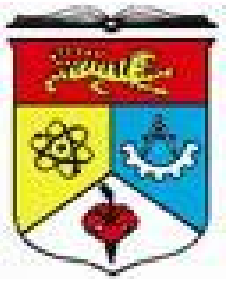

DEPARTMENT OF MEDICINE
UNIVERSITI KEBANGSAAN MALAYSIA

SONATA Trial – Sleep Optimization with Acoustic Therapy: A Polysomnography-Based Pre-Post Study

FF-2026-126
Version 1 Date : 1 March 2026

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CHAPTER I

INTRODUCTION

BACKGROUND AND RATIONALE

Insomnia is a highly prevalent sleep disorder characterized by persistent difficulty initiating or maintaining sleep, often accompanied by impaired daytime functioning. Chronic insomnia affects approximately 10–15% of the adult population and is associated with significant physical, psychological, and socioeconomic burden. Traditional management strategies, including cognitive behavioral therapy for insomnia (CBT-I) and pharmacotherapy, have shown varying levels of effectiveness, with some patients remaining refractory to standard interventions or experiencing unwanted side effects.

Recent advances in sleep neuroscience have revealed that disturbances in endogenous brain rhythms, particularly reductions in slow-wave activity (SWA) and altered sleep spindle patterns, play a key role in the pathophysiology of insomnia. (1) These findings have sparked interest in non-pharmacological neuromodulation approaches to restore healthy sleep architecture.

One such approach is personalized nocturnal sound frequency therapy, in which low-frequency auditory stimuli (e.g., pink noise or slow oscillation-matched tones) are delivered during sleep to entrain and enhance specific sleep-related brain oscillations. Studies in healthy individuals and patients with insomnia have demonstrated that such stimulation can augment slow-wave sleep (N3), reduce nocturnal arousals, and improve perceived sleep quality. Personalized algorithms that adapt sound delivery based on real-time EEG signals further enhance these devices' efficacy and user experience.

Despite growing evidence supporting the utility of sound-based sleep modulation, there is limited data on its application in diverse insomnia subtypes and its effect as measured by gold-standard sleep studies such as polysomnography (PSG). This study uses a pre-post PSG design to evaluate the impact of personalized sound frequency therapy on objective sleep architecture and subjective sleep outcomes in patients with insomnia. The findings may provide new insights into the therapeutic potential of acoustic brainwave modulation and support its integration into personalized insomnia care.

CHAPTER II

RESEARCH OBJECTIVE

Primary Objective:

To evaluate the effect of daily personalized sound frequency therapy on sleep architecture (N1/N2/N3 %, REM %, total sleep time, sleep latency, sleep efficiency) measured by polysomnography after 12 weeks of intervention.

Secondary Objectives:

- To evaluate the effect of daily personalized sound frequency therapy after 12 weeks of intervention

  - Sleep quality; using Pittsburgh Sleep Quality Index(PSQI) questionnaire ,
  - Insomnia; using Insomnia severity index(ISI) questionaire,
  - apnea-hypopnea index (AHI) assessed by polysomnography
  - daytime sleepiness; using the Epworth Sleepiness Score (ESS) intervention.

- To assess user adherence, tolerability, and acceptability of the sound therapy.

Hypothesis

There is an improvement in terms of sleep architecture, sleep quality (PSQI), insomnia severity (ISI), apnea-hypopnea index (AHI), and daytime sleepiness (ESS) with sound frequency therapy after 12 weeks of intervention.

CHAPTER III

LITERATURE REVIEW

Insomnia and Altered Sleep Architecture

Insomnia is a disorder of hyperarousal, marked not only by subjective complaints of poor sleep but also by objective alterations in sleep architecture. Studies using polysomnography have shown that individuals with insomnia often exhibit increased sleep latency, reduced sleep efficiency, decreased slow-wave sleep (N3), and fragmented REM sleep. These findings suggest that interventions targeting sleep architecture may be essential in improving insomnia outcomes beyond behavioral strategies alone. (2)

Brain Oscillations and the Role of Slow-Wave Sleep

Slow-wave activity (0.5–4 Hz) during non-rapid eye movement (NREM) sleep is associated with key restorative functions of sleep, including synaptic downscaling, memory consolidation, and metabolic clearance. Insomnia patients often have reduced amplitude and incidence of these slow oscillations, which have been proposed as a physiological biomarker of hyperarousal. (3, 4)

Auditory Stimulation as a Non-Pharmacological Sleep Modulation Tool

Auditory stimulation during sleep, especially low-frequency stimuli such as pink noise, has gained attention as a novel approach to enhance slow-wave sleep. A previous study demonstrated that closed-loop auditory stimulation, timed with endogenous slow oscillations, significantly increased SWA and memory retention in healthy individuals. (5) Subsequent studies confirmed that these enhancements can improve perceived sleep quality and reduce sleep onset latency. (6, 7)

Personalized Acoustic Stimulation Devices

Commercially available sleep technologies (e.g., Dreem, Sleep Shepherd, Kokoon, Somnox) now incorporate personalized or adaptive sound therapy, using EEG-informed algorithms or preset frequencies tailored to individual sleep cycles. Arnal, Thorey (8)2020) validated the Dreem headband as a reliable alternative to full PSG in measuring brain activity and delivering auditory stimulation. These devices enable home-based delivery of sound stimulation and make scalable interventions possible.

Efficacy in Insomnia and Other Populations

While most trials have been conducted in healthy adults, early evidence suggests

potential benefits for insomnia populations. A randomized controlled trial integrating auditory stimulation into behavioral therapy showed improved sleep maintenance and reduced arousals. However, large-scale clinical trials measuring changes in PSG-confirmed sleep stages post-intervention remain limited.

Knowledge Gaps and Justification for Current Study

Despite promising preliminary data, studies are often limited by small sample sizes, lack of control for insomnia subtypes, and insufficient objective measures such as PSG. Furthermore, the differential effects of personalized sound therapy in insomnia patients vs. good sleepers remain underexplored. This study addresses these gaps by evaluating both subjective and polysomnography-based outcomes in patients with insomnia following a 12-week course of personalized sound therapy.

Nonetheless, there is a more recent randomized, single blind crossover study done by Aloulou (9), comparing sleep quality between subjects listening to personalized sound sequences vs non personalized placebo right before bedtime, as opposed to the usual nighttime acoustic therapy. The results showed that sleep quality improved with personalized sound frequency both objectively and subjectively.

CHAPTER IV

METHODOLOGY

Study Design:

A prospective, single-arm, longitudinal pre–post interventional study. Intervention duration: 12 weeks.

Baseline and follow-up PSG (full-night polysomnography).

Study Population:

Insomnia patients/hospital staff in Hospital Canselor Tuanku Muhriz UKM

Inclusion Criteria:

- Adults aged 18–60 years
- With sleep disturbances based on the PSQI score of >5 and/or ISI score $\geq$ 15

Exclusion Criteria:

- Central sleep apnea
- Epilepsy
- Current use of sedative-hypnotics or neurostimulation devices
- Shift workers (people with different working hours patterns, for example morning, afternoon, night shifts)
- Pregnancy
- Moderate to severe OSA (AHI $\geq$15)
- Presbycusis or other significant hearing loss
- Patients with psychiatric disorder

SAMPLE SIZE CALCULATION

Sample Size Justification:

The proposed study uses a pre-post interventional design comparing sleep architecture parameters before and after 12 weeks of personalized sound frequency therapy in the same subjects.

Based on similar published trials on acoustic stimulation in sleep research Ong, Lo (7), the primary outcome is comparing the percentage of slow-wave sleep (N3 stage) pre- and post-intervention, and its association with memory retention.

Assumptions for calculation:

- Effect size (Cohen's d): Moderate effect size assumed (d = 0.6), in line with existing studies showing ~5–10% absolute change in N3 percentage.
- Power: 95%
- Alpha level: 0.05 (two-tailed)
- Paired comparison: Same subjects serve as their own control.

Using standard formulas for the paired t-test:
$n = [(Z(1-\alpha/2) + Z(1-\beta)) * \sigma / \delta]^2$

Where:
- $Z(1-\alpha/2) = 1.96$ for 95% CI
- $Z(1-\beta) = 1.28$ for 90% power
- δ = expected mean difference in N3 (%)
- σ = standard deviation of the paired difference.

Based on previous literature, an expected mean difference of ~5% with a standard deviation of 8% yields:
$n = [(1.96 + 1.28) * / 0.6]^2 \approx 29.16$

To account for dropouts and non-adherence, a 20% attrition buffer is added:
$30 \times 1.2 = 40$ subjects (rounded up).

Thus, a final sample size of 40 participants must detect a clinically meaningful change in sleep architecture with sufficient power and significance.

Type of Sampling

The sampling method used in this study is purposive sampling.

Intervention:

At baseline, participants will undergo a comprehensive evaluation that includes a level 2 full-night polysomnography (PSG) conducted within 48 hours before starting the intervention, completion of standardized questionnaires such as the Insomnia Severity Index (ISI), Epworth Sleepiness Scale (ESS), and Pittsburgh Sleep Quality Index (PSQI), as well as documentation of sleep and medical history.

Following baseline assessment, participants will receive a wearable sound stimulation device programmed with personalized low-frequency auditory stimuli (e.g., pink noise or slow-wave–matched sounds). The patient will self-administer the therapy at home, for one hour in the morning (upon waking) and one hour in the evening (around 5 p.m. until just before sleep). The recommended device volume is above 30%, with a frequency range between 15 and 20,000 Hz. Acceptable devices include in-ear, open-ear, or standard headphones, while bone conduction devices are excluded.

During the 12-week intervention period, participants must maintain daily device usage logs with at least 80% compliance and participate in weekly remote check-ins for monitoring and support.

At post-intervention (after 12 weeks), participants will undergo a repeat PSG and complete post-treatment ISI and PSQI questionnaires and an adherence and tolerability survey to assess user experience, compliance, and acceptance of the sound therapy.

Clinically meaningful changes were defined based on established MCIDs: reduction in ≥3 points for PSQI(10), and ≥6 points for ISI (11).

Outcome Measures:

Primary Outcome:

- Change in sleep architecture

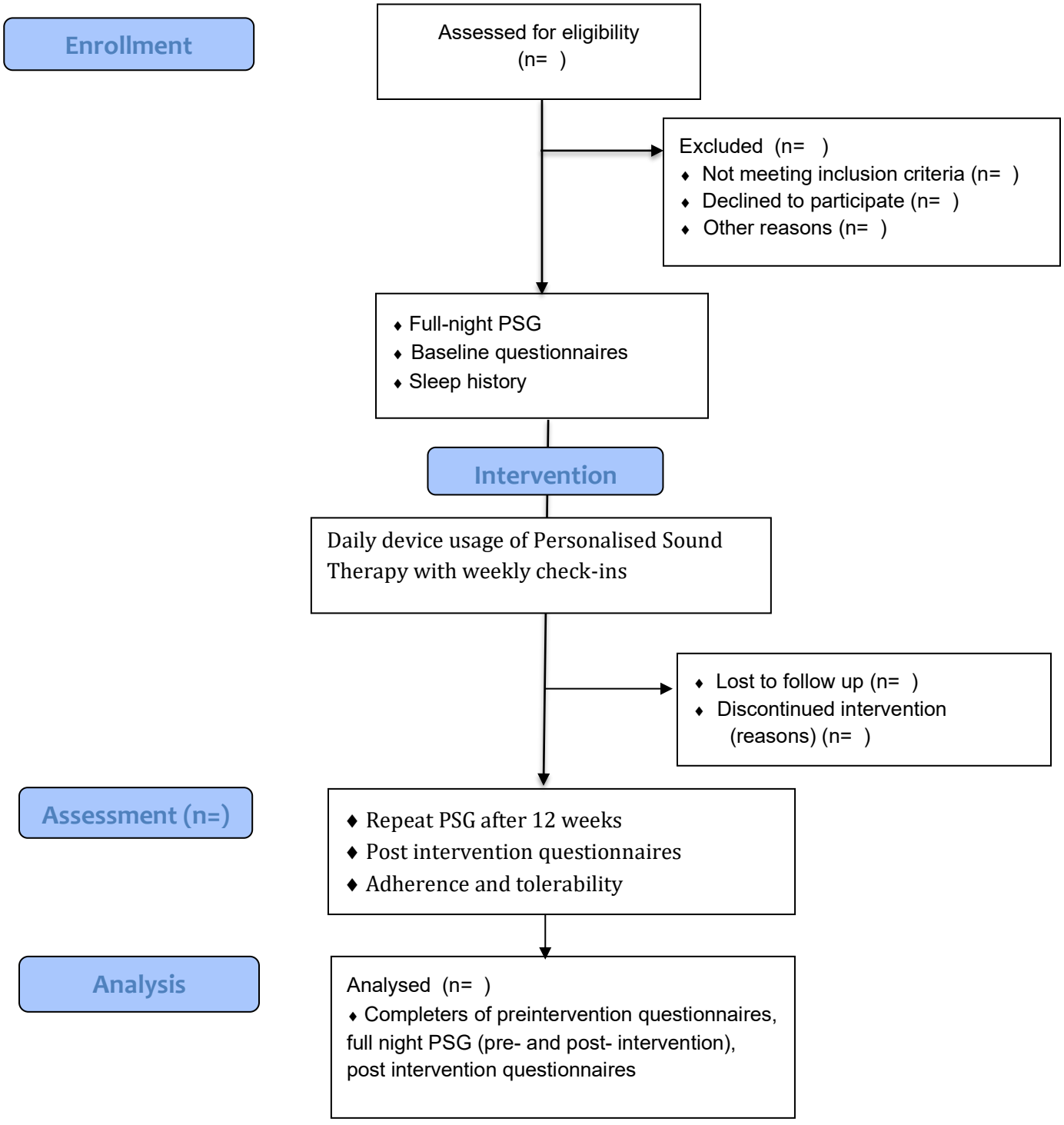
Secondary Outcomes:

- Change in ISI
- PSQI scores
- Change in AHI
- Side effect; and compliance (in % days used)
-Assess user adherence, tolerability, and acceptability of the sound therapy

Data Analysis:

- Paired t-tests or Wilcoxon signed-rank test for within-group comparisons
- Regression analysis to explore predictors of response

FLOW DIAGRAM



OPERATIONAL TERMS DEFINITION

1. Insomnia Severity Index (ISI)
   The Insomnia Severity Index is a validated self-reported questionnaire that assesses insomnia's nature, severity, and impact over the previous month. It consists of 7 items, each scored 0–4, with total scores ranging from 0–28. Higher scores indicate greater insomnia severity. An ISI score of > 15 indicates moderate insomnia.

   2. Apnea-Hypopnea Index (AHI)
   The Apnea-Hypopnea Index quantifies sleep-disordered breathing events per hour, calculated during a polysomnography (PSG). It is the sum of apneas (complete cessation of airflow) and hypopneas (partial reduction in airflow) divided by total sleep time in hours.
   - AHI <5: Normal
   - AHI 5–14: Mild OSA
   - AHI 15–29: Moderate OSA
   - AHI ≥30: Severe OSA

   3. Pittsburgh Sleep Quality Index (PSQI)
   The PSQI is a 19-item self-report questionnaire that assesses subjective sleep quality and disturbances over the past month. It yields 7 component scores, which are summed to give a global score (0–21). **A score >5 indicates poor sleep quality**.

   4. Epworth Sleepiness Scale (ESS)
   The ESS questionnaire is used to assess a patient's excessive daytime sleepiness (EDS) subjectively by rating their likelihood of dozing off during eight activities. **A score of > 10 indicates excessive daytime sleepiness.**
   -<10: normal
   -11-12: mild excessive daytime sleepiness
   -13-15: moderate excessive daytime sleepiness
   -16-24: severe excessive daytime sleepiness

   5. Sleep Architecture
   Sleep architecture refers to the structure and pattern of sleep stages recorded during overnight polysomnography. It includes Non-Rapid Eye Movement (NREM) stages (N1, N2, N3) and Rapid Eye Movement (REM) sleep. Key

parameters include percentages of time spent in each stage, total sleep time (TST), sleep latency, sleep efficiency, and arousal index.

6. Treatment Success Definition

A. Objective Criteria

If Baseline Sleep Efficiency < 85%

- Treatment success is defined as improvement in sleep efficiency (SE) meeting any of the following:
    - Absolute increase ≥ 5 % from baseline; or
    - Relative increase ≥ 10 % if baseline SE < 75 %; or
    - Achievement of SE ≥ 85 % after intervention.

If Baseline Sleep Efficiency ≥ 85%

- Treatment success requires:
- Maintenance of SE within ± 3 % of baseline (no decline > 3 %), and
- Improvement in at least one additional objective parameter:
    - Wake after sleep onset (WASO) ↓ ≥ 20 min or ≥ 20 %
    - Sleep onset latency: ↓ ≥ 10 min or ≥ 20%
    - N3 (slow-wave sleep): ↑ ≥ 5 % absolute or ≥ 20 min (without TST/REM loss)
    - Arousal index: ↓ ≥ 3‑5 events/hour

B. Subjective Criteria (Patient-Reported Outcomes)

At least one of:

- PSQI: ≥ 3-point reduction (MCID)
- ISI: ≥ 6-point reduction (MCID)
- ESS ≥ 2 points reduction in score

C. Composite Responder Definition

- Treatment Success Responder: meets both A (objective per stratum) and B (subjective).
- Partial Physiological Responder: meets A only.
- Subjective Responder: meets B only.
- Non-Responder: meets neither.

CHAPTER V

RESEARCH ETHICS

Ethical approval approved the Research Ethics Committee of Universiti Kebangsaan Malaysia, FF-2026-126. All participants will provide written informed consent before enrolment. Participant confidentiality will be protected by coding all data. Participants can withdraw at any point without affecting their standard medical care.

CHAPTER VI

PATIENT INFORMATION SHEET

***Research Title**:*

SONATA Trial – Sleep Optimization with Acoustic Therapy: A Polysomnography-Based Pre-Post Study

Purpose of Study:

This study aims to evaluate the effects of daily sound therapy on sleep architecture using full-night polysomnography (PSG). The sound is delivered through a wearable device using personalized sound frequencies (e.g., pink noise). The study assesses the therapy's effect on deep sleep (N3), sleep latency, efficiency, and insomnia symptoms, using questionnaires and PSG readings before and after 12 weeks of therapy.

What will the study involve?

Participation is voluntary. If you agree, you will undergo:

- Two overnight sleep studies (polysomnography)
- Wear a sound stimulation device for 1 hours in the morning and evening respectively daily for 12 weeks
- Complete sleep-related questionnaires (PSQI, ISI, ESS) before and after therapy
- Weekly check ins from researcher (support and monitoring)

You will not receive sedatives or new medications for this study. Your usual medical care will not be affected.

Benefits:

- Potential improvement in sleep quality and duration
- Non-pharmacological therapy with a low side-effect profile
- Free use of a wearable sound stimulation device for the duration of the study

Risks:

• Minor discomfort from wearing the sound device (Adjustment could be made to suit participant if required)
• Possible ear irritation or skin reaction at the device site
• No physical or invasive procedure will be performed
• Might have risk of worsening sleep/headache/seizure and affect daily activities

Do you have to take part?

Participation in this study is voluntary. If you agree to take part, then you will be asked to sign the "Informed Consent Form". You will be given a copy of the form and this Information Sheet.

Data & Confidentiality:

The data from this study will be made into a report which may be published. Access to the data is only by the research team and the REC UKM team. The data will be reported in a collective manner without reference to an individual. Hence your identity will be kept confidential.

Payment and compensation

You do not have to pay nor will you be paid to participate in this study. You do have to pay for the usual hospital charges.

Right to Refuse or Withdraw:

You may refuse or withdraw from the study at any point without affecting your medical care or relationship with the hospital.

Who can I ask about the study?

If you have any questions, you can direct them to the research team. You can also contact the REC UKM for clarifications.

Dr. Ho Yun Nyen
Department of Internal Medicine
Hospital Canselor Tuanku Muhriz (HCTM), UKM
Mobile : 017-4146071

CHAPTER VII

INFORMED CONSENT FORM

Research Title:
SONATA Trial – Sleep Optimization with Acoustic Therapy: A Polysomnography-Based Pre-Post Study

Researcher's Name:
Prof. Dr. Mohamed Faisal Abdul Hamid / Dr. Azat Azrai Azmel / Dr. Mas Fazlin Jailaini / Dr. Ho Yun Nyen

I, ……, IC No: ……..,

- Have read all the information in the Patient Information Sheet and understand the aim and purpose of this study.
- I have been given enough time to think about it, and my questions have been answered satisfactorily.
- Understand that I may freely withdraw from this study at any time without reason or repercussions.
- Understand that anonymity will be ensured in the final write-up.

I understand all the above and voluntarily agree to participate in this research study, follow the study procedures, and provide the necessary information as requested.

…… …….

Signature/Thumbprint Date

…… ……

Witness Signature Researcher Signature

……. Ho Yun Nyen (941107-14-5782)

Witness Name /IC no Researcher Name

……. ……

Date Date

CHAPTER IX

DATA COLLECTION SHEET

Name: _____
IC No: _____
Contact: _____
Age: _____ Gender: M/ F
Occupation: _____
Weight: _____kg
Comorbidities: _____
_____
_____

Baseline PSG Results:
- N1: ___% N2: ___% N3: ___% REM: ___% TST: ___ mins AHI: _____

Post-Intervention PSG Results:
- N1: ___% N2: ___% N3: ___% REM: ___% TST: ___ mins AHI: _____

PSG baseline and post-intervention

	N1 (%)	N2 (%)	N3(%)	REM (%)	TST (mins)	AHI
Pre therapy						
Post therapy						

Questionnaires:
- ISI: ___ PSQI: ___ ESS: ___
Device Usage Log: _____

	ISI	PSQI	ESS
Pre therapy			
Post therapy			

CHAPTER X

Gantt chart

Progression / Timeline	Aug - Oct 2025	Nov 2025- Feb 2026	March 2026- March 2027	April –June 2027	July – Dec 2027	Jan 2028
Literature review & Preparation of Research proposal						
Approval of HCTM Research and Ethics Committee						
Patient recruitment						
Data entry and analysis						
Final result and manuscript submission						
Final report presentation						

CHAPTER XII

APPENDICES

Appendices may include patient brochures, device instructions, additional forms, or letters.

Questionnaires used:

Insomnia Severity Index (ISI)

Insomnia Severity Index (ISI)

Name: _____ **Date:** _____

1. Please rate the current (i.e., last 2 weeks) **SEVERITY** of your insomnia problem(s).

	None	Mild	Moderate	Severe	Very
Difficulty falling asleep:	0	1	2	3	4
Difficulty staying asleep:	0	1	2	3	4
Problem waking up too early:	0	1	2	3	4

2. How **SATISFIED**/dissatisfied are you with your current sleep pattern?

Very Satisfied				Very Dissatisfied
0	1	2	3	4

3. To what extent do you consider your sleep problem to **INTERFERE** with your daily functioning (e.g. daytime fatigue, ability to function at work/daily chores, concentration, memory, mood, etc.).

Not at all Interfering	A Little	Somewhat	Much	Very Much Interfering
0	1	2	3	4

4. How **NOTICEABLE** to others do you think your sleeping problem is in terms of impairing the quality of your life?

Not at all Noticeable	Barely	Somewhat	Much	Very Much Noticeable
0	1	2	3	4

5. How **WORRIED**/distressed are you about your current sleep problem?

Not at all	A Little	Somewhat	Much	Very Much
0	1	2	3	4

Guidelines for Scoring/Interpretation:

Add scores for all seven items (1a+1b+1c+ 2+3+4+5) = _____
Total score ranges from 0-28
- 0-7 = No clinically significant insomnia
- 8-14 = Subthreshold insomnia
- 15-21 = Clinical insomnia (moderate severity)
- 22-28 = Clinical insomnia (severe)

Pittsburgh Sleep Quality Index (PSQI)

Subject's Initials_____ID#_____Date_____Time_____AM PM

PITTSBURGH SLEEP QUALITY INDEX

INSTRUCTIONS:
The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night?

   BED TIME _____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

   NUMBER OF MINUTES _____

3. During the past month, what time have you usually gotten up in the morning?

   GETTING UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)

   HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you . . .

a) Cannot get to sleep within 30 minutes

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

b) Wake up in the middle of the night or early morning

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

c) Have to get up to use the bathroom

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

d) Cannot breathe comfortably

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

e) Cough or snore loudly

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

f) Feel too cold

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

g) Feel too hot

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

h) Had bad dreams

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

i) Have pain

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

j) Other reason(s), please describe_____

_____

How often during the past month have you had trouble sleeping because of this?

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

6. During the past month, how would you rate your sleep quality overall?

Very good _____

Fairly good _____

Fairly bad _____

Very bad _____

7. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all _____

Only a very slight problem _____

Somewhat of a problem _____

A very big problem _____

10. Do you have a bed partner or room mate?

No bed partner or room mate _____

Partner/room mate in other room _____

Partner in same room, but not same bed _____

Partner in same bed _____

If you have a room mate or bed partner, ask him/her how often in the past month you have had . . .

a) Loud snoring

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

b) Long pauses between breaths while asleep

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

c) Legs twitching or jerking while you sleep

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

d) Episodes of disorientation or confusion during sleep

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

e) Other restlessness while you sleep; please describe_____

_____

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

Epworth Sleepiness Scale (ESS)

	Would never nod off 0	Slight chance of nodding off 1	Moderate chance of nodding off 2	High chance of nodding off 3
Sitting and reading				
Watching TV				
Sitting, inactive, in a public place (e.g., in a meeting, theater, or dinner event)				
As a passenger in a car for an hour or more without stopping for a break				
Lying down to rest when circumstances permit				
Sitting and talking to someone				
Sitting quietly after a meal without alcohol				
In a car, while stopped for a few minutes in traffic or at a light				

CHAPTER XII

REFERENCES

1. Lustenberger C, Maric A, Dürr R, Achermann P, Huber R. Triangular relationship between sleep spindle activity, general cognitive ability and the efficiency of declarative learning. PloS one. 2012;7(11):e49561.
2. Baglioni C, Spiegelhalder K, Lombardo C, Riemann D. Sleep and emotions: a focus on insomnia. Sleep medicine reviews. 2010;14(4):227–38.
3. Perlis M, Giles D, Mendelson W, Bootzin R, Wyatt J. Psychophysiological insomnia: the behavioural model and a neurocognitive perspective. Journal of sleep research. 1997;6(3):179–88.
4. Riemann D, Krone LB, Wulff K, Nissen C. Sleep, insomnia, and depression. Neuropsychopharmacology. 2020;45(1):74–89.
5. Ngo H-VV, Martinetz T, Born J, Mölle M. Auditory closed-loop stimulation of the sleep slow oscillation enhances memory. Neuron. 2013;78(3):545–53.
6. Leminen MM, Virkkala J, Saure E, Paajanen T, Zee PC, Santostasi G, et al. Enhanced memory consolidation via automatic sound stimulation during non-REM sleep. Sleep. 2017;40(3):zsx003.
7. Ong JL, Lo JC, Chee NI, Santostasi G, Paller KA, Zee PC, et al. Effects of phase-locked acoustic stimulation during a nap on EEG spectra and declarative memory consolidation. Sleep medicine. 2016;20:88–97.
8. Arnal PJ, Thorey V, Ballard M, Hernandez A, Guillot A, Jourde H. The Dreem headband as an alternative to polysomnography for EEG signal acquisition and sleep staging. BioRxiv. 2019; 662734.
9. Aloulou A, Chauvineau M, Destexhe A, Léger D. Listening to the sound of your own brain waves enhances sleep quality and quantity. Sleep Medicine. 2025:106755.
10. Qin Z, Zhu Y, Shi D-D, Chen R, Li S, Wu J. The gap between statistical and clinical significance: time to pay attention to clinical relevance in patient-reported outcome measures of insomnia. BMC Medical Research Methodology. 2024;24(1):177.
11. Yang M, Morin CM, Schaefer K, Wallenstein GV. Interpreting score differences in the Insomnia Severity Index: using health-related outcomes to define the minimally important difference. Current medical research and opinion. 2009;25(10):2487–94.