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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.

Secondary outcomes include the Freiburg Mindfulness Inventory, the Fear avoidance Beliefs Questionaire, the STAI state anxiety inventory, the STAI state trait inventory and a series (14) of Quantitative Sensory Tests measured at baseline and at the completion of the 4-week intervention period. Significant differences between groups will be identified using the two-sample t-test or the Rank Sum test where appropriate. Additionally two 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. Given the number of statistical tests that will be required for the secondary outcomes analyses, a p-value less than 0.005 will be used to identify potential significant outcomes 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 ($p < 0.05$).