Virtual Reality Guided Acupuncture Imagery Treatment for Chronic Low Back Pain

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The use of imagery to treat illness has a long history in medical practice. Although still under investigation, research findings support the notion that the brain responds in similar ways to imagined experiences as it does to actual experience. Thus, underlying the functional nature of mental imagery may be shared neurocognitive operations that support both imagination and perception. Acupuncture is a unique, invasive treatment modality and has been recommended for the treatment of cLBP by the American College of Physicians. Studies have shown that the experience of acupuncture needle stimulation and the visualization of acupuncture needle stimulation can provoke overlapping activations in brain regions, such as the anterior insula (AI), anterior cingulate cortex (ACC), and periaqueductal grey (PAG).

Based on above findings, *the PI and his team developed a new treatment modality,* whereby participants watch a 2-dimensional (2D) video of acupuncture that was previously administered to their own body and imagine it being concurrently applied, viz., 2D video-guided acupuncture imagery treatment (2D-VGAIT). We found that 2D-VGAIT can produce an analgesic effect in healthy subjects. In a more recent pilot study, we found that 2D-VGAIT can produce comparable symptom relief to real acupuncture after a 1-month (6 treatments) intervention in cLBP patients. Nevertheless, the reality simulation of 2D-VGAIT can be improved.

Recently, Virtual Reality (VR) has drawn the attention of researchers. VR allows for the simulation of physical presence in the real or imagined worlds. As a powerful tool for studying body representation and creating perceptual body-ownership transfer illusions, literature suggests that VR is more effective in reducing pain than 2D screen applications. This unique property of VR may further increase 2D-VGAIT's efficacy.

Specific Aim: Perform a feasibility study of cLBP treatment using the developed VRGAIT system. cLBP patients will be recruited and randomized to VRGAIT and VRGAIT control conditions. Primary outcomes will be feasibility-related assessments (recruitment, retention, fidelity, satisfaction, and safety). Secondary outcomes will be clinical outcomes, presence, imagery vividness, and acupuncture deqi sensations.

Detailed experimental procedure

Subject recruitment. Patients with non-specific cLBP will be recruited.

Randomization. Patients who pass the screening will be randomized to the VRGAIT or VRGAIT control group using a centrally generated, variable-sized block design.

Endpoints. Primary outcomes will be feasibility-related outcomes such as recruitment, retention, fidelity, satisfaction, and safety. Secondary outcomes will include clinical outcomes and vividness and presence scales.

Blinding. Due to the nature of the intervention, patients cannot be blinded as to whether they receive VRGAIT or VRGAIT control. All outcome assessors will be blinded to the treatment each patient receives.

Session 1 will be a baseline session that will include clinical outcome measures and other related assessments and videotaping for VRGAIT treatment. Similar to our previous studies, we will explain the potential underlying mechanism of how imagery treatment works and the procedures for this study. Next, the subject will receive: 1) a brief, real acupuncture treatment,

which will be videotaped using a VR camera; 2) a cotton swab touching non-acupuncture sites, which will also be videotaped as a VRGAIT control condition. All subjects will experience brief acupuncture and swab touch to avoid the potential confounding provoked by brief acupuncture treatment. Subjects will then be introduced to the MGH Acupuncture Sensation Scale (MASS) to report the sensations they experienced during acupuncture treatment and cotton swab touch**.**

Outcomes

Participant Satisfaction Survey is a 5-point Likert scale (5 = very satisfied; 1 = completely dissatisfied) used to assess participant satisfaction at the end of the study.

29-item Patient-Reported Outcomes Measurement Information System (PROMIS-29): We will use PROMIS-29 to assess pain intensity (using an 11-point numeric rating scale [NRS]), physical function, depression, anxiety, fatigue, sleep disturbance, interference and social role, and activity in the past 7 days.

Pain Bothersomeness Scale: This is a self-reported measure of cLBP pain severity that is commonly used to assess clinical chronic pain. Participants rate how bothersome their LBP was during the previous week with a VAS scale (0–10) from “not at all bothersome” (0) to “extremely bothersome” (10).

MGH Acupuncture Sensation Scale (MASS) is a scale developed to measure sensations evoked by acupuncture treatment. The MASS will be applied after each treatment.

Vividness Scale is a 0-10 vividness scale to measure imagery vividness during the intervention. The scale ranges from Not Vivid/Unclear (0) to Vivid/Clear (10).

Symptoms and Adverse Events: Symptoms and adverse events during or after treatment will be recorded after each treatment.

Sessions 2-7 will be treatment sessions. Subjects will receive VRGAIT or the VRGAIT control based on the randomization across 4 weeks (2 times per week during weeks 1-2, 1 time per week during weeks 3-4).

Session 8 will be an assessment session identical to Session 1.