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Statistical Analysis Plan

Managing Pain: Testing the dosing and social aspects of exercise therapy using a multi-school collaborative approach with human participants.

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Managing Pain: Testing the dosing and social aspects of exercise therapy using a multi-school collaborative approach with human participants.

This is a single-blind, single center pseudo-randomized clinical trial comparing three treatment groups (3-day, 5-day, 10-day treadmill exercise) versus a control group (no exercise).

The primary outcome is a change in Quantitative Sensory Testing. This includes a series (8) of Quantitative Sensory Tests measured at baseline and at the completion of the 1-week intervention period. The tests include measurement of: 1) Mechanical Sensitivity Threshold, 2) Constant Heat Pain Intensity, 3) Constant Heat Pain Unpleasantness, 4) Radiant Heat Sensitivity, 5) Radiant Heat Pain, 6) Pressure Pain Threshold, 7) Constant Pressure Pain Intensity, and 8) Constant Pressure Pain Unpleasantness. These tests are measured at two sites (calf and forearm). Significant differences between groups for tests (#2-8, per body site) will be identified using a one-way ANOVA comparing percent change from baseline (post-test (i.e. day 6)/baseline test (i.e. day 0)). Given the number of statistical tests that will be required for the primary outcome measurements, $p < 0.01$ will be utilized for each body site. An additional test for mechanical sensitivity (#1) will be measured at each site using a rank sum test at $p < 0.05$.

The secondary outcomes for this study include (1) HR during exercise, (2) Borg RPE before and after exercise and (3) testing “acute” effects of exercise on QST testing.

HR during exercise and Borg RPE are measured to make sure that exercise causes a change in HR and/or perceived exertion. HR and Borg data will be analyzed using percent change from start of exercise (post-exercise/pre-exercise) with two-way ANOVA for 3 treatment groups (3-day, 5-day, 10-day) across time (day 1, 3, 5) with an adjusted p value of $p < 0.03$. Control group will not be included in that analysis as HR was not measured on the control days and perceived exertion is at “0” on all days.

For acute effects of exercise, participants were given the 7 QST tests (#2-8) described above (on each forearm and calf) 5 min and 30 min after each exercise (or control session) on days 1, 3, and 5. Significant differences between groups for these tests (per body site) will be identified using a two-way MANOVA comparing percent change from baseline (post-exercise/baseline test (i.e. day 0)) across the three days (day 1, day 3, day 5) and at the 5 min and 30 min time QST measuring point. Given the number of statistical tests ($n=7$) that will be required for the QST secondary outcome measurements, $p < 0.01$ will be utilized for each body site.

The following demographic variables will be collected and compared between groups to further check against potential bias; age, handedness, body mass index (BMI), baseline heart rate (HR), baseline blood pressure (BP), baseline IPAQ-short, and SIAS (social interaction anxiety scale). A significant difference in the proportion handedness will be tested using the Chi-Square test where $p < 0.05$ will be considered significant. All other continuous variables will be tested using the one-way ANOVA to test for significance differences between the four study groups ($p < 0.05$).