8/24/21

Cover Letter

To Whom It May Concern:

We would like to submit our protocol entitled " **Immersive Virtual Reality Improves Satisfaction In Laboring Women"** for your consideration as a clinical trial in www.clinicaltrials.gov.

All authors have contributed significantly, and that all authors are in agreement with the content of this trial.

Authors state that the protocol for the research project has been approved by a suitably constituted Ethics Committee of the institution within which the work was undertaken and that it conforms to the provisions of the Declaration of Helsinki.

Thanking you beforehand for your kind consideration.

Immersive Virtual Reality Improves Satisfaction In Laboring Women

Objective: To evaluate the effectiveness of immersive Virtual Reality (VR) in laboring women on patient satisfaction as a distractive tool and pain relief.

Methods: Randomized, controlled clinical trial with 42 laboring women allocated to VR intervention and control groups. Among the VR group, patient satisfaction with the use of VR was assessed by a Virtual Reality Satisfaction Survey and questioning whether they would choose VR in future labor. As a primary outcome patient satisfaction scores regarding the overall labor and delivery experience were compared between the two groups. A secondary outcome was pain assessed by a visual pain rating scale in the early and active phases of labor in both groups. Psychometric information was also collected from participants in each group using Beck Anxiety Inventory and Beck Depression Inventory.

STUDY PROTOCOL

Labor is a long and painful process for women. The neuraxial blockade, which includes epidural, spinal, and combined spinal-epidural analgesia, is presently the gold standard for pain control in laboring women. (*ACOG Committee Opinion #295: Pain Relief During Labor : Obstetrics & Gynecology,* n.d.) (Anim-Somuah et al., 2018) However, improving the whole labor and delivery experience for women is more complex and requires providing individualized care including alternative treatments.

Opioid and non-opioid pharmacotherapies, patient-controlled analgesia (PCA), nitrous oxide are all used with variable success for labor pain. (Nanji & Carvalho, 2020)

Acupuncture, hypnosis, yoga, hydrotherapy, massage, relaxation techniques, and transcutaneous electronic nerve stimulation (TENS) are among the adjuvant treatments provided to women in labor. (Dowswell et al., 2009; Madden et al., 2016; Smith, Levett, Collins, Armour, et al., 2018; Smith, Levett, Collins, Dahlen, et al., 2018)

Recent literature indicates the successful use of immersive virtual reality (VR) for a variety of painful medical procedures. (Atzori et al., 2018; Faruki et al., 2019; Maani et al., 2011;

Mosadeghi et al., 2016; Walther-Larsen et al., 2019; Wang et al., 2020)Via wearing the VR goggles the user has the illusion of going inside the 3D computer-generated world and visiting novel environments. Immersive VR is hypothesized to reduce pain through distraction, a non-pharmacologic attentional mechanism. The user's brain is preoccupied with the flood of information presented by the virtual environment restricting the mind from processing pain signals. (Hoffman et al., 2004)
We hypothesized that laboring women find immersive VR as a beneficial tool for their overall labor and delivery experience. We randomly assigned women in labor admitted to our Labor and Delivery floor to a VR group or a control group.

This is a randomized, controlled, single-center clinical trial in which we enrolled 42 women admitted during labor. The investigators randomized these women to immersive virtual reality (VR) or control group following their approval and written consent. This study protocol is approved by the Institutional Ethics Committee of Acibadem Mehmet Ali Aydinlar University (IRB protocol no: 2020-18/07). The primary objective of this study is to assess whether immersive VR was feasible and improved patient satisfaction in laboring women. We will assess patient satisfaction among VR users and compare patient satisfaction regarding overall labor and delivery experience between the two groups. Our second objective is to assess whether VR provided pain relief in the latent or active phase of labor. The investigators will also evaluate anxiety and depression in both groups on admission as potential confounders. The study will take place at Acibadem Maslak Hospital, a private hospital affiliated with Acibadem University School of Medicine in Istanbul, Turkey. Enrollment will be completed between November 2020 and June 2021.

Participants of this study were primigravida or multigravida presenting with labor who are candidates for vaginal delivery with no known risk factors. The inclusion criteria were women between 18-42 years of age at 37-41 weeks gestation with a singleton pregnancy, vertex presentation, no history of chronic medical conditions, absence of pregnancy complications, and admission with documented labor by cervical exam and regular uterine contractions. Women with a diagnosis of migraine, headache, dizziness, motion sickness, epilepsy, psychiatric disorders, visual or auditory disabilities, history of cesarean section were excluded. A priori power analysis was performed to estimate the sample size with a power (1-β) of 80%, a significance (α) of 0.05 and an allocation ratio of 1. We assumed a neutral satisfaction score of 50 out of 100 (SD=12.5) for the control group and hypothesized 25% increase in satisfaction scores with the use of VR. A sample size of 17 subjects per group were computed to be

required to observe this difference. For this analysis *G**Power software was used. For potential drop outs we decided to enroll 21 subjects in each group. Subjects were randomized to an intervention (VR) group (n=21) or a control group (n=21) using a random number generator (www.random.org).

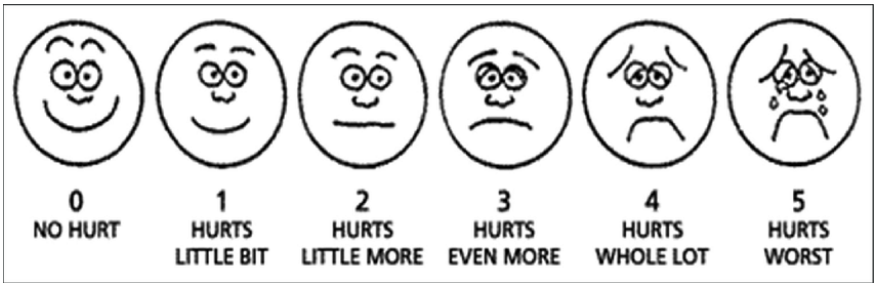
The authors will use Oculus Quest All-in-one VR Gaming Headset (128 GB) VR system. Before the intervention, the authors will introduce the equipment and instruct study participants on how to wear and activate the headsets. Anxiety and depression scales will also be applied on admission. The laboring women who enrolled in the VR group will first wear the headsets in early labor (Cervical dilation 3 cm) for 20 minutes. The patients will be offered to choose among several virtual environments including orange sunset, green meadows, black beginning, red savannah, blue deep, blue moon, blue ocean, white winter, and red fall. Cards printed out from the images of the Nature Trek application representing these novel immersion options will be provided to the patients to help them pick up their preferred environment in advance. The second implementation of VR headsets will be after the epidural analgesia in the active phase of labor for another 20 minutes (Cervical dilation 6-7cm). After the second intervention, the “Virtual Reality Satisfaction Survey” will be applied by the investigators. Patients will be asked to fill out a visual pain rating scale right before and after the VR use in early and active labor.

For participants randomized to the control group, VR headsets will not be used and the clinic’s standard of care in laboring women will be followed. Anxiety and depression scales will be applied to each subject on admission. Participants in this group will fill out a visual pain rating scale both in the latent and active phases of labor.

To evaluate the effectiveness of immersive VR in laboring women, the investigators will evaluate patient satisfaction with the use of VR among the intervention group. Patient satisfaction with overall labor and delivery experience and pain scores will be compared between the intervention and control groups.
Patient satisfaction with the use of VR will assess by a "Virtual Reality Satisfaction Survey", a 10 question survey prepared by our team: with 0 being the lowest and 100 being the highest possible VR satisfaction score. Investigators will also ask these women whether they would like to use VR in future labor. Patient satisfaction with overall labor and delivery experience will be assessed using a Visual Analog Scale (VAS). All discharged women will be called after a week following discharge from the hospital and will be asked to rate their overall childbirth experience on a scale from 0 to 10. Zero indicates the most negative experience possible and 10 indicates the highest satisfaction possible. The investigators classified a score of 8 to 10 as

high satisfaction. Pain scores both in early and active labor in each group will be assessed using Wong-Baker Faces Pain Rating Scale. The scale shows a series of 6 faces ranging from a happy face at 0, or "no hurt", to a crying face at 5, which represents "hurts like the worst pain imaginable (Figure 1).

Figure 1: Wong-Baker Faces Pain Scale



Anxiety levels of study participants will be assessed with Beck Anxiety Inventory (BAI). This inventory consists of 21 items, each scored from 0 to 3. This is a self-report questionnaire measuring somatic and cognitive parts of anxiety. The total score is calculated by finding the sum of 21 items. A score of 0 to 7 indicates minimal anxiety, 8 to 15 mild anxiety, 16 to 25 moderate anxiety, and 30 to 63 is associated with severe anxiety.

For the assessment of depression in each group, Beck Depression Inventory will be used. It consists of 21 items which is a multiple-choice test and gives a score ranging from 0 to 63. Each answer is scored on a scale value of 0-3. Measures of 0–9 indicate that a person is not depressed, 10–18 indicates mild-moderate depression, 19–29 indicates moderate-severe depression and 30–63 indicates severe depression. This self-rated test estimates the signs of depression such as pessimism, feeling of failure, self-dissatisfaction, punishment, crying, insomnia.

Reference:

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