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Title: Comparing Brief Relaxation period to Virtual Reality period in reducing dental anxiety prior to root canal treatment; a randomized control trial

NCT #: 05720897

Methods Protocol

Inclusion Criteria

In order to participate in the study, patients must have been between the ages of 18 to 90 years old and have the capacity to independently give consent for root canal treatment. The participant must have been proficient in English and have no visual or hearing impairments that would interfere with listening with earphones or utilizing virtual reality glasses. Subjects must also need non-surgical root canal treatment.

Exclusion Criteria

Subjects may not have participated in the study if they have a history of vertigo or severe motion sickness. They must not have required nitrous oxide sedation, nor pharmacologic anxiolytics or sedatives for treatment. In addition, self-reporting of any severe psychiatric disease, medical history of seizures, concussions, or severe neurological conditions, visual and hearing impairments, and reporting of a cardiac pacemaker or defibrillator, would rule out patients from this study.

Materials

The project will require the following: Oculus Quest2 (*Meta Quest; Meta2 VR Headset*); Maxwell 190319 Stereo Headphone, Black (*Amazon*), Dell Optiplex 7050 Computer, ComfortCuff 506N3 Series (*Criticare Systems Inc.).*

Sample Size

With a sample size of 28 patients per group completing the study, the study will have an 80% power to detect changes in the patient's self-reported anxiety as measured by their responses to the psychometrically validated STAI instrument of 3.6 (within each group an effect size of 0.55) and differences of a 5.0between groups (an effect size of 0.77). The calculations are based on paired and two-sample t-test calculations, respectively, and these calculations assume a within-group standard deviation of 6.5 for change in STAI and a two-sided 5% significance level. To account for a 5% dropout rate, 30 patients will be enrolled per group.

Methodological Procedures for Relaxation Interventions: ABR vs RVR

Institutional Review Board (IRB) submission was secured after an internal Research Committee first gave approval of study.

Auditory Brief Relaxation (ABR)

This study's brief relaxation period consisted of an 8 minute ABR with 90 seconds of relaxing background music, five-minutes of an audio recording performed by a Certified Health and Well-being Coach and Qualified Teacher of Mindfulness-Based Stress Reduction and ending with another 90 seconds of relaxing outgoing music. The recording consisted of suggestive elements for how the patient can reduce their anxiety in real-time. The guided relaxation lasted approximately five minutes and involved the patient focusing on their scanning their body for tension and diaphragmatic breathing.

Relaxation Virtual Reality (RVR)

The VR headset used for this project was headset by Meta 2. The experience involved a nonmotive and noninteractive virtual reality experience. Patients required a very brief training on how to place and adjust the headset for comfort and volume, and a glass of water was available within arm's reach. Controllers were not distributed to participants for the RVR to be more uniform and to avoid an interactive, gamification experience. The standardized app that was presented during the RVR session was NatureTrek App (*GreenerGames*). In this program, the participant choose and immersed themselves within one of 11 themed for approximately 8 minutes to align with the comparative relaxation time of the ABR group and to increase the likelihood that the patient experiences a sense of immersion and presence. Examples of the scenes included savannah, beach, meadow, and space. If there were any technical or health related issues during the experience, a trained dental assistant or endodontic dental resident will be always in sight of participants.

Recruitment and Enrollment of Experimental Subjects & Protocol for Data Collection

Candidates for the study were selected from patients that were scheduled in graduate endodontic clinic for evaluation of non-surgical root canal therapy (NSRCT). A biostatistician randomized 60 participants for the study to split participants between Audio Alone Relaxation (ABR) and Relaxation Virtual Reality (RVR). The randomization list was generated using R statistical software to randomly assign participants equally to the two groups, using a block randomization to ensure group balance throughout study enrollment. The researcher and a

Clinical Research Coordinator worked together to administer randomized assignments. This is non-blinded study in such that both researcher and Clinical Research Coordinator knew the type of intervention being provided to which participant. Either the Clinical Research Coordinator or researcher acquired written, informed consent for enrollment of patients into the study, and the patient's age and gender. There was no initiative or incentive for patients willing to participate in the study. Once consent was obtained and all related questions answered, the investigator, delivered either the placement of headphones for a brief auditory relaxation period (ABR) of five minutes, or the use of relaxation virtual reality (RVR) using a VR headset. Both of these interventions were applied after consent and just prior to administration of local anesthetic. There were three data collection points in which evaluations were conducted. At T0 prior to the beginning of endodontic treatment, the following measurements were conducted: (1) Vitals were recorded for blood pressure and heart rate (2) patient's perceived anxiety was evaluated by having patients complete State-Trait Anxiety Indicator (STAI) and (3) a verbal response was requested of the patient using a Visual Analog Scale (VAS). VAS was used as a complementary measure as well as an effective stand-alone measure. T1 data collection occurred approximately 10 minutes after T0 and after the aforementioned intervention of the ABR or RVR in which (1) the patient's blood pressure (BP), and heart rate (HR) were taken and (2) a response given to the VAS. Finally, at T2 which is after the completion of the endodontic treatment inclusive of the final radiograph, once again the (1) BP and HR was collected (2) the STAI was completed and (3) the response to VAS again completed. \

Informed Consent

All subjects were required to read, acknowledge they understood, and sign a document of informed consent before they could participate in the study. The subject received a copy of the consent form.

Study Procedure and Protocol: Timeline

1. After patient is brought back to the operatory and verbal introductions, rapport building, and agenda setting has occurred then the patient's medical history is reviewed which is the standard of care for endodontic treatment.
2. The patient was invited to participate in the study during the evaluation of the patient's dental needs. During the reading of the consent process, the researcher

reviewed with the patient all related inclusion/exclusion criteria for this study in order to first determine if the participant might qualify for the study.

3. The researcher verbally reviewed and got written consent for both the Non-surgical Root Canal Therapy (NSRCT) – {standard of care procedure} and the research study.
4. If the subject qualified, the participant was selected randomly to be a part of the RVR or ABR group, as per the randomization sheet.
5. *T0*: Blood pressure and heart rate recordings were recorded by the student investigator & STAI and VAS completed by participant.
6. Intervention: VR headsets or earphones with AAR were applied by the investigator and the patient experienced the intervention (approximately 8 minutes).
7. *T1:* VAS completed by participant and BP & HR are recorded.
8. Administration of local anesthesia and non-surgical root canal therapy performed by endodontic resident and timer began for treatment.
9. *T2*: STAI, VAS, BP, HR all recorded at the end of the appointment which was after final radiograph.
10. Dismissal of patient and treatment stops. In order to test both study hypotheses, repeated measures of ANOVAs will be conducted to test for any changes in time across T1, T2, and T3 for STAI and VAS Scores, BP and HR within the ABR and RVR groups and to compare between the two groups. In addition, associations of the outcomes with socio-demographic and related factors data will be tested by adding these factors as covariates in additional repeated measures of ANOVAs. Specific socio-demographic and related factors data to be collected will include: Age, gender, race/ethnicity, previous experience with auditory relaxation and relaxation by virtual reality and length of time for endodontic treatment. Two-sided 5% significance levels will be used for all inferential statistical analyses.

Statistical Analysis

With a minimum sample size of 28 patients per group (ABR Group; n=30 & VRR Group; n=28) having completed the study, the study has an 80% power to detect changes in patient's self-reported anxiety as measured by their responses to the psychometrically validated STAI instrument of 3.6 within each group (with an effect size of 0.55) and differences of a 5.0

between groups (with an effect size of 0.77). The calculations are based on paired and two-sample t-test calculations, respectively, and these calculations assume a within-group standard deviation of 6.5 for change in STAI and a two-sided 5% significance level.

Chi-square tests and two-sample t-tests were used to compare the two groups by differences in demographic characteristics. Due to non-normality of the outcomes, Wilcoxon Signed Rank tests were used to test for changes in the outcomes over time within each group, and Mann-Whitney U tests were used to compare the outcomes between the two groups at each time. Additional exploratory analyses to evaluate the associations of demographic characteristics with changes in the outcomes were performed using cumulative logistic regression. A two-sided 5% significance level was used for all tests. Analyses were performed using SAS version 9.4 (SAS Institute, Inc., Cary, NC, USA).