Assessment of the Safety and Efficacy of Weighted Wearable Blankets in Healthy Infants During Sleep

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Background & Rationale

Approximately 3.6 million infants are born in the United States each year according to CDC data, and sleep plays a critical role in their overall health and development. Sleep impacts infant physical growth, brain development, emotional well-being, physical health, feeding/digestion, and regulation of biological rhythms[1]. Parents/caregivers play a crucial role in creating a safe and comfortable sleep environment for infants, vital for infant well-being, but also providing space for caregivers to get the rest that they need. Despite this importance, a survey from Owlet Baby Care found that nearly half of all parents with children 6 months or younger get just 1-3 hours of uninterrupted sleep a night. Weighted wearable blankets have gained popularity in recent years due to their potential benefits in promoting better sleep and relaxation. Some key potential benefits include: deep pressure stimulation, a calming effect, enhanced sleep and sleep quality, and reduced restlessness. Parents are utilizing weighted wearable blankets, so infants sleep longer and with fewer disruptions.

There is little evidence evaluating the safety of weighted wearable blankets in infants and the risk of sleep-related injury. A number of doctors and safe sleep advocates argue that weighted wearable blankets might compress infant chests, making it harder for them to breathe, pump blood, and move around. The American Association of Pediatrics (AAP) has speculated the addition of weight to an infant's chest could cause compression, making chest expansion more difficult, and reducing respiration. The AAP believes the additional blanket covering the infant increases the possibility of overheating, a risk factor for SIDS[2-5]. Preliminary data from a small sample study commissioned by Nested Bean suggests weighted wearable blankets are associated with reductions in oxygen saturation levels in infants at increasing weights, although oxygen saturation levels remained within normal ranges at all weights tested. In contrast, in a pilot study of infants with Neonatal Abstinence Syndrome (NAS), the use of weighted wearable blankets reduced NAS symptoms but did not significantly change infant temperature or breathing rates and no adverse events were observed[6]. The Consumer Product Safety Commission has received one report of a fatality due to suffocation associated with the Nested Bean weighted infant sleep product, but the infant was also on an infant lounger which can pose a suffocation and asphyxiation risk.

To date, there is no evaluation of the safety or efficacy of weighted wearable blankets on healthy infants during overnight use in the peer-reviewed scientific literature. These are the conditions in which these products are used by consumers, with infants sleeping unobserved throughout the night. Given the rising popularity in the use of weighted wearable blankets in infants and the risk speculated, a study of the potential impact of weighted wearable blankets on infant vital signs is warranted.

An initial pilot safety study will assess the risk of an infant overheating and/or experiencing lowered respiration via measurement of vital signs in a controlled clinical environment while wearing a weighted wearable blanket. Participants will also be observed for any hindrance in their ability to move due to the weighted wearable blanket. A member of the study team will be present during the intervention and continuously monitor the infant's vital signs, allowing for immediate evaluation and correction if needed. We plan to expand this study to include an at-home cohort in the near future (see secondary objective).

Objectives

- **Primary Objective:**
  To pilot an investigation on the impact of weighted wearable blankets on vital signs and infant movement in healthy infants during nap polysomnogram.
- **Secondary Objective:**
  To investigate the efficacy of weighted wearable blankets on sleep patterns in healthy infants during overnight sleep.

Outcome Measures/Endpoints

Endpoints	Measurement	Timeframe
Heart Rate	EKG	At start, duration of nap
Respiratory Rate	Respiratory effort belts	At start, duration of nap
Body Temperature	Manual recording (Ear thermometer)	At start (before wrapping the participant in the blanket); at the end of the study and during a (feed) break (before unwrapping the participant from the blanket)
Oxygen Saturation	Pulse oximetry	At start, duration of nap
Infant Movement	Observation	Duration of nap

Eligibility

The target population for this study are healthy infants, aged 0-12 months, weighing at least 8 or more lbs. Individuals of any sex, race or ethnicity may participate. The study population is restricted to this specific age group because the objective is focused on the safety and efficacy of weighted wearable blankets on infants.

Inclusion Criteria

1. Ability of parent, caregiver or legal guardian/representative to understand a written informed consent document and choose to participate in the study.
2. 0-12 months of age
3. Weight ≥ 8 lbs
4. Gestational age ≥ 37 weeks
5. Health status: healthy infant without underlying cardiac, neurological, or pulmonary disorders.
6. Infant is naive to a weighted wearable blanket.

Exclusion Criteria

1. Health status: medical diagnosis associated with underlying cardiac, neurological, or pulmonary disorder.
2. Weight < 8 lbs
3. Gestational age < 37 weeks
4. Gestational use of marijuana, alcohol, or illicit drugs
5. Home environment: use of cigarettes, vaping, e-cigarettes, or marijuana
6. Infant is not naive to a weighted wearable blanket.

Study Design

Direct observational pilot study of the safety of weighted wearable blankets on a minimum of (10) healthy infants aged 0-12 months with nap polysomnogram. Participants will be placed in a weighted wearable blanket, in accordance with their age/weight/height, by their parent or caregiver under the supervision of a member of the study team. After being put to sleep on their back, the participant will remain in the weighted wearable blanket until completion of the nap polysomnogram.

Enrollment/Recruitment

The target number of total participants is a minimum of 10 infants. The recruitment strategy aims to achieve representation of minority groups that reflects the demographics of the population in the catchment area. At least 5 infants must be 0-3 months and all others can be any age between 0 and 12 months of age.

Participants will be recruited in a variety of ways:

Flyers will be posted in the hospital(s) and/or on campus in places frequented by potential participants (e.g., elevators, food courts, parking garage elevators) or public places such as parks, grocery stores or churches. In addition, we will provide flyers and/or brochures to the various maternity wards at Riley, University & Methodist.

Brochures will be available for patients referred to the Sleep Center at Riley or established patients at a clinic visit. Patients who are already scheduled for a sleep study, and meet eligibility criteria, will be contacted by phone and introduced to the study. If the patient is interested, we will send the brochure and the consent (either by USPS or email).

The flyers and brochures will be shared with faculty physicians (in the division of Pediatric Pulmonology, Allergy and Sleep Medicine) as well as RN and other staff in the Sleep Center and maternity wards (for informational purposes only, they will not consent subjects). We might also include the flyer in weekly newsletters and/or internal communications.

Social media ads will be placed on Facebook and/or Instagram and clicking on this ad will direct potential participants to the study's web site

(https://dreamlandbabyco.com/pages/clinical-trial) where they can find phone and email information for the study team.

Study Procedures

During this study, participants will have one study visit. This visit will take place in the Sleep Center at Riley Hospital for Children at IU Health.

- Informed consent – we will explain the study and ask for written consent; participants will receive a signed copy of the consent to keep
    - depending on how the participant was recruited, the informed consent discussion and written consent may have already occurred virtually
- Review of inclusion/exclusion criteria
- Collection of demographic data (infant age, sex, weight) and review of clinical data (current medications, other non-pharmacologic interventions, evidence of cardiac, neurological, or pulmonary disorders) from participant medical records and parent report
- Vital signs measurements (heart rate, respiratory rate, body temperature, oxygen saturation) will be obtained at baseline and monitored throughout the sleep study
- Height and weight measurements will be obtained once, at baseline
- Participants will be placed in weighted wearable blanket such that the blanket does not cover the head/face or restrain the infant
- Participants will then be put to sleep on their backs
- Vital signs will be monitored over a 6–8-hour period with standard polysomnography equipment
- Upon infant awakening at the end of the nap, the weighted wearable blanket will be removed, and vital sign measurements will be repeated
- One week after the nap polysomnogram, subjects will be contacted by phone to complete a short questionnaire

The following stopping parameters will be used for this study. Parameters are noted when the infant is quietly sleeping and the changes observed are not due to agitation or crying. Baseline data will be recorded before and after placing the infant into the weighted, wearable blanket.

Endpoint	Stopping Parameters
Heart rate	Persistent increase by >20 from baseline for 15 minutes
Respiratory rate	Persistent increase by >10 from baseline for 15 minutes
Body temperature	Increase by more than 2º from baseline
Oxygen saturation	Persistent drop by >10% from baseline
Infant movement	Agitation and unable to settle to sleep >15 minutes

If any of the stopping parameters are met, the weighted blanket will be opened to assess if the weighted blanket is responsible for the change. If determined yes, the weighted blanket will be removed and the nap polysomnogram will be terminated.

Reportable Events

We will follow the IU HRPP Reportable Events Policy and Guidance, as needed. Severe adverse events (SAEs) will be reported to the FDA in accordance with 21 CFR 312.32.

An adverse event (AE) is defined as any untoward medical occurrence associated with the use of a drug or device in humans, whether or not considered drug- or device-related. An SAE is defined as an adverse event or suspected adverse reaction is considered "serious" if, in the view of the investigator, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Collection of AEs and SAEs will begin at the time of consent.

Loss of confidentiality is always a potential adverse event and will be reported per existing Indiana University and Indiana University Health policies.

Study Withdrawal/Discontinuation

Participants are free to withdraw from participation in the study at any time for any reason.

The study team may discontinue a participant from the study for any of the following reasons:

- Unacceptable adverse event(s)
- Significant study intervention non-compliance
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

Statistical Considerations

Sample Size Considerations

In the pilot safety study, the total sample size will be a minimum of 10 infants. All participants will receive the same intervention. Data from all participants who complete both baseline and follow-up assessments will be included in the analysis.

Statistical Analysis Plans:

Primary Analysis (Safety)

Means and standard deviations for each vital sign will be calculated at both baseline and during the intervention. Summary statistics based on demographic and baseline characteristics will be gathered. A Paired t-test will be performed to compare the means

of each vital sign at baseline and during the intervention. We will also use a linear mixed effect model to determine differences in vital signs.

The t-statistic and corresponding p-value will be calculated at a significance level of 0.05 alpha. If the p-value is less than 0.05, this will be interpreted as a statistically significant difference in the vital sign before and after wearing the weighted wearable blanket. If the p-value is greater than 0.05, this will be interpreted as no significant difference in the vital sign before and after wearing the weighted wearable blanket.

Reporting and Documentation of Results

Measures and Instruments

Polysomnography (PSG) Equipment

PSG will be conducted using a multi-channel PSG system Respironics Alice G3 that is designed for sleep studies. The system will include the following components: Electroencephalography (EEG) to measure brain activity, Electromyography (EMG) to monitor muscle activity, Electrooculography (EOG) to record eye movements, Electrocardiography (ECG) for heart rate monitoring, Respiratory effort belts to measure chest and abdominal movements, Nasal and oral airflow sensors to monitor airflow, Pulse oximetry to measure oxygen saturation levels, and Video recording for behavioral monitoring during sleep. Prior to each PSG recording, the equipment will be calibrated according to American Academy of Sleep Medicine (AASM) guidelines to ensure accurate measurements, and quality control checks will be performed regularly to ensure proper functioning of sensors and electrodes during the study. The following physiological variables will be continuously measured and recorded during PSG:

- Electroencephalography (EEG): EEG electrodes will be placed according to the international 10-20 system to record brain activity and identify sleep stages (e.g., wake, NREM, REM).
- Electromyography (EMG): EMG electrodes will be positioned to monitor muscle activity, including chin and limb muscles, to assess muscle tone and movements during sleep.
- Electrooculography (EOG): EOG electrodes will be used to detect eye movements, which are important for distinguishing sleep stages and identifying rapid eye movement (REM) sleep.
- Electrocardiography (ECG): ECG electrodes will be placed to monitor heart rate and detect any cardiac abnormalities during sleep.
- Respiratory Parameters: Respiratory effort belts will record chest and abdominal movements to assess breathing patterns; Nasal and oral airflow sensors will measure airflow and detect apnea and hypopnea events; and Pulse oximetry will monitor oxygen saturation levels.

Privacy/Confidentiality

All study data will be treated as confidential information. Similarly, the participant's medical history will also be treated as confidential with no identifiable information released or shared with individuals outside the study team.

Follow-up and Record Retention

All study records will be kept in a secured office or locked file cabinet or on a password protected computer server at the study site. Only the study investigators and research team will have access to the link between the participant information. Information linking a participant's name to a participant identification number will be stored securely.

Regulatory Compliance

This study will be carried out in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP). Study investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, the proposed informed consent form, recruitment materials, and all subject-facing materials will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participants are enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

References

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