The Feasibility of Immersive Virtual Reality as a treatment for Chronic Back Pain

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Overview of Study

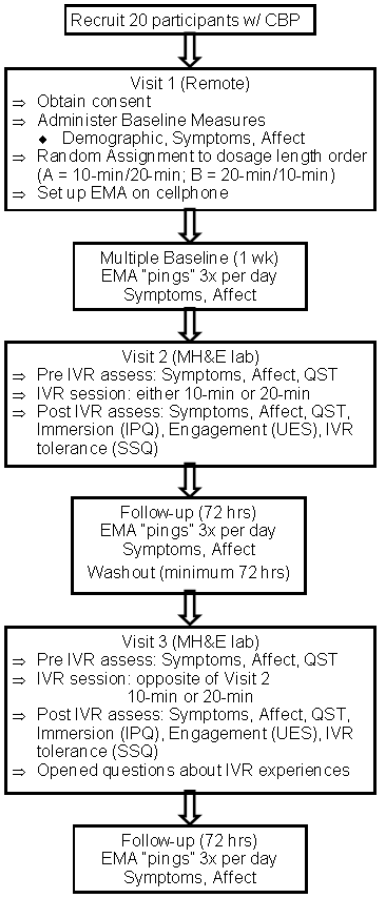
In the proposed project we will evaluate the feasibility of IVR and assess the initial effects of IVR on symptoms, affect, and tolerance to cutaneous stimuli. In this single-arm trial, we will recruit 20 adults with CBP. Prior to their IVR experience, subjects will complete multiday baseline assessments using ecological momentary assessment (EMA) methodology to establish typical levels of symptoms and affect. They will return for two counterbalanced IVR sessions: one 10-minute and one 20-minute. Immediately after each session we will measure current symptoms and affect using valid and reliable self-report questionnaires, and we will measure changes in tolerance to cutaneous stimuli using quantitative sensory testing. We will measure symptoms and affect for 72 hours after each experimental session using EMA to determine if there is a carryover. At the completion of this study, we will continue to work with stakeholders to develop clinically relevant IVR interventions for people with CBP. Our study will have two aims:

Aim 1: Determine the feasibility and clinical usability of using IVR as an intervention for people with CBP.

Aim 2a: Examine the magnitude of the effects of IVR on symptoms, affect, and tolerance to cutaneous stimuli.

2b: Examine the effect of dosage (10 min, 20 min) on symptoms, affect, and tolerance to cutaneous stimuli.

Grant Flow Chart



Study Design: This is a cross-over feasibility trial.

Subjects: We will recruit 20 people with chronic back pain.

Inclusion/Exclusion criteria: Inclusion criteria: 30 to 65 years old; Low Back Pain that has lasted greater than 3 months due to non-cancer related injury or illness. Exclusion criteria: People with back pain due to rheumatic (e.g. rheumatoid arthritis or fibromyalgia) or central neurological disorders (e.g. stroke, multiple sclerosis, spinal cord injury); vision to see IVR programs; insufficient upper extremity coordination to operate IVR controls; insufficient cognitive ability to answer questionnaires or learn to use the IVR; unable to understand and respond to English. Subjects must have access to a cell phone or tablet for baseline and follow-up EMA testing. There are no exclusion criteria based on sex, race, ethnicity, or sexual orientation.

Recruitment: Throughout the grant we will work with Tufts CTSI Recruitment and Retention Support Unit (RSSU) to devise customized, multi-modality strategies to minimize accrual time and maximize participant retention in research studies. Strategies include: 1) We will access the Brigham & Women's Chronic Pain Registry and mail letters to appropriate candidates. 2) We will query the Tufts Medical Center's Clinical Academic Research Enterprise Trust (CLARET) data warehouse to identify eligible patient population. The CLARET is a centralized clinical data warehouse that aggregates clinical information from various Tufts Medical Center's systems. 3) The Tufts Medical Center website publicly posts general information about all research studies so that people can identify and contact studies. 4) We will deploy targeted advertising using Facebook Ads; 5) We will place fliers/advertisement placed in the following CBP program waiting areas: Brigham & Women's, Tufts Chronic pain, Medford Chronic pain.

Outcome measures

Our study will include feasibility measures and magnitude of effect measures: Feasibility measures will examine the practicalities of investigating implementation of IVR for people with CBP and subjects' preferences and tolerance to the protocol.

Item	Measurements
Recruitment	Responses to different recruitment methods; # contacting study; # coming to study; # consented; Recruitment generating appropriate subjects; # willing to be randomized
Adherence/Fidelity	Immersion into VR (Igroup Presence Questionnaire [IPQ]); Engagement in IVR (User Engagement Scale [UES]); # of breaks; # of subjects completing study; Completeness of data collection
Burden	Length of time to complete measures, length of time for ecological momentary assessment (EMA) responses, subjects' perception of burden (open-ended questions)
Tolerance	Tolerance to IVR (Simulator Sickness Questionnaire [SSQ]); minutes in IVR experience; tolerance to Quantitative Sensory Testing (QST); open-ended question responses
Stakeholder input	Open ended questions about perceptions and preferences.

Measures for the magnitude of effect will address symptoms, affect and tolerance to cutaneous stimuli. All the proposed measures are valid and reliable measures of the proposed construct.

Item	Measurements
Symptoms	
Pain	Pain Visual Analogue Scales (VAS) (EMA and Session), PROMIS pain interference scale (Session)
Fatigue	PROMIS Daily Fatigue Scale (EMA and Session), PROMIS Fatigue Scale

	(Session)
Affect	Positive and Negative Affect Scale (PANAS) (EMA and Session)
Quantitative Sensory Testing (QST) (Session)	
Hyperalgesia	Mechanical Pressure Pain Thresholds (MPPTh) will be assessed using a digital pressure algometer on the right upper trapezius and right thumb MP joint. Mechanical Temporal Summation of Pain (MTSP) will be assessed using weighted pinprick stimulators. We will apply a train of 10 stimuli at the rate of 1 per second on the middle finger of the right hand, and subjects will rate the painfulness of the first, fifth, and tenth stimulus.

Intervention Immersive Virtual Reality (IVR)

Our IVR experiences will be delivered with the Oculus RiftS system (headset and hand controllers) using commercially available VR software. IVR sessions will last either 10 or 20 minutes. Subjects will select an IVR experience that appeals to them.

Protocol

Visit 1 (remote): We will obtain informed consent. Subjects will complete surveys on demographics and symptoms (pain, fatigue) and affect. Subjects will be randomly assigned to receive the 10 min or 20 min IVR session first.

We will also upload the EMA technology onto the subject's phone or tablet. Visit 1 will take up to ~1 hour.

Multiple Baseline EMA: Visit 2 will be scheduled 1-2 weeks later. During the time between visits we will use ecological momentary assessment (EMA) technology to collect multiple measures of pain, fatigue and affect. In EMA subjects respond to prompts delivered through their cell phone or tablet ("pings") with documentation of current symptoms. It is a well-recognized method to capture immediate, synchronized experiences in subjects' natural environments. During this data collection period subjects will be "pinged" 3x daily and asked to rate their current levels of pain, fatigue, and affect. Time to complete these responses will be less than 5 minutes.

Visit 2: We will collect current pain, pain interference, fatigue and affect, and QST. Subjects will receive an IVR session lasting either 10 or 20-min depending upon randomization. They will rate their current pain, fatigue, and affect, and we will complete QST. At the end of both sessions the subjects will rate their experiences of immersion using the Igroup Presence Questionnaire, engagement using the Use Engagement Scale (UES), and simulation tolerance using the Simulator Sickness Questionnaire (SSQ). Visit 2 will take about ~1 hour.

Post Visit 2 EMA: Subjects will complete three more days of 3x a day prompts for pain, fatigue and affect.

After Visit 2 we will follow-up with subjects using EMA for at least 72 hours to determine if there is any carryover of effect of IVR. This period will also act as a washout period before returning for the third visit.

Visit 3 will be the same as Visit 2. Participants will complete 10- or 20- minutes of VR depending upon randomization. We will complete a short semi-structured interview.

Analysis

Aim 1 - Feasibility: We will identify the number of people from each referral source who contacted study personnel, volunteered to participate, and signed the consent. We will assess adherence to study protocols, including percentages completing outcome measures (including EMA) and completing both visits. We will assess IVR tolerance using the Simulator Sickness Questionnaire, pain threshold testing tolerance through direct questions, and the degree to which subjects felt engaged in the experience using the Igroup Presence Questionnaire. We

will determine how long it takes to complete the various parts of the study and how many breaks or incompletes occur during the intervention protocol. We will also examine expectations and perceptions of the IVR experience using open-ended questions.

Aim 2 - Effect: We will calculate effect sizes to compare baseline data to scores obtained immediately after completing IVR sessions. Symptoms and affect: We will examine the immediate effect of the IVR sessions by comparing the baseline symptom data with scores taken after completing the session. Tolerance to cutaneous sensory input: We will assess baseline and pre-session pain threshold levels with immediate post session measurements. To examine differences related to dosage, we will calculate an effect size between those who received the 10-minute IVR and those who received the 20-minute IVR session.