

Cranial Electrotherapy Stimulation on Acute Stress

NCT06034496

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Statistical Analysis Plan (SAP)

Manipulation Check. To ensure effective stress induction, we will assess AA, HR, CORT, and subjective stress responses to stress exposure during the baseline session. We will compare sampled AA levels from immediately prior to (pre) to immediately after stress exposure (i.e., time points pre and 0-min post-task). We will compare mean HR from immediately prior to (pre) to during stress exposure (i.e., during the RMT, SOT, DMT). We will compare sampled CORT levels from immediately prior to (pre) to 0-minutes after stress exposure (i.e., time points pre and 0-min post-task). We will compare STAI-S scores from immediately prior to (pre) to immediately after stress exposure. For these analyses, we will conduct paired t-tests.

Physiological & Biochemical Responses to CES. To evaluate physiological and biochemical responses to CES, we will use analysis of variance (ANOVA)s to assess the effect of CES Group (2: Active, Sham), Session (2: Baseline, Follow-up), and Time (pre-task, 0-min, 20-min, 40-min, 60-min post-task) on each of six outcome measures: HR, HRV, RR, tonic PD, AA, and CORT (number of levels varies as a function of outcome measure and is described as follows). Each response measure will be assessed in a discretized time series based on its sampling times; continuous measures (e.g., HR) will be discretized into pre-stress versus during-stress time periods. For HR, HRV, respiration, and tonic PD, pre-stress will be calculated as the mean of the one-minute time period immediately preceding the beginning of the tasks, and during-stress will be calculated as the mean of the entire behavioral task performance. For AA and CORT, we will include all five time points in the analysis (i.e., pre-task, 0-min, 20-min, 40-min, 60-min post-task).

Cognitive & Affective Responses to CES. To evaluate the cognitive and affective responses to CES, we will use mixed ANOVAs to assess the effect of CES Group (2: Active, Sham) and Session (2: Baseline, Follow-up) on each of four cognitive outcome measures, and one affective outcome measure. Cognitive measures include RMT overall accuracy, SOT absolute angular direction error, SOT absolute distance estimate error, DMT discriminability (d'), and DMT response criterion (c). Affective measures include STAI-S scores, and we will use a mixed ANOVA to assess the effect of CES Group (2: Active, Sham), Session (2: Baseline, Follow-up), and Time (pre-task, 0-min, 20-min, 40-min, 60-min post-task).

Mixed ANOVAs will be conducted using package `rstatix` (ver. 0.7.0; Kassambara, 2023) in R (ver. 4.1.2). Mixed ANOVA assumptions will be checked using package `rstatix` (ver. 0.7.0; Kassambara, 2023) in R (ver. 4.1.2). Extreme outliers will be identified, removed, and mean imputed. Normality will be assessed with Shapiro-Wilk Normality Test; non-normal data will be log-transformed. Homogeneity of variance will be assessed with Levene's Test and confirmed all groups had the same or similar variance. Mauchly's test of sphericity will be automatically conducted and corrected for in the mixed ANOVAs analysis.