

Official Grant Title: Virtual Human Technology for Patients with Chronic Pain

Working Title: Virtual Human–Delivered Interviews for Patients with Chronic Pain: Feasibility, Acceptability, and a Pilot Randomized Trial of Standard Medical, Psychosocial, and Educational Interviews

NCT #: 04349033

Date: October 15, 2021

Statistical Analysis Plan

To test our aim (whether interviews affected pain-related outcomes about one month later), we will conduct intent-to-treat (ITT) analyses using data from all patients, accommodating missing values on outcomes using maximum likelihood parameter estimation. Two-way repeated-measures ANOVAs with one between-subjects factor (experimental condition) and one within-subject factor (time) will be tested using linear mixed effects models (using the MIXED procedure in SAS 9.4; Cary, NC). Analyses will focus on time by group interactions (indicating group differences in change from baseline) for two specific comparisons: 1) Psychosocial vs. Standard; and 2) Educational vs. Standard. We will also inspect changes from baseline within each of the three experimental conditions separately using post-hoc contrasts. We will include VH voice (human vs. computer) as a covariate in all models and include age and education as covariates in sensitivity analyses.