the analysis could have also limited the results as it was done entirely online. A more controlled, in-person setting could have yielded more accurate results.

Discussion

Recommendations for Future Research

Recommendations for future studies should include designing different software/hardware tailored to diverse patient populations, ages, and cultures. Furthermore, future studies should examine the cost/benefit of VR to facilitate compliance and possibly lead to healthcare cost reductions. These studies could also design their product specifically for the healthcare sector to provide the most significant distraction at the lowest cost and encumbrance. Future trials should also evaluate standardized order sets that interpose immersive VR as an early non-drug option for analgesia.

Conclusions

The data looks promising for using immersive distraction as an adjunct to anesthesia to decrease pain levels in patients experiencing acute procedural pain. Of the studies reviewed, only one showed no difference between the standard of care and VR, whereas the other 8 showed decreased pain levels in patients experiencing acute pain. Nevertheless, the quality and quantity of the current research are limited. Before VR can be utilized effectively, there is a need for further analysis.

The technology for VR is advancing at a fast rate. The studies in this review used relatively low-tech VR systems compared to the new generation of VR systems today that are more immersive, more portable, less expensive, and easier to use. The future of immersive VR is now. This relatively new technology shows great promise and wide application. However, it is necessary to investigate its applications and determine the best match for immersive VR in managing acute procedural pain management and other health-related conditions.

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Appendix A: Matrix Table

Citation	design	Participants	interventions	Pain outcome measure	Procedure	outcome	results
Hoffman 2000[11]	Randomized and counter-balanced cross over study	12 burn patients (19-47 years old)	Immersive VR (Spider-world) vs. no distraction	VAS	Dressing change	Time spent thinking about pain, average and worst pain, pain bothersome and unpleasant/ 0-100 VAS	(+) All pain ratings for all pain measures were significantly lower during VR than in the control condition
McSherry 2017[15]	RCT	A total of 18 participants. Ages ranged from 20 to 73 years, averaging (± SD) 38.4±15.5 years. The majority of participants were male (N = 18; 72%), and 12 of the 18 (66%) participants had a history of prior substance abuse	IVR headgear vs. no IVR headgear	VNS	Wound care	The number of patient requests for opioid administration during the procedure was significantly less in the wound procedures with IVR than without IVR ($\chi 2 = 9.9$; df = 3; P = 0.02). Only 11% of the participants requested opioid administration during the wound procedure 2 or 3 times during the IVR procedures, but 60% of participants asked for opioid administration during the wound procedure 2 or 3 times when no IVR was used.	(+) During painful wound care procedures, IVR significantly reduced the amount of opioid medication administered during the procedure compared with no IVR.
Spiegel 2019[16]	a prospective, randomized, comparative effectiveness trial	There were 120subjects (61VR;59control)	Patients in the experimental group received a library of 21 VR experiences	NRS, VAS	Inpatient pain relief	There were 120 subjects (61 VR; 59 control). The mean within-subject difference in immediate pre-and post-intervention pain scores was more considerable in the VR group (-1.72 points; SD 3.56) than in the control group (-0.46 points; SD 3.01); this difference was significant in favor of VR (P < .04	(+) VR significantly reduces pain versus an active control condition in hospitalized patients. VR is most useful for severe pain
Guo2015[10]	RCT	98 patients ages 18-65	experimental group: Patients were distracted during their dressing change using VR. Control group: Patients did not use the VR equipment.	VAS	Hand injury wound care	The difference in visual analog scale scores between the two groups before the dressing change was not statistically significant (t=0196,p>005), but the scores became statistically significant after the dressing change(t=30792,p<001).	(+)Virtual reality distraction can effectively alleviate pain among patients with a hand injury undergoing a dressing change.
JahaniShoorb 2015[12]	RCT	30 Female patients age 18-34	The intervention group received the usual treatment with VR (video glasses and	NPRS	Episiotomy repair	There were statistically significant differences between the pain score during episiotomy repair in both groups (P=0.038)	(+)Virtual reality is an effective complementary non-pharmacological method to reduce pain during episiotomy repair.

			local infiltration 5 ml solution of lidocaine 2%), and the control group only received local infiltration (5 ml solution of lidocaine 2%)				
Jeffs 2014[13]	RCT	28 Patients ages 10-17	participants were randomly assigned to one of three groups during wound care: standard care, passive distraction watching a movie, or virtual reality (VR) using a tripod-arm device rather than an immersive helmet.	APPT-WGRS	Burns wound care	The VR group was the only group with an estimated decrease in pain perception from baseline pre-procedure pain to procedural pain reported. Adolescents pretreated with opiate analgesics, and female adolescents reported more pain during wound care.	(+)On average, the VR group reported less pain during the burn wound care procedure than either the PD or SC group,
Kipping 2012[14]	RCT	Forty-one adolescents(11–17years)	The intervention group used an off-the-shelf VR head-mounted display. And the control group had access to tv, stories, music, and caregivers.	VAS, FLACC	Burns wound care	Nursing staff reported a statistically significant reduction in pain scores during dressing removal and significantly fewer rescue doses of Entonox given to those receiving VR than those receiving standard distraction.	A minimal pain reduction achieved using off the shelf VR
Gold2018[9]	RCT	143 participants ages 10-21	randomized to receive either VR or standard of care when undergoing routine blood draw	VAS, CAS	Venipuncture	Findings showed that VR significantly reduced acute procedural pain and anxiety compared with SOC. A significant interaction between patient-reported anxiety sensitivity and treatment condition indicated that patients undergoing routine blood draws benefit more from VR intervention when they are more fearful of physiological sensations related to anxiety.	(+)Given the immersive and engaging nature of the VR experience, VR can act as a preventive intervention transforming the blood draw experience into a less painful, potentially pain-free routine medical procedure, particularly for pediatric patients with high anxiety sensitivity.
Walker 2014[8]	RCT	43 male patients ages 18-70	The control group underwent	VAS	Rigid cystoscopy		(+/-)We concluded no benefit to VR

			routine cystoscopy, and the VR group underwent cystoscopy with VR.			No data endpoints showed a statistically significant difference between the two groups.	distraction mitigating pain in male patients during cystoscopy.
Matheve 2020[19]	RCT	Eighty-four patients age 18 to 65 years old	patients with chronic nonspecific low back pain in the intervention group (n = 42) performed a single exercise session with non-immersive VR games. In contrast, those in the control group (n = 42) completed the same exercises without VR games.		Movement with low back pain	VR distraction had a hypoalgesic effect during (Cohen's d = 1.29) and immediately after (Cohen's d = 0.85) the exercises, and it also reduced the time spent thinking of pain (Cohen's d = 1.31)	(+) Large effect sizes of VR distraction induced hypoalgesia were observed. This suggests that non-immersive VR games can be used when it is deemed essential to reduce the pain during exercises in patients with chronic nonspecific low back pain

Appendix B: QI Project Consent

FIU | FLORIDA INTERNATIONAL UNIVERSITY

CONSENT TO PARTICIPATE IN A QUALITY IMPROVEMENT PROJECT

"Uses of Immersive Virtual Reality Distraction as an adjunct to anesthesia to decrease levels of pain in patients experiencing acute procedural pain."

PURPOSE OF THE PROJECT

1. You are being asked to be in a quality improvement project. The goal of this project is to Determine the feasibility of the use of immersive virtual reality as a distraction to reduce pain levels in patients experiencing pain,

DURATION OF THE PROJECT

Your participation will require about 30 minutes of your time.

PROCEDURES

If you agree to be in the project, we will ask you to do the following things:

RISKS AND/OR DISCOMFORTS

There are no foreseeable risks with you for participating in this project.

BENEFITS

The following benefits may be associated with your participation in this project: An increase in cholesterol management knowledge, which will help you to better assess medication adherence and guidelines implementations to reduce the risk of cardiovascular events. The overall objective of the program is to increase the quality of healthcare delivery, improving the health indicator of our patients, and increase patient engagement.

ALTERNATIVES

There are no known alternatives available to you other than not taking part in this project. However, if you like to receive the educational material given to the participants in this project, it will be provided to you at no cost

CONFIDENTIALITY

The records of this project will be kept private and will be protected to the fullest extent provided by law. If, in any sort of report, we might publish, we will not include any information that will make it possible to identify you as a participant. Records will be stored securely, and only the project team will have access to the records.

COMPENSATION & COSTS

There is no cost or payment to you for receiving the health education and/or participating in this project.

RIGHT TO DECLINE OR WITHDRAW

Your participation in this project is voluntary. You are free to participate in the project or withdraw your consent at any time during the project. Your withdrawal or lack of participation will not affect any benefits to which you are otherwise entitled. The investigator reserves the right to remove you without your consent at such time that they feel it is in the best interest.

RESEARCHER CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues relating to this research project, you may contact James Pyle. at 740-294-1422, Jpyle004@fiu.edu or Dr. Jorge Valdes at 305-348-7729, jvalde@fiu.edu.

IRB CONTACT INFORMATION

If you would like to talk with someone about your rights of being a subject in this project or about ethical issues with this project, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT

I consent by participating in the survey. I have read the information in this consent form and agree to participate in this project

Appendix C: IRB Exemption Broward

Institutional Review Board - Human Research Protections

Broward Health Medical Center
Broward Health Coral Springs
Broward Health Imperial Point
Broward Health North

Salah Foundation Children's Hospital
Broward Health Weston
Community Health Services
Broward Health Physician Group

DATE: 04/15/2021

TO: James Pyle

FROM: Broward Health Institutional Review Board

RECORD NUMBER: 2021-039

STUDY TITLE: "Uses of Immersive Virtual Reality Distraction as an adjunct to anesthesia to decrease levels of pain in patients experiencing acute procedural pain: An Educational Module"

RE: NOT HUMAN SUBJECT RESEARCH DETERMINATION

Dear James Pyle:

This is to advise you that your project, ""Uses of Immersive Virtual Reality Distraction as an adjunct to anesthesia to decrease levels of pain in patients experiencing acute procedural pain: An Educational Module" " was reviewed on behalf of the Broward Health Institutional Review Board and was declared "not research involving human subjects" based on the definitions provided in the U.S. Department of Health and Human Services Code of Federal Regulations found at 45 CFR 46.102.

Please note, this determination does not absolve the Principal Investigator from complying with other federal, state, or local laws or institutional policies and procedures that may be applicable in the conduct of this project.
This determination applies to your project in the form and content as submitted to the IRB for review. Any variations or modifications to this project involving the participation of human subjects must be approved by the IRB prior to implementing such changes. Please maintain a copy of this determination for your records.

Thank you for submitting your project to the IRB for consideration.

The Broward Health Institutional Review Board – FWA00001248 operates in accordance with the Office of Human Research Protections and U.S. Food and Drug Administration (FDA) regulations. The Broward Health Institutional Review Board complies with the ICH guidelines on Good Clinical Practice (GCP) where they are compatible with the FDA and HHS regulations.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Broward Health IRB's records.

Appendix D: IRB Exemption FIU

FIU | FLORIDA INTERNATIONAL UNIVERSITY

Office of Research Integrity
Research Compliance, MARC 414

MEMORANDUM

To: Dr. Yasmine Campbell
CC: James Pyle

From: Maria Melendez-Vargas, MIBA, IRB Coordinator

Date: April 5, 2021

Protocol Title: "Uses of Immersive Virtual Reality Distraction as an adjunct to anesthesia to decrease levels of pain in patients experiencing acute procedural pain: An Educational Module"

The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the **Exempt Review** process.

IRB Protocol Exemption #: IRB-21-0112 **IRB Exemption Date:** 04/05/21
TOPAZ Reference #: 110191

As a requirement of IRB Exemption you are required to:

1) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
3) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

Special Conditions: N/A

For further information, you may visit the IRB website at http://research.fiu.edu/irb.

MMV/em

Appendix F: QI Project Survey

Pretest and Posttest Questionnaire:

Immersive Virtual Reality

INTRODUCTION

The primary aim of this QI project is to improve the knowledge of immersive virtual reality treatment for acute procedural pain

Please answer the question below to the best of your ability. The questions are either in multiple choice or true/false format. These questions are meant to measure knowledge and perceptions on identification, referral, management and patient education on perinatal mental health conditions.

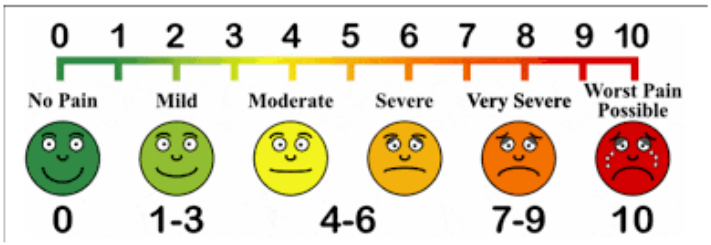
PERSONAL INFORMATION

1. **Gender:** Male Female Other
2. **Age:** _____
3. **Ethnicity:**

Hispanic Caucasian African American Asian Other

QUESTIONNAIRE (PRE- and POST-TEST)

1. **Select all the different ways to treat pain.**
    a. opioids
    b. hypnosis
    c. Distraction
    d. NSAIDs
2. **Immersive virtual reality involves a _____ immersion**
    a. Multi-sensory
    b. Single sensory
    c. No sensory



3. **What scale is this**
    a. (VAS)
    b. (GRS)
    c. (VAT)
    d. (NPRS)
4. While a patient is experiencing pain, can a distraction reduce the patient's pain level?
    a. Yes
    b. No
    c. Not sure

5. **Snow world was created for _____ patients undergoing dressing changes:**
    a. burn
    b. Chemo
    c. Obestetrics
6. **Immersive VR can include _____**
    a. Video Games
    b. Board games
    c. Tic tac toe
    d. Paper rock scissors
7. **Immersive VR has been shown to reduce _____**
    a. Anxiety
    b. Happiness
    c. Anger
    d. Appetite
8. **Children receiving routine veinapuncture that were more ____ responded best to the use of immersive VR therapy**
    a. Anxious
    b. Hyper-active
    c. Sad
    d. Hungry
9. **Patient's receiving immersive VR therapy were ____ likely to request pain medication or require rescue does of nitrous oxide**

a. More

b. Less

10. If available at your facility how likely are you to use immersive VR as an adjunct?

a. Extremely likely

b. somewhat likely

c. Neither likely nor unlikely

d. Somewhat unlikely

e. Extremely unlikley