Study Document Cover Page

Official Title: Brain Dynamic Audio Stimulation for Improving Sleep Quality and Circadian Rhythm in Healthcare Workers
Short Title: Brain Dynamic Audio Stimulation
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Principal Investigator: Hong-Min, Lin
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Study Protocol

Title:
Effectiveness of Brain Dynamic Audio Stimulation for Improving Insomnia and Sleep Cycles in Healthcare Professionals (BDAS-HP)

Protocol ID: 11404-012
Institution: Chi Mei Medical Center, Tainan, Taiwan
Principal Investigator: Hong-Min Lin, MD
IRB Number: CMMC IRB No. 11404-012
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1. Background and Rationale

Healthcare professionals are at high risk of insomnia and impaired sleep quality due to shift work, occupational stress, and high cognitive demands. Poor sleep is associated with decreased attention, emotional dysregulation, burnout, and increased medical errors.

Brain Dynamic Audio Stimulation (BDAS) is a non-invasive auditory intervention that delivers frequency-specific sound patterns designed to entrain neural oscillations toward brainwave frequencies associated with relaxation and sleep, particularly theta (θ) and delta (δ) bands. This mechanism is hypothesized to facilitate sleep initiation and improve sleep stability.

The present study aims to evaluate the clinical feasibility and preliminary effectiveness of BDAS using both subjective outcomes (Insomnia Severity Index, ISI) and objective sleep-related parameters derived from short-duration polysomnographic EEG recordings, sleep onset latency, and sleep efficiency.

2. Objectives

Primary Objective:
To evaluate changes in insomnia severity, measured by the **Insomnia Severity Index (ISI)**, before and after BDAS intervention.

Secondary Objective:
To assess changes in:

- Sleep onset success rate
- Sleep onset latency

- Sleep efficiency following BDAS exposure

To explore short-term changes in **sleep stage distribution** using EEG-based sleep hypnograms.

3. Study Design

This is a **prospective, single-group, pretest-posttest interventional study**.
Fifteen healthcare professionals aged 20–65 years with subjective sleep disturbances will be recruited. Participants will undergo a **30-minute BDAS session daily for two consecutive weeks** in a controlled environment at Chi Mei Medical Center.
Pre- and post-intervention assessments include ISI and quantitative EEG recordings.

4. Participants

Inclusion Criteria

- Licensed healthcare workers at Chi Mei Medical Center (nurses, physicians, therapists, social workers).
- Age 20–65 years.
- Subjective sleep disturbance for at least one month.
- Willing and able to participate for two weeks.
- Provided written informed consent.

Exclusion Criteria

- Current use of hypnotics, antidepressants, or psychiatric medications.
- Diagnosed sleep disorders (e.g., OSA, narcolepsy).
- Neurological or psychiatric illness, epilepsy, or severe chronic disease.
- Hearing impairment affecting audio perception.
- Pregnancy or breastfeeding.

5. Intervention: Brain Dynamic Audio Stimulation (BDAS)

Participants will receive **30 minutes of BDAS** each night for 14 days.
The audio files consist of sound frequencies designed to entrain brainwave patterns associated with deep relaxation (delta, theta) and restorative sleep.
Sessions will take place in a quiet, dimly lit room under standardized conditions.
No pharmacological agents will be administered.

6. Outcome Measures

Primary Outcome:

Subjective Outcome

- Insomnia Severity Index (ISI)
    - Baseline (pre-intervention)
    - Post-intervention (after 2 weeks of BDAS use)

Objective Outcomes

- EEG-derived sleep hypnogram based on AASM criteria
- Sleep onset success rate
- Sleep onset latency (seconds)
- Sleep efficiency (sleep time / total recording time)

EEG, EOG, and EMG signals are used to infer sleep stages (Wake, N1, N2, N3, REM).

7. Statistical Analysis

ISI Score Analysis

- **Paired-sample t-tests** to compare pre- and post-intervention ISI scores
- Effect sizes calculated using **Cohen's d** and **Hedges' g**

Sleep Onset Latency Analysis

- Independent-sample t-tests are used to compare latency before and after two weeks of use
- Each sleep session is treated as an independent observation to maximize statistical power

Sleep Efficiency Analysis

- Independent-sample t-tests comparing pre-intervention and post-intervention sleep efficiency
- Effect sizes reported using Cohen's d and Hedges' g

Statistical Significance

- Two-tailed tests
- **$p < 0.05$** considered statistically significant

8. Ethical Considerations

This study was approved by the Institutional Review Board of Chi Mei Medical Center (IRB No. 11404-012).
All participants will provide written informed consent prior to enrollment.
Participants can withdraw at any time without penalty.

9. Data Management

All participant data will be de-identified and stored on secure,
password-protected institutional servers.
Only authorized investigators will have access.
Data will be used solely for research and academic publication purposes.

10. Dissemination and IPD Sharing Statement

Individual participant data will not be shared outside the research team due to institutional confidentiality policies.
Aggregated and anonymized results will be presented in scientific conferences and peer-reviewed journals.

11. Contacts and Location

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