Mindfulness + tDCS to reduce urgency incontinence in women

NCT# 04652869

Primary Outcomes: Data Analysis Plan

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Primary Outcomes: Data Analysis Plan. Prior to hypothesis testing, descriptive statistics and graphic displays will be used to identify outliers, missing data, and patterns of attrition, and to guide transformations and appropriate tests. The primary analyses will be evaluated via mixed model regressions with Bonferroni post-hoc comparisons. Mixed model regression features advantages over traditional regression due to the ability to handle repeated assessments of both predictor variables and outcome variables. For **Aim 1**, We will assess feasibility as >85% study completion, acceptability as a score ≥50 on 8-item post-study survey rating (scale 0-100), and mindfulness compliance as an average rating ≥75 on the compliance survey (scale 0-100). We will use chi-square to assess attrition differences between groups, and one-way ANOVA to assess differences in acceptability and compliance ratings. For **Aim 2**, mixed model regressions will test the main effects of experimental group (1=MI, 2=tDCS, and 3=MI+tDCS) on ICIQ-FLUTS score (pre, post, and follow-up), UUI episodes, and urgency survey scores (3-day mean score at baseline, last three days before re-test, and last 3-days of follow-up) as dependent variables. Pre-intervention (baseline) levels of each dependent variable will be entered as a covariate in respective regression models. This process will be repeated for **Aim 3**, with separate models evaluating treatment effects on Stroop RT and cue-provoked urgency. For Stroop RT, the primary dependent variable will be post-test minus pre-test change. For cue-provoked urgency, the primary dependent variable will represent a double-difference score of urgency minus safe cues, and post-test minus test.