Wearable Auricular Neurostimulation Modulates Acute Stress Physiology and Symptom Response in a Randomized Sham-Controlled Study

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Introduction

Acute stress triggers rapid autonomic, neuroendocrine, and inflammatory responses that can impair cognition, emotional regulation, and behavioral performance[1,2]. Persistent dysregulation of these pathways contributes to adverse neuropsychiatric and physiologic outcomes, motivating development of non-pharmacologic interventions capable of modulating stress responses without sedative or cognitive side effects. Auricular neurostimulation has emerged as a promising bioelectronic medicine strategy because stimulation of vagal and trigeminal afferents can influence central autonomic networks involved in stress regulation and inflammatory signaling[3–6].

Despite increasing interest in wearable neuromodulation, many existing wearable neurostimulation systems remain poorly suited for prolonged ambulatory use or integration into operational environments due to wired configurations, poor ergonomics, and incompatibility with head borne equipment. To address these limitations, a next-generation wearable transcutaneous auricular neurostimulation (tAN) system, Sparrow Hawk, was developed through an iterative user-centered engineering process incorporating feedback from combat medics and military subject matter experts. The device was specifically designed to minimize interference with helmets, hearing protection, and tactical communication systems while supporting cable-free ambulatory operation in austere environments.

Recent advances in wearable biosensing technologies further enable real-time biochemical assessment of stress-related physiology, including neuroendocrine and inflammatory biomarkers[7,8]. The present study represents the first clinical evaluation of this newly engineered wearable auricular neurostimulation platform and assessed its effects on subjective stress responses, physiologic biomarkers, and performance outcomes during a validated laboratory acute stress paradigm.

Fig 1. Sparrow Hawk tAN Device

Methods

A next-generation wearable, cable-free auricular neurostimulation platform (Sparrow Hawk) was engineered for continuous ambulatory use and compatibility with operational head-borne equipment, including helmets and tactical communication systems. Device development incorporated iterative prototyping and human factors feedback from combat medics and military operational personnel to optimize ergonomics, retention, usability, and integration into constrained operational environments.

The newly developed system was evaluated in its first clinical study using a randomized, double-blind, sham-controlled design. Forty healthy adults underwent a validated laboratory acute stress induction protocol while receiving either active or sham stimulation. Participants were randomized prior to stress exposure, and both participants and study personnel responsible for data collection were blinded to group assignment.

Subjective stress responses were assessed using the Stress Monitoring and Response Tool (SMART). Objective performance outcomes were assessed at baseline and post-stressor using the Psychomotor Vigilance Task (PVT), Match-to-Sample (MTS) task, and Purdue Pegboard Test (PPT). Continuous physiologic monitoring was performed using a wearable sweat biosensor platform capable of measuring cortisol, interleukin-6 (IL-6), tumor necrosis factor-alpha (TNF-α), and melatonin throughout the stress protocol.

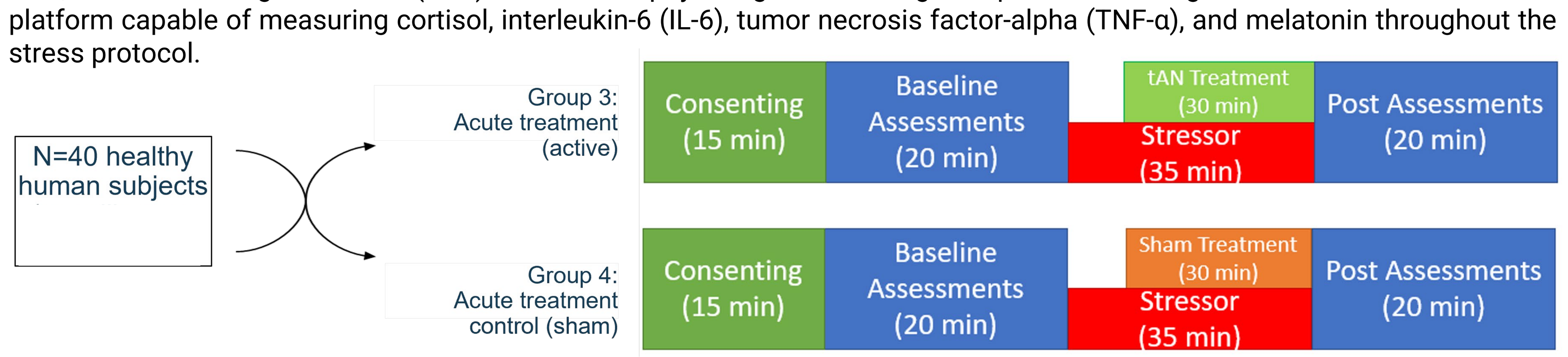


Fig 2. Study Design

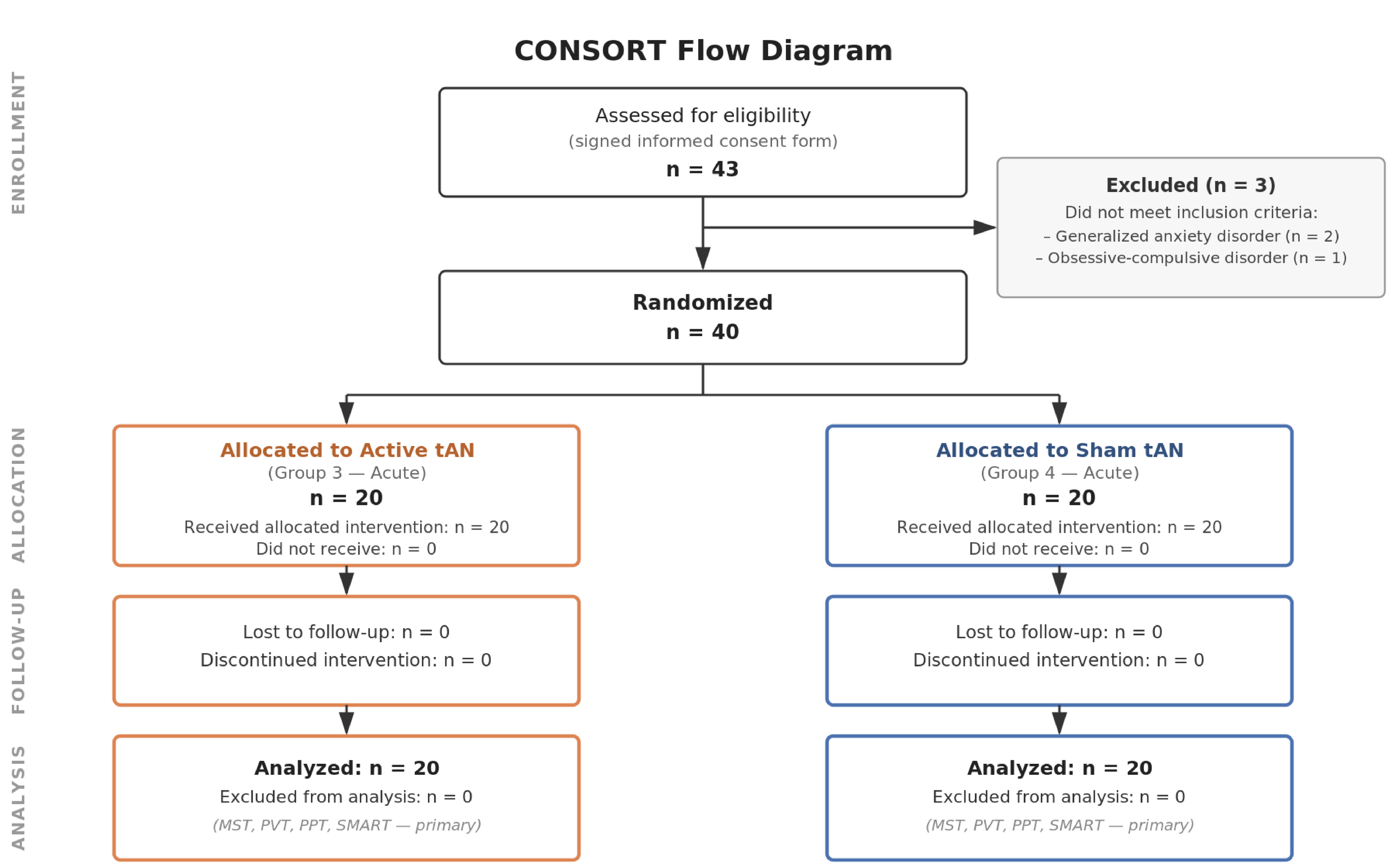


Fig 3. CONSORT Flow Diagram

Clinical Trial Results

Forty participants completed the study protocol, representing the first successful clinical deployment of the newly engineered Sparrow Hawk wearable auricular neurostimulation system. The device maintained stable ambulatory operation throughout the experimental protocol and was compatible with continuous physiologic monitoring and performance assessment procedures. Performance outcomes remained stable across the experimental protocol. No significant decrements were observed in Psychomotor Vigilance Task (PVT), Match-to-Sample (MTS), or Purdue Pegboard Test (PPT) performance following stress exposure, and no significant differences were observed between active and sham stimulation groups. These findings suggest that physiologic stress modulation occurred without measurable impairment in cognitive or psychomotor function.

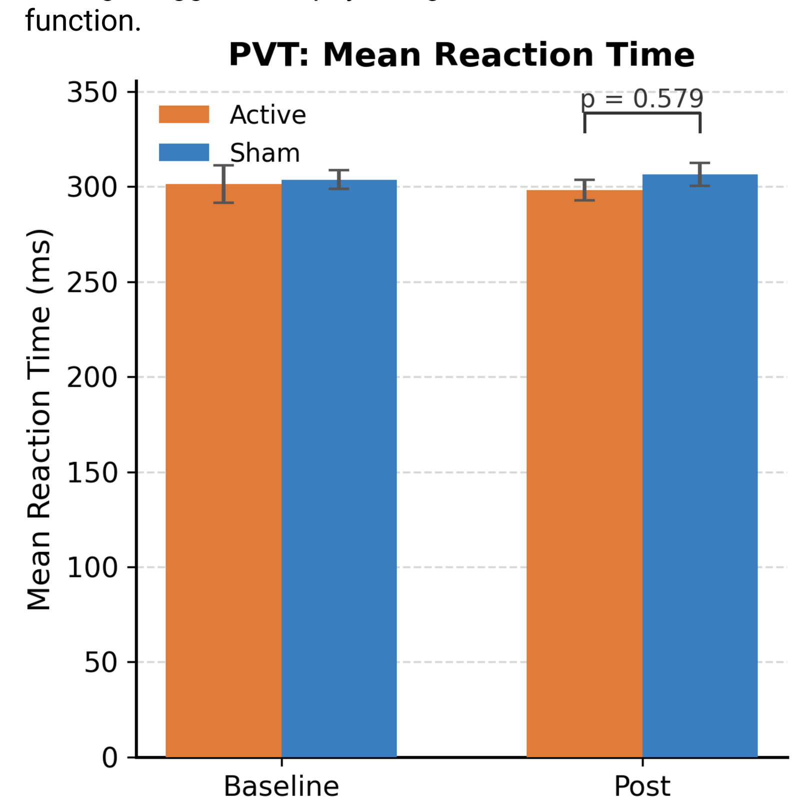


Fig 4. Effects of tAN Reaction Time with PVT Task. No significant differences were seen between Baseline and Post PVT assessments. No significant differences were seen in performance between Active and Sham tAN groups.

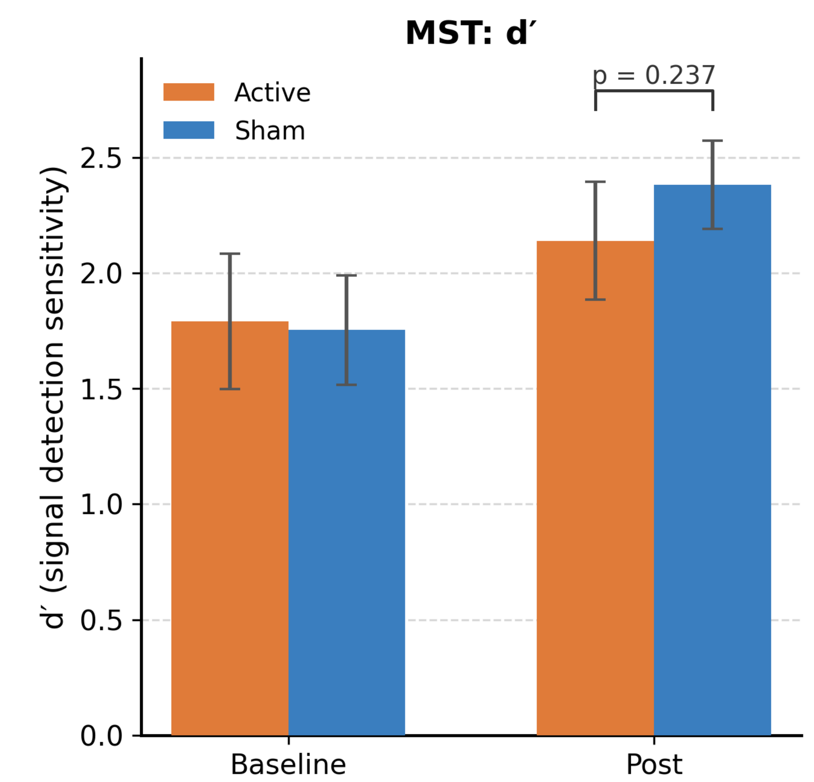


Fig 5. Effects of tAN on Match-To-Sample Task. Match-to-Sample scores trended upwards from Baseline to Post alluding to no effect of the stressor. No significant difference was seen between Active and Sham tAN groups.

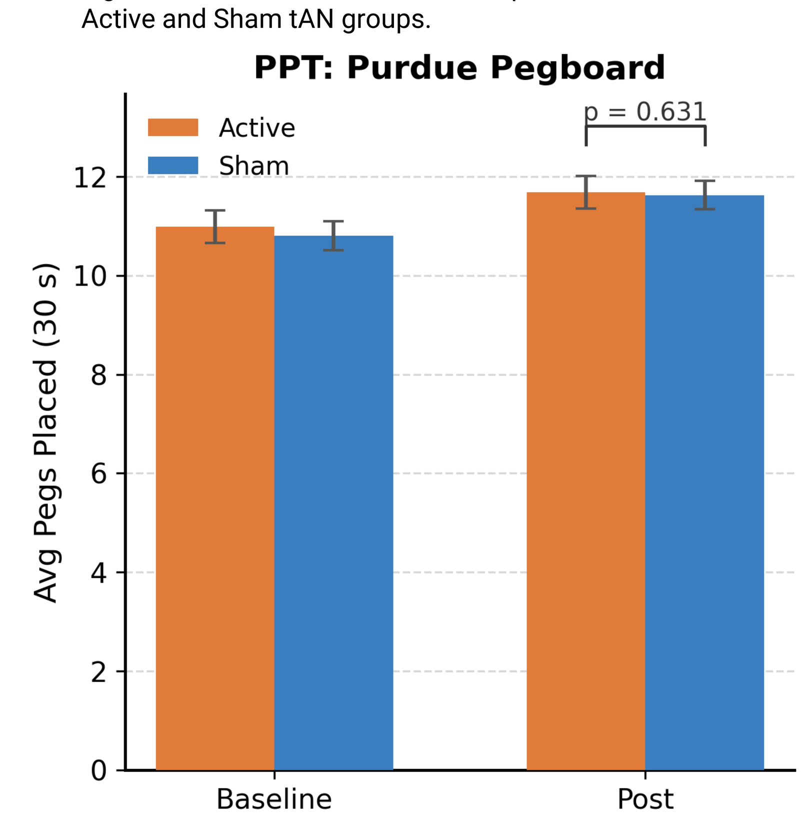


Fig 6. Effects of tAN on Purdue Pegboard Task. Purdue Pegboard scores trended upwards from Baseline to Post in both groups, again alluding to no effect of the stressor. No significant difference was seen between the Active and Sham tAN groups.

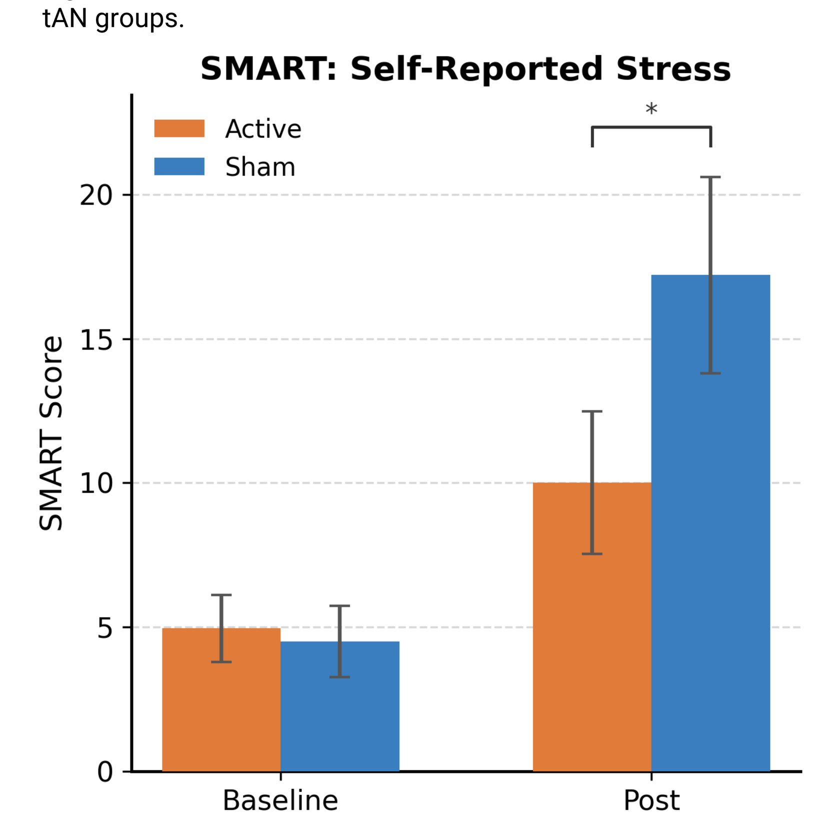


Fig 7. Effects of tAN on Perceived Stress. Both the Active and Sham groups demonstrated a significant increase from Baseline to Post timepoint, indicating a subjective effect of perceived stress. The Active group significantly attenuated this subjective increase as compared to Sham ($p<0.05$).

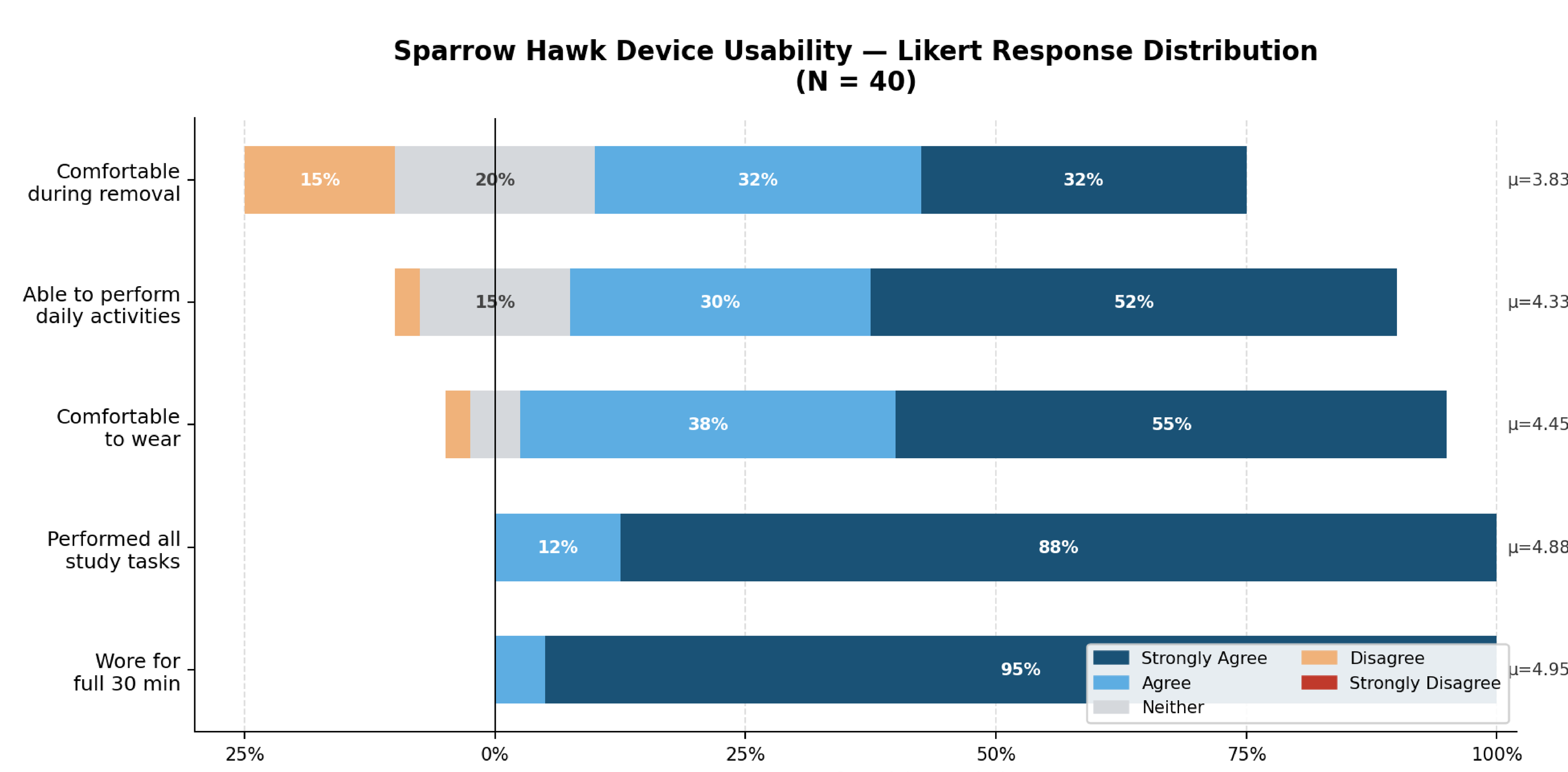
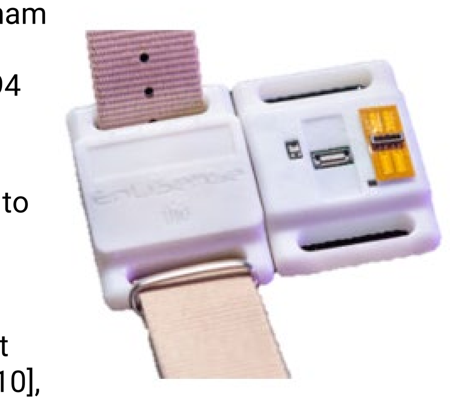


Fig 8. Usability of Military-Grade Sparrow Hawk. Diverging stacked bar chart of Likert-scale usability ratings for the Sparrow Hawk device (N = 40, Groups 3–4 combined). Bars show the percentage of participants selecting each response category (Strongly Disagree to Strongly Agree, color-coded) for five usability statements; mean Likert score (μ) is listed at right for each item. Items are ordered by descending disagreement, from "Comfortable during removal" (μ=3.83) to "Wore for full 30 min" (μ=4.95).

The acute stress paradigm produced robust increases in subjective stress symptoms across both groups, confirming successful stress induction. SMART questionnaire scores increased from pre- to post-stressor exposure in both groups, indicating worsening symptom burden (higher scores = worse symptoms). The active group increased from 4.95 ± 1.17 to 10.00 ± 2.47 (paired t-test: $p = 0.022$), whereas the sham group increased from 4.50 ± 1.23 to 17.20 ± 3.40 ($p < 0.001$). Change scores were significantly greater in the sham group compared with the active group (12.70 ± 2.94 vs. 5.05 ± 2.03; independent t-test: $p = 0.038$), suggesting that active stimulation attenuated worsening of stress-related symptoms following the stressor.

TNF-α: The Sham group showed a significant post-stressor TNF-α increase relative to baseline (β = +0.41, 95% CI [+0.22, +0.60], $p < 0.001$), confirming that the MAST produced an inflammatory response. The Active group significantly attenuated this increase (Phase:post × Active: β = −0.43, 95% CI [−0.63, −0.23], $p < 0.001$). Cortisol: The LME revealed a significant group difference in post-phase cortisol elevation not detected in the primary analysis (Phase:post × Active: β = −0.31, 95% CI [−0.52, −0.10], $p = 0.004$), indicating Active participants had attenuated cortisol responses relative to Sham. Melatonin: During the stimulation period, the Active group showed a significantly larger melatonin elevation compared to Sham (Phase:during × Active: β = +0.78, 95% CI [+0.36, +1.20], $p < 0.001$). No significant pre-to-post group difference was observed ($p = 0.86$).



Corti Wearable

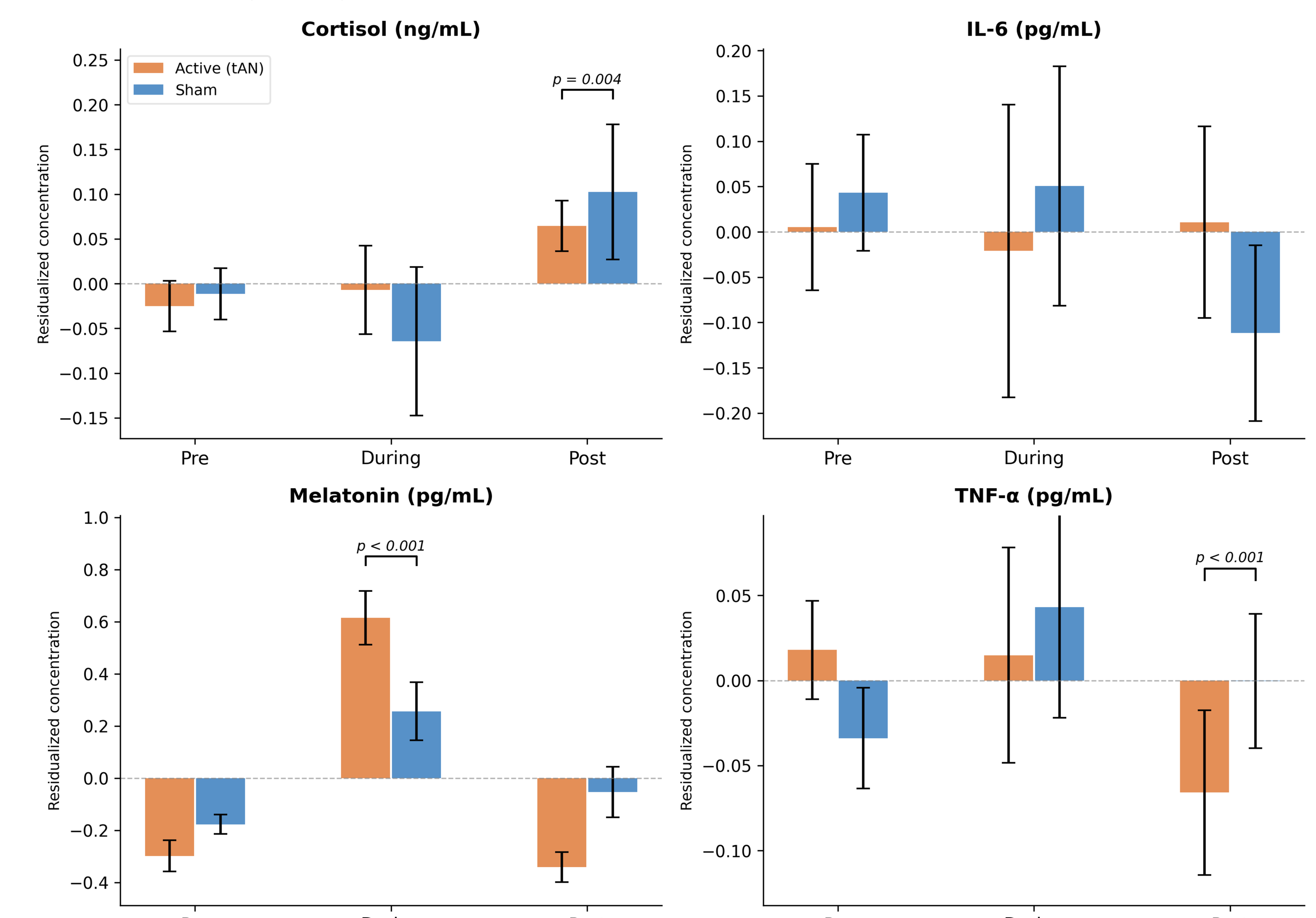


Fig 9. Effects of tAN on Biomarkers collected via Sweat. Biomarkers were collected with the Corti Device (EnLiSense) via sweat on the forearm. Biomarker data was analyzed with a linear mixed effects model fitted for each individual biomarker including their individual temperature and humidity data for residualization.

Discussion

This study demonstrates both the engineering feasibility and physiologic efficacy of a next-generation wearable auricular neurostimulation platform for acute stress modulation. Active stimulation attenuated subjective stress symptoms while reducing cortisol and inflammatory biomarker responses, supporting modulation of autonomic and neuroimmune pathways involved in stress regulation[3,5].

Importantly, these physiologic effects occurred without measurable decrements in cognitive or psychomotor performance, suggesting that wearable auricular neurostimulation may mitigate stress responses while preserving operational and behavioral function. Preservation of performance capacity is particularly relevant for operational, occupational, and clinical environments where stress reduction approaches must avoid sedation or cognitive impairment.

The Sparrow Hawk system was developed through an iterative user-centered engineering process incorporating feedback from combat medics and operational subject matter experts. Design priorities included cable-free ambulatory operation, ergonomic stability, and compatibility with helmets and communication systems. This study represents the first clinical deployment of this newly engineered wearable neuromodulation platform.

The integration of wearable neuromodulation with continuous sweat-based biochemical sensing further provides a novel framework for real-time evaluation of bioelectronic interventions and may support future development of adaptive or closed-loop neuromodulation systems. Ongoing work is focused on next-generation refinement and scalable manufacturing optimization for broader translational deployment.

References

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