# STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

## Comparison of Sensory-Based and Behavioral Sleep Interventions in Individuals With Sleep Problems

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| **Official Title** | Comparison of Sensory-Based and Behavioral Sleep Interventions in Individuals With Sleep Problems |
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| **Study Location** | Istanbul, Türkiye |

**PUBLIC DISCLOSURE NOTICE**

This document is prepared for public posting on ClinicalTrials.gov. It contains no participant names or direct personal identifiers.

## 1. Protocol Synopsis

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| **Study Design** | Three-arm, randomized, controlled, parallel-group, single-blind clinical study |
| **Planned/Analyzed Sample** | 54 participants; 18 participants per group |
| **Study Arms** | Sensory-based intervention + sleep hygiene; behavioral intervention + sleep hygiene; sleep-hygiene control |
| **Intervention Duration** | Six weeks |
| **Assessment Time Points** | Baseline and immediately after the six-week intervention |
| **Primary Outcome** | Pittsburgh Sleep Quality Index (PSQI) total score |
| **Secondary Outcomes** | Sleep Hygiene Index; Beck Anxiety Inventory; WHOQOL-BREF; Occupational Balance Questionnaire-11; Adolescent/Adult Sensory Profile; sleep diary; heart-rate variability; Xiaomi Mi Band 5 sleep parameters |
| **Analysis Software** | IBM SPSS Statistics for Windows, Version 26.0 |
| **Statistical Significance** | Two-sided $p < 0.05$ |

## 2. Background and Rationale

Sleep is a fundamental physiological process that supports cognitive functioning, emotional regulation, immune function, metabolism, and daily occupational performance. Poor sleep quality is associated with daytime dysfunction, anxiety, reduced quality of life, and impaired participation in meaningful activities. Although pharmacological options are commonly used, non-pharmacological approaches are increasingly emphasized because they can address modifiable behavioral and environmental contributors to sleep problems.

Behavioral approaches such as progressive muscle relaxation and diaphragmatic breathing aim to reduce physiological arousal and support consistent pre-sleep routines. Sensory-based approaches, including olfactory and auditory environmental modulation, aim to create a more regulating sleep context. Direct comparisons of sensory-based and behavioral interventions delivered alongside standardized sleep-hygiene education remain limited. This study was therefore designed to compare these approaches with a sleep-hygiene control condition.

## 3. Objectives and Hypotheses

### 3.1 Primary Objective

To compare the effects of sensory-based and behavioral sleep interventions, each delivered in addition to standardized sleep-hygiene education, with sleep-hygiene education alone on sleep quality in individuals reporting sleep problems.

### 3.2 Secondary Objectives

- To compare changes in sleep hygiene.
- To compare changes in anxiety symptoms.
- To compare changes in quality of life and occupational balance.
- To examine changes in sensory processing patterns.

- To compare changes in autonomic nervous system activity measured through heart-rate variability.
- To compare device-derived sleep duration and sleep-stage parameters.

### 3.3 Hypotheses

The null hypotheses state that there are no statistically significant between-group differences in changes in sleep quality, sleep hygiene, anxiety, quality of life, occupational balance, sensory profile, autonomic nervous system activity, or device-derived sleep parameters.

## 4. Study Design

This was a three-arm randomized controlled study with a parallel-group design. Eligible participants were allocated to a sensory intervention group, a behavioral intervention group, or a control group. Assessments were completed at baseline and after the six-week intervention period under standardized conditions. Randomization and intervention delivery were performed by the same researcher. To reduce analysis bias, coded data were analyzed by an independent statistician who was not informed of group allocation; the study was therefore conducted as a single-blind trial.

## 5. Study Setting and Participants

Participants were recruited from adults accessible to the research team who reported sleep-related problems and volunteered to participate. Recruitment and study procedures were coordinated through Istanbul Atlas University.

### 5.1 Eligibility Criteria

Eligibility was assessed using the criteria recorded in the approved thesis protocol. Before public upload, the final wording below should be checked against the ethics-approved application and registry record.

- Adult participant able to understand and communicate in Turkish.
- Self-reported sleep problem and eligibility according to the study screening procedure.
- Mini-Mental State Examination score sufficient to complete study procedures.
- Voluntary participation and provision of written informed consent.
- Ability and willingness to complete baseline and post-intervention assessments and follow the assigned six-week program.

### 5.2 Exclusion Criteria

- A health condition that would prevent safe participation or substantially interfere with the intervention or assessments.
- A cognitive, communication, visual, or hearing limitation that would prevent completion of study procedures.
- Use of a concurrent intervention or a major treatment change likely to confound sleep outcomes.
- Failure to complete required baseline or post-intervention assessments.
- Withdrawal of consent.

## 6. Sample Size

Sample size was calculated in G*Power using a one-way omnibus analysis of variance for three groups with $\alpha = 0.05$. A Hedges-corrected Cohen's d of approximately 0.89 reported for PSQI outcomes was adapted to the three-arm design, yielding an estimated Cohen's f of approximately 0.42. With equal group allocation, 18 participants per group (total N = 54) provided approximately 77% power for f = 0.42; the minimum detectable effect at 80% power was approximately f = 0.435.

## 7. Randomization, Allocation, and Blinding

Eligible participants were randomly assigned in equal numbers to one of the three study arms. Group allocation was implemented by the study researcher. Participant and intervention-provider blinding was not feasible because of the nature of the interventions. Outcome data were coded, and the independent statistician remained blinded to group identity.

## 8. Interventions

### 8.1 Standardized Sleep-Hygiene Education (All Groups)

All participants received a standardized six-session sleep-hygiene education program based on evidence-informed recommendations. Core topics included maintaining a regular sleep-wake schedule; avoiding caffeine, nicotine, and alcohol before bedtime; arranging an appropriate sleep environment; regulating light, noise, and room temperature; limiting behaviors that interfere with sleep; and supporting healthy daily routines. Educational content was made available through an online social-media platform, and adherence was supported through weekly telephone contact.

### 8.2 Sensory-Based Intervention Group

In addition to sleep-hygiene education, participants received a sensory-based program designed to regulate the pre-sleep environment. The program incorporated olfactory and auditory sensory strategies, including the use of selected essential oils and structured sound input such as pink noise, according to standardized written instructions. Participants were instructed in safe home use, and adherence was monitored during weekly telephone calls.

### 8.3 Behavioral Intervention Group

In addition to sleep-hygiene education, participants received progressive muscle relaxation and diaphragmatic breathing exercises. Progressive muscle relaxation was delivered using a standardized audio recording, and diaphragmatic breathing was taught as a technique to support autonomic regulation and relaxation. Participants received audio material and written instructions for home practice. Adherence was monitored and supported through weekly telephone calls.

### 8.4 Control Group

Participants in the control group received the standardized sleep-hygiene education and weekly follow-up but did not receive the additional sensory-based or behavioral intervention components during the six-week study period.

### 8.5 Intervention Standardization and Adherence

Intervention content, instructions, duration, and follow-up procedures were standardized across participants within each study arm. Weekly telephone contacts were used to review implementation, answer questions, document adherence, and support completion of the assigned program.

## 9. Outcome Measures

| Outcome | Instrument/Variable | Time Point | Unit |
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| Primary | Pittsburgh Sleep Quality Index total score | Baseline; post-intervention | points |
| Secondary | Pittsburgh Sleep Quality Index component scores | Baseline; post-intervention | points |

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| Secondary | Sleep Hygiene Index | Baseline; post-intervention | points |
| Secondary | Beck Anxiety Inventory | Baseline; post-intervention | points |
| Secondary | WHOQOL-BREF domain scores | Baseline; post-intervention | points |
| Secondary | Occupational Balance Questionnaire-11 | Baseline; post-intervention | points |
| Secondary | Adolescent/Adult Sensory Profile quadrants | Baseline; post-intervention | points |
| Secondary | Heart-rate variability parameters | Baseline; post-intervention | milliseconds and normalized/ratio units |
| Secondary | Deep, light, REM, awake, and total sleep duration from Xiaomi Mi Band 5 | Baseline; post-intervention | minutes |

## 10. Assessment Procedures

All participant-reported and physiological assessments were performed before the intervention and after completion of the six-week program. To improve comparability, assessments were repeated under the same standardized conditions and, where applicable, by the same researcher. Participants received pre-assessment instructions intended to minimize external influences on autonomic and sleep-related measurements.

For objective sleep monitoring, participants wore a Xiaomi Mi Band 5 on the non-dominant wrist during nighttime sleep. They were instructed to put the device on immediately before bedtime and remove it after waking. Data were synchronized with the Zepp Life mobile application. The recorded parameters included total sleep time, light sleep duration, deep sleep duration, REM sleep duration, and awake time.

## 11. Safety, Risks, and Discontinuation

The interventions were non-pharmacological and home based. Anticipated risks were minimal but could include temporary discomfort during relaxation exercises, dislike of sensory stimuli, headache, nausea, respiratory irritation, or skin/allergic sensitivity associated with essential oils. Participants were instructed to discontinue an intervention component and contact the research team if discomfort or an adverse reaction occurred. Serious or unexpected events were to be documented and managed according to institutional procedures.

## 12. Ethics and Informed Consent

The study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained before participation. Participant confidentiality was maintained through coded study identifiers. Direct personal identifiers were not included in analysis datasets or public documents. Ethics approval identifier: [Istanbul Atlas University Non-Interventional Scientific Research Ethics Committee, E-22686390-050.99-78596, September 29, 2025]

## 13. Data Management and Confidentiality

Data were collected using coded identifiers and stored in password-protected electronic files accessible only to authorized research personnel. The allocation code was not provided to the statistician until the primary analyses were completed. Study documents intended for public disclosure contain no participant names or direct identifiers.

## 14. Statistical Analysis Plan

### 14.1 General Principles

Analyses were performed using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). All statistical tests were two-sided, and $p < 0.05$ was considered statistically significant. Continuous variables were summarized using mean and standard deviation and, where appropriate, median and distributional information. Categorical variables were summarized as frequency and percentage.

### 14.2 Distributional Assumptions

The normality of continuous variables was evaluated using the Shapiro-Wilk test. Selection of parametric or non-parametric tests was based on distributional characteristics and the scale of measurement.

### 14.3 Baseline Comparisons

Baseline demographic and clinical characteristics were compared across the three groups to assess group comparability. Continuous variables were analyzed using one-way ANOVA or the Kruskal-Wallis test, as appropriate. Categorical variables were compared using chi-square or an appropriate exact test.

### 14.4 Within-Group Analyses

Baseline and post-intervention measurements within each group were compared using the paired-samples t test for normally distributed variables and the Wilcoxon signed-rank test for non-normally distributed variables.

### 14.5 Between-Group Analyses

The three groups were compared at baseline, at post-intervention, and for change scores ($\Delta$ = post-intervention minus baseline). Normally distributed variables were analyzed using one-way ANOVA. When the omnibus ANOVA was statistically significant, Tukey's honestly significant difference test was used for pairwise comparisons. Non-normally distributed variables were analyzed using the Kruskal-Wallis test; significant omnibus findings were followed by Mann-Whitney U pairwise comparisons.

### 14.6 Effect Sizes

For one-way ANOVA, eta squared ($\eta^2$) was reported. Values of 0.01, 0.06, and 0.14 were interpreted as small, medium, and large effects, respectively. Where feasible, effect sizes were interpreted together with confidence intervals and p values.

### 14.7 Missing Data and Analysis Population

The primary analysis used participants with available baseline and post-intervention outcome data. The number of missing observations was to be reported for each outcome. No imputation procedure was prespecified in the available thesis methods; therefore, analyses were based on available cases unless otherwise documented in the final study record.

### 14.8 Multiplicity

The primary outcome was the PSQI total score. Secondary outcomes were considered supportive and exploratory. Because the available analysis plan did not prespecify a global multiplicity adjustment across

all secondary outcomes, secondary p values should be interpreted cautiously and together with effect sizes and the consistency of findings.

### 14.9 Deviations from the Statistical Analysis Plan

Any material deviation from this analysis plan was to be documented, justified, and dated before interpretation of the affected results.

## 15. Publication and Dissemination

Findings may be presented in a master's thesis, scientific meetings, peer-reviewed publications, and the ClinicalTrials.gov results record. Reporting will use aggregated data and will not identify individual participants.

## 16. Administrative Information

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| **Protocol Version** | 1.0 |
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| **NCT Number** | NCT07638605 |
| **Ethics Approval** | E-22686390-050.99-78596 |
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| **Data Monitoring Committee** | Not established; minimal-risk, short-duration academic study. |