Virtual Reality Guided Acupuncture Imagery Treatment for Chronic Low Back Pain

NCT06814470

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Biostatistical analysis plan

Consistent with NCCIH recommendations for feasibility studies, we will report the following feasibility outcomes: 1) recruitment: proportion of participant enrolled from the total number of patients screened; 2) retention: proportion of number of subjects who complete all assessments by the total subjects enrolled); 3) fidelity: the proportion of completed/planned intervention sessions (VRGAIT and VRGAIT control); 4) satisfaction: proportion of participants having therapy satisfaction scores above the midpoint; and 5) safety: symptoms and adverse events reported by the participants.

For exploratory analysis of secondary clinical and other related outcomes, we will: 1) perform within-group comparison (pre- vs post-treatment) using paired t-tests to explore the modulation effects of VRGAIT and VRGAIT control on clinical outcomes, deqi sensations, presence and vividness; 2) explore the effects of VRGAIT and VRGAIT control using mixed-model regression. The regression model will include subject as a random effect; fixed effects will include treatment group, treatment time point (baseline, 4 weeks), and their interaction. Covariates such as age, gender, and ERS scores will also be included in the model to reduce subject heterogeneity.