Infant Sleep Hygiene Education Program RCT – Protocol / Statistical Analysis Plan

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1. Study Title

The Impact of a Comfort Theory-Based Infant Sleep Hygiene Training Program on Infant Sleep Habits and Parental Self-Efficacy

2. Background

Sleep is a vital physiological function that significantly impacts children's physical, cognitive, motor, and emotional development (Hudson et al., 2020). A healthy sleep pattern is essential for children's growth, development, and overall well-being (El-Sheikh & Kelly, 2017). Sleep, a key driver of brain development (de Goot et al., 2024), has positive effects on memory, language, executive functions, and overall cognitive development (Tham et al., 2017; Hernandez-Reif & Gungordu, 2022). On the other hand, sleep problems experienced in early childhood have been associated with developmental delays in neurocognitive, social-emotional, and physical health areas, as well as impairments in family functioning (Hysing et al., 2016).

Sleep habits change rapidly during early childhood, and individual differences can be observed (Tham et al., 2017). Although sleep duration problems generally decrease with age, the most intense sleep problems and nighttime awakenings occur particularly during infancy (Williamson et al., 2019; Oras et al., 2020). Nighttime awakenings are common during the first year, with infants under 1 year of age waking up an average of 2-3 times per night (Oras et al., 2020). When the infant is unable to calm themselves and fall back asleep after these awakenings, parents may perceive this as a sleep problem (Hiscock & Davey, 2018).

Sleep problems experienced during infancy are a significant source of stress for parents and can negatively affect the mother-infant relationship (Ophoff et al., 2018; Tikotzky, 2016; Vertsberger et al., 2020). While some parents view sleep regulation as a developmental goal (Sviggum et al., 2018), others have less confidence in their instincts and feel the need for professional guidance (Hsu et al., 2017; Cook et al., 2020). Furthermore, how parents perceive their infant's sleep is closely related to their self-efficacy levels; high self-efficacy may lead to perceiving sleep problems as less problematic (Cato et al., 2024; Werner et al., 2022). Therefore, educating and supporting parents on infant sleep is of great importance for both child and family health (Vieira, et al., 2020; Basınlı & Kahraman, 2018). Research shows that educational programs for parents contribute to infants developing healthy sleep habits, increasing nighttime sleep duration, and improving self-regulation skills related to falling asleep and staying asleep (McDowall et al., 2017; Basınlı & Kahraman, 2018; Svavarsdottir et al., 2025). Therefore, well-designed and implemented educational programs can prevent sleep problems in infants or reduce existing problems (Basınlı & Kahraman, 2018; Svavarsdottir et al., 2025).

Although various infant sleep interventions exist, many are heterogeneous in content and intensity, and some behaviorally oriented approaches raise ethical and developmental

concerns due to potential negative effects on parent–infant attachment and stress regulation. Structured, attachment-sensitive, sleep hygiene–based educational interventions initiated during pregnancy remain limited.

3. Study Objectives

Primary Objectives:

1. Evaluate the effectiveness of a structured Infant Sleep Hygiene Education Program on:
    - Parental self-efficacy regarding infant sleep
    - Infant sleep outcomes: night waking frequency, sleep duration, sleep onset latency, routine consistency

Secondary Objectives:

1. Examine adherence to program-recommended behaviors (bedtime routines, environmental hygiene, soothing strategies etc.)
2. Assess infant sleep diary indicators, including bedtime/start of sleep routine
3. Investigate parental self-efficacy as a potential mediator of the intervention's effect on infant sleep outcomes
4. Evaluate parental knowledge gain and satisfaction with the education program

Study Hypotheses

H1. Clinical and Psychosocial Effects

- **H1.1:** The Comfort Theory–based Infant Sleep Hygiene Education Program delivered to pregnant women at 24–32 weeks gestation will have a significant effect on infants' sleep habits.
- **H1.2:** The program will significantly improve parental self-efficacy regarding infant sleep.
- **H1.3:** Parental self-efficacy will play a significant mediating role in the program's effect on infants' sleep habits.

H2. Evaluation of the Educational Program (Kirkpatrick Model)

- **H2.1 (Reaction – Level 1):** Participants will report high levels of satisfaction with the Infant Sleep Hygiene Education Program.
- **H2.2 (Learning – Level 2):** Participants' knowledge of infant sleep hygiene will increase significantly after the program.
- **H2.3 (Behavior – Level 3):** Parents will demonstrate higher levels of positive infant sleep-supportive practices in the postnatal period.
- **H2.4 (Results – Level 4):** Outcomes on infant sleep habits and parental self-efficacy will be evaluated under the hypotheses outlined in H1.

4. Study Design

Randomized controlled trial with **two arms**:

1. **Intervention Arm:** Infant Sleep Hygiene Education Program (structured prenatal sessions and postnatal follow-up support)
2. **Control Arm:** Routine Antenatal Care (No Intervention)

Randomization: Participants will be randomly allocated to the intervention or control group.

Masking: Outcome assessors will be blinded to group allocation. Participant identifiers will be coded to maintain masking.

5. Participants

Population: Pregnant women, any self-identified gender, biologically female, ≥18 years old
Healthy Volunteers: Yes

Inclusion criteria

1. Being a primiparous pregnant woman (first pregnancy)
2. Being between 24 and 32 weeks of pregnancy
3. Having a risk-free pregnancy
4. Not having a mental disorder
5. Speaking and understanding Turkish as a native language
6. Being literate
7. Not having received training on infant sleep
8. Agreeing to participate in the study

Exclusion criteria

1. The baby being born outside of the 38th to 42nd week of pregnancy
2. The baby having a birth weight of less than 2,500 grams or more than 4,000 grams
3. The baby being admitted to the neonatal intensive care unit after birth
4. The baby having a condition that affects sleep, such as colic or hernia
5. The baby having a chronic illness
6. The parent wanting to leave work

6. Intervention Details

Intervention Arm:

- Developmentally appropriate sleep expectations
- Infant temperament-sensitive approaches
- Consistent and predictable bedtime routines and bedtime routine applications
- Environmental sleep hygiene (light, noise, temperature)
- Responsive soothing strategies
- Parental coping and stress regulation skills

Control Arm:

- Routine antenatal care without structured sleep education

7. Outcome Measures

Primary Outcome Measures:
Parental self-efficacy regarding infant sleep
Baseline (prenatal), 1, 3, and 6 months postpartum
Will be measured with the Turkish version of UPPSEISI
Infant sleep habits and patterns
Night waking, total sleep duration, sleep onset latency, sleep routine consistency
1, 3, and 6 months postpartum

Secondary Outcome Measures:
Adherence to recommended sleep-supportive behaviors
Infant sleep diary indicators, including bedtime/start of sleep routine
Mediating role of parental self-efficacy
Parental knowledge gain before and after education sessions
Parental satisfaction after each session
Attendance and engagement during sessions

8. Statistical Analysis Plan

- **Software:** SPSS 27.0
- **Descriptive Statistics:** Frequency, percentage, mean, standard deviation
- **Normality Tests:** Kolmogorov-Smirnov ($n \geq 30$)
- **Parametric Tests:** Applied if skewness and kurtosis indices within ±2 (George & Mallery, 2020)
- **Main Analysis:**
    - Mixed ANOVA (Karma ANOVA) for repeated measures: group × time interactions on pre-test, post-test, and follow-up scores
    - If assumptions not met: Linear Mixed Models (LMM)
- **Mediation Analysis:** Structural Equation Modeling (SEM)
    - Parental self-efficacy as mediator on infant sleep outcomes
    - Testing direct, indirect, moderator, and mediator effects
    - Fit indices: CFI, TLI, RMSEA, χ^2/df

9. Data Collection Procedures

Pre-Implementation:
After obtaining necessary ethics committee and institutional approvals, eligible pregnant women attending the Karabük Training and Research Hospital Obstetrics Outpatient Clinic "Pregnancy School" will be identified in consultation with the responsible education nurse/midwife. Women meeting inclusion criteria and registered at the Pregnancy School will be provided with detailed face-to-face information about the study and invited to participate in

the pilot implementation. Written and verbal informed consent will be obtained from all participants who agree to join.

Pilot Implementation:
A pilot study will be conducted with 6 voluntary pregnant women (first pregnancy, 24–32 weeks gestation, no pregnancy risks) to evaluate:

- Comprehensibility of educational content
- Session duration and suitability
- Adequacy of materials
- Reliability and clarity of measurement instruments
- Identification of potential implementation issues
- Researcher's implementation skills

If the pilot indicates insufficient power, the number of participants will be increased.

Implementation Phases:

1. **Baseline (Pre-Test) Assessment and Intervention Delivery:**
   Eligible pregnant women will be invited to participate, and written informed consent will be obtained. Participants will complete the **Pregnancy Information Form** and the **Uppsala Parent Infant Sleep Self-Efficacy Scale (UPPSEISI)** as pre-test measures. Participants will be assigned a participant ID number and randomized into the intervention or control group. Contact information will be collected to maintain communication via group-specific WhatsApp groups for follow-up and support.
2. **Intervention Delivery:**
   A mutually convenient schedule for education sessions will be determined through WhatsApp polls. The intervention consists of six structured sessions, delivered twice per week in small groups (6 participants per group) at the hospital's Pregnancy School unit. Prior to the first session, participants will be provided with an overview of the weekly program. Each session includes a module booklet for participants to reinforce and practice the learned content. Flexible scheduling allows participants who miss a session to attend another session within the same week.
3. **Post-Intervention (Post-Test) Assessment:**
   After completion of the educational sessions, participants in both the intervention and control groups will complete the **UPPSEISI** again to assess changes in parental self-efficacy.
4. **Follow-Up Assessments:**

- **1 Month Postpartum:** Participants will complete the **Maternal and Infant Identification Form**, the **Revised Brief Infant Sleep Questionnaire (BISQ-R)**, and the **Behavioral Tracking Form**. Participants in the intervention group may request additional counseling.

- **3 Months Postpartum:** Participants will complete the **Maternal and Infant Identification Form**, **BISQ-R**, **Infant Sleep Diaries**, and **UPPSEISI**. Counseling will continue for the intervention group if requested.
- **6 Months Postpartum:** Participants will complete the **Maternal and Infant Identification Form**, **BISQ-R**, and **UPPSEISI**. After all follow-ups, control group participants will receive the full **Comfort Theory–Based Infant Sleep Hygiene Education Program Module Booklet**. All participants will receive identical educational materials.

This structured data collection process ensures comprehensive evaluation of both the educational program's impact on parental self-efficacy and infant sleep, as well as adherence to recommended sleep-supportive practices.

10. Ethical Aspects of the Study

The study will be conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Ethical approval for the study has been obtained from the Non-Interventional Clinical Research Ethics Committee of Karabük University (2025/2459). Institutional approval will be obtained from Karabük Training and Research Hospital, where the study will be conducted. Before being included in the study, pregnant women will be verbally informed that participation is voluntary, that they can withdraw at any time, and that the study's purpose and data will be used solely for scientific purposes. Verbal and written consent (Informed Consent Form) will be obtained from individuals who agree to participate in the study.

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