Study Protocol with Statistical Analysis Plan

NeuroFinance Human Stress Trial During Financial and Informational Volatility (NFHST)

Protocol ID: NFHST-2026-001
Version: 3.0
Document Date: May 27, 2026
Sponsor: Truway Health, Inc.
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Study Type: Prospective Decentralized Observational Study

Background and Scientific Rationale

Financial market volatility, digital information exposure, economic uncertainty, and prolonged media consumption may contribute to measurable physiologic stress responses and behavioral alterations. Emerging wearable biosensor technologies permit continuous remote monitoring of autonomic nervous system metrics, sleep characteristics, cardiovascular parameters, and behavioral indicators associated with stress exposure. This decentralized observational study is designed to evaluate physiologic and behavioral responses associated with financial and informational stress environments using wearable biosensor monitoring systems and validated psychometric instruments.

Primary Objective

To evaluate changes in autonomic and physiologic stress biomarkers associated with financial and informational stress exposure over time.

Secondary Objectives

• Evaluate sleep quality and sleep efficiency changes
• Assess anxiety symptom severity
• Assess perceived stress burden
• Correlate physiologic biomarkers with psychometric outcomes

Study Design

This study is a prospective decentralized observational study utilizing wearable biosensor monitoring and validated psychometric questionnaires. Participants will undergo remote physiologic monitoring during routine daily activities and periods of financial or informational stress exposure. Commercially available wearable devices may be utilized to collect:

• Heart rate variability

• Resting heart rate
• Sleep duration
• Sleep efficiency
• Electrodermal activity
• Activity metrics

Validated questionnaires including the Generalized Anxiety Disorder-7 (GAD-7) and Perceived Stress Scale-10 (PSS-10) may be administered electronically during scheduled study intervals.

Study Population

Adult participants exposed to varying levels of financial market activity, occupational stress, economic stress environments, and digital media exposure may be enrolled.

Inclusion Criteria

• Adults age 18 years or older
• Ability to provide informed consent
• Access to compatible wearable biosensor technology
• Ability to complete electronic questionnaires

Exclusion Criteria

• Conditions significantly impairing participation
• Current incarceration or institutionalization
• Participation in conflicting interventional studies

Primary Outcome Measures

Change in Heart Rate Variability (HRV)
Heart rate variability will be quantified using root mean square of successive differences (RMSSD) measured in milliseconds using wearable electrocardiographic or photoplethysmographic devices. Higher RMSSD values generally indicate lower physiologic stress burden and improved autonomic flexibility.

Change in Sleep Duration
Sleep duration will be measured in hours per night using wearable sleep monitoring devices.

Change in Resting Heart Rate
Resting heart rate will be measured in beats per minute using wearable biosensor devices.

Change in Perceived Stress Scale-10 (PSS-10) Total Score
The validated 10-item Perceived Stress Scale questionnaire will be utilized. Scores range from 0 to 40, with higher scores indicating greater perceived psychological stress and worse outcomes.

Secondary Outcome Measures

Change in Sleep Efficiency
Sleep efficiency percentage measured using wearable sleep tracking systems.

Change in Galvanic Skin Response (GSR)
Electrodermal activity measured in microsiemens using wearable biosensor devices to assess sympathetic nervous system activation.

Change in Generalized Anxiety Disorder-7 (GAD-7) Total Score
The validated GAD-7 questionnaire will be utilized. Scores range from 0 to 21, with higher scores indicating greater anxiety symptom severity and worse psychological outcomes.

Statistical Analysis Plan

Descriptive statistics will summarize baseline physiologic and demographic characteristics. Continuous physiologic variables including heart rate variability, sleep duration, sleep efficiency, resting heart rate, and galvanic skin response will be analyzed using longitudinal repeated-measures approaches and mixed-effects regression models where appropriate. Psychometric questionnaire outcomes including GAD-7 and PSS-10 scores will be analyzed longitudinally across study intervals. Correlation analyses may evaluate associations between physiologic biomarkers and psychometric stress measures. Missing data may be addressed through mixed-model maximum likelihood estimation or multiple imputation methods depending on missingness patterns. Statistical significance will utilize a two-sided alpha threshold of 0.05.

Ethics and Human Subjects Protections

This observational study will be conducted in accordance with applicable human subjects research standards and ethical principles described in the Declaration of Helsinki. Participation is voluntary and participants may withdraw at any time. Data collected from wearable monitoring devices and questionnaires will be de-identified prior to analysis where applicable.

Version History

Version	Date	Description
1.0	May 20, 2026	Initial Draft
2.0	May 24, 2026	PRS Revisions
3.0	May 27, 2026	Statistical Analysis Plan Added