

Randomized Controlled Trial of Treatment to Optimize Heart Rate Variability for Persistent Post-Concussion Symptoms

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* age 18 or older * History of military service * Self-Reported hx of 1 or more mild TBI * Most recent TBI more than 1 year ago * Significant Persistent Post-Concussion Symptom burden (Neurobehavioral Symptom Inventory \[NSI\] total score greater than or equal to 20). * Current Sleep Difficulties * Fluent English * Able to provide Informed Consent

Exclusion Criteria:

* Any TBI with severity greater than mild (i.e., Moderate or Severe TBI defined as initial injury loss of consciousness (LOC) duration \>30 minutes, posttraumatic amnesia (PTA) duration \>24 hours, or traumatic hemorrhage on head computerized tomography (CT) and determined by the study investigator based on information gathered during administration of the study's validated TBI structured interview instrument. * Conditions or medications that can affect HRV measurement (pacemaker or an implant that stimulates your heart (e.g., cardioverter-defibrillator or ICD); heart transplant or heart surgery within the last year, including bypass or other surgery, but not including a stent) * Hx of stroke * Mental conditions that may impede adherence (e.g., dementia, psychotic disorder, panic disorder)

Conditions & Interventions

Interventions:

OTHER: HRV Coherence Ratio, BEHAVIORAL: NSI, BEHAVIORAL: Pittsburgh Sleep Quality Index (PSQI), BEHAVIORAL: Quantitative Sleep Measures, BEHAVIORAL: Patient Global Impression of Change (PGIC), BEHAVIORAL: Cognitive Performance/NIH Toolbox Cognitive Battery, OTHER: Pain Interference/TBI-QoL Pain Interference Short-Form, BEHAVIORAL: Patient Health Questionnaire-9 (PHQ-9), BEHAVIORAL: PTSD Checklist for DSM-5 (PCL-5), OTHER: HRV Biofeedback (HRV-B), OTHER: Psychoeducational (Edu) Comparator Intervention

Conditions:

Autonomic Nervous System Disease, Concussive Injury, Mild Traumatic Brain Injury, Post Traumatic Stress Disorder, Persistent Post Concussion Syndrome

More Information

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Principal Investigator:

Phase: PHASE2

IRB

Number:

System ID: NCT07071350

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