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Statistical Analysis Plan

Combined exercise and meditation as a treatment for patients with chronic back pain

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Combined exercise and meditation as a treatment for patients with chronic back pain

This is a single-blind, single center randomized clinical trial comparing a treatment group (MedExT) versus a control group. The current analysis plan is specific to this study for reporting and publication purposes but is part of a larger study. The primary outcome of this study is to compare the post Roland-Morris Disability Questionnaire scores between the two independent groups. This will be achieved by comparing the mean post disability score for the MedExT group to the mean post disability score for the control group using a two-sample t-test (or the Mann-Whitney-Wilcoxon rank sum test if normality does not hold) in which a one-sided p-value < 0.05 will be considered a significant improvement in the MedExT group.

Three secondary treatment responses will be studied. The first will test whether the MedExT group will significantly increase mean scores on the Freiburg Mindfulness Inventory as determined by a two-sample t-test or the Rank Sum test given distributional properties of the data ($P < 0.05$). The second will explore whether the MedExT treatment will significantly influence a mean change in responses on the three psychological inventories administered; the Fear Avoidance Beliefs Questionnaire, the STAI state anxiety inventory and the STAI state trait inventory, $p < 0.02$. The third outcome measured will study mean response changes in the series of 14 Quantitative Sensory Tests measured at baseline and at the completion of the 4-week intervention period. Significant mean pre/post differences between groups will be identified using the two-sample t-test or the Rank Sum test where appropriate adjusting the significance level to 0.005. Additionally two pain outcome measures will be repeatedly observed throughout the study taken at baseline and on each intervention day. These measures are the VAS pain intensity score and the VAS pain unpleasantness. A repeated measures multivariate analysis of variance (MANOVA) procedure will be used to determine if the vector of timed responses is significantly different between the two study groups.

The following demographic variables will be collected and compared between groups to further check against potential bias; age, sex, handedness, body mass index (BMI), baseline heart rate (HR), baseline blood pressure (BP), baseline IPAQ-short and mean number of steps taken per day over the 4-week intervention period. Difference in the proportion of sex/handedness will be tested using the Fisher's Exact test where a p-value less than 0.05 will be considered significant. All other continuous variables will be tested using the two-sample t-test to test for significance differences between the two study groups ($p < 0.05$).