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
Document Type: Informed Consent Form
IRB Number: CMMC IRB No. 11404-012
Organization Name: Chi Mei Medical Center (CMMC)
Principal Investigator: Hong-Min, Lin
Document Date: 2026-01-01
Version: 2.0
Confidentiality Statement: This document contains confidential information intended for regulatory and research purposes only.

Informed Consent Form for Research Participants

Version: 2
Date: January 1, 2026
Institutional Review Board: Chi Mei Medical Center IRB (CMMC IRB No. 11404-012)
Principal Investigator: Dr. Hong-Min Lin
Department: Department of Family Medicine, Chi Mei Medical Center
Contact: +886-6-2812811 ext. 56029 / Mobile: +886-910-207449
Study Title:
English: *Effectiveness of Brain Dynamic Audio Stimulation for Improving Insomnia and Sleep Cycles in Healthcare Professionals (BDAS-HP)*

Study Title

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

---

1. Study Background

This study is a **non-drug, non-invasive human research study**. It uses **Brain Dynamic Audio Stimulation (BDAS)**, an auditory intervention that delivers frequency-specific sound patterns intended to promote relaxation and facilitate sleep onset.

Sleep disturbance and insomnia are common among healthcare professionals due to shift work, occupational stress, and irregular schedules. Poor sleep quality has been associated with impaired concentration, emotional instability, burnout, and increased risk of medical errors.

Unlike pharmacological treatments, which may cause dependency or side effects, BDAS represents a **non-pharmacological and low-risk approach** to improving sleep. This study aims to evaluate whether BDAS can improve insomnia symptoms and sleep efficiency in healthcare workers.

2. Purpose of the Study

The purpose of this study is to evaluate the effects of BDAS on:

- **Insomnia severity**, measured using the Insomnia Severity Index (ISI)
- **Sleep-related parameters**, including sleep onset, sleep efficiency, and sleep stage patterns derived from short-duration EEG recordings

Approximately **15 healthcare professionals** will participate. BDAS will be used nightly for **two consecutive weeks**.

---

3. Eligibility Criteria

Inclusion Criteria

- Age 20–65 years
- Licensed healthcare professional (e.g., physician, nurse, therapist, or allied health worker)
- Self-reported sleep disturbance
- Normal hearing ability sufficient for audio stimulation
- Willingness to participate for two weeks and provide written informed consent

Exclusion Criteria

- Use of hypnotics, antidepressants, or psychotropic medications within the past month
- Diagnosed sleep disorders (e.g., obstructive sleep apnea, narcolepsy)
- Neurological or major psychiatric disorders
- Significant hearing impairment
- Inability to comply with study procedures

---

4. Study Procedures

This study uses a **single-group, pretest–posttest design**.

Study procedures include:

1. **Baseline assessment**
    - Completion of the Insomnia Severity Index (ISI)
    - Short-duration EEG sleep recording (approximately 24 minutes)
2. **Intervention**
    - Use of Brain Dynamic Audio Stimulation once nightly before sleep
    - Duration: **14 consecutive days**
3. **Post-intervention assessment**
    - Repeat ISI questionnaire
    - Repeat EEG sleep recording

EEG, EOG, and EMG signals will be used to classify sleep stages according to standardized criteria. No drugs, injections, or invasive procedures are involved.

---

5. Possible Risks or Discomforts

This study involves **minimal risk**.

- BDAS is non-invasive and uses sound only
- EEG recording is non-invasive and painless

Some participants may experience mild discomfort such as temporary fatigue or unfamiliar sensations related to audio exposure. If any discomfort occurs, participation can be paused or discontinued at any time.

All adverse events will be documented and reported to the IRB as required.

---

6. Alternative Treatments

Participation in this study is voluntary. You may choose other methods to manage sleep problems, including medical consultation or lifestyle modifications, outside of this study.

---

7. Expected Benefits

You may or may not experience direct personal benefit. Potential benefits include:

- Improvement in insomnia symptoms
- Better sleep initiation and efficiency

The study may also contribute to scientific knowledge regarding non-pharmacological sleep interventions for healthcare workers.

---

8. Participant Responsibilities

Participants are asked to:

- Use BDAS as instructed
- Maintain usual sleep habits during the study
- Avoid caffeine, alcohol, and strenuous exercise before EEG recordings
- Complete questionnaires and assessments as scheduled
- Inform the research team of any discomfort or decision to withdraw

---

9. Confidentiality and Data Protection

- Your identity will be replaced with a coded study ID
- All data will be stored on encrypted, password-protected institutional servers
- Only authorized research personnel will have access
- Data will be retained for **five years** and then permanently destroyed

Regulatory authorities (e.g., IRB) may review study data for oversight purposes.

---

10. Compensation and Medical Care

No financial compensation is provided for participation.

If any injury occurs as a direct result of participation, appropriate medical consultation will be provided, and your legal rights will not be affected.

---

11. Participant Rights and Contacts

You may ask questions at any time.

- **Study-related questions:**
  Dr. Hong-Min Lin
  Tel: +886-6-2812811 ext. 56029
- **Questions about participant rights:**
  Chi Mei Medical Center IRB
  Tel: +886-6-2812811 ext. 53720

---

12. Withdrawal from the Study

You may withdraw from the study at any time without penalty or impact on your medical care.

Upon withdrawal, you may choose:

☐ Allow previously collected data to be used
☐ Request destruction of your collected data

---

13. Data Retention and Future Use

Data will be stored for five years and then securely destroyed.

Any future use of de-identified data beyond this study will require additional IRB approval.

---

14. Ownership and Publication

All study data and results belong to **Chi Mei Medical Center** and will be used for academic and scientific purposes only. No personal identifying information will be published.

---

15. Signatures

(1) Investigator's Statement

I have explained this study, including its purpose, procedures, risks, and benefits, to the participant.

Principal Investigator / Co-Investigator: _____
Signature: _____
Date: _____

Other researcher(s) involved in the explanation: _____
Date: _____

(2) Participant Consent

I have read and understood the information above. All questions have been answered to my satisfaction. I voluntarily agree to participate in this research.

Participant Name: _____
Signature: _____
Date of Birth: _____
Phone: _____
Date: _____

☐ Male ☐ Female

(3) Legal Representative (if applicable)

Name: _____
Signature: _____
Relationship: ☐ Parent ☐ Guardian
Date: _____

(4) Witness (if applicable)

Name: _____
Signature: _____
Date: _____
☐ The participant is unable to read; contents were explained and understood.
☐ Fingerprint of: _____

Note:

This consent form applies to non-drug, non-device human research studies in accordance with Taiwan's *Human Subjects Research Act*.