Efficacy of a Novel Sleep Device to Promote Sleep Continuity in Infants

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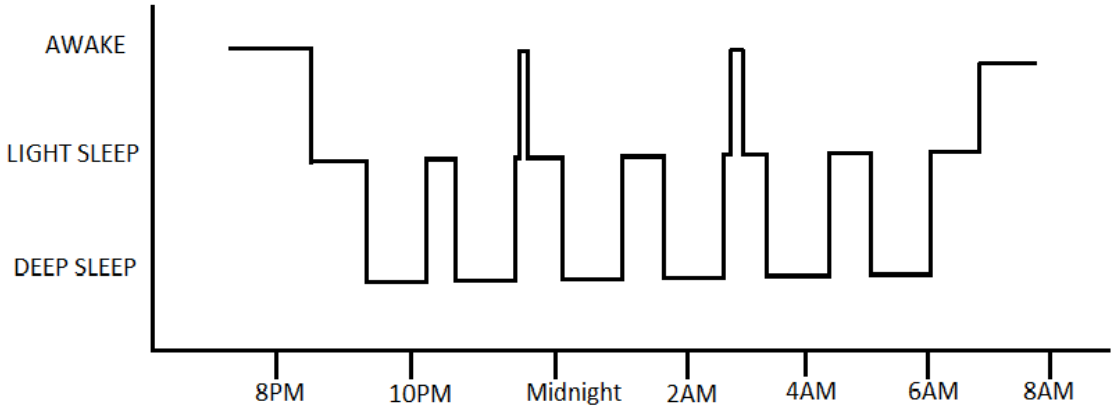
Study Purpose: Objectives and Hypothesis to be tested

The study will evaluated whether use of a novel sleep device in the form of a crib mattress for one month improves sleep metrics in infants aged 2 months to 12 months. Sleep metrics will include both objective measures of sleep captured by the device as well as parent report.

The hypothesis is that use of the sleep device over one month will lead to improved sleep quantity and quality.

Background and Significance

Behavioral insomnia of childhood due to sleep-onset associations is a well-studied clinical entity. The science behind infant insomnia explains why some children wake up repeatedly at night. Based on what we know about sleep, the term "sleeping through the night" is a misnomer. No human being actually sleeps through the night, infants included. Nighttime sleep occurs in cycles in which we dive into deeper stages of sleep, then emerge into lighter stages at the end of the cycle. The cycle lasts about 60 minutes for infants and 90 minutes for adults.[1] There is often an awakening at the end of a sleep cycle during light sleep. Here is a simplified diagram:



An infant that "sleeps through the night" is able to simply go back to sleep during the *normal* awakenings at night. However, an infant with sleep onset association disorder is unable to fall back asleep. This sleep disorder is termed behavioral insomnia of childhood, sleep-association subtype by the International Classification of Sleep Disorders.[2] It involves difficulty sleeping through the night due to needing caregiver involvement to transition from awake to asleep. For example, if a parent consistently rocks an infant during the process of falling asleep at the beginning of the night, the infant learns to associate the transition of falling asleep to that particular intervention. The rocking is the sleep association for the child. When the infant awakens at night during a normal awakening, the infant begins to cry until rocked to sleep once again. This happens repeatedly through the night, often times separated by an hour (the time it takes to go through another sleep cycle). It leads to disruption to both the infant and parent's sleep.

Treatment of sleep onset associations can start as early as four months of age and often involves techniques known as "extinction" or "modified extinction". Both techniques have a great deal of sleep research to support safety and efficacy.[3] The American Academy of Sleep Medicine has a practice parameter recommending these treatment techniques.[4] However, implementation of these techniques is challenging due to infants/toddlers crying regularly during the process and the stress it creates in caregivers. Many parents give up and subject both themselves and their children to months (and sometimes years) of poor sleep as a result, which has a myriad of health consequence. In contrast,

successfully implementing a strategy to help a child sleep leads to a multitude of benefits, including improved behavior in the child, improved mood in adults, and even better marital satisfaction for caretakers.[5]

The problem is quite common, with estimates of 20-30% of young children experiencing sleep challenges.[3] Infants between the ages of six months to one year are particularly susceptible to sleep difficulties, with 25-50% still awakening at night.[6] A straight-forward, safe solution with ease of application, decrease in level of child distress, and proven efficacy is vital to help young children get the sleep they need.

The device in this project works by detecting when a child is awake, produces a sound and motion to soothe a child back to sleep (thereby creating a new sleep association), and then over the course of weeks, weans the child from this new association by decreasing the output from the device based on sensor input and the internal algorithm of the device. This would slowly teach a child to self-soothe, thereby allowing for more continuous sleep.

Research Design and Procedures

The study will be a prospective trial with subjects serving as their own internal controls. Goal enrollment is 20 children over the course of six months. Goal enrollment is based on an *a priori* power analysis performed by a Duke biostatistician.

Schedule of Events:

1. Screening visit/Consent
   Data collection at screening visit:
   DOB
   Weight
   Height
   Past Medical History
   Medications
   Household members, including number of siblings and age
   Sleep environment: Where does child sleep at night? Does the child use a crib?
   Prior trial of sleep training: What methods used and how long?

   Inclusion/Exclusion criteria reviewed

   Caregiver consented

2. Day 1 of study
   a. Mattress delivery – Program coordinator meets family at mutually agreed upon location and give them mattress and instructions on use.
   b. Family fills out questionnaires to obtain baseline metrics via Qualtrics
3. Day 5 of study – check-in call from study team to ensure everything going well and answer any questions.
4. Day 15 of study – check-in call from study team to answer any questions.
5. Day 30 – mattress returned to study coordinator. Parents fill out questionnaire via Qualtrics

Metrics captured by the device via micro SD card:
1. Number of minutes of crying at night
2. Number of minutes of wakefulness
3. Number of minutes of wakefulness between time asleep and time awake
4. Number of minutes of quiet wakefulness
5. Number of minutes of quiet wakefulness between time asleep and time awake
6. Number of total discrete crying episodes
7. Total length of time asleep
8. Total length of time in crib
9. Sleep latency

Parent reported metrics at baseline and end of study measured via Qualtrics survey:
1. Number of times parents report crying per night
2. Number of times child is removed from crib per night
3. Parent's self-reported length of child's sleep
4. Parent's rating of the child's sleep quality
5. Parent's rating of the child's daytime behavior
6. Parent's self-reported subjective sleepiness - Epworth Sleepiness Scale (ESS)
7. Parent rating of bonding with child
8. Parent mood and stress scale
9. Parent depression scale

Selection of Subjects

Inclusion criteria:
1) Age between 2-12 months.
2) Meets clinical criteria for behavioral insomnia of childhood, sleep association subtype, as defined by the International Classification of Sleep Disorders Manual.

Exclusion criteria:
1) Diagnosed comorbid health problem that may disrupt sleep.
2) History of birth prior to 37 weeks gestational age.

Subjects will be recruited from well child visits at the Duke Primary Care offices at Brier Creek and Durham Pediatrics.

Subject Recruitment and Compensation

Subjects will be recruited directly by pediatrician during well-child checks between the ages of 2 months and 12 months. Pediatricians at the Duke Primary Care offices at Brier Creek and Durham Pediatrics will be informed of the study so they can also discuss it with eligible patients. The area served by this office has a heterogeneous demographic.

Approximately 25 subjects will be recruited. Subjects will not receive any compensation for participation in the study.

Consent Process

Consent process will be conducted by PI and/or CRC. Parents or legal guardian will provide consent. The consent process will take place via Duke-licensed Zoom software, which establishes a secured telecommunication portal. We will not enroll subjects whose parents are unable to provide legally effective consent. The consent form will be in English. E-consent through REDCap will be used.

Study Interventions

The smart mattress device would work by detecting when a child is awake using two sensors, an accelerometer and a microphone. When awake and crying, the device would produce a sound and gentle internal vibration to soothe the child back to sleep (thereby creating a new sleep association). Based on data from previous nights, the internal algorithm of the device will eventually switch modes into a "sleep training" mode. In this mode, the device will wean the child off of this new association by decreasing the output from the device gradually over the course of weeks. This would slowly teach a child to self-soothe, thereby allowing for more continuous sleep.

Risk/Benefit Analysis

The risks for participation are minimal. There is potential risk of worsening of sleep during the course of the study. For example, the infant has to sleep on a new surface or does not soothe with the motion and sound produced, thereby worsening sleep. As far as risks from the electronics of the device itself, the device uses off-the-shelf electronics and power supply that pose minimal risk, as these components undergo safety testing prior to commercialization. Benefit includes potential to improve the child's sleep by eliminating sleep associations.

Cost to Subject

There will be no costs associated with participation in this study.

Data Analysis and Statistical Considerations

The proposed study design was discussed with a biostatistician to determine goal enrollment. Power analysis to achieve an *a priori* confidence level of 80% was evaluated for a variety of metrics. Since we do not have a pilot study to determine standard deviation (SD) of metrics to be measured, we determined SD by dividing approximate range in each metric by 5. Paired T-tests will be used for analysis.
For the following metrics, an N of 20 is necessary:

1. Number of total discrete crying episodes
2. Number of discrete crying episodes between time asleep and time awake

Power Calculation:

Power	N	δ1	σ	Size	Alpha	Beta
0.80729	20	2.0	3.0	0.667	0.050	0.19271

For the following metrics, an N of 14 is necessary:

1. Number of minutes of crying at night (total)
2. Number of minutes of crying between time asleep and time awake
3. Number of minutes of quiet wakefulness

4. Number of minutes of quiet wakefulness between time asleep and time
5. Number of minutes of wakefulness
6. Number of minutes of wakefulness between time asleep and time awake

Power Calculation:

Power	N	δ1	σ	Size	Alpha	Beta
0.82156	14	10.0	12.0	0.833	0.050	0.17844

For the following metrics, an N of 12 is necessary:

A. Total length of time asleep
B. Total length of time in bed

Power Calculation:

Power	N	δ1	σ	Size	Alpha	Beta
0.83997	12	45.0	48.0	0.938	0.050	0.16003

Ineligible subjects will be withdrawn from statistical analysis. Estimated accrual rate is 5 subjects per month. Target accrual is 25 subjects (assuming 20% drop out with goal of 20 subjects that complete the study). Time to target accrual is 5 months.

Data and Safety Monitoring

There are unlikely to be any adverse events for this study. The principal investigator and study coordinator will monitor data and study participant safety. Participants will have the phone number and email address for research study staff to report any areas of concern.

The study coordinator will collect, enter, and complete a quality check on study data each month. Data will be stored in REDCap database.

Study discontinuation:

Patients will be discontinued if there are significant adverse effects that are judged to outweigh possible benefits. Risk of such events is low given the nature of this device.

Adaptations to COVID-19

Participants for the study will be recruited during already scheduled well-child check-ups from our Duke Primary Care Pediatric practice at Brier Creek and Durham Pediatrics. The caregiver will be interviewed via videoconference to ensure the child meets eligibility criteria. Consent will also be performed via teleconference, and the mattress will be delivered directly to the participants with minimal direct interaction. Collection of the mattress will be arranged without face-to-face interaction and each mattress will be sterilized prior to reuse. Data analysis will be performed remotely.

References

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