Respiratory Biofeedback Sensor for Yoga Practice for Youth with Chronic Pain

NCT number: 05791435

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Data Analysis:

Numeric data will be summarized using mean (SD) or median (Interquartile range) as appropriate, and categorical data will be summarized using frequencies and percentages. Baseline and demographic characteristics will be compared using t-test, Mann-Whitney U test or Fisher exact tests as appropriate. A mixed effects repeated measures analysis of variance (ANOVA) will be used to compare the mean changes in breathing phase angle (degrees), labored breathing index (unit), blood oxygen level (%), respiratory rate (unit), pain acceptance scale, PROMIS pediatric pain interference scale, and PROMIS youth anxiety short form over time. Likert scale measures will be used as both numeric and categorical forms, thereby, a generalized mixed effects model will also be used to compare the changes in Likert scale over time. Model assumptions will be checked before analysis. All tests will be two-tailed at the level of significance of 0.05. Statistical software SAS, version 9.4, or R (version 4.05) will be used for the analysis.

Sample size and power:

The primary goal is the change in breathing phase angle from baseline to after the yoga therapy regimen. In accordance with data from a previous study [29] the baseline mean (SD) phase angle is 40 (12) degrees, and after 8 weeks of yoga therapy we expect the phase angle to be 15 (9) and 30 (9) in the instructional + biofeedback group, and instructional alone group, respectively. A sample size of 8 subjects in each group can detect the above changes in phase angle with a power more than 80% at the level of the significance of 0.05. Assuming 25% attrition rate a sample size of 20 (10 + 10) subjects is planned for this study.