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Virtual Reality for Pain Management During High Resolution Manometry: A Randomized Clinical Trial

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Abstract

Objective: High resolution esophageal manometry (HRM) is the gold standard for the diagnosis of esophageal motility disorders. HRM is typically performed in the office with local anesthesia only, and many patients find it unpleasant and painful. The aim of this study was to examine the effects of the use of a virtual reality (VR) headset on pain and anxiety outcomes in patients with dysphagia undergoing HRM.

Methods: Patients with dysphagia were prospectively recruited and randomized to undergo HRM with and without VR distraction. Data collected included the State-Trait Anxiety Inventory-6 (STAI6), the Short-Form McGill Pain Questionnaire (SFMPQ), heart rate, and galvanic skin response (GSR) tracings.

Results: Forty subjects completed the study, including 20 subjects in the intervention arm and 20 in the control arm. There was evidence of a significant positive effect of VR on calmness (p = .0095) STAI6 rating, as well as on physiologic measures of pain with significantly decreased GSR rise time (p = .0137) and average rate of change of conductance change (p = .0035).

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Level of Evidence: 2

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Conclusion: Use of VR during HRM catheter insertion increased calmness compared to control. Change of skin conductance was also reduced in the VR group, suggesting decreased physiologic pain. This study supports consideration of the use of VR as a distraction tool to improve patient comfort during HRM.

Lay Summary:

In this randomized controlled study, the use of virtual reality as a distraction tool during outpatient-based esophageal manometry improved calmness and physiologic measures of pain compared to control.

Keywords

laryngology; gastroenterology; esophageal manometry; virtual reality; anxiety; pain

Introduction

High Resolution Esophageal Manometry (HRM) is the gold standard for diagnosing esophageal motility disorders and provides valuable data for medical decision making.[1] HRM is routinely performed without systemic anesthesia or sedation. However, many patients report a largely unpleasant experience, as they must be awake during catheter placement through the nasopharynx to the stomach, and subsequent deglutitive tasks.[2,3] Pain and anxiety during HRM are an impediment to patients agreeing to have the procedure and, for many, interferes with procedure completion.

Some patients cannot tolerate the catheter insertion while awake, and occasionally, conscious sedation is offered as a method of analgesia during catheter placement. One recent study found negligible effects of Midazolam and Fentanyl as sedative agents on HRM data, with limitations of small sample size and limited generalizability.[4] However, sedation necessitates careful cardiovascular monitoring. It also increases resource utilization and procedural time as the patient must fully wake up before manometry can begin.

Virtual Reality (VR) allows immersion in a 3D computer-simulated universe with the use of head-mounted displays, headphones/speakers, motion tracking systems and various integrated interactive devices.[5] VR has been used effectively as a distraction method for pain and anxiety alleviation in diverse clinical settings such as urology office procedures, pediatric dentistry, burn unit dressing changes, and physical therapy.[5–9] VR has recently been studied in outpatient laryngeal procedures requiring transnasal procedures, demonstrating a potential for anxiety alleviation during procedures.[10] However, to date, there are no publications on the use of VR as a distraction tool in HRM.

Current VR headsets allow for unencumbered nasal, oral and neck access, all potentially needed for HRM. Based on the efficacy of VR in reducing pain and/or anxiety via distraction in other procedures, we hypothesized that VR can be an effective palliative tool during the performance of HRM. Herein, we evaluated the efficacy of VR distraction in combination with standard analgesia protocol in alleviating pain and anxiety during

HRM probe insertion compared to standard analgesia protocol only with a non-blinded randomized controlled trial.

For the first time in otolaryngology, VR effect on pain outcomes were measured both with validated patient questionnaires and objective quantitative physiologic measures, including heart rate and galvanic skin response. Additionally, a qualitative assessment of subjects' experience with VR in the intervention group was conducted using semi-structured interviews. Proceduralists' perception of patients' comfort during esophageal manometry with the VR headset in combination with standard analgesia compared to standard analgesia protocol only was also assessed.

Materials and Methods

Research Design and Participants

Approval for this study was obtained from the Institutional Review Board at Weill Cornell Medical College (Protocol Number 20–01021300). The trial was registered online (ClinicalTrials.gov Identifier: NCT05218967). We conducted a prospective non-blinded, randomized controlled trial between February 2022 and August 2022 at our institution. We recruited English-speaking adults from the otolaryngology, gastroenterology, and general surgery clinics scheduled to undergo outpatient HRM. Exclusion criteria for study participation included: (1) use of psychotropic or analgesic medication within the 12 hours prior to HRM due to the possible confounding effect on pain or anxiety perception, (2) uncorrected visual impairment, and (3) motion sickness or vertigo. Patients who met these criteria and consented to participation were enrolled for the trial and assigned randomly to either (1) VR distraction intervention in addition to standard analgesia protocol (flushing of nostrils with 6 mL of 2% viscous lidocaine) during HRM, or (2) standard analgesia protocol only during HRM. Randomized assignment was performed using a computer-generated randomizer (randomization.com) and was communicated to participants after consent.

Procedures and Equipment

After consent, subjects who were randomized to the VR group were placed into the VR environment following standard anesthesia protocol. These subjects were immersed in VR for three minutes and continued wearing the headset throughout HRM catheter insertion, generally the most uncomfortable part of the procedure. Following HRM catheter insertion, subjects remained in VR for three minutes before removal of the headset and initiation of the HRM swallow protocol, as it is unknown whether VR affects measurements taken during HRM. In the control group, patients underwent HRM catheter placement only with the standard anesthesia protocol without the VR headset.

The VR headset was the Oculus Quest (Meta, Menlo Park, CA, USA). We used a VR environment provided by Take-Pause (Brooklyn, NY, USA), an evidence-based application focused on mindfulness breathing practices for anxiety reduction requiring no head movement or use of the VR hand controllers.[11] Take-Pause offers an immersive scenic environment with a butterfly oscillating every 12 seconds. Instructions played through the VR headset speakers for the initial 5 minutes of the simulation instructed the subject to relax

and breathe at the same cadence as the butterfly's movement. A two-dimensional image of the VR environment is shown in Figure 1.

Outcome Measures

The primary outcome was evaluated with the six-question State-Trait Anxiety Inventory (STAI-6) before and after HRM performance, the Short-Form McGill Pain Questionnaire (SF-MPQ) after HRM performance, and objective quantitative physiologic measures as described below. All survey data was collected and managed using Research Electronic Data Capture (REDCap), a secure, web-based software platform designed to support data capture for research studies.[12]

The STAI-6 is a validated six-item short-form version of the STAI, used to measure anxiety using 4-point Likert scale ratings, assessing how calm, tense, upset, relaxed, content, and worried a subject feels.[13] Each question of STAI-6 may be analyzed individually or summed to provide a STAI-6 total score, for a total of seven outcomes. The SF-MPQ was administered to evaluate quality and intensity of subjects' pain with HRM.[14] The main component of SF-MPQ includes 15 questions which are rated using a 4-point Likert scale. The 15 questions are summed to obtain an SF-MPQ total score, ranging from 0 to 45. Eleven of the 15 questions provide a 'sensory' pain score, ranging from 0 to 33, and the remaining four questions provide an 'Affective' pain score, ranging from 0 to 12. The remaining two items of the SF-MPQ estimate total perceived pain with a visual analogue scale (VAS), and 6-point Likert scale rated Present Pain Intensity (PPI) index. Subjects were asked to focus their SF-MPQ ratings on the pain associated with HRM performance.

Measures of physiologic response to HRM in both the VR and control group included: (1) heart rate (HR); (2) galvanic skin response (GSR); (3) GSR maximum slope of conductance; (4) GSR maximum slope rise time; (5) GSR average rate of conductance change. HR was measured before and during insertion of the HRM catheter, while GSR measures were recorded throughout the entire procedure. GSR measures skin conductivity which can change with stress induced sweating or vasoconstriction. Larger changes in GSR are associated with more substantial autonomic nervous system activation. GSR maximum slope of conductance was measured to investigate whether the VR experience blunted the instantaneous rate of GSR change. Similarly, GSR slope rise time served to measure the average rate at which subjects experienced physiologic stress, which may be proportional to the pain experienced.[15] All physiologic data were collected using PowerLab bioamplifier (ADInstruments, Sydney, Australia). HR was measured on the hand with a force transducer converted to frequency of arteriolar beats using cyclic measurements in LabChart software (v8.1.24, ADInstruments, Sydney, Australia). The galvanic skin response was measured using a two-electrode system on the hand and provided an output in conductance in microsiemens. LabChart software computed the rate of change of conductance as derivative of the conductance with respect to time. The time taken to reach maximum conductance was manually extracted. This elapsed time and absolute change in conductance were used to calculate average rate of change of conductance. A photograph of the experimental set-up during manometer insertion is shown in Figure 1. A sample tracing of GSR data displayed in LabChart is shown in Figure 2.

For our secondary aims, proceduralists completed a Likert scale survey focusing on their assessment of patient comfort and, if used, their experience with the VR headset. Failure to complete procedure, adverse events, difficulties with the procedure, and any deviation from standard performance of esophageal manometry were recorded. Subjects who received the VR intervention responded to a brief semi-structured interview on whether (1) VR helped them cope with HRM; (2) they would use VR again during a similar procedure; and (3) they would recommend VR to a friend undergoing HRM. Interviews were manually transcribed and imported to NVivo (Version 12, Massachusetts, USA), which was used to organize transcripts and codes. Two authors (KA and SS) independently inductively coded transcripts to identify underlying themes in subjective descriptions of the VR experience after all data had been collected.[16]

Statistical Methods

All statistical analyses were completed using R version 4.1.1. An alpha of $p < .05$ was used as the level for statistical significance. Type 1 error adjustments (e.g., Holm-Bonferroni) were not used to correct for multiple comparisons.

Mann-Whitney U tests were used to examine differences between the VR and No VR groups in SF-MPQ's Affective sub score, Sensory sub score, Total score, and VAS ratings. An ordinal cumulative link regression model was used to examine differences between the VR and No VR groups in SF-MPQ's PPI.

Ordinal cumulative link regression models were also used to examine the relationship between VR groups, time (pre/post HRM), and the interaction between the two on STAI's six individual questions. Similarly, a linear regression was used to examine the relationship between VR groups, time (pre/post HRM), and the interaction between the two on STAI-6's sum score. Linear regressions were also used to examine the relationship between VR groups, time (pre/post HRM), and the interaction between the two on heart rate and the four GSR physiologic outcomes.

Models containing significant interactions were followed up with post-hoc testing of main effects. Linearity, homogeneity of variance, normality of residuals, and outliers were visually inspected prior to all inferential data analyses. Assumptions of linearity and normality of residuals appeared violated upon visual inspection for all GSR outcomes, and therefore log transformations were used.

Results

Forty patients were enrolled from March until August 2022, with 20 subjects randomized to the VR or the control group. The VR group had 7 males and 13 females, with a mean age of 52.6 years (SD 16.0 years). The non-VR group had 15 males and 5 females, with a mean age of 48.1 years (SD 18.8 years). Patients who declined to enroll were not asked to disclose their reason for non-participation. A small number, though unprompted, cited their unfamiliarity with VR technology, their concern for motion sickness, or their baseline anxiety regarding the procedure. Flow diagram is in Figure 3. No serious complications were observed.

Pain Outcomes

Model results for the five SF-MPQ outcomes are outlined in Table 1A. No statistically significant relationships were identified between groups (VR/Control) for SF-MPQ sensory pain ratings, affective pain ratings, sum score, VAS, or PPI.

Anxiety Outcomes

Model results for the seven STAI outcomes are outlined in Table 1B. Except for STAI ratings for calmness, no significant relationships were identified between STAI outcomes and treatment group (VR/control), or STAI outcomes and time (pre/post HRM). A significant group by time interaction, however, was observed for calmness (Figure 3). Therefore, Wilcoxon Signed-Rank Tests were used to examine differences in calmness separately for the VR and No VR groups as an effect of time, and Mann Whitney U Tests were used to examine differences in calmness between the VR and control group separately for the before HRM and after HRM time points. Results revealed a significant increase (improvement) in calmness over time for the VR group ($p = .0192$; 95% CI: −2.000 – −0.499), but not for the control group ($p = .8244$; 95% CI: −1.000 – 1.000). Median calmness ratings increased for the VR group from 2.0 before HRM insertion to 3.5 after HRM insertion but were unchanged for the control group with a median rating of 3.0. There were no statistically significant differences in calmness between the VR and control groups before ($p = .058$; 95% CI: −2.615 – 1.000) or after ($p = .224$; 95% CI: −1.000 – 3.311) HRM insertion (Figure 4).

Physiologic Response Measures

Model results for the five physiologic outcomes are outlined in Table 2. Linear regression revealed a small but statistically significant difference in average conductance rate of change between treatment groups ($p = .043$; 95% CI: −1.11 – −0.02; $R^2 = .104$; Table 2). No statistically significant relationships were identified between treatment group and heart rate, GSR, maximum slope of conductance, nor maximum slope of conductance rise time. Of note there was one missing data point for heart rate after insertion due to motion artifact, leading to n=39 for this measurement.

Proceduralist Survey

Model results for the four proceduralist outcomes are outlined in Table 3. Of the 40 procedures, 37 were completed by one proceduralist (18 of which were VR) and the remaining 3 were completed by a second proceduralist (2 of which were VR). No statistically significant relationships were identified between treatment group (VR/Control) and responses pertaining to difficulty of the exam, success of the exam, perceived discomfort, and perceived agitation. Most responses ‘somewhat disagreed’ (2/5) that VR interfered with the completion of the HRM procedure (n = 16; 80%). Most of the responses ‘somewhat agreed’ (4/5) that VR benefited the patient during the completion of the HRM procedure (n = 16; 80%).

Interviews

Verbal, qualitative responses to a survey were collected from 16 of the 20 VR group participants and analyzed. One subject who was randomized into the VR group chose not to respond to the survey about their experience, and three responses were lost to technological difficulties. Twelve subjects (75%) indicated that the VR experience helped them cope with the procedure. Fourteen subjects (87.5%) indicated that they would use VR again if provided the option when undergoing another similar procedure and that they would recommend VR to a friend undergoing HRM.

During interview analysis, the key positive effects of VR were related to the VR's calming, relaxing, distracting, and soothing effects. One participant (ID-29) noted that the VR "was a nice guide to regulate my breathing," a sentiment expressed by multiple participants regarding VR's soothing impact on respiratory regulation and subsequent decrease in general anxiety. Participants commonly cited the VR experience as a distraction from the discomfort of their procedure (n=7; 43.8%) as one noted (ID-10) that "it was distracting in that I didn't have to think much about things entering through my nose." Overall, patients found that the VR had a calming and relaxing effect even if they were not familiar with the VR prior to the procedure. Only one participant said they would not recommend VR to friends undergoing a similar procedure. One noted (ID-11) that VR use should be patient specific "because the VR headset can be disorienting." Some patients who were uncertain about the positive impact VR had on their experience expressed ambivalence about future use; however, some also noted that it did not make their experience worse than expected. Code frequency is in Table 4.

Discussion

Our study is the first to evaluate VR as a distraction strategy during outpatient HRM placement, which is a notoriously uncomfortable procedure that is typically performed awake to elicit volitional deglutition. Over the past two decades, the applications of VR distraction in anxiety and pain management have multiplied.[17,18] With improved and less expensive commercial technology, VR has been recognized as an effective distraction tool to palliate discomfort in diverse settings. Distraction re-allocates a patient's attention from a painful stimulus to a non-painful one and diminishes the perception of pain.[19] VR holds promise of reducing the need for pharmaceutical approaches to analgesia and anxiolysis, including in acute, chronic and procedural pain. Despite the high prevalence of office-based interventions in otolaryngology, few studies have evaluated the impact of VR on patients' pain and anxiety experience during awake procedures. In postoperative nasal endoscopic debridement, patients experienced significantly less anxiety with VR distraction.[20] In a small randomized control trial with 8 patients per treatment arm, VR reduced distress during office-based laryngology procedures including biopsy, laser ablation and injection laryngoplasty.[10] Pain and anxiety, however, were not significantly affected in this study. We did not find significant difference between the VR and control groups on the SF-MPQ and VAS evaluation of subject-reported pain and discomfort. While there was no significant change in the composite score of the STAI-6, the VR group had significantly higher

post-procedure calmness compared with the non-VR group, suggesting possible anxiolytic benefit as a result of the intervention.[13]

Our study is also the first to assess physiologic response associated with pain using GSR and HR with VR intervention in otolaryngology. HR is known to increase when patients experience pain.[21] GSR, or electrodermal activity, measures the electrical activity conducted through sweat glands in the skin.[22] Electrodermal activity is thought to reflect the activity of the sympathetic nervous system (i.e. physiological arousal). Skin sympathetic nerves are activated in response to stress or other stimuli, increasing permeability of eccrine sweat glands, resulting in changes in skin conductivity. Although GSR has been studied since the 19th century for monitoring emotional change, the first report about the application of GSR monitoring for pain measurement was not published until 2002.[14] GSR monitoring is now routinely used in studies on acute and chronic pain.[23] In our study, use of VR was associated with non-significant, modestly lower HR. While absolute GSR conductance changes were not statistically significant between treatment groups, we found that the average rate of conductance increase was slower in the VR group. Rate of change in skin conductance is not well established as a correlate to sympathetic activity or discomfort. However, its correlation with VR subjects' increased calmness suggests possible relevance as an objective measure of systemic discomfort. A slower activation of sweat glands leading to slower increase in skin conductance may be influenced by the potential of VR to blunt sympathetic activity caused by a painful procedure.

Our qualitative results add to existing studies on VR in office-based otolaryngology procedures that only inquired whether patients would want to use VR for future similar procedures in the future.[10] They are also useful in understanding why the VR group may have experienced increased calmness during the procedure. Qualitative analysis of subjects' experience identified common positive impacts including its calming, distracting, relaxing, and soothing effects. Some patients described anxiety going into the procedure and felt that VR soothed and calmed them. This may suggest that the anxiolytic effects of VR may extend beyond the procedure itself. These qualitative findings are consistent with prior work suggesting that VR can be useful in reducing preoperative and procedural anxiety and discomfort.[10,20,24] Three subjects in the VR group expressed they felt VR was not helpful, and only one felt that VR was not effective at improving their procedure experience and they would not use it again. Subjects in the VR group overwhelmingly felt VR improved their experience thanks to its calming or distracting effects, consistent with the STAI-6 findings.

Another unique aspect of our study is the inclusion of proceduralists' perspective on VR feasibility during HRM. In 90% (n=18) of the HRM cases performed with VR, the proceduralist was confident that the VR did not affect performance of the procedure. Even though the headset rests on the face, proceduralists' survey responses indicate that it did not interfere with nasal access. As new VR hardware is developed, slimmer device profiles may improve ease of application in otolaryngological procedures. Though there was no significant difference in proceduralist-perceived discomfort or agitation, proceduralists thought subjects in the VR group benefitted from the intervention in most cases (90%, n=18). There was no significant difference in difficulty or success of HRM completion between groups, further substantiating the feasibility of VR immersion during HRM. Indeed,

transnasal procedures are commonly performed in the awake patient, and are known to be associated with pain. The effect of lidocaine for pain management has been studied before, including in HRM, with mixed results.[25] A Cochrane review of eight randomized controlled trials concluded that topical anesthetic did not reduce pain or discomfort.[26] Researchers have suggested further investigation of topical anesthetic during transnasal manometry is indicated, as transnasal manometry is particularly painful.[27,28]

One salient limitation of our study is the lack of blinding. We did not use a sham VR intervention in the control group,[29] which meant that subjects knew which group they were assigned to and may have modified their self-reports as a result. Additionally, there was limited blinding during data analysis due to GSR dataset annotation as VR immersion was initiated and concluded. Additional bias may have emerged from subject self-selection for the study. This limits the generalizability of the results as some patients who may experience limited benefit are not included in the dataset. Patients who declined to participate most frequently voiced unfamiliarity or discomfort with VR or pre-existing anxiety regarding HRM. In some cases, the VR headset obstructed the proceduralist's access to the nasal passages, requiring the researcher to slightly readjust the VR headset. This change in headset position may have impacted the immersive nature of the VR environment. Furthermore, data on prior experience with VR and mindfulness was not collected and may have been a useful variable. Future studies should focus on this qualitative patient experience to further determine the validity of VR headset use during procedures as standard of care. This study was conducted in one academic medical center, which may limit generalizability. During collection of physiologic data, accuracy of acquisition devices was occasionally subject to motion artifact.[30] An original recruitment goal of 56 patients was set at the beginning of the project based on power analysis derived from prior studies examining the use of VR in office laryngology procedures. However, limited patient volume and time for study completion presented an obstacle for meeting this goal.[31] While age between groups was well matched, sex was imbalanced. The VR group had more than twice as many females. A larger, multi-center randomized control trial may result in more balanced groups and have delineated findings of smaller effect size that our single-center study was not able to capture.

Conclusion

This study is the first to evaluate the impact of VR on adult pain and anxiety during outpatient HRM and the first to use GSR to objectively quantify periprocedural discomfort and anxiety during VR immersion in otolaryngology. While reported pain was not changed, we found significantly improved calmness during the procedure and significant physiologic indications of reduced pain with a slower average conductance rate of change of subjects in the VR group. VR distraction is a promising non-pharmaceutical intervention to improve patients' experience during HRM, while maintaining sufficient situational awareness for patients to follow procedural deglutitive instructions.

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References:

1. Baldwin D, Puckett Y. Esophageal Manometry. In: StatPearls. StatPearls Publishing; 2022. Accessed February 21, 2023. http://www.ncbi.nlm.nih.gov/books/NBK559237/
2. Walamies MA. Perception of esophageal manometry. Dis Esophagus. 2002;15(1):46–49. doi:10.1046/j.1442-2050.2002.00224.x [PubMed: 12060042]
3. Yadlapati R, Kahrilas PJ, Fox MR, et al. Esophageal motility disorders on high-resolution manometry: Chicago classification version 4.0©. Neurogastroenterol Motil. 2021;33(1):e14058. doi:10.1111/nmo.14058 [PubMed: 33373111]
4. Su H, Carlson DA, Donnan E, et al. Performing High-resolution Impedance Manometry After Endoscopy With Conscious Sedation Has Negligible Effects on Esophageal Motility Results. J Neurogastroenterol Motil. 2020;26(3):352–361. doi:10.5056/jnm20006 [PubMed: 32606257]
5. Indovina P, Barone D, Gallo L, Chirico A, De Pietro G, Giordano A. Virtual Reality as a Distraction Intervention to Relieve Pain and Distress During Medical Procedures: A Comprehensive Literature Review. Clin J Pain. 2018;34(9):858. doi:10.1097/AJP.0000000000000599 [PubMed: 29485536]
6. Moon JY, Shin J, Chung J, Ji SH, Ro S, Kim WH. Virtual Reality Distraction during Endoscopic Urologic Surgery under Spinal Anesthesia: A Randomized Controlled Trial. J Clin Med. 2019;8(1):2. doi:10.3390/jcm8010002
7. Walker MR, Kallingal GJS, Musser JE, Folen R, Stetz MC, Clark JY. Treatment Efficacy of Virtual Reality Distraction in the Reduction of Pain and Anxiety During Cystoscopy. Mil Med. 2014;179(8):891–896. doi:10.7205/MILMED-D-13-00343 [PubMed: 25102532]
8. Asl Aminabadi N, Erfanparast L, Sohrabi A, Ghertasi Oskouei S, Naghili A. The Impact of Virtual Reality Distraction on Pain and Anxiety during Dental Treatment in 4–6 Year-Old Children: a Randomized Controlled Clinical Trial. J Dent Res Dent Clin Dent Prospects. 2012;6(4):117–124. doi:10.5681/joddd.2012.025 [PubMed: 23277857]
9. Jeffs D, Dorman D, Brown S, et al. Effect of Virtual Reality on Adolescent Pain During Burn Wound Care. J Burn Care Res. 2014;35(5):395–408. doi:10.1097/BCR.0000000000000019 [PubMed: 24823326]
10. Chang J, Ninan S, Liu K, Iloreta AM, Kirke D, Courey M. Enhancing Patient Experience in Office-Based Laryngology Procedures With Passive Virtual Reality. OTO Open. 2021;5(1):2473974X20975020. doi:10.1177/2473974X20975020
11. Butt M, Kabariti S, Likourezos A, et al. Take-Pause: Efficacy of mindfulness-based virtual reality as an intervention in the pediatric emergency department. Acad Emerg Med Off J Soc Acad Emerg Med. 2022;29(3):270–277. doi:10.1111/acem.14412
12. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an international community of software platform partners. J Biomed Inform. 2019;95:103208. doi:10.1016/j.jbi.2019.103208 [PubMed: 31078660]
13. Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the Spielberger State-Trait Anxiety Inventory (STAI). Br J Clin Psychol. 1992;31(3):301–306. doi:10.1111/j.2044-8260.1992.tb00997.x [PubMed: 1393159]
14. Melzack R The short-form McGill Pain Questionnaire. Pain. 1987;30(2):191–197. doi:10.1016/0304-3959(87)91074-8 [PubMed: 3670870]
15. Sanchez-Comas A, Synnes K, Molina-Estren D, Troncoso-Palacio A, Comas-González Z. Correlation Analysis of Different Measurement Places of Galvanic Skin Response in Test Groups Facing Pleasant and Unpleasant Stimuli. Sensors. 2021;21(12):4210. doi:10.3390/s21124210 [PubMed: 34205302]
16. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77–101. doi:10.1191/1478088706qp063oa
17. Difede J, Hoffman H, Jaysinghe N. Innovative use of virtual reality technology in the treatment of PTSD in the aftermath of September 11. Psychiatr Serv Wash DC. 2002;53(9):1083–1085. doi:10.1176/appi.ps.53.9.1083
18. Lier EJ, de Vries M, Steggink EM, Ten Broek RPG, van Goor H. Effect modifiers of virtual reality in pain management: a systematic review and meta-regression analysis. Pain. Published online March 22, 2023. doi:10.1097/j.pain.0000000000002883

19. McCaul KD, Malott JM. Distraction and coping with pain. Psychol Bull. 1984;95(3):516–533. [PubMed: 6399756]

20. Gray ML, Goldrich DY, McKee S, et al. Virtual Reality as Distraction Analgesia for Office-Based Procedures: A Randomized Crossover-Controlled Trial. Otolaryngol--Head Neck Surg Off J Am Acad Otolaryngol-Head Neck Surg. 2021;164(3):580–588. doi:10.1177/0194599820942215

21. Terkelsen AJ, Mølgaard H, Hansen J, Andersen OK, Jensen TS. Acute pain increases heart rate: differential mechanisms during rest and mental stress. Auton Neurosci Basic Clin. 2005;121(1–2):101–109. doi:10.1016/j.autneu.2005.07.001

22. Frank E, Carlson B, Hu A, et al. Assessment and Treatment of Pain during In-Office Otolaryngology Procedures: A Systematic Review. Otolaryngol--Head Neck Surg Off J Am Acad Otolaryngol-Head Neck Surg. 2019;161(2):218–226. doi:10.1177/0194599819835503

23. Bijur PE, Silver W, Gallagher EJ. Reliability of the visual analog scale for measurement of acute pain. Acad Emerg Med Off J Soc Acad Emerg Med. 2001;8(12):1153–1157. doi:10.1111/j.1553-2712.2001.tb01132.x

24. Ganry L, Hersant B, Sidahmed-Mezi M, Dhonneur G, Meningaud JP. Using virtual reality to control preoperative anxiety in ambulatory surgery patients: A pilot study in maxillofacial and plastic surgery. J Stomatol Oral Maxillofac Surg. 2018;119(4):257–261. doi:10.1016/j.jormas.2017.12.010 [PubMed: 29317347]

25. Wahba G, Neshkova E, Jutras G, et al. Lidocaine before esophageal manometry and ambulatory pH monitoring: A randomized controlled trial. Neurogastroenterol Motil Off J Eur Gastrointest Motil Soc. 2021;33(12):e14167. doi:10.1111/nmo.14167

26. Sunkaraneni VS, Jones SE. Topical anaesthetic or vasoconstrictor preparations for flexible fibre-optic nasal pharyngoscopy and laryngoscopy. Cochrane Database Syst Rev. 2011;(3):CD005606. doi:10.1002/14651858.CD005606.pub2 [PubMed: 21412890]

27. Hernandez J, Leverson G, Thibeault S. Effect of Lidocaine on Comfort and Swallowing Pressures During Pharyngeal High-Resolution Manometry. Dysphagia. 2021;36(3):439–442. doi:10.1007/s00455-020-10157-4 [PubMed: 32683497]

28. Knigge MA, Marvin S, Thibeault SL. Safety and Tolerability of Pharyngeal High-Resolution Manometry. Am J Speech Lang Pathol. 2019;28(1):43–52. doi:10.1044/2018_AJSLP-18-0039 [PubMed: 30515521]

29. Garcia LM, Birckhead BJ, Krishnamurthy P, et al. Three-Month Follow-Up Results of a Double-Blind, Randomized Placebo-Controlled Trial of 8-Week Self-Administered At-Home Behavioral Skills-Based Virtual Reality (VR) for Chronic Low Back Pain. J Pain. 2022;23(5):822–840. doi:10.1016/j.jpain.2021.12.002 [PubMed: 34902548]

30. Hossain MB, Posada-Quintero HF, Kong Y, McNaboe R, Chon KH. A Preliminary Study on Automatic Motion Artifact Detection in Electrodermal Activity Data Using Machine Learning. Annu Int Conf IEEE Eng Med Biol Soc IEEE Eng Med Biol Soc Annu Int Conf. 2021;2021:6920–6923. doi:10.1109/EMBC46164.2021.9629513

31. Liu KY, Ninan SJ, Laitman BM, Goldrich DY, Iloreta AM, Londino AV. Virtual Reality as Distraction Analgesia and Anxiolysis for Pediatric Otolaryngology Procedures. The Laryngoscope. 2021;131(5):E1714–E1721. doi:10.1002/lary.29148 [PubMed: 33017065]

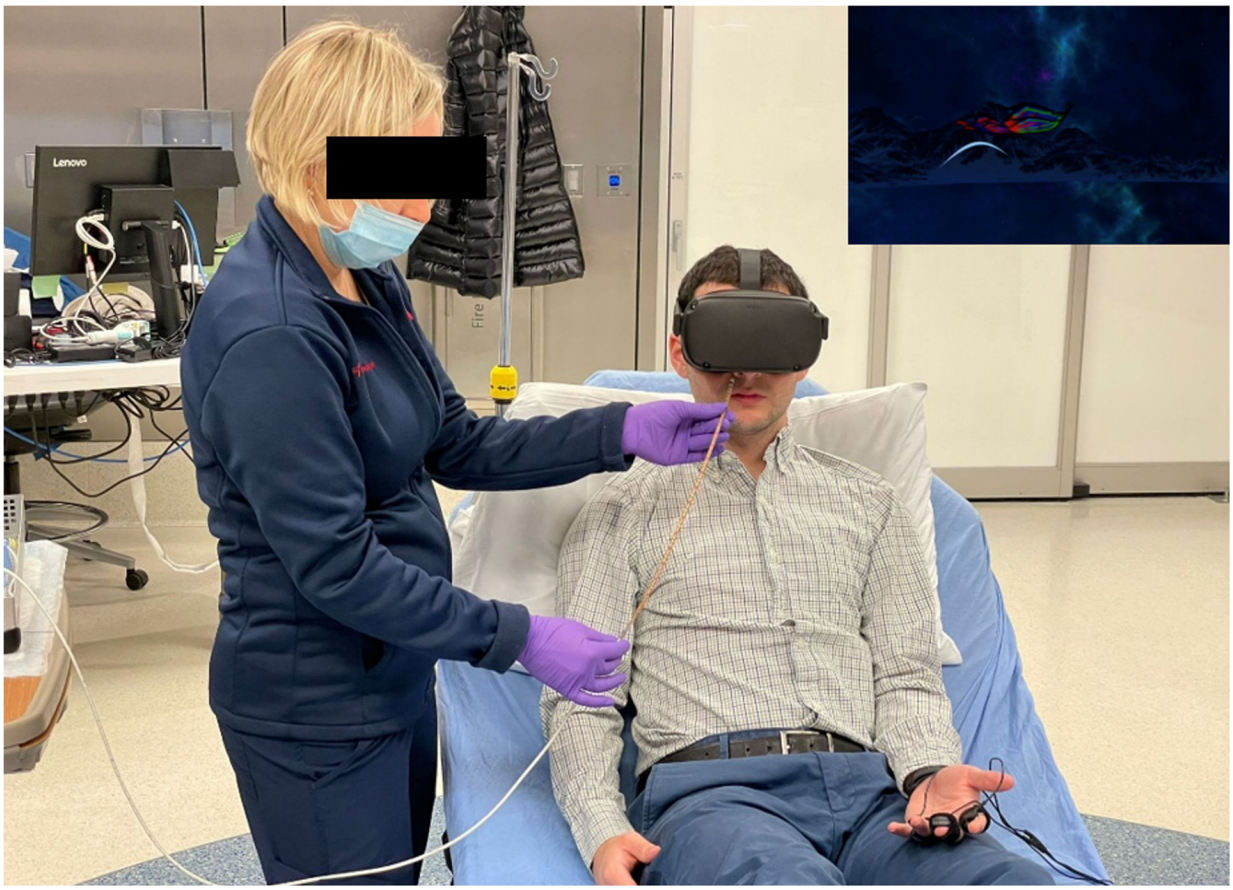

Figure 1.
Image of a researcher immersed in virtual reality while wearing heart rate and galvanic skin response monitors on the left hand. The proceduralist is holding an HRM probe at the nostril of the researcher to illustrate access to the nose. The inset in the top right corner illustrates the butterfly floating in the virtual reality environment.

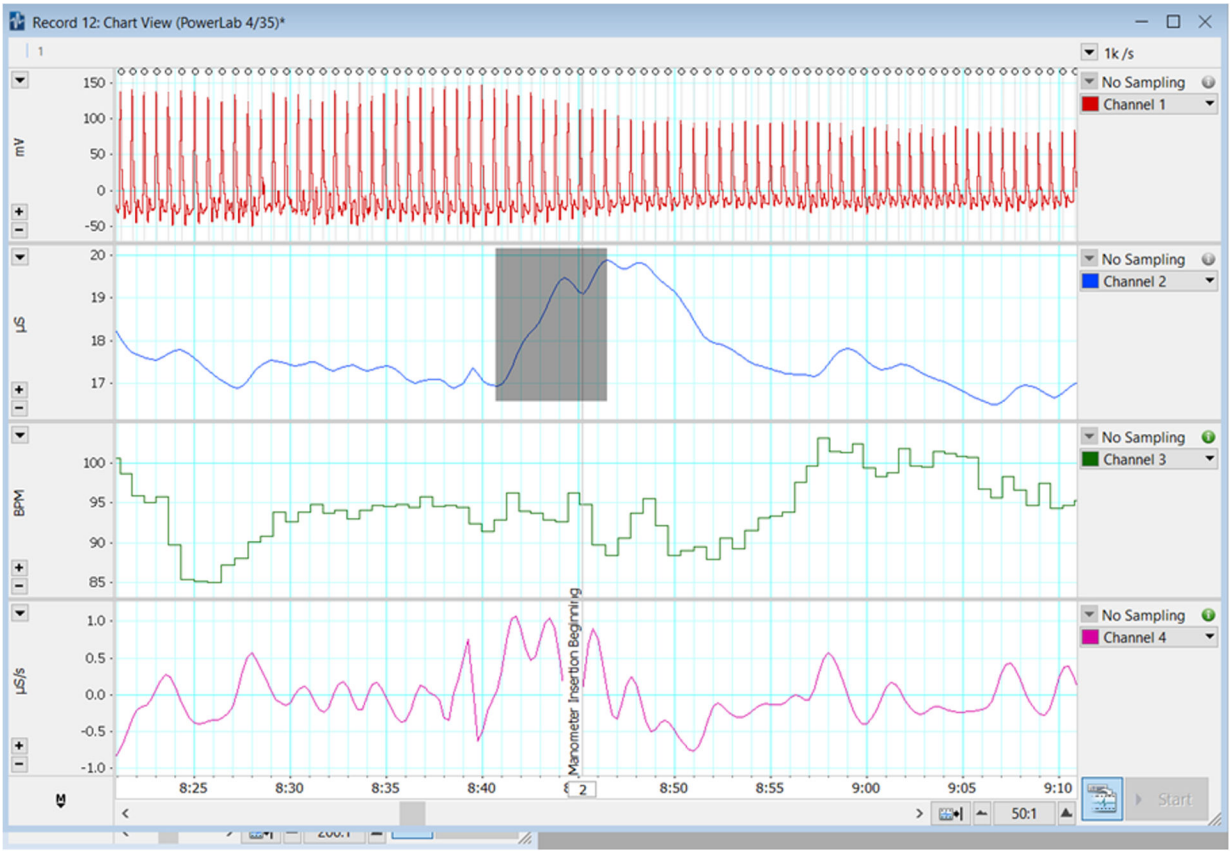

Figure 2.

This image illustrates a sample recording from LabChart Software. Channel 1 (red) indicates input from the force transducer which correlates with arterial propagation of heart beats. Channel 2 (blue) indicates the conductance between the two electrodes on the palmar surface of the hand. Channel 3 (green) indicates heart rate derived from a cyclic measurements function applied to channel 1 data. Channel 4 (pink) indicates the derivative of conductance (channel 2, blue) with respect to time taken at a frequency of 4 Hz. Note annotation at time 8:45 indicating beginning of manometer insertion.

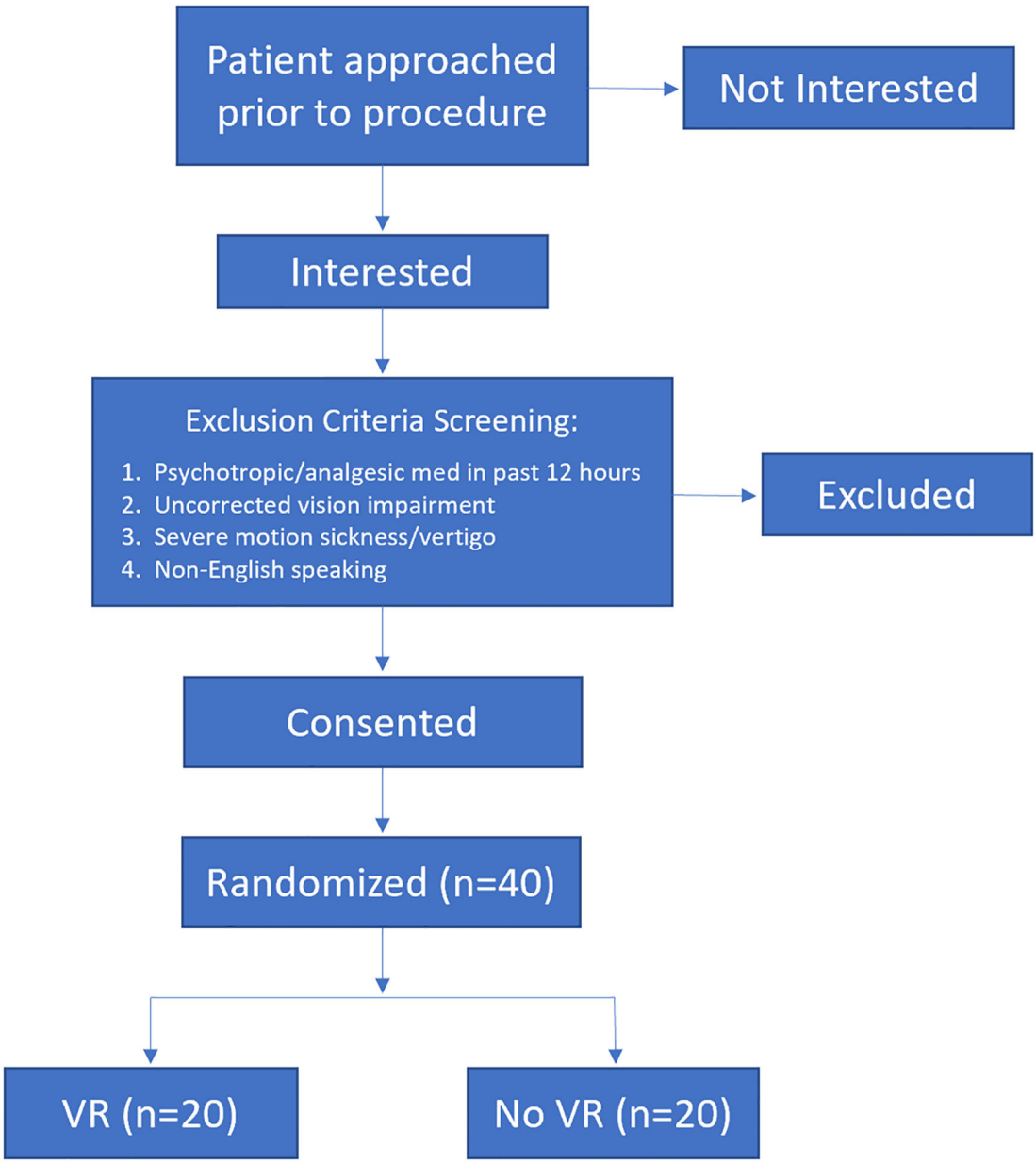

Figure 3.
Enrollment Flow Diagram

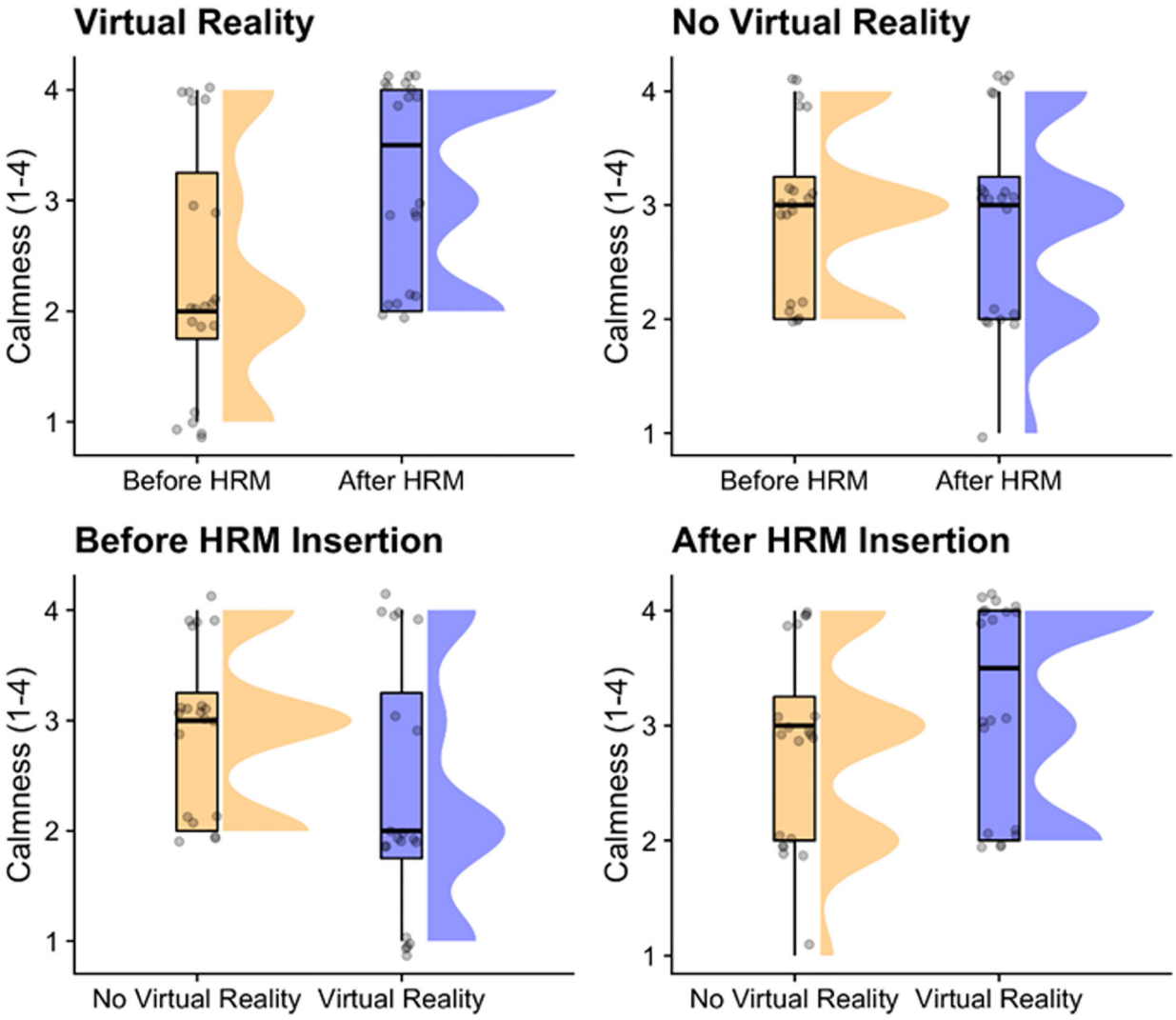

Figure 4.

Responses to STAI-6 Calmness Question. Differences in STAI ratings of calmness as an effect of treatment group (Virtual Reality and No Virtual Reality, row 2) and time (Before HRM and After HRM, row 1) Abbreviations: high resolution manometry (HRM)

Table 1.

Model Results for Pain (1A) and Anxiety (1B) Outcomes with Glossary (applicable for Tables 1–3).

Predictors	**The independent variable**
Estimates	**The effect size of the predictor (independent) variable on the outcome (dependent) variable**
CI	**The 95% confidence interval of the true effect size**
P	**The probability of obtaining the observed results, assuming the null hypothesis is true**
(intercept)	**The overall grand mean of the outcome variable**
Observations	**Number of data points collected**
Group (VR/No VR)	**Comparison between the VR group and Non-VR group, with VR as the reference group**
R^2/ R^2adjusted	**Coefficient of determination of the regression model / R^2adjusted for the number of variables**
R^2Nagelkerke	**Nagelkerke's coefficient of determination for logistic regression**

Table 1A.

	Sensory		
Predictors	***Estimates***	***CI***	***p***
(Intercept)	7.40	5.48 – 9.32	**<0.001**
Group (VR/No VR)	0.42	−2.29 – 3.14	0.753
Observations	40		
R^2 / R^2 adjusted	0.003 / −0.024		
	Affective		
Predictors	***Estimates***	***CI***	***p***
(Intercept)	3.20	2.32 – 4.08	**<0.001**
Group (VR/No VR)	0.07	−1.17 – 1.31	0.909
Observations	40		
R^2 / R^2 adjusted	0.000 / −0.026		
	Sum Score		
Predictors	***Estimates***	***CI***	***p***
(Intercept)	10.60	7.97 – 13.23	**<0.001**
Group (VR/No VR)	0.49	−3.22 – 4.21	0.789
Observations	40		
R^2 / R^2 adjusted	0.002 / −0.024		
	VAS		
Predictors	***Estimates***	***CI***	***p***
(Intercept)	38.42	30.82 – 46.03	**<0.001**
Group (VR/No VR)	1.59	−9.17 – 12.35	0.766
Observations	40		
R^2 / R^2 adjusted	0.002 / −0.024		
	PPI		
Predictors	***Odds Ratios***	***CI***	***p***
Group (VR/No VR)	0.95	0.42 – 2.16	0.906

Observations	40		
R^2 Nagelkerke	0.000		

Table 1B.

		Composite	
Predictors	***Estimates***	***CI***	***p***
(Intercept)	13.20	12.71 – 13.69	**<0.001**
Group (VR/No VR)	−0.14	−0.84 – 0.56	0.687
Time (Before/After)	0.07	−0.63 – 0.77	0.840
Group * Time	−0.00	−0.99 – 0.99	1.000
Observations	80		
R^2 / R^2 adjusted	0.003 / −0.037		
		Calm	
Predictors	***Odds Ratios***	***CI***	***p***
Group (VR/No VR)	0.82	0.46 – 1.47	0.502
Time (Before/After)	1.82	1.01 – 3.29	**0.045**
Group * Time	2.72	1.18 – 6.28	**0.019**
Observations	80		
R^2 Nagelkerke	0.113		
		Tense	
Predictors	***Odds Ratios***	***CI***	***p***
Group (VR/No VR)	1.16	0.65 – 2.07	0.608
Time (Before/After)	0.68	0.38 – 1.21	0.192
Group * Time	0.55	0.24 – 1.26	0.158
Observations	80		
R^2 Nagelkerke	0.053		
		Upset	
Predictors	***Odds Ratios***	***CI***	***p***
Group (VR/No VR)	0.89	0.38 – 2.06	0.778
Time (Before/After)	1.50	0.65 – 3.48	0.345
Group * Time	0.40	0.12 – 1.31	0.131
Observations	80		
R^2 Nagelkerke	0.071		
		Relaxed	
Predictors	***Odds Ratios***	***CI***	***p***
Group (VR/No VR)	0.69	0.39 – 1.22	0.205
Time (Before/After)	1.29	0.73 – 2.28	0.379
Group * Time	1.56	0.70 – 3.51	0.280
Observations	80		
R^2 Nagelkerke	0.043		
		Content	
Predictors	***Odds Ratios***	***CI***	***p***

Group (VR/No VR)	0.78	0.44 – 1.37	0.384
Time (Before/After)	1.07	0.61 – 1.88	0.809
Group * Time	0.93	0.42 – 2.07	0.865
Observations	80		
R^2 Nagelkerke	0.011		
		Worried	
Predictors	***Odds Ratios***	***CI***	***p***
Group (VR/No VR)	1.46	0.82 – 2.62	0.198
Time (Before/After)	0.56	0.31 – 1.02	0.056
Group * Time	0.55	0.24 – 1.26	0.156
Observations	80		
R^2 Nagelkerke	0.098		

Table 2.

Physiologic Outcomes.

	Heart Rate After Insertion		
Predictors	***Estimates***	***CI***	***p***
(Intercept)	11.04	−3.13 – 25.20	0.123
Group (VR/No VR)	14.28	−5.75 – 34.32	0.157
Baseline Heart Rate	0.89	0.71 – 1.07	**<0.001**
Group * Baseline Heart Rate	−0.17	−0.42 – 0.09	0.194
Observations	39		
R^2 / R^2 adjusted	0.852 / 0.839		
	log(Absolute Conductance Change)		
Predictors	***Estimates***	***CI***	***p***
(Intercept)	1.07	0.76 – 1.38	**<0.001**
Group (VR/No VR)	0.01	−0.43 – 0.45	0.974
Observations	40		
R^2 / R^2 adjusted	0.000 / −0.026		
	log(Maximum Rate of Conductance Change)		
Predictors	***Estimates***	***CI***	***p***
(Intercept)	−0.21	−0.46 – 0.04	0.103
Group (VR/No VR)	−0.24	−0.59 – 0.12	0.186
Observations	40		
R^2 / R^2 adjusted	0.045 / 0.020		
	log(Conductance Rise Time)		
Predictors	***Estimates***	***CI***	***p***
(Intercept)	3.28	2.95 – 3.61	**<0.001**
Group (VR/No VR)	0.40	−0.06 – 0.87	0.086
Observations	40		
R^2 / R^2 adjusted	0.075 / 0.051		
	log(Average Conductance Rate of Change)		
Predictors	***Estimates***	***CI***	***p***
(Intercept)	−2.31	−2.69 – −1.92	**<0.001**
Group (VR/No VR)	−0.56	−1.11 – −0.02	**0.043**
Observations	40		
R^2 / R^2 adjusted	0.104 / 0.080		

Table 3:

Proceduralist Reported Outcomes

	Difficulty		
Predictors	***Odds Ratios***	***CI***	***p***
Group (VR/No VR)	1.00	0.42 – 2.38	1.000
Observations	40		
R^2 Nagelkerke	0.000		
	Success		
Predictors	***Odds Ratios***	***CI***	***p***
Group (VR/No VR)	0.68	0.24 – 1.91	0.468
Observations	40		
R^2 Nagelkerke	0.020		
	Uncomfortable		
Predictors	***Odds Ratios***	***CI***	***p***
Group (VR/No VR)	0.87	0.37 – 2.07	0.756
Observations	40		
R^2 Nagelkerke	0.003		
	Agitation		
Predictors	***Odds Ratios***	***CI***	***p***
Group (VR/No VR)	1.36	0.57 – 3.29	0.489
Observations	40		
R^2 Nagelkerke	0.015		

	Virtual Reality (N=20)
“I believe virtual reality interfered with the HRM procedure”	
1 (strongly disagree)	2 (10.0%)
2 (somewhat disagree)	16 (80.0%)
3 (neutral)	2 (10.0%)
4 (somewhat agree)	0 (0%)
5 (strongly agree)	0 (0%)
Missing	0 (0%)
“I believe virtual reality benefited the patient during the HRM procedure”	
1 (strongly disagree)	0 (0%)
2 (somewhat disagree)	0 (0%)
3 (neutral)	2 (10.0%)
4 (somewhat agree)	16 (80.0%)
5 (strongly agree)	2 (10.0%)
Missing	0 (0%)

Table 4.

Code Frequency

Code	Number of References
Calming	4
Distracting	7
Non-Specific Positive	10
Relaxing	6
Soothing	2
Unhelpful	4