

Targeted Transcutaneous
Stimulation to Restore Autonomic
Cardiovascular Health in Veterans
with Spinal Cord Injury

NCT05180227

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Statistical analysis plan:

The primary outcome variable will be systolic blood pressure. Data will be analyzed with a mixed-modeling approach to determine which stimulation parameters consistently yield increases in systolic blood pressure. Participant will be modeled as a random effect and stimulation characteristics as fixed effects including: cathodal stimulation site (T7/8, T9/10, T11/12, and L1/2); stimulation frequency (30, 60, 120 Hz); waveform (monophasic, biphasic, asymmetric biphasic); pulse width (40 - 1000 μ s); carrier frequency (0, 10kHz); and stimulation current (0–120mA). To quantify the effect size of each participant's optimal tSCS parameters, each participant's blood pressure response will be compared to baseline blood pressure to calculate Cohen's d and confidence intervals. All analyses will be performed using R software. The lme4 package will be used to perform the mixed-models analyses for the ratio-scale data. The ordinal package in R will be used to analyze the Likert-scale-type data. The 95% level of confidence will be used. We used the R software simr package for multi-level models for power calculations with fixed effects variables of waveform and electrode site. Given the number of repeated measurements of SBP in each participant, we anticipate having *95% power to detect <2-mm-Hg mean differences at the 95% level of confidence.