Improving Sleep In Young Children

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ABSTRACT

Sleep disorders are a serious problem in the United States alone, affecting between 50 and 70 million individuals. Between 20% and 30% of toddlers, infants and preschoolers around the world suffer from problems with falling asleep or staying asleep throughout the night. One of the most common sleep problems in young children is delayed sleep onset (DSO). This occurs when the child has difficulty going to bed within 20 minutes. Night waking episodes, when the child wakes up at least once per night and does not reinitiate sleep independently, are another common problem. DSO and night waking episodes in children can negatively impact caregiver sleep as well. Because these children lack the ability to self-soothe, their caregiver(s) have to wake up and help them fall back to sleep. One evidence-based intervention for DSO is letting the child “cry it out”, also called “extinction”. However, some caregivers are not comfortable with this method. Other interventions include moving the child’s bedtime back by small increments until the child’s desired bedtime is reached, called fading. Fading interventions have been

effective when paired with response cost, but this has only been studied in the case of one typically developing child. This pilot study tested a novel fading intervention for typically developing children between the ages of two and six. During the intervention, caregivers moved the child's bedtime back by 15 minutes every night and woke them at the same time every morning. Sleep was monitored using ActiGraphs to objectively examine frequency of night waking episodes and how well the intervention worked over 3.5 to 6.5 weeks. By implementing this pilot study of sleep, I aimed to determine the feasibility, acceptability, and preliminary effectiveness of a sleep intervention in promoting independent sleep onset (ISO) and less frequent night waking episodes in typically developing preschool aged children with DSO. While the two caregivers who completed this intervention demonstrated that it was feasible for some, it was not feasible for the 12 caregivers who declined to participate in either part or all parts of the study. The two caregivers who completed this intervention found it to be acceptable. The intervention was also effective at reducing night waking episodes in both participants. For one participant, diaries revealed night waking episodes were reduced from five episodes during baseline (an average of one episode per night) to zero at intervention and post-intervention. For the other participant, the sleep diary revealed eight night waking episodes during baseline, three episodes during the intervention, and the caregiver reported qualitatively that night waking episodes had ceased altogether post-intervention (the caregiver did not fill out diaries during post-intervention). The intervention was also effective at promoting ISO, which was found to continue past the post-intervention phase based on a follow up email survey for both participants. Both caregivers reported a decrease in the length of time it took their child to fall asleep independently from 30 minutes at baseline to 15 minutes at post-intervention. Limitations of this study included a small sample size, homogeneity of participants, unforeseen barriers to approval

of the study, including difficulties with recruitment due to the COVID-19 pandemic, and multiple barriers to participants completing the study as written in the protocol. Future studies of sleep should include larger, more diverse samples, seek to reduce caregiver barriers to participation, and increase feasibility of sleep interventions for night waking and delayed sleep onset.

Keywords: independent sleep onset, night waking, bedtime fading

Improving Sleep in Young Children

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CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

In the United States alone, between 50 and 70 million people suffer from a sleep disorder (Colten and Altevogt, 2006). While sleep disorders can affect people of all ages, there is a growing body of evidence that sleep problems are particularly prevalent in children aged 5 or younger (Etherton et al., 2016; Hiscock et al., 2007; Moore et al., 2008). Night waking episodes and general bedtime problems are two of the most common sleep problems seen by pediatricians, affecting between 20% and 30% of infants and toddlers and up to 5% of school aged children around the world (Mindell et al., 2006; Moore et al., 2008). While these sleep problems can affect children of all ages, night waking episodes are most common in infants and toddlers (Moore et al., 2008).

There are negative outcomes associated with children getting less than the recommended amount of sleep for their age group, according to the American Academy of Sleep Medicine (Paruthi et al., 2016). Overall, sleep problems can negatively impact the cognitive development of young children and are associated with a lower health related quality of life (Hiscock et al., 2007; Mindell et al., 2006). In terms of cognitive functioning, regularly getting too little sleep is associated with learning and attention problems in children (Paruthi et al., 2016). Children's physical health is also negatively impacted by sleep problems. For example, shorter sleep duration increases risk of obesity in children (Li et al., 2017). Behavioral issues have also been noted in children that do not get enough sleep (Paruthi et al., 2016). In fact, one study of two-year-old children found that night waking episodes, shorter sleep duration and sleep onset problems were all associated with a greater likelihood of social-emotional problems (Hysing et al., 2016). Unfortunately, such sleep problems that show up during infancy have been shown to persist into later childhood if left untreated (Mindell et al., 2006). Pediatric sleep problems can also be detrimental to the child's caregivers and family members, by putting strain on the parent-child relationship and increasing parent stress (Byers et al., 2011; Mindell et al., 2006). Sleep problems in infants are also associated with higher levels of maternal depression (Hiscock & Wake, 2002).

Sleep Onset Delay and Night Waking Episodes

Of the bedtime problems that can affect young children, sleep onset delay (SOD) is a common problem in children ages 4-5 years. SOD is characterized by trouble falling asleep within 20 minutes of going to bed (Costa et al., 2013), usually resulting in the child's bedtime being pushed back later than parents would prefer. Night waking episodes, in which the child wakes up at least once every night and does not reinitiate sleep independently, are also prevalent and tend to be comorbid with SOD (Meltzer et al., 2010). One of the most common clinical complaints in pediatric behavioral sleep medicine is infants and toddlers who wake multiple times during the night, requiring parental assistance to return to sleep (Mitzer et al., 2015).

One common reason for sleep onset delay and night waking episodes in children ages 3-5 is napping (Meltzer, Hiruma, Avis, Montgomery-Downs & Valentin, 2015). One study examining circadian rhythms compared toddlers who nap to toddlers who do not and found that toddlers who nap have later bedtimes and sleep onset times than those who do not take naps. The napping group consisted of children who slept during daily nap times for at least one out of five days of baseline, while the non-nappers slept only at night. However, the total 24-hour sleep time was similar for both groups despite differences in sleep onset times and bedtimes (Akacem et al., 2015). Total sleep time suggested that a toddler's sleep needs can be met with either a biphasic or monophasic sleep pattern. However, biphasic patterns, which include naps, may result in less sleep at night (Akacem et al., 2015). Thus, SOD is more common in children who take afternoon naps, sleep in a caregiver's bedroom, or those who need a family member to be present as they fall asleep (Costa et al., 2013).

Treatments for Sleep Problems

Extinction

Research-supported treatments for SOD and night waking episodes often include behavioral interventions (Mindell et al., 2006; Moore et al., 2008). One of the most popular behavioral interventions for SOD and waking at night is extinction, which is also known as letting the child "cry it out" (Mindell et al., 2006; Moore et al., 2008). Extinction has been studied the longest of any intervention for sleep problems in children and has a large body of evidence supporting it (Kuhn et al., 2020; Moore et al., 2008). To implement extinction, caregivers must put the child to bed at the same time every night and ignore any negative behaviors like screaming or crying (Mindell et al., 2006; Moore et al., 2008). If adults can consistently avoid reinforcing negative behaviors, the research suggests the child's behaviors will disappear over time or become "extinct". However, some parents find it stressful to ignore their children's distress for prolonged periods of time (Kuhn et al., 2020; Etherton et al., 2016; Moore et al., 2008; Sadeh et al., 2010). This discomfort can lead parents to implement extinction incorrectly by attending to their children's cries some of the time and giving them intermittent reinforcement for behavior that isn't compatible with sleep. Some caregivers may eventually abandon the practice altogether depending on the severity of the behaviors (Kuhn et al., 2020; Etherton et al., 2016). Unfortunately, when caregivers are not consistent and give in to children's negative behaviors, the undesirable sleep behaviors are likely to continue because they are reinforced by the caregivers' attention (Kuhn et al., 2020; Etherton et al., 2016; Moore et al., 2008).

Alternative Treatments

For parents who are not comfortable implementing extinction, bedtime fading is an alternative treatment for sleep problems in typically and atypically developing children (Delemere & Dounavi, 2018; Piazza & Fisher, 1991a). In a fading procedure, the child's initial bedtime is delayed so that they fall asleep quickly, and then moved back in increments until a parent-approved, pre-established bedtime is reached (Mindell et al., 2006). The first step in a fading procedure is identifying an initial bedtime when the child is tired enough to fall asleep within 15 minutes, known as rapid sleep onset (RSO) (Piazza & Fisher, 1991a). In previous studies, the initial bedtime has been set by calculating the average bedtime of the child and adding a half an hour (e.g., if the average sleep onset time was 11:00, the initial bedtime would be set to 11:30) (Piazza & Fisher, 1991a). Once the child is falling asleep within 15 minutes for two nights in a row, the bedtime can be made 15 minutes earlier the next night, and so on. However, if the child does not fall asleep quickly for two consecutive nights, they are put to bed 15 minutes later the next night to help initiate RSO. This cycle continues until the parent approved bedtime is reached (Piazza & Fisher, 1991a).

More recent studies of bedtime fading have added an element called "response cost" (Mindell et al., 2006). Bedtime fading with response cost includes taking the child out of bed for an hour if the child does not fall asleep within 15 minutes (Mindell et al., 2006). While 60 minutes is the typical duration in the literature, one study of a typically developing two-year-old girl successfully reduced the response cost to 30 minutes (Ashbaugh & Peck, 1998). Along with the original fading procedure, a strict wake time is implemented every morning, and daytime sleeping is restricted to age-appropriate naps (Mindell et al., 2006). This combination of bedtime fading and response cost has decreased sleep latency and night waking episodes in atypically developing children (Sanberg, Kuhn & Kennedy, 2018), but has only been studied in one typically developing child (Ashbaugh & Peck, 1998).

The bedtime fading procedure, with and without response cost, has several benefits that the extinction procedure does not. First, bedtime fading has been shown to be an effective and acceptable intervention across all age groups, including infants and preschool age children (Asbaugh & Peck, 1998; Gradisar et al., 2016; Piazza & Fisher, 1991a). Fading can decrease sleep onset time in children and increase sleep duration, without causing parent or child distress that can occur with extinction (Mindell et al., 2016; Gradisar et al., 2016). Bedtime fading has also been shown to decrease the number of night waking episodes young children experience, which can lower parent stress (Piazza & Fisher, 1991a; Ashbaugh & Peck, 1998). While this intervention has evidence for effectiveness, the American Academy of Sleep Medicine recommends it only as a Guideline (moderate level of evidence) rather than Standard (high level of evidence) given its very limited evidence in typically developing children (Morgenthaler et al, 2006).

Methods for Assessing Sleep

At least one reason research on sleep in young children is limited is due to the difficulty of accurately measuring sleep. There are many different methods for assessing sleep, including sleep studies performed in a lab or hospital, home sleep tests, tracking devices, and self-assessment measures (Ibanez, Silva & Cauli, 2018). These methods are reviewed below.

Polysomnography

The most advanced of sleep measurement methods involves tracking sleep in a sleep laboratory or hospital with access to a wide variety of medical equipment (Ibanez, Silva & Cauli, 2018). Polysomnography (PSG), also referred to as a "sleep study" is a medical test used for diagnosing sleep disorders (Mayo Clinic, 2018). The test simultaneously measures brain activity, oxygen levels, respiration, and eye and leg activity of patients (Ibanez, Silva & Cauli, 2018). By measuring body functions and sleep phases during sleep, the goal of PSG is to identify when current sleep patterns are interrupted and for what reason (Mayo Clinic, 2018). Because of its specificity, PSG is currently the gold standard of sleep measurement **(**Ibanez, Silva & Cauli, 2018). The main advantage of PSG is its sensitivity and ability to distinguish between different phases of sleep (Ibanez, Silva & Cauli, 2018). However, it can be expensive and time consuming, and it does not measure sleep in a natural context (Ibanez, Silva & Cauli, 2018). It can be particularly difficult for young children to sleep outside the home in an unfamiliar environment, making PSG a less suitable choice for toddlers and preschoolers. Previous studies of PSG use in children found that it produced disturbed sleep during the procedure compared to at home, and children exhibited a limited ability to cooperate during the procedure (Beck & Marcus, 2009; Hawley et al., 2006).

Other Measures of Sleep

A multiple sleep latency test (MSLT) is another sleep study meant to identify excessive daytime sleepiness and determine how long it takes the patient to fall asleep, while also identifying sleep phases (Ibanez, Silva & Cauli, 2018). It is a standard measure used to diagnose hypersomnia and narcolepsy in adults, by measuring how quickly the patient falls asleep during the day. The MSLT starts the morning after PSG and lasts 24 hours, requiring the patient to sleep in five scheduled timeslots with two hour breaks in between (Ibanez, Silva & Cauli, 2018). It is considered appropriate for the diagnosis of narcolepsy in children, but only in those age five and above (Aurora et al., 2012). However, there is a paucity of research of the MSLT as a measure of behavioral issues such as night waking episodes or delayed sleep onset in children.

A maintenance of wakefulness test (MWT) is performed during the day and requires the patient to stay awake for 4 or 5 periods of 40 minutes without exposure to daylight. It is meant to measure the alertness of the patient and if they can stay awake in a relaxed environment (Ibanez, Silva & Cauli, 2018). The patient is connected to a heart rate monitor, a brain activity monitor, and chin muscle and eye movement activity is tracked throughout the test. If the patient falls asleep for 90 seconds at a time during the test, it is ended immediately (Ibanez, Silva & Cauli, 2018). The MWT has been validated for the use of diagnosing narcolepsy in children, but much like the MSLT, has not been studied for the use of diagnosing behavioral sleep problems in children (Zandieh et al., 2013).

Self-Report

Sleep Questionnaires, or sleep scales, are quick and efficient measures of sleep duration and quality that can be completed by the patient (and/or caregiver) at home (Ibanez, Silva & Cauli, 2018). Some sleep questionnaires will reference sleep duration and sleep quality, while others are more behavior-based and ask strictly about bedtime behavior (Kuhn et al., 2020). Despite the inherent subjectivity of self-report measures, multiple validation studies have found sleep questionnaires to be reliable measures of patient sleep (Chervin et al., 2000; Lucas et al., 2016; Natale et al., 2014; Yang et al., 2017). Sleep questionnaires provide a convenient alternative to sleep studies, as they can be completed anywhere without assistance from a medical professional (Ibanez, Silva & Cauli, 2018). While self-report directly from the patient is usually preferred, young children are not always reliable sources of self-report data. For children with sleep problems, clinicians usually have parents fill out questionnaires on their behalf (Hill, 2011). Previous studies of child sleep assessment have found parent report questionnaires to be reliable measures of sleep patterns, but not night waking episodes (Iwasaki et al., 2010). To accurately assess the number of night waking episodes a child has, objective measures of sleep may be preferable (Iwasaki et al., 2010). There also tends to be variability in accuracy of parent report data, which tends to be more accurate for weekdays than weekends (Iwasaki et al., 2010). Parent-report sleep questionnaires like the Children's Sleep Habit Questionnaire and the Child Behavior Checklist 1.5-5 have been shown to be reliable and valid measures of certain dimensions of child sleep such as sleep onset latency and duration (Achenbach & Rescorla, 2000; Owens et al., 2000).

Pediatric sleep diaries are another method of home sleep tracking. The format of sleep diaries can vary, but generally they require the caregiver to write down when the child goes to sleep, the duration of sleep, if there were night waking episodes, and any naps that were taken during the day. Parent-report pediatric sleep diaries are often utilized to learn more about a child's sleep patterns (Allen et al., 2013). Parents are generally better at estimating their children's sleep latency than the children themselves (Combs et al., 2019). Sleep diaries have been used with preschool populations to assess sleep onset latency, with acceptable agreement with objective measures of sleep like an accelerometer (Tsai et al., 2018). Compared to parent-report questionnaires, sleep diaries completed by parents tend to have greater agreement with accelerometer results in terms of sleep onset latency assessment (Iwasaki et al., 2010). However, previous research has also suggested that parents have a tendency to overestimate their child's sleep duration (Dayyat et al., 2011; Short et al., 2013). This inconsistency has prompted many researchers to also include an objective measure of pediatric sleep, such as an accelerometer, alongside diaries in studies of pediatric sleep (Allen et al., 2013; Tsai et al., 2018; Veatch et al., 2016).

Devices

Devices used to track sleep in research include smartphone applications, commercial accelerometers, and research grade accelerometers, such as those made by ActiGraph. There is little evidence that smartphone applications are reliable or valid measures of tracking or estimating sleep when compared to polysomnography in adults (Bhat et al., 2015). Research examining the accuracy of phone applications in sleep tracking in children, especially toddlers, is scarce. A recent review of the current literature suggested that smartphone applications may be useful for identifying sleep disordered breathing (add the reference here for this statement), but more research is needed to establish the accuracy of apps in identifying sleep-wake cycles. To date, only one study has examined the accuracy of a smartphone application used to track sleep in children specifically. This study examined a phone application called the Sleep Cycle App and its accuracy at tracking sleep in 25 children ages 2-14 when compared to polysomnography. The findings of this study suggested that smartphone apps lack adequate accuracy to be used as a clinical tool for sleep measurement in children, as there was no correlation between total sleep time or sleep latency when comparing the app to polysomnography (Patel et al., 2017).

Commercial Accelerometers

Commercial accelerometers, such as the Fitbit, have been primarily used to measure physical activity (Wood, Kuntsi, Asherson & Saudino, 2008). They are typically worn on the wrist, and often claim to measure sleep as well as physical activity. While much sleep research has focused on accelerometers worn by adults, these devices can also be used to track sleep in children (Lange et al., 2016, Weiss et al., 2010). While PSG is considered the gold standard in sleep research, using accelerometers can be advantageous because they allow for continuous recording for days and even weeks at a time. Accelerometers also provide an objective measure of sleep behaviors and do not require an adult to constantly monitor the child (Ancoli-Israel et al., 2003). Compared to PSG, accelerometers are more convenient, cost effective, and provide a way to measure sleep in the natural setting (Ancoli-Israel et al., 2003; Ibanez, Silva & Cauli, 2018). Accelerometers also have a higher specificity than smartphone applications when it comes to tracking sleep in children (Toon et al., 2016).

Research on the use of accelerometers to measure sleep in preschool populations is scarce. There are multiple brands of accelerometers that can be used to measure sleep, including Fitbits and Apple Watches (Meltzer, Hiruma, Avis, Montgomery-Downs & Valentin, 2015; Roomkham et al., 2019). However, there is limited research on the use of these devices in measuring children's sleep. Two studies using different Fitbit models examined each model's ability to measure sleep. In one study of children and adolescents ages 3-17, researchers compared the validity and reliability of the Fitbit Ultra accelerometer to PSG and two different ActiGraph accelerometers (considered the Gold Standard of accelerometers). Regardless of the Fitbit Ultra mode used (sensitive or normal), total sleep time was not as accurate as PSG or ActiGraphs. The sensitive mode overestimated total sleep time, while the normal mode underestimated it in comparison to both PSG and ActiGraphs (Meltzer, Hiruma, Avis, Montgomery-Downs & Valentin, 2015). In another study using the Fitbit Charge HR, children ages 9-11 were assigned to the Fitbit group or the PSG group. The Fitbit Charge HR had a sensitivity of 95.8% for detecting sleep and a specificity of 56.3% in detecting waking episodes. Researchers concluded that compared to PSG, Fitbit wake detection was poor (Godino et al., 2020).

ActiGraphs

ActiGraphs are wrist-worn devices containing accelerometers that are designed to track sleep. While they share a common feature with commercial accelerometers, they are more commonly used in sleep research and have a strong evidence base suggesting they are comparable to PSG for sleep measurement. Multiple studies have found ActiGraphs to be more valid and reliable sources of sleep measurement than commercial accelerometers (Dickinson, Caszier & Cech, 2016; Godino et al., 2020; Meltzer, Hiruma, Avis, Montgomery-Downs & Valentin, 2015).

There are many available brands of accelerometers that can be used to measure sleep. The ActiGraph is one brand that is commonly used (DeVries et al., 2006). The ActiGraph can be worn around the waist, wrist, or ankle depending on what outcome is being measured (Ancoli-Israel et al., 2003). Typical placement for measuring sleep in children is on the wrist, but it has also been measured on the ankle in previous studies. Because a standard placement for ActiGraph wear during sleep has not been established, researchers have examined the impact placement had on measuring sleep activity. In a preschool population, researchers examined ActiGraph specificity for detecting sleep-wake patterns. Most participants wore it on the ankle (n=56), but two participants had difficulty with ankle placement and instead wore it on the wrist. ActiGraph specificity was poor overall (specificity = 24%), even after correcting for error (specificity = 27%), compared to video recording. Researchers did not report significant differences between the ankle and wrist placement groups (Sitnick et al., 2008). In another study of children ages one to five, researchers matched ActiGraph measures of sleep-wake patterns with reported sleep-wake times from sleep diaries completed by mothers. When matched with data from diaries, ActiGraph estimates of sleep-wake patterns were moderately correlated with the caregiver report, ($r = .42$, $p = .004$). This was true despite the combination of both ankle and wrist placement for children 2 to 5 years old (Acebo et al., 2005). When combined with parent-report measures, research suggests that the ActiGraph can be a reliable and valid measure of sleep-wake patterns; however, this measurement tool may not be as accurate as direct observation methods.

Other researchers have compared wearing ActiGraphs on the waist to the wrist to measure sleep in children, and the results have been mixed. For a study of sleep-wake states in 20 children ages seven to 12, participants wore an ActiGraph at both sites to assess if placement impacted sleep estimations. Results suggested that wrist placement was comparable to waist placement, as sleep-wake state agreement between the two sites was 92.5% (Paavonen et al., 2002). However, a study of sleep in 62 10-year-old children wearing ActiGraphs found that waist placement tended to overestimate total sleep time (TST) in comparison to wrist placement. TST was higher when measured at the waist compared to the wrist (73.8 min, $p < 0.001$) (Hjorth et al., 2012). Further research is needed to determine the effects of different ActiGraph placement sites on the sensitivity and specificity for sleep measurement. In addition, research should also focus on sleep in preschool populations, as most of the previous research has focused on middle-aged children.

Conclusion

Two of the most prevalent sleep problems in young children include SOD and night waking episodes (Meltzer et al., 2010). These problems impact parent sleep schedules as well because they wake in the night to deal with children who are not independently falling asleep or staying asleep through the night. These sleep problems can lead to negative health outcomes for both children and parents because sleep is an important part of a healthy lifestyle. Given the importance of sleep for overall health, it is imperative for children with sleep problems to go to bed early enough to get a full night's sleep and stay asleep throughout the night.

Current Study

The current study evaluated the feasibility, acceptability, and preliminary effectiveness of an intervention on sleep quality, SOD, and night waking episodes in typically developing young children (fading with response cost). In comparison to other methods of treatment, our intervention did not require caregivers (defined as the primary adult in charge of care from this point forward in the paper) to ignore their children at night and had the goal of adding evidence of its effectiveness in typically developing children. We also anticipated this sleep intervention would be acceptable to caregivers. This study had the following aims and hypotheses:

Aim 1: To examine the feasibility of the intervention for caregivers to implement at home. Hypothesis 1: I hypothesized that caregivers would be able to implement the intervention as described in the protocol.

Aim 2: To examine the acceptability of the intervention among caregivers. Hypothesis 2: I hypothesized that a majority (>50%) of caregivers would find this intervention acceptable. I expected caregiver stress levels to decrease from baseline to post-intervention. Further, I expected themes from qualitative data to reveal specific areas of strength or weakness regarding acceptability of the intervention.

Aim 3: To examine the effectiveness of an intervention on sleep quality, delayed sleep onset, night waking episodes, and total sleep time in young children. Hypothesis 3a: I hypothesized that sleep quality would improve using fading with response cost. Hypothesis 3b: I hypothesized that sleep onset latency would be reduced using fading with response cost. That is, the young children who underwent the intervention would see a decrease in sleep onset latency at the end of the intervention compared to baseline. Hypothesis 3c: I also hypothesized that the number of night waking episodes would decrease after the intervention compared to baseline.

Hypothesis 3d: I also hypothesize that the average total sleep time will increase after the intervention compared to baseline.

CHAPTER 2: METHODS

Participants

Participants included two typically developing children between the ages of two and five years old. A small sample size is commonly used in multiple baseline design studies utilizing pediatric sleep interventions (Delemere & Dounavi, 2018; Kuhn et al., 2020; Morgan & Morgan, 2008; Piazza & Fisher, 1991a, 1991b; Sanberg, Kuhn & Kennedy, 2018). Families were recruited via self-referral through flyers posted throughout the community, as well as through the East Carolina University (ECU) Listserv, which included all current ECU faculty, staff, and students. For this study, only families with children with difficulty with falling asleep and night waking episodes were included. The criteria for inclusion included typically developing children between the ages of two and five. Children had to have two caregivers present in the home, biological or otherwise, as higher levels of stress and lowered ability to follow through with a sleep intervention would be more likely in single caregiver households, particularly if the child also had siblings present in the home. Children who participated had to have acceptable levels of compliance (e.g., ability to follow directions when meeting with the primary investigator, no behavior problems reported by caregivers). Children also had to spend most of their time in one household, as traveling between two or more households and experiencing different bedtime routines on a regular basis could have impacted the effectiveness of my intervention. Exclusionary criteria included a current diagnosis of a physiologically based sleep disorder, a diagnosis of genetic or developmental disorders, and behavioral disorders (diagnosed with attention deficit hyperactivity disorder [ADHD], Oppositional Defiant Disorder, and/or anxiety disorders). Given that this intervention targeted typically developing children with difficulty falling asleep, the presence of other sleep disorders, developmental disorders or behavioral disorders could have been confounding to study implementation and results. If English was not the primary language spoken by the family or child, they were also excluded due to study personnel only speaking English.

Procedures

Recruitment and Consent

Potential participants' families were self-referred through flyers posted throughout the community, and were also recruited through the ECU email Listserv. The recruitment plan for this study evolved over the course of several years, with the initial plan being that behavioral health providers at a local private practice would provide referrals for this study. However, due to the impact of the COVID-19 pandemic the practice was no longer able to provide patient referrals once the study was underway. This impacted recruitment and lowered the overall number of participants that were able to be recruited.

The study was approved by the East Carolina University Institutional Review Board (IRB) for approval. Families were approached by phone and/or email following referral to the study. The study was explained in detail to the caregiver, and any questions the caregiver had were answered. Following verbal consent, an online consent form was emailed to the caregiver prior to their first participation in the study. Families completed questionnaires online via RedCAP email link. Some questionnaires were completed again during the intervention and post intervention phases (see Measures, below and Table 1). The sleep diaries were initially completed in RedCap, but due to the first participant having continuous problems with submitting the diaries, a Google sheet was used for the diaries instead. ActiGraphs were dropped off and picked up by caregivers on ECU's campus, and the primary investigator instructed and demonstrated for each family how to properly wear and use the ActiGraph. In addition, each family was sent a link to a video instructing them how to use and wear the ActiGraph. The study primary investigator (PI) contacted families via email within 24 hours of pickup of the ActiGraph to answer any questions and confirm appropriate use.

Design

Results were evaluated using a nonconcurrent multiple baseline design. The time spent in the study was 3.5 weeks for one participant and 6.5 weeks for the other.

Baseline

Participants' bedtime routine was not altered in baseline, which lasted for approximately one week for both families. The primary caregiver identified for the study completed a sleep diary every morning and evening, which included the time the child was put into bed, the time that the child fell asleep, and the time the child woke up. Caregivers also had their child wear an ActiGraph continuously during the baseline period.

Intervention

The first session occurred 5-9 days after the baseline assessment, in person with the PI. Sleep concerns were assessed, and the intervention protocol was described to the primary caregiver. The primary caregiver was also emailed a fidelity checklist outlining the intervention protocol for the first three days and nights. After the first three days, the caregiver was contacted by the PI regarding any questions or concerns they may have about the intervention. Based on all caregivers' preferences, follow up regarding fidelity of implantation occurred via email. Caregivers were also encouraged to reach out to the PI and request any additional phone sessions as needed via email. The child wore the ActiGraph continuously for the first six days during the intervention period. The caregiver in charge of bedtime completed the sleep diary each night and each morning. Once the target bedtime was reached, the treatment ended.

Post-Intervention

After the intervention, the sleep diaries continued to be completed by the caregiver in charge of bedtime for another week to track naps, changes in sleep onset latency, and night waking episodes after the intervention. The Children's Sleep-Wake Scale and a caregiver acceptability rating were also completed by the caregiver. The child wore the ActiGraph continuously for six days post-intervention.

Sleep Intervention

Before the intervention began, the primary investigator worked with caregivers to select a set wake time that was strictly followed, even on weekends. The wake time was based on consideration of wake time during baseline and the needs and preferences of the family (e.g., school start time). For the remainder of the study, caregivers were asked to wake their child at the set wake time every day regardless of how well they slept during the night. Caregivers were also asked to prevent any daytime sleeping to the best of their ability, except for developmentally appropriate naps as defined by the American Academy of Sleep Medicine (Paruthi et al., 2016). Given that both children were in daycare and caregivers had no control over napping that occurred at daycare during the week, they were instructed to ask their daycare to track the length of naps so they could be reported in the sleep diaries.

Participants' initial adjusted bedtime was 30 minutes later than the average time of sleep onset during baseline, to increase homeostatic sleep drive when the child was put to bed. Caregivers were asked to conduct the child's bedtime routine as normal, with the exception of placing the child in bed at the adjusted bedtime. After placing the child in bed, the caregiver left the room. Fifteen minutes after putting the child to bed, the caregiver returned to the room to determine if the child was awake. If the child was awake, the caregiver then implemented the "response cost."

Response consisted of taking the child out of bed for 30 minutes. During this time, the child was free to engage in an activity of their choice, as long as it was not known to interfere with sleep. Restricted activities included, but were not limited to, caffeine, sugar consumption, and screen time (Fuller et al., 2017; Warzak et al., 2011; Xu et al., 2016). Caregivers were made aware of all restricted activities and were made aware of the negative impact of blue light on sleep, and that it would interfere with the intervention. The PI then discussed potential activities that were appropriate with the caregiver during the in-person visit before the intervention occurred, and a list of acceptable activities was discussed and agreed upon (e.g., reading books, playing with a toy). Access to sleep during the response cost interval was restricted. At the end of the 30-minute interval, the child was returned to his or her bed. After 15 minutes, the caregiver again checked to see if the child was awake. If the child was awake, they again were removed from bed for 30 minutes. Response cost was continued until the child fell asleep within 15 minutes of being placed in bed.

Bedtime was moved earlier by 15-minute increments from the initial bedtime each day until the desired bedtime (determined by the caregiver(s) and age-appropriate norms) was reached. The intervention phase duration was different for both participants but lasted no longer than six weeks for either participant. Throughout the study, wake time remained consistent. If the child was ready for bed before the "assigned" bedtime each evening, they were allowed to go to bed, as long as the total sleep time did not exceed 13 hours including naps. In comparison to other methods of treatment, this intervention did not require caregivers to ignore their child's crying at night (which the extinction method would require). This helped children reach their goal bedtime while increasing caregiver acceptability of the intervention.

Measures

Caregiver Protocol and Fidelity Checklist

Before implementing the intervention, caregivers were provided with a caregiver protocol form with step-by-step instructions on how to implement the intervention, beginning with the first night of intervention (See Appendix A). This form was also used as a fidelity checklist for caregivers to self-monitor if they were implementing the intervention effectively. If any part of the checklist was unclear, caregivers were encouraged to reach out to the PI via phone or email.

Demographics

Demographic information included caregiver-reported child age, gender, race, and ethnicity. caregiver-reported income and education level was also collected. Caregivers were asked to report the total number of people in the home, the ages of any siblings, if the child shared a bedroom, the ages of any other people the child shared the room with, and a description of sleep environment (e.g., was it noisy, were there blackout curtains, white noise machines, etc.).

Sleep Diary

The caregiver in charge of bedtime was asked to record data regarding their child's sleep habits, including data on the number of times the child woke during the night (night waking episodes), length of naps during the day, the number of times the child left the bed after being put in it at night, and the child's total sleep time in a 24 hour period. Additionally, caregivers recorded how long it took the child to fall asleep each night (sleep onset latency). Each instance of response cost was documented in the sleep diary. Caregivers were also trained in person to complete the sleep diaries using verbal instruction and modeling by the PI. The sleep diaries were monitored periodically by the researcher for correct completion. During baseline, intervention and post-intervention phases, the data was collected daily via RedCAP link initially. However, due to continuous problems with completion of the RedCAP surveys reported by the first participant, a Google sheet with all identifying information removed was used for each participant instead (See Table 1). See Appendix B.

Caregiver Acceptability

At the end of the study, caregivers were given an acceptability measure to determine how acceptable they found the intervention. The Behavior Intervention Rating Scale – Revised (BIRS-R) is a revised version of the 24-item Likert scale developed by Von Brock & Elliott

(1987) to assess consultees' acceptability of various behavioral interventions, with higher scores indicating greater acceptability. Reliability of the BIRS-R has been established, with an internal reliability alpha coefficient of .97. Item-level responses on the BIRS-R range from 1 (low acceptability) to 6 (high acceptability). Total scores on the BIRS-R range from 22-110, with 110 being the highest possible score. Higher total scores indicate greater acceptability (Sheridan, 1992). See Appendix C.

Parental Stress Scale

The Parental Stress Scale (PSS) is an 18-item questionnaire assessing parents' feelings about their parenting role, exploring both positive aspects (e.g. emotional benefits, personal development) and negative aspects of parenthood (e.g. demands on resources, feelings of stress). The possible range of the PSS is 18 (low stress) to 90 (high stress). In the initial study of psychometric evidence for the PSS, normative data for parents of children without behavior problems suggested the average score was 37.1, with a standard deviation of 8.1. This study also found scale scores to be reliable, with a coefficient α of .83 and an average inter-item correlation of .23. Six weeks later, a test–retest correlation was .81 (Berry & Jones, 1995). On the PSS, respondents indicate how much they agree or disagree with each of the 18 statements. Responses are scored as follows: (Strongly disagree = 1, Disagree = 2, Undecided = 3, Agree = 4, Strongly agree = 5). The PSS was administered during baseline and post-intervention. See Table 1 and Appendix D.

Child Sleep Hygiene Scale (CSHS)

The CSHS is a 17-item measure of sleep hygiene in children ages two to eight, including items such as "Naps 4 hours before bedtime" and "Caffeine 4 hours before bedtime" (Harsh et al., 2002). Items are scored on a 6-point Likert-type scale from 0 "never" to 5 "always". Higher scores indicate better overall sleep hygiene. This measure also provides subscale scores for the following areas: physiological, cognitive, emotional, environmental, bedtime routines and sleep stability. The internal consistency of the CSHS is acceptable, α=.76 (Harsh et al., 2002). In the present study, the CSHS was conceptualized as a control variable, in order to ensure basic sleep hygiene was not the primary issue related to sleep difficulty. The CSHS was collected at baseline and post-intervention. See Table 1 and Appendix E.

Children's Sleep-Wake Scale (CSWS)

The CSWS is a 25-item parent report measure of sleep quality in typically developing children ages two to eight (LeBourgeois et al., 2001). For example, "When it's time to go to bed, your child…goes straight to the bed". Items are scored on a 6-point Likert-type scale from 0 "never" to 5 "always". The CSWS provides scores for five subscales, including Going to Bed, Falling Asleep, Maintaining Sleep, Reinitiating Sleep, and Returning to Wakefulness. It also yields a composite score for overall sleep quality, with higher scores indicating better sleep quality. The highest possible score is a 6. The CSWS has been shown to have acceptable internal consistency ($\alpha = .81$ for subscales, $\alpha = .91$ for total scale) and strong test-retest reliability (r = .67 - .84) (LeBourgeois & Harsh, 2015). To increase sensitivity to change, wording of this questionnaire was altered from "in the past month" to "in the past week". The CSWS was administered during baseline and post-intervention (See Table 1). See Appendix F.

ActiGraphy

Caregivers met in person with the PI after consent and before the baseline phase was implemented to pick up the ActiGraph GT3x-BT (ActiGraph, Pensacola, FL) for the baseline phase. The PI demonstrated how to wear the ActiGraph correctly on her own body, then observed the caregiver place it on the child's body and provided corrective feedback verbally as needed. A sticker was chosen by the child, and then placed on each ActiGraph to indicate which side of the ActiGraph should be facing upwards on the child. Caregivers were also given a link to a video that demonstrated how to properly wear an ActiGraph, in case they needed a reference. The ActiGraphs were worn by the child during the baseline phase, which varied but lasted no less than five days for either participant, six days during intervention, and six days post-intervention (starting the day after the intervention ended).

ActiGraph Log

During the timeframes the child was to wear the ActiGraph, caregivers completed an ActiGraph log for the child. If the ActiGraph was removed for any reason (e.g., child being sick or swimming), there was a documented explanation of circumstances that led to its removal.

Data Analysis Plan

For the first aim, feasibility was assessed using qualitative data from the study (e.g., did the families complete the full intervention; was the researcher able to check the sleep diaries frequently enough to ensure completion). Any barriers experienced by caregivers or the PI throughout the process were documented and included as part of determining feasibility.

For the second aim, descriptive statistics were used to report caregiver acceptability of the intervention. Any response other than “disagree” or “strongly disagree” on the acceptability question of the Behavior Intervention Rating Scale – Revised (BIRS-R) was considered “acceptable”.

To examine the effectiveness of the intervention on sleep quality, delayed sleep onset. night waking episodes, and total sleep time (Aim 3), the data were analyzed using a multiple baseline design. Data came from the CSWS (sleep quality) and sleep diaries completed by the caregiver, and the outcome variables were sleep quality, sleep onset latency, and night waking episodes. Additional exploratory analysis included total sleep time, as reported in the sleep diaries. ActiGraph data was used as an additional measure to confirm caregiver report of sleep diary and intended to resolve differences between caregiver-reported data and ActiGraph data during the first week of intervention and for the full week of post intervention. Data from sleep diaries were also used to compare total sleep time, sleep onset time, and night waking episodes before the intervention and after to calculate Tau U, a measure of effect size (Kuhn et al., 2020).

Given that this was a multiple baseline design study, data were first analyzed visually to examine trends, variability, and consistency within and between the participants. Baseline was determined once data trends were stable (not increasing or decreasing) in sleep onset latency per sleep diaries. Typically, this requires a minimum of 5 stable data points for each participant. The data were also free of trends or had a significant trend in the opposite direction of our prediction before the intervention was implemented (Kratchowill et al., 2010). The implementation phase was staggered across participants, and each participant’s intervention data was stable (minimum of 5 stable data points for sleep onset latency) before terminating the intervention (Kratchowill et al., 2010). After all data had been collected, an effect size was calculated for each series of data points in the baseline phase compared to the post-intervention phase.

Sleep Diary Data Analysis

Data from caregiver reported sleep diaries were analyzed using Microsoft Excel. Time series plots were used to examine changes between the baseline, intervention, and post intervention periods for each participant over time. Tau U was also used as a non-parametric effect size for changes between baseline and intervention phases and intervention and post-intervention phases (Kuhn et al., 2020). Tau-U was calculated using an online calculator at https://singlecaseresearch.org.

ActiGraph Data Analysis

ActiGraph sleep data was analyzed using the ActiLife Software Version 6 Sleep Analysis Tool. The Sadeh algorithm was chosen because it has been validated for use with children in the previous literature (Sadeh, Sharkey & Carskadon, 1994). A recent study used the Sadeh algorithm with preschool children, where it was shown to have a higher correlation with sleep diaries than the Tudor-Locke algorithm (Zhenya & Ying, 2023). Sleep times in ActiLife were validated against sleep times logged in sleep diaries. ActiGraph estimates of sleep and wake times were used when missing data was present in sleep diaries. Averages for total sleep time, sleep onset latency, and night waking episodes were calculated in Microsoft Excel.

CHAPTER 3: RESULTS

Two families completed the full study protocol, one family completed all initial questionnaires and part of the baseline phase, and one participant completed only the initial questionnaires (see Table 1). All four families reported their child's race as white and not of Hispanic/Latino descent, that both caregivers were present in the home and married, and that each child had their own bedroom. The biological mother was the primary caregiver and was employed full time, and the highest level of education completed by the caregiver was graduate or professional school, for all four families.

Table 1

Sociodemographic Characteristics of Participants at Baseline

Baseline Characteristics	Participant 1	Participant 2	Participant 3	Participant 4
Child Age (in years)	3	3	5	2.9
Child Sex	Male	Female	Male	Male
Who lives in home?	Biological Mother, Biological Father	Biological Mother, Biological Father, Sibling (7 years old)	Biological Mother, Biological Father, Siblings (7 and 1 years old)	Biological Mother, Biological Father, Sibling (4.9 years old)

Child's Sleep Environment	Blackout curtains and white noise machine	Black out curtains, noise machine, timed nightlight	Caregiver responded "No"	Blackout curtains, white noise machine, humidifier
Annual Household Income	>$150,000	$100,000-149,999	>$150,000	$75,000-99,999
Child History of Psychological or Sleep Conditions	None	None	None	History of sleep apnea – resolved with removal of tonsils and adenoids

Note. Participant 3 only completed questionnaires, and Participant 4 only completed the initial baseline phase.

Baseline Questionnaires

Four total families completed baseline questionnaires (see Table 2).

Table 2

Baseline Questionnaire Scores

Baseline Questionnaire	Participant 1	Participant 2	Participant 3	Participant 4

Parental Stress Scale Total Score (90 = highest, higher scores indicate more stress)	37	37	53	65
Children's Sleep Wake Scale Total Sleep Score (6 = highest, *m* =4.09, SD =0.8, higher scores indicate better sleep quality)	3.92	4.12	4.73[a]	3.52
Children's Sleep Hygiene Scale (85=highest, higher scores indicate better sleep hygiene)	75	71	61	68

Note. Participant 3 only completed questionnaires, and Participant 4 only completed the initial baseline phase.

[a] Falling Asleep Subscale and Returning to Wakefulness Subscale had missing items, so overall score does not include these subscales.

Post Intervention Questionnaires

Only Participants 1 and 2 completed post intervention questionnaires.

Sleep Hygiene

Participants were administered the Children's Sleep Hygiene Scale (CSHS) as a pre and post intervention measure to control for sleep hygiene as a factor that could be exacerbating sleep problems. For Participant 1, scores on the CSHS decreased by one point from baseline (Total Score=75) to post-intervention (Total Score=74). For Participant 2, scores on the CSHS increased by 3 points from baseline (Total Score=71) to post-intervention (Total Score=74), indicating that sleep hygiene remained relatively stable and within the normal range for both participants before and after the intervention.

Feasibility

Intervention feasibility was measured by examining the number of participants who completed the intervention, as well as qualitative examination of participant-reported barriers to implementation. Of 14 total caregivers who reached out via email with interest in participating in the intervention, four completed the informed consent and baseline questionnaires. Of those four, three completed the baseline phase of the intervention. Only two participants completed all three phases of the intervention, as one caregiver chose to drop out after baseline.

Participant Barriers. Reasons for not participating in the study provided by the ten caregivers who chose not to participate included the following: lack of support/agreement from spouse, the presence of other children in home with sleep difficulties, inability to follow study protocol due to vacation/inconsistent schedules, and disinterest in changing their child's current bedtime routine. Of the two participants who completed questionnaires but not the entire study, one dropped out without providing a reason (e.g., stopped responding to multiple email attempts to reach them and set up a time to meet) and the other dropped out after completing the baseline phase due to their child's sleep having improved since the initial time they reached out.

Additional barriers reported by those who did participate in part or all of the study included getting the ActiGraph wet (despite clear instructions provided verbally and in writing to keep the ActiGraph dry) and requiring a replacement, which disrupted the timeline of data collection as it took over 24 hours to meet and exchange it for a new one. Another barrier included adjusting and tracking nap times during the day while the child was at daycare, difficulty completing sleep diaries on time, and having vacations coming up that interfered with the intervention. Overall, themes that appeared across participants as a significant barrier to feasibility include: 1) busy or inconsistent schedules, 2) being on vacation and 3) difficulty remembering to complete the sleep diaries twice daily. All these barriers impacted feasibility from the participants' perspective.

Researcher Barriers. From the researcher's perspective, there were multiple barriers to completion of the intervention as described, including recruitment. Recruitment was difficult due to changes in the original recruitment plan occurring before recruitment and data collection occurred. Originally, the majority of referrals were expected to come from a community partnership with a local private practice. However, due to the impact of the COVID-19 pandemic and other factors outside of the researcher's control, the practice was unable to provide referrals for this study. This greatly reduced the number of targeted, eligible participants the researcher was able to reach and eliminated the screening process that would have occurred through the private practice psychology providers to ensure goodness of fit for the study. Recruitment ultimately consisted of posting flyers throughout the community (e.g., doctor's offices and preschools) and the ECU email ListServ. Furthermore, the study had to be approved by the Internal Review Board (IRB) at ECU before data collection could begin, and this process was made lengthier than usual due to the COVID-19 pandemic. The requirement for in-person visits led to much back and forth with the IRB regarding safety practices (e.g., requirement of all parties wearing masks), which extended the timeline of the IRB completion and led to a delay in data collection.

Sleep Diaries. Another barrier included multiple issues related to the sleep diaries. Firstly, there were ongoing technical difficulties with online reporting systems (RedCap) that led participants to have problems completing the sleep diaries initially. Eventually, this led to the creation of a Google sheet system, which contained the same information but which required additional time to create on the part of the researcher. Secondly, all participants had difficulty remembering to complete the diaries twice a day despite receiving automatic daily and nightly reminders, which required the researcher to frequently monitor the diaries and send additional reminders via email or phone. There were times in which the PI had competing obligations that delayed her ability to check that the diaries were being completed daily, which led to missing data when participants forgot to track their child's sleep.

Communication with Participants. Communication between the researcher and participants was another barrier, for several reasons. Firstly, all participants expressed disinterest in phone communication and requested email rather than phone contact. Secondly, scheduling ActiGraph pickup and dropoff times was difficult as busy schedules made it difficult for caregivers to come to the research lab multiple times throughout the study. Finally, at multiple time points, there was a delay in the ending of one study phase and the start of the next phase due to participants not being able to pick up the ActiGraphs immediately, which interfered with continuity of data collection.

Caregiver Acceptability

Acceptability of the intervention was measured using the Behavior Intervention Rating Scale – Revised (BIRS-R), with higher scores indicating greater acceptability. Scores on the BIRS-R range from 22-110. Higher scores indicate greater acceptability. Participant 1 reported a score of 105, and participant 2 reported a score of 109, indicating high acceptability from both participants. Both caregivers who completed the intervention also provided ratings of 5 (agree) on a Likert-type scale to the statements “I would suggest the use of this intervention to other parents” and “I like the procedures used in the intervention” on the BIRS-R.

Caregiver Stress

As an additional measure of acceptability, caregiver stress was measured using the PSS before and after the intervention to determine if caregiver stress remained stable or changed. Scores on the PSS range from 18 to 90, with lower scores indicating lower levels of caregiver stress. The average score on the PSS is 37.1, with a standard deviation of 8.1 (Berry & Jones, 1995). At baseline, the caregiver of participant 1 obtained a score of 37. Post-intervention, the caregiver of participant 1 obtained a score of 32. The caregiver of participant 2 also obtained a score of 37 at baseline. Post intervention, the caregiver of participant 2 obtained a score of 31. Both caregivers' scores remained in the average range before and after the intervention, suggesting stress remained relatively stable from baseline to post-intervention.

Effectiveness of Sleep Intervention

To examine the effectiveness of the intervention (Aim 3), we examined sleep quality, sleep onset latency, and the frequency of night waking episodes during baseline and post intervention to determine if variables had changed from baseline. Data for this aim only included participants 1 and 2.

Sleep Quality

Participants were administered the CSWS to assess sleep quality (higher scores indicate higher quality). Normative data for the CSWS suggests an average total scale score of 4.09 and a standard deviation of 0.8 (LeBourgeis & Harsh, 2017). For Participant 1, there was an increase in sleep quality from baseline (Total Score = 3.92) to post-intervention (Total Score = 5). For Participant 2, there was also an increase in sleep quality from baseline (Total Score = 4.12) to post-intervention (Total Score = 4.72).

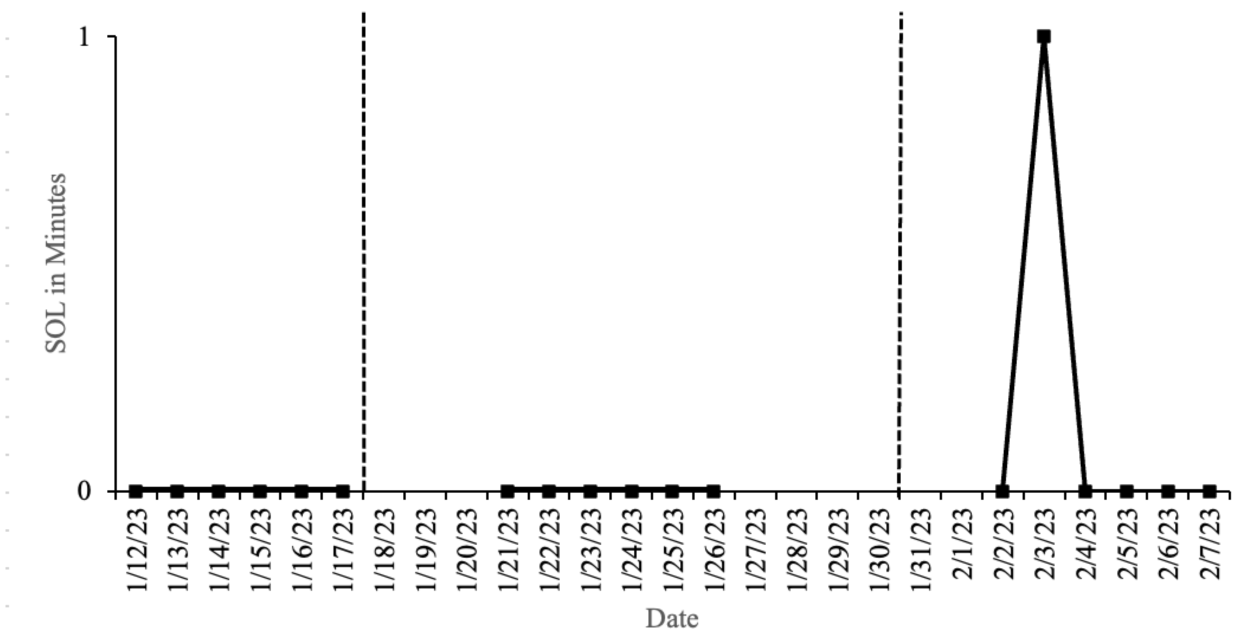
Sleep Onset Latency (SOL)

Participant 1.

ActiGraph. Based on ActiGraph data, it took Participant 1 an average of 0 minutes to fall asleep during the baseline phase and the intervention phase, and an average of one minute to fall asleep during the post-intervention phase (see Table 3). There was a change of one minute in SOL from the baseline phase to the post-intervention phase (Baseline mSOL = 0 minutes, Post-Intervention mSOL = 1 minute). Effect size for changes between the baseline and post-intervention phases were calculated using Tau U. For the baseline phase compared to the post-intervention phase, there was not a significant effect ((τ)= 0.1667, p = 0.6310), see Figure 1.

Figure 1

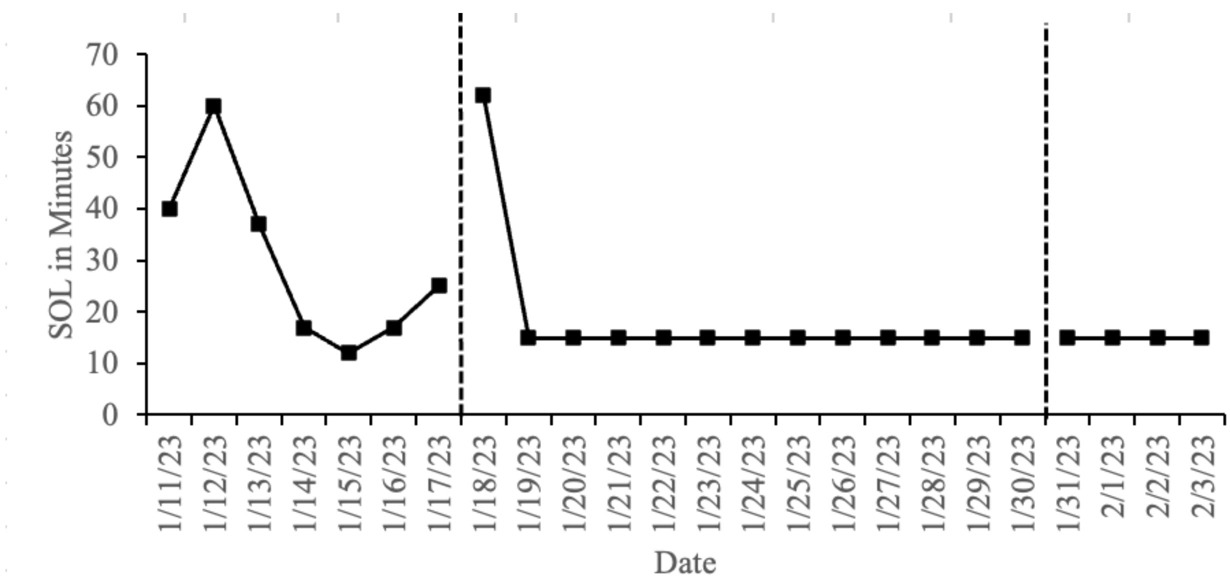
Time Series Plot of SOL for Participant 1 Based on Actigraph Data



Sleep Diaries. Based on the caregiver report for Participant 1, SOL decreased from baseline to post-intervention. It took Participant 1 an average of 29.75 minutes to fall asleep during the baseline phase, an average of 18 minutes during the intervention phase, and an average of 15 minutes during the post-intervention phase (see Table 3). There was missing data during the post-intervention phase due to the caregiver forgetting to continue filling out diaries after four days. However, based on the four available data points, SOL was improved from baseline and stable during post-intervention phase (see Figure 2).There was a significant effect when comparing baseline to post-intervention, ((τ)= -0.6154, p = 0.0205, CI 90% -1<>-0.179).

Figure 2

Time Series Plot of SOL for Participant 1 Based on Sleep Diaries

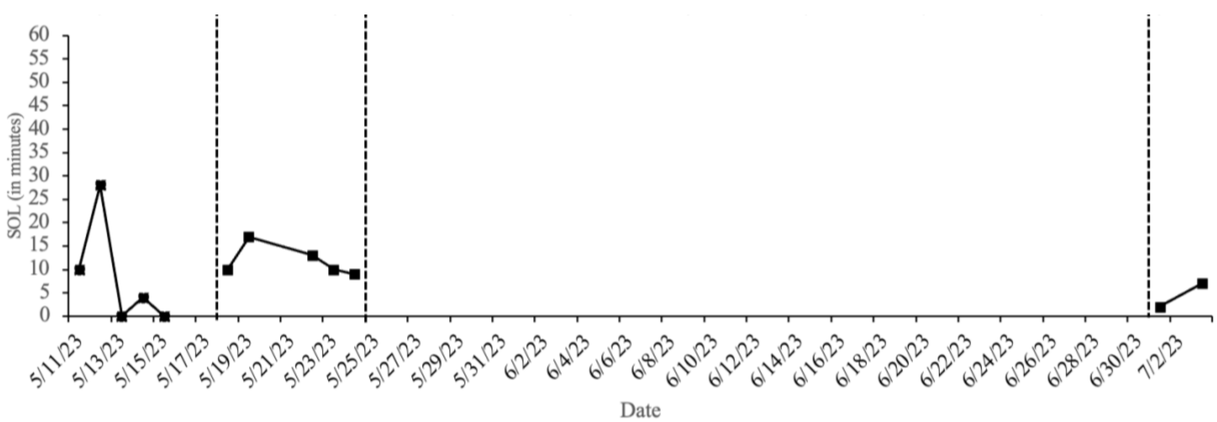


Participant 2.

ActiGraph. ActiGraph data during the post-intervention phase for participant 2 was very limited due to user error/technology malfunction, such that there were only two data points for post-intervention phase. On average, it took Participant 2 eight minutes to fall asleep during baseline, 11.8 minutes to fall asleep during intervention, and 4.5 minutes to fall asleep during post-intervention. There was a change of 3.5 minutes in average SOL from the baseline phase to the post-intervention phase (Baseline *m*SOL = 8 minutes, Post-Intervention *m*SOL = 4.5 minutes). Effect size for changes between the baseline and post-intervention phases were calculated using Tau U. For the baseline phase compared to the post-intervention phase, there was not a significant effect ((τ)=0.5000 , p = 0.3329), see Figure 3.

Figure 3

Time Series Plot of SOL for Participant 2 Based on ActiGraph Data



Sleep Diaries. Based on diaries for Participant 2, SOL decreased between the baseline and intervention phases (Baseline *m*SOL = 30.38, Intervention *m*SOL = 17.98) (see Table 3) (see Figure 4). There was not available quantitative data for the post-intervention phase due to the caregiver not recording the data in the diary. However, based on a qualitative report via email, the caregiver indicated that the child's SOL was "very consistent with the previous week" during the week of post-intervention. The average SOL from the last three days of the sleep diary (in which the caregiver was not using response cost) was 14 minutes. This would suggest SOL decreased from baseline to post-intervention (see Table 3). An effect size could not be calculated due to the missing data.

Figure 4

Time Series Plot of SOL for Participant 2 from Sleep Diaries During Baseline and Intervention Phases

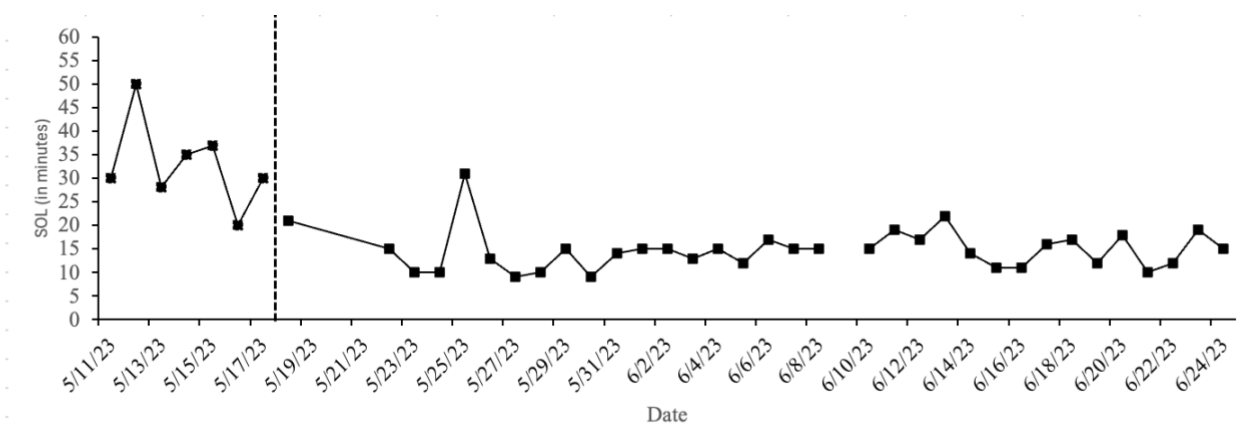


Table 3

Sleep Onset Latency (Average Number of Minutes During Each Phase)

	Reporting Method	Participant 1	Participant 2
Baseline	ActiGraph	0 minutes	8 minutes
	Sleep Diary	29.75 minutes	30.38 minutes
Intervention	ActiGraph	0 minutes	11.8 minutes
	Sleep Diary	18 minutes	17.98 minutes
Post-Intervention	ActiGraph	1 minute	4.5 minutes
	Sleep Diary	15 minutes	14 minutes [a]

[a] Caregiver did not complete the sleep diary for post-intervention, but this is time from the last three days of intervention in which no response cost was used. Qualitatively, the caregiver reported improved sleep onset latency during the post-intervention phase via email.

Night Waking Episodes

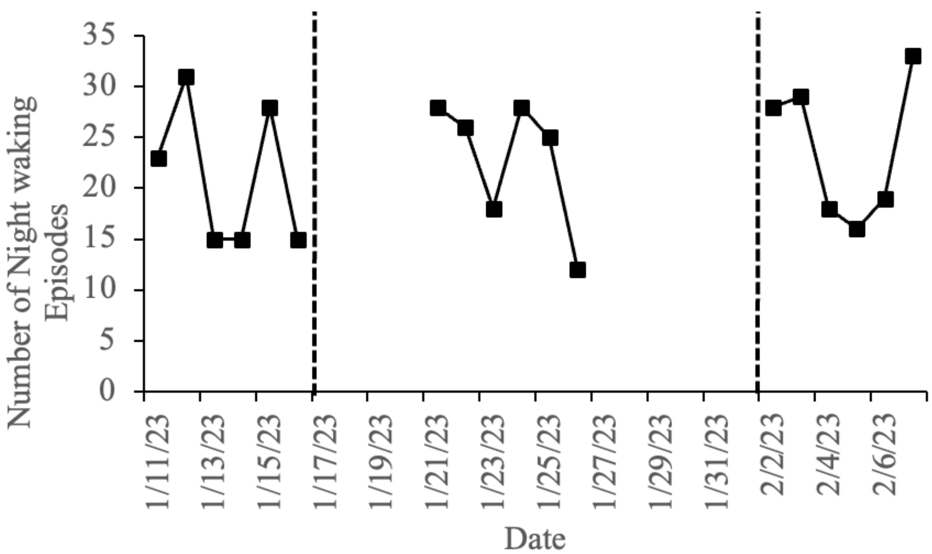
Participant 1.

ActiGraph. For Participant 1, average night waking episodes increased from baseline (*m*=21 wakings) to post-intervention (*m*=24 wakings) (see Table 4). Effect size for changes between the baseline and post-intervention phases were calculated using Tau U. For the baseline phase compared to the post-intervention phase, there was not a significant effect ((τ)= 0.3611, p = 0.2980).

See Figure 5.

Figure 5

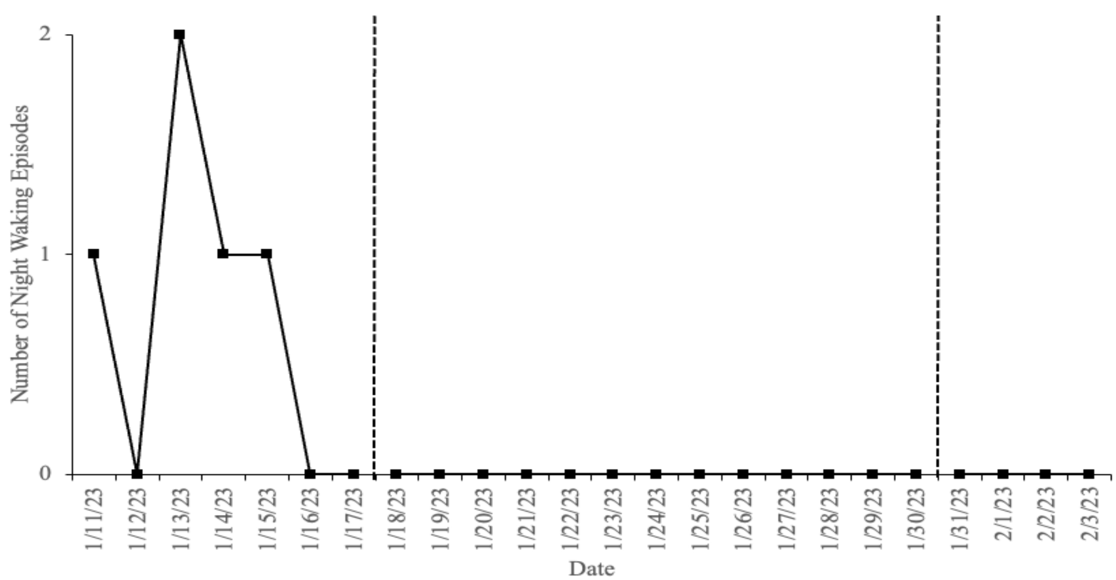
Time Series Plot of Participant 1 ActiGraph Night Waking Episodes



Sleep Diaries. Based on the sleep diaries, there were 5 total night waking episodes for participant 1 during the baseline phase. There were no reported night waking episodes during either the intervention or post-intervention phases (see Table 4). Of note, there were limited data for the post-intervention phase (four data points) due to the caregiver forgetting to continue filling out diaries after four days of the post-intervention phase. However, based on those four data points, no night waking episodes were reported, and there was a decrease in night wakings from 5 wakings at baseline to zero wakings during post-intervention (see Figure 6). An effect size was calculated, although it is typically recommended that there be a minimum of 5 data points when calculating an effect size for single case research (Landman, Bogaerts, & Spreen, 2024). There was not a significant effect from the baseline phase to the post intervention phase, ((τ)= -0.5714, p =0.1306).

Figure 6

Time Series Plot of Night Waking Episodes for Participant 1 from Sleep Diaries

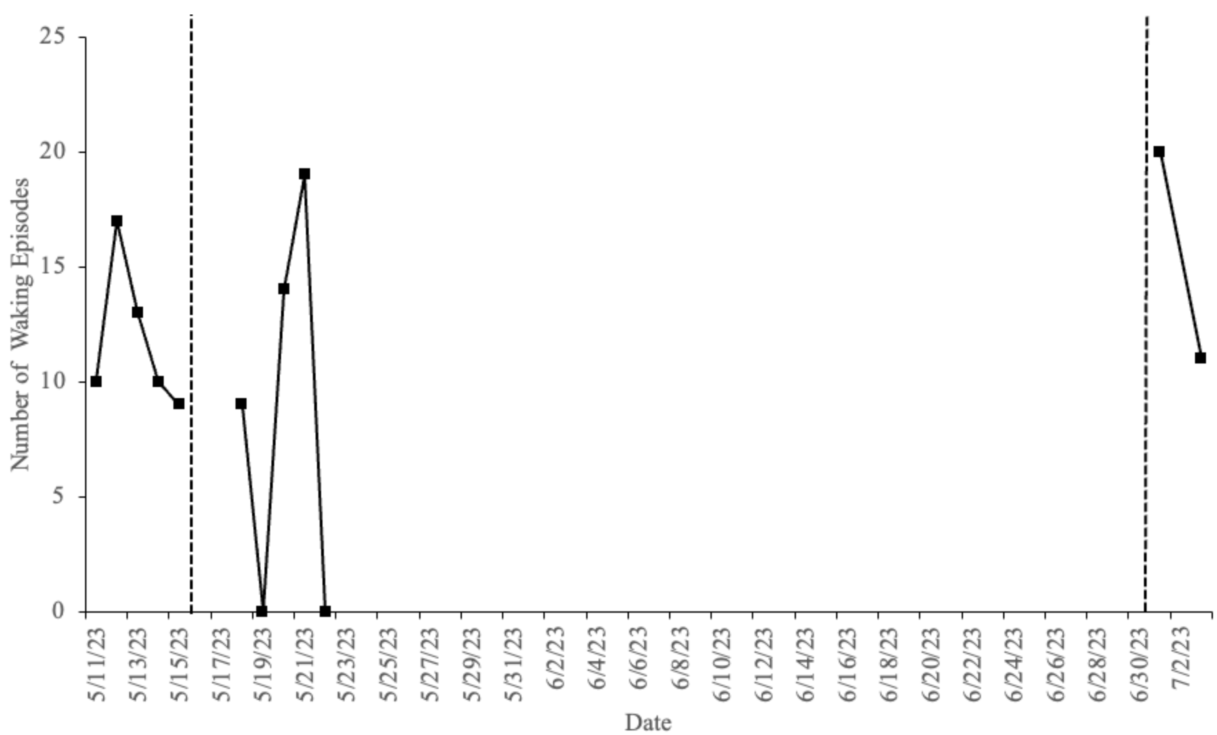


Participant 2.

ActiGraph. Based on ActiGraph data for Participant 2, night waking episodes increased from baseline (Total Wakings=59, *m*=21 wakings) to post-intervention (Total Wakings=41, *m*=24 wakings) (see Table 4). Effect size for changes between the baseline and post-intervention phases were calculated using Tau U. For the baseline phase compared to the post-intervention phase, there was not a significant effect ((τ)= 0.6000, p = 0.2453). See Figure 7.

Figure 7

Time Series Plot of Night Waking Episodes for Participant 2 Based on ActiGraph Data



Sleep Diaries. For Participant 2, there was limited diary data due to the caregiver not tracking night waking episodes during the post-intervention phase. The caregiver reported night waking episodes decreased from a total of 8 episodes at baseline to a total of 3 episodes during the intervention phase (see Table 4). Average number of night waking episodes each night also decreased from an average of 3 waking episodes per night to one night waking episode per night from baseline to post-intervention. An effect size was not calculated, because there were no data points in the diaries for post-intervention. However, the caregiver reported qualitatively that night waking episodes had ceased after the intervention phase. See Figure 8.

Figure 8

Time Series Plot of Night Waking Episodes for Participant 2 from Sleep Diaries

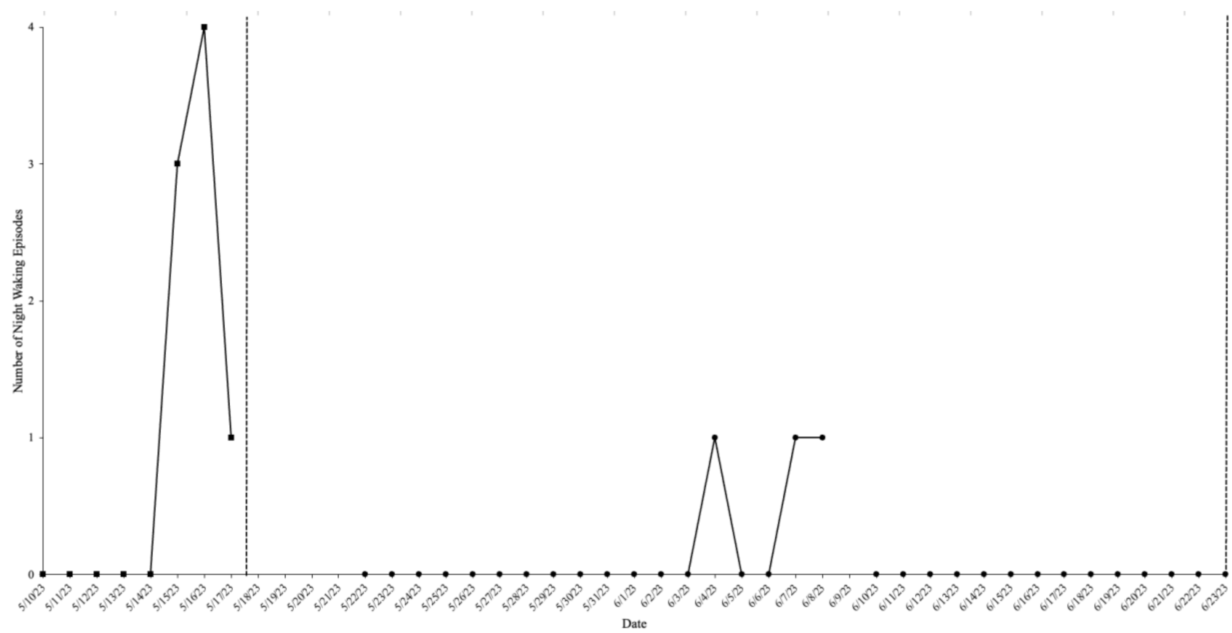


Table 4

Total Number of Night Waking Episodes for Each Phase

Night Waking Episodes	Reporting Method	Participant 1	Participant 2
Baseline	ActiGraph	127	59
	Sleep Diaries	5	8
Intervention	ActiGraph	137	42
	Sleep Diaries	0	3
Post-Intervention	ActiGraph	143	41
	Sleep Diaries	0	N/A*

*Caregiver did not complete the diary, but reported fewer night waking episodes during post-intervention via email.

Exploratory Analyses of Effectiveness

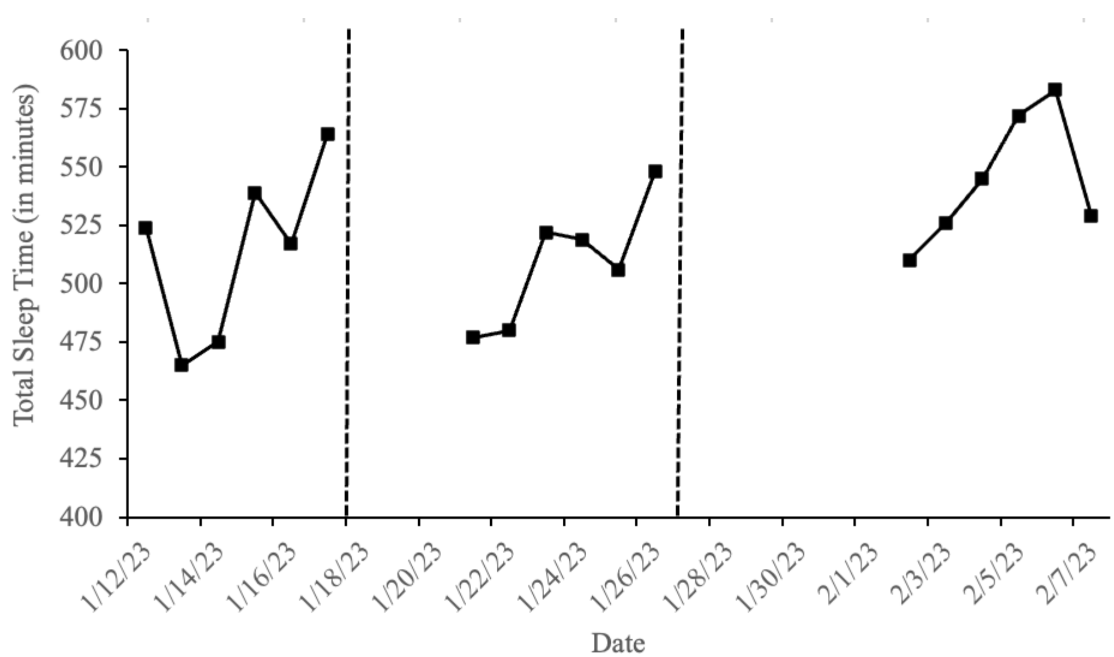
Total Sleep Time (TST)

Participant 1.

ActiGraph. For Participant 1, the average Total Sleep Time (TST) during the baseline phase was 514 minutes. There was an increase of 30 minutes in average TST from the beginning of baseline to the end of post-intervention (Initial *m*TST = 514 minutes, End *m*TST = 544 minutes) for Participant 1 (see Figure 9). For the baseline phase compared to the post-intervention phase, there was not a significant effect ((τ)= 0.5000, p = 0.1495).

Figure 9

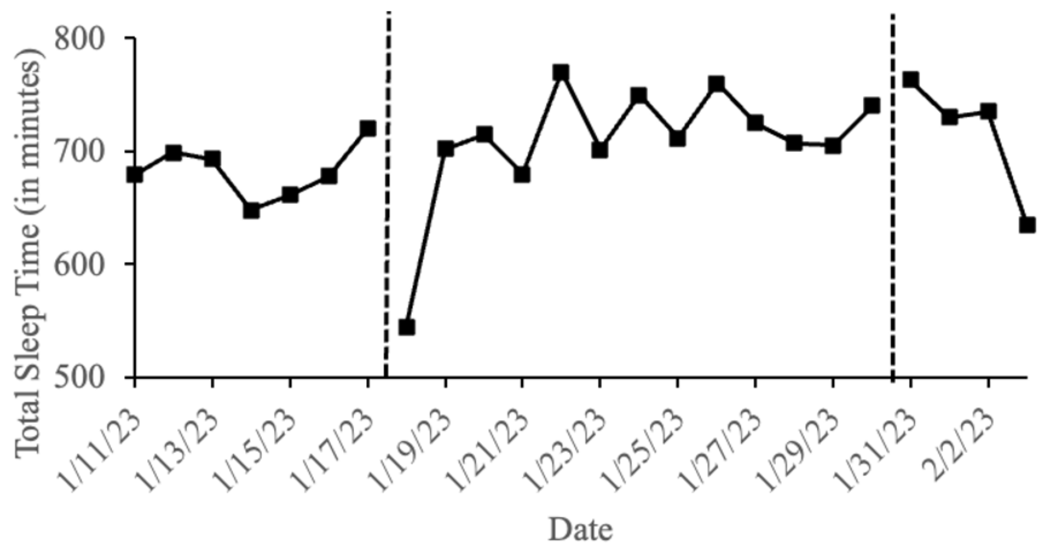
Time Series Plot of Total Sleep Time for Participant 1 from ActiGraph Data



Sleep Diaries. Based on the diaries for Participant 1, there was an increase of 29.62 minutes in average TST during the baseline phase (*m*TST = 682.54 minutes) compared to the post-intervention phase (*m*TST = 715.75 minutes). For the baseline phase compared to the post-intervention phase, there was not a significant effect ((τ)= 0.5000, p = 0.2008).

Figure 10

Time Series Plot of Total Sleep Time for Participant 1 from Sleep Diaries

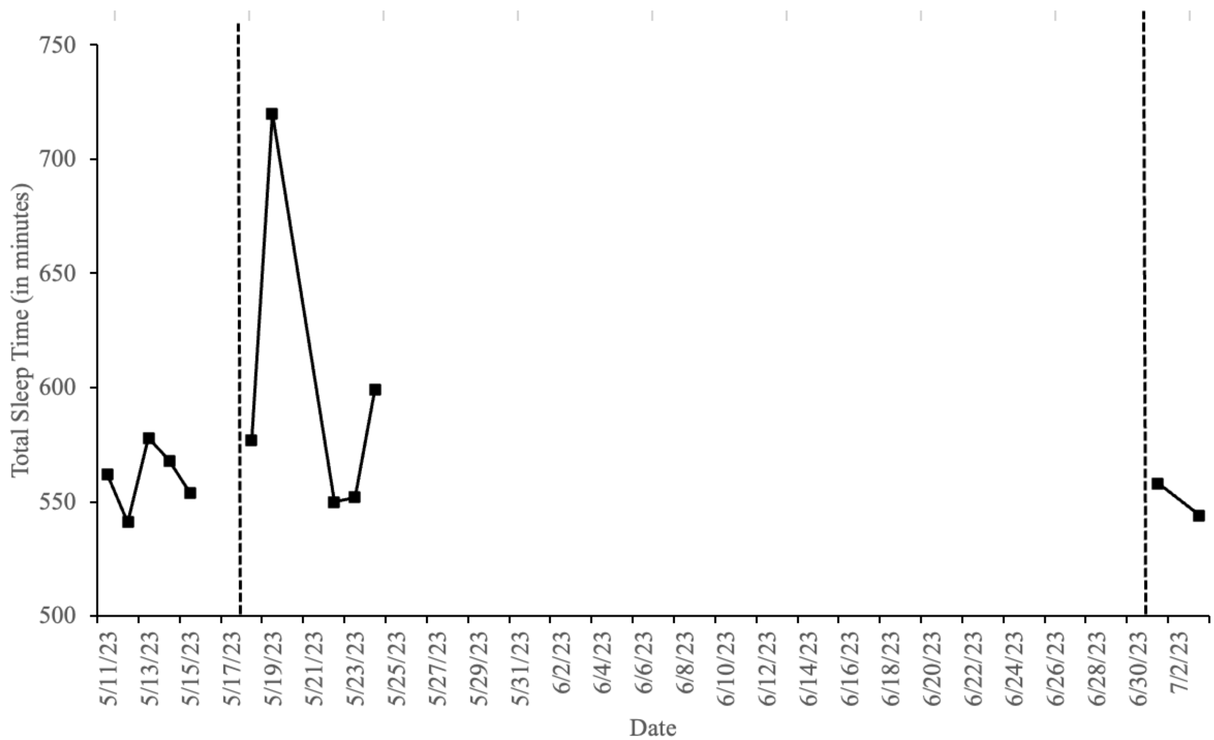


Participant 2.

ActiGraph. There was a decrease in average TST from baseline to post-intervention of 9.6 minutes (Initial *m*TST = 560.6 minutes, End *m*TST = 551 minutes). For the baseline phase compared to the post-intervention phase, there was not a significant effect ((τ)= -0.4000, p = 0.4386). Of note, only two data points from the post-intervention phase were usable from the ActiGraph after analysis. See Figure 11.

Figure 11

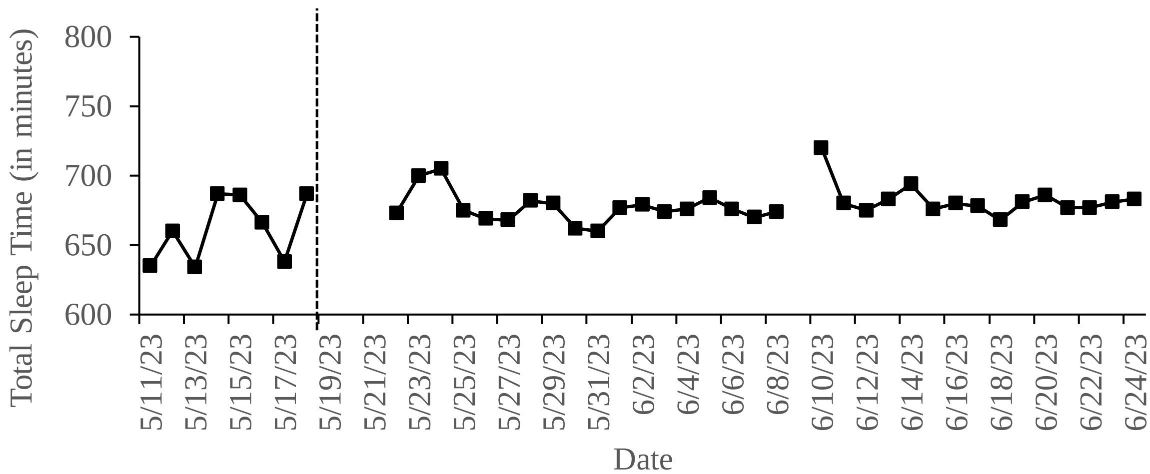
Time Series Plot of Total Sleep Time for Participant 2 from ActiGraph Data



Sleep Diaries. The caregiver of Participant 2 did not complete the sleep diary during the post-intervention phase. However, during the baseline phase, the average TST was 661.6 minutes per night. During the intervention phase, the average TST was 679 minutes per night. The caregiver noted via email that the child’s sleep during post-intervention was consistent with the last week of intervention, so it is possible TST would have remained increased from baseline during this phase. No effect size was calculated due to lack of post-intervention data points.

Figure 12

Time Series Plot of Total Sleep Time for Participant 2 from Sleep Diaries



Total Sleep Time (in minutes)
800
750
700
650
600
5/11/23
5/13/23
5/15/23
5/17/23
5/19/23
5/21/23
5/23/23
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CHAPTER 4: DISCUSSION

Overall, this study aimed to examine a) the feasibility of this sleep intervention, b) the acceptability of the intervention, and c) the effectiveness of the intervention at improving sleep quality, reducing night waking episodes, and decreasing SOL. We also examined changes in total sleep time as an exploratory aim. Overall, findings generally revealed that this intervention was not feasible for one caregiver who attempted to complete it and dropped out during the baseline phase. However, it was both feasible and acceptable to the other two caregivers who participated, as evidenced by their ability to complete the protocol as described and their responses on a measure of acceptability.

In terms of effectiveness of this intervention, outcomes depended on the method of data collection. Based on ActiGraph data, this intervention did not appear to be effective at reducing night waking episodes for either participant. It was effective at decreasing SOL for one participant, but increased SOL for the other. Total sleep time increased for one participant and decreased for another.

Based on caregiver diaries, both night waking episodes and SOL decreased for both participants, indicating caregiver-perceived effectiveness of the intervention. Sleep quality (as measured by a questionnaire), appeared to increase for both participants from baseline to post-intervention. Total sleep time increased for Participant 1 from baseline to post-intervention based on caregiver report, and the caregiver of Participant 2 reported that post-intervention sleep was identical to the last week of intervention, which suggests increases in TST from baseline were likely maintained during post-intervention.

Feasibility

The first aim of this study was to determine if this intervention would be feasible for caregivers of the targeted children. Making predictions about feasibility was difficult, as studies of bedtime fading interventions focusing on caregiver feasibility and including typically developing young children are scarce in the previous literature. The original study upon which this intervention was based, which included four children with severe cognitive impairment, did not report feasibility as an outcome. However, the study did report some limitations that may have impacted feasibility. These included that two of the participants were living in an inpatient psychiatric unit and were supervised by trained professionals, who were well equipped to implement this intervention. Additionally, the other two participants had caregivers that were "highly educated and highly motivated" to complete the intervention. Thus, for families with less education or motivation, for which the caregivers were solely responsible for implementing the intervention, this intervention may have been less feasible (Piazza & Fisher, 1991a, 1991b). One more recent meta-analysis of multiple behavioral sleep interventions for children of all ages with neurodevelopmental disabilities found that these behavioral interventions, some of which included bedtime fading, were generally feasible for families (Rigney et al., 2018). One study specifically using a bedtime fading intervention with young children with neurodevelopmental disabilities also found the intervention to be feasible for caregivers (Johnson et al., 2013). Another study using ActiGraphs to track sleep during a bedtime fading intervention with young children on the autism spectrum did not specifically examine feasibility. However, researchers reported that 70% of families in the study (final n=80, original n=114) who started the intervention were able to complete it successfully, suggesting relatively good feasibility (Malow et al., 2014). Researchers also reported barriers to completion for the 30% of participants who dropped out, including the intervention being “too time consuming”, ActiGraph malfunction leading to data loss, and the child’s inability to tolerate wearing the ActiGraph (Malow et al., 2014). Thus, I expected this study would be feasible for the majority of caregivers who participated, especially given that they all had high levels of education; however, I anticipated some difficulties with ActiGraphy and the overall time commitment of the study.

In this study, of 14 total families who reached out initially to the PI, only two were able to complete this study in its entirety. One participant completed the baseline phase but due to ongoing problems that occurred during this phase (e.g., an ActiGraph being broken and no longer collecting data when it was submerged in water, frequent family vacations that disrupted the child’s sleep schedule and made sleep tracking difficult), the caregiver was unable to complete the intervention. This would suggest the intervention was not feasible for this participant. Furthermore, the two participants that did complete the intervention still had noticeable difficulty completing online sleep diaries twice a day, which led to the loss of some data and the intervention lasting longer for one family than it should have. Ultimately, it can be concluded that this intervention proved not to be feasible for most families or for the researcher. It is also worth noting that of the families that did complete any phase of the intervention, all of them had at least one caregiver in the home who had attended graduate or professional school.

Acceptability

Another aim of this study was to examine if this intervention was acceptable to the caregivers, given the previous research suggesting that some caregivers have difficulty using the “cry it out method” because they do not find it acceptable. It was hypothesized that families would find this intervention acceptable, because it did not require the child to be in distress and "cry it out" as many traditional sleep interventions do. In previous research, some caregivers have reported that ignoring their children's distress for prolonged periods of time is not tolerable (Kuhn et al., 2020; Etherton et al., 2016; Moore et al., 2008; Sadeh et al., 2010). Such caregivers were unable to handle the level of distress this type of intervention can cause and ceased attempting the intervention altogether. The literature suggests this leads to worsened sleep problems in the long run (Kuhn et al., 2020; Etherton et al., 2016).

The current intervention used a bedtime fading with response cost procedure, which has minimized caregiver distress related to the sleep intervention in previous studies (Mindell et al., 2016; Gradisar et al., 2016). In line with previous research, both families completed the current intervention without voicing concerns about the procedures, and indicated on a measure of caregiver acceptability that they found the intervention to be acceptable.

Caregiver Stress

Caregiver stress was also included as a measure of acceptability, as previous research has found that sleep problems are related to increased caregiver stress (Byers et al., 2011; Mindell et al., 2006). It was hypothesized that decreased stress due to the intervention would make it more acceptable for families. Of the four families who completed the measure of caregiver stress at baseline, the two who completed the intervention in its entirety exhibited the lowest baseline levels of caregiver stress. However, for both of these families, their caregiver stress scores slightly decreased after the intervention. This is consistent with previous studies of caregiver stress and child sleep (Byers et al., 2011; Mindell et al., 2006).

Of note, the two participants who completed baseline questionnaires but were unable to complete the study had higher levels of baseline caregiver stress than the two participants who did complete the study. Previous research has found that sleep problems can strain the parent-child relationship and cause an increase in caregiver stress (Byers et al., 2011; Mindell et al., 2006). Given the extreme homogeneity of all four participants, it is possible that higher baseline levels of caregiver stress were a factor that impacted these two participants' ability to complete the study. An intervention to reduce caregiver stress may be helpful for families whose baseline levels of stress are so high that they are unable or unwilling to engage in a sleep intervention.

Effectiveness at Reducing Night Waking Episodes/Decreasing SOL

ActiGraphs

The third aim sought to determine the preliminary effectiveness of the intervention to decrease night waking episodes and SOL in the children that participated. Based on previous literature, there is evidence that bedtime fading interventions can decrease night waking and sleep onset latency in pediatric populations (Mindell et al., 2016; Gradisar et al., 2016). Determining the effectiveness of this intervention was made difficult by lack of agreement between the two forms of measurement used (caregiver sleep diaries and ActiGraphs). Based on ActiGraph data, night waking episodes increased from baseline to post-intervention for both participants. Average SOL increased for Participant 1 and decreased for Participant 2 from baseline to post-intervention, indicating a mixed level of success.

Caregiver Sleep Diaries

Based on caregiver sleep diaries, families reported significant improvements in both the amount of time it took their child to fall asleep upon getting into bed (sleep onset latency) and the number of night waking episodes their children experienced from baseline to post-intervention. They both also reported an increase in total sleep time from baseline to post intervention. According to the caregiver diaries for Participant 1, they were falling asleep consistently within 15 minutes of being put to bed and experienced no night waking episodes during the post-intervention phase, compared to 5 total night waking episodes during the baseline phase. Participant 2 forgot to fill out the sleep diaries during the post-intervention phase, but indicated at the end of the post-intervention phase that their child's night waking episodes had decreased and that their child was falling asleep consistently within 15 minutes of being put to bed during the post-intervention phase. Furthermore, both families indicated continued improvements and consistent sleep via email follow up (one at 3 months and one at 6 months). Thus, for these two families, this intervention was considered effective.

Regarding the significant discrepancy between ActiGraph data and data collected from caregiver sleep diaries for both SOL and night waking episodes, there is some evidence in the previous literature that this is to be expected. Overall, previous research has shown mixed findings regarding the agreement between objective and subjective measures of sleep. Mindell and colleagues (2006) reported that sleep diaries are as reliable as actigraphy. Other studies have found that caregiver report diaries may be biased and tend to overestimate total sleep time and underestimate night waking episodes, compared to more objective measures of sleep (Ashbaugh and Peck 1998; Delemere & Dounavi, 2018; Sadeh 2011). In the current study, there were a larger number of night waking episodes according to ActiGraph data compared to caregiver report data for both participants. ActiGraph data suggested night waking episodes increased from baseline to post intervention for both participants, while caregivers reported the opposite. Some of the ActiGraph data was confounded by user error (e.g., forgetting to put the ActiGraph on the child), and for one participant the ActiGraph failed to collect usable data for 5 days during the post-intervention period. ActiGraphs also have the capacity to identify "micro-arousals", which occur as a natural part of the sleep cycle, and may have recorded these as night waking episodes. These micro-arousals may not have been noticeable by caregivers if the child did not require caregiver assistance to fall back asleep.

In terms of SOL, some discrepancy would be expected during the intervention phase given that the caregivers were instructed to wait for 15 minutes before checking on their child after putting them to bed. This would make the caregiver unable to determine if SOL was less than 15 minutes, potentially leading to overestimation of SOL. Additionally, it is possible that while children were already asleep, caregivers unintentionally woke their children while performing these checks in all phases, which would lead to longer SOL reported by the caregiver than the ActiGraph. Contrary to the diaries, the ActiGraphs frequently reported a SOL of zero for both participants (e.g., that the child frequently fell asleep within zero minutes of being put into bed). It is likely that the true SOL falls somewhere in between what was reported in the diaries and by the ActiGraphs. Despite the discrepancy between caregiver report and ActiGraph data, both caregivers reported consistently improved sleep (no night waking episodes and reduced sleep onset from baseline) at 6 month follow up. Given clinical decision making often relies on caregiver report and decision-making, this intervention appeared to be effective for both participants.

Sleep Quality

The quality of Participant 1 and 2’s sleep increased from baseline to post-intervention, and for one participant it was improved by greater than one standard deviation. Notably, Participants 1 and 2 reported higher baseline sleep quality than one family who completed baseline questionnaires but did not agree to participate in the intervention. At baseline, sleep quality was highest for Participant 3, who completed only the baseline phase. However, this does not reflect the full sleep quality score because of missing data on the sleep quality questionnaire. It is possible that this family might have had a lower sleep quality score had they completed all of the items on the questionnaire.

Sleep Hygiene

Overall, all four families who completed the baseline questionnaires reported good sleep hygiene practices (white noise machines, blackout curtains, child having his/her own bedroom) at baseline. Good sleep hygiene was also characterized by lack of behaviors before bedtime that can disrupt sleep, including but not limited to consumption of caffeine or sugar and use of electronic devices. No family reported any behaviors at bedtime that are known to contribute to sleep disruption. Thus, their children’s sleep problems were not likely related to poor sleep hygiene for any family that completed questionnaires. Of note, Participants 1 and 2 reported the highest levels of sleep hygiene at baseline. Further, both participants’ sleep hygiene remained high, with differences of one and three points between baseline and post-intervention. Ruling out poor sleep hygiene as a factor in the child’s sleep at baseline and seeing it remain consistent adds to evidence that the intervention itself is what contributed to improvements in sleep. It is worth noting that there appeared to be a ceiling effect for sleep hygiene, in that the initial sleep hygiene scores were so high for both participants that there was very little room to increase during post-intervention.

Limitations

One of the greatest limitations of this study was the small number of participants, and the relative homogeneity of the sample that did participate. All participants who completed baseline questionnaires (n=4) reported similar demographics (SES, marital status, race/ethnicity, highest level of education completed by a caregiver, and employment status). Of note, all participants who completed baseline questionnaires had high SES and had completed graduate or professional school. Overall, the recruitment process made it difficult to recruit families with more limited resources or a lower education level, making it difficult to say if this study would generalize to families different from the participants. There was also a lack of diversity in terms of race/ethnicity, as all participants who completed baseline questionnaires were White, Non-Hispanic individuals. Two participants reported being employed in academia and conducting research as part of their employment (one who completed the intervention and one who completed part of the baseline phase). It is unclear if families from more diverse backgrounds and places of employment would be able to complete the intervention, particularly filling out the sleep diaries regularly.

Another limitation was the impact of the COVID-19 pandemic and the changing timeline of this study, particularly related to adjusting the study to comply with the Institutional Review Board (IRB), which had stricter requirements for in-person meetings after the pandemic.

Initially, the study was created pre-pandemic, with the intent to recruit most participants from a local private practice that provided behavioral sleep interventions to children. However, the study was delayed for over a year. Post-pandemic, referrals from this organization were no longer feasible, and a main source of participant recruitment was lost. The study ultimately relied solely on flyers posted throughout the community and the ECU Listserv for recruitment, which required another amendment to the original IRB. Further, due to more restrictions and safety practices being placed on research studies during and after the pandemic by IRB, the process to have the IRB completed was lengthy. Due to unexpected delays in response by IRB staff, it took months for the IRB to be approved, which delayed data collection. This process was particularly slow due to the study involving in-person face-to-face contact for ActiGraph drop off and pick up, which meant specific safety procedures (e.g., using face masks) had to be clearly outlined in the IRB.

Another limitation of this study was related to difficulties with technology and how heavily the study relied on technology for data collection. Families had to come to the research lab space to pick up and drop off the ActiGraph devices at multiple time points throughout the study, which made data collection more difficult. Some ActiGraph data was lost during the pickup and drop off periods, as families were not always able to come to the lab immediately after one week of each phase had occurred. Families having busy schedules contributed to some phases of the research project being delayed or extended outside of the ideal window of time to collect data. When ActiGraph data was not available due to caregivers forgetting or choosing not to put the device on their child, the PI had to rely solely on caregiver report from completing online sleep diaries, which was often inconsistent as some families were unable to remember to complete the sleep diaries. For one family, the online diaries the researcher set up in RedCap did not work for the first week of baseline. In another family's case, the online diary was not completed for the entire post-intervention phase due to failure to remember on the family's part, and the ActiGraph did not collect any data during this phase due to technological difficulties, meaning most sleep data from the post-intervention phase was lost for this family.

Clinical Implications and Future Directions

In future studies, researchers may wish to consider the burden of data collection procedures on families and adjust them accordingly. All the families had difficulty completing the sleep diaries twice daily, even with twice daily email reminders. If possible (e.g., with a full research team), researchers should monitor completion of diaries twice daily throughout the intervention to avoid long periods of missing data due to caregiver forgetfulness. Tracking sleep in an app on the caregiver's phone may be a solution to difficulty experienced by both caregivers, as this may be more user-friendly to do on a cell phone than using a Google Sheet. Further, if in-person drop off and pick up of ActiGraphs can be eliminated, this may reduce barriers to participation for some families and increase the number of possible participants. Because longer battery life could reduce or eliminate the need for travel, configuring the ActiGraphs to collect fewer data points would help to conserve battery life and therefore reduce travel burden between study phases. It may also be helpful to use video monitoring as an alternative to sleep tracking devices as a less burdensome objective measure, as many parents already use video monitoring in their children's bedrooms.

Future studies using this intervention may also wish to include more diverse populations. Researchers may wish to consider how exclusionary criteria (e.g., adequate sleep hygiene, two caregiver households) may impact sample size and diversity of participants. Recruiting participants with diversity in racial/ethnic backgrounds, socioeconomic status, education, and family status (children living in situations other than two-caregiver households) would increase generalizability and provide useful information about feasibility, acceptability and effectiveness in different populations. Future studies should also consider including children with behavioral difficulties, as no participants in this study exhibited behavioral problems that interfere with sleep, making it unclear how this specific intervention would work with children exhibiting behavior problems at bedtime.

Given that caregiver stress and sleep problems are connected, it may be helpful to examine caregiver stress as part of assessing readiness for sleep intervention. Some caregivers with high levels of stress may not be able or willing to participate in a lengthy sleep intervention, even if it would likely lower their stress over time. Providing an intervention to reduce caregiver stress for caregivers with high stress at baseline may increase follow-through with a sleep intervention.

Finally, researchers may also wish to consider evidence-based guidelines for sleep duration in preschoolers when setting wake times with families to ensure children are getting enough sleep. Lack of sleep could be a contributing factor in sleep problems for young children. Previous research suggests that preschoolers need 10-13 hours of sleep per night, including naps, so wake times should be set accordingly to reach this goal (Paruthi et al., 2016).

Caregivers of typically developing young children with delayed sleep onset and/or night waking episodes may wish to examine their child's sleep hygiene as a first line of intervention, as having good sleep hygiene practices can mitigate the need for intervention. Caregivers should also ensure their children are getting enough sleep every night, based on their children's age. Guidelines for sleep hygiene and recommended amount of sleep by age are readily available online: (e.g., https://www.nationwidechildrens.org/specialties/physical-therapy-sports-and-orthopedic/resources/sleep-hygiene). Stanford Medicine has recommendations for sleep hygiene based on the developmental stage of the child: (https://www.stanfordchildrens.org/en/topic/default?id=healthy-sleep-habits-90-P02286). If sleep hygiene is determined by the caregiver to be good, caregivers should note that bedtime fading may be more effective with a response cost element. The current study suggests effectiveness is maintained when shortening the interval of response cost from 30 minutes to 15 minutes.

Sleep psychologists should first assess sleep hygiene when treating children with DSO and night waking episodes and provide psychoeducation for families regarding the importance of sleep hygiene and getting adequate sleep. If sleep hygiene is good, sleep psychologists may wish to consider caregiver stress, as well as caregiver's comfort level with tolerating their child's distress during a sleep intervention when treating children with delayed sleep onset or night waking episodes. While the "cry it out" method has much research suggesting it is highly effective, some caregivers may not find this method acceptable and therefore may implement it incorrectly or refuse to implement it at all. In such cases, sleep psychologists may wish to suggest a bedtime fading with response cost intervention to reduce caregiver stress surrounding their child's crying at night and increase likelihood of follow through. It is also imperative to explain to the family that sleep interventions require a time commitment, and should be completed during a window of time in which the family is not traveling and the primary caregiver(s) feel prepared to potentially and temporarily get less sleep as part of the intervention process.

Conclusions

In conclusion, this intervention was not feasible for most participants. This is likely due to difficulty with recruitment due to multiple factors outside the researcher's control, using a bedtime fading with response cost protocol, ActiGraphs to track sleep which required scheduling coordinating multiple pick ups and drop offs with families, and using caregiver diaries to track sleep, which required completion twice a day. However, the two participants who completed it found it both acceptable and effective. The most difficult part of the study for participants appeared to be using the ActiGraphs as outlined in the protocol and remembering to complete the sleep diaries twice daily. This study contributes to the literature on using bedtime fading in combination with response cost as an acceptable means of improving sleep quality, reducing night waking episodes, and reducing delayed sleep onset in typically developing young children. It also suggests preliminary effectiveness of this intervention, though more research is needed given the homogeneity and small size of the sample in this study.

Future studies may wish to adjust the methods of data measurement to be easier for caregivers to complete (e.g., not requiring in person pick up of devices at multiple time points in the study, improved interface of online questionnaires), which may increase feasibility for families to participate. Studies may also consider reducing burden for families by using devices that can track sleep for longer periods. Alternatively, video monitoring to improve accuracy of sleep tracking should be considered. Video monitoring may also reduce burden for caregivers so they do not have to be responsible for using a device, and is likely to be acceptable, as many caregivers use sleep monitors for their children.

Finally, caregivers and sleep psychologists should assess the child's sleep hygiene before any intervention occurs and assess the child's average total sleep within a 24 hour period to ensure it is commensurate with available guidelines. This should help to rule out poor sleep hygiene or inadequate sleep time as a factor in the child's sleep quality, delayed sleep onset, or night waking episodes. Psychologists should assess how comfortable a caregiver is with allowing their child to "cry it out" before recommending specific interventions. Psychologists may suggest bedtime fading, or bedtime fading with response cost, as a viable alternative for caregivers who are not comfortable with letting their child "cry it out".

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Appendix A. Sleep Intervention Protocol & Fidelity Checklist

Night 1

- After the child's **initial bedtime** has been determined, the intervention will begin by making the child's bedtime the first night of intervention **30 minutes later** than the initial bedtime (e.g., if the initial bedtime is 10:00, the new bedtime will be 10:30). This will ensure that the child is sleepy on the first night of intervention.
    - You will put the child to bed at the new bedtime following their normal bedtime routine and then leave the room. You will go back to check on them in 15 minutes.
    - If the child is asleep **within 15 minutes**, you will record that time in the sleep diary and you are not required to do anything else.
    - If the child **does not fall asleep within 15 minutes**, you will take them out of bed – this is called "response cost". During response cost, you will take them out of bed and keep them awake for 30 minutes. During this time, they are allowed to engage in an activity of choice, so long as the activity is not known to interfere with sleep.
        - Acceptable activities: reading, playing with non-electronic toys or games
        - Unacceptable activities: screen time (any electronic device), eating/drinking caffeine or sugar
    - Once 30 minutes has passed, you will put the child back into bed and leave the room. You will wait another 15 minutes and then check on them again. If they are

asleep, you record that time in the sleep diary. If they are still awake, you take them out of bed and repeat the “response cost” by taking them out of bed for 30 minutes again. This is repeated until the child is asleep within 15 minutes of being put in the bed.

Day 2

- You should have already established a set wake time with the researcher that works for your schedule. This is the time you will wake your child up and take them out of bed **every morning** during the intervention, regardless of how they slept the night before. They should not be allowed to sleep during the day, unless they are taking a nap.
- **Naps** are allowed if they are a normal part of the child’s routine. During the intervention, nap times will be based on the child’s naps during baseline **and** sleep recommendations from the National Sleep Foundation. They will be allowed to nap for as long as they napped on average during baseline – however, the child’s total sleep time in a 24-hour period should still be within the NSF recommendations. For example, for children ages 3-5, the recommended total sleep time is 10-13 hours. If their baseline average nap time would put them under 10 hours or over 13 hours of total sleep in a 24-hour period, the nap time must be adjusted so they are within 10-13 hours of total sleep time.

Night 2

- Starting on the second night of intervention, you will make the child’s **bedtime 15 minutes earlier**. For example, if the child was put to bed at 10:30 on night one, they will be put to bed at 10:15 on night two. The same procedure is used again – if they fall asleep within 15 minutes of being put to bed, record it in the sleep diary. If they do not, use response cost to keep them out of bed and awake for 30 minutes. Then, put them back to bed and see if they fall asleep within 15 minutes. If not, response cost is used again. Always record their final sleep time in the sleep diary.

Day 3

- Wake the child and remove them from bed at the set wake time, regardless of how they slept the night before.

Night 3 and Beyond

- From this point forward, you will make the child's bedtime **15 minutes earlier** each night, until the desired bedtime is reached. You will continue to use response cost if they do not fall asleep **within 15 minutes** of being put to bed.
- Each morning, you will wake them up at the set wake time, regardless of how they slept the night before. This includes waking them and removing them from bed at the **same time every day of the week**, including weekends.
- Continue this process until you've reached the desired bedtime, or until 6 weeks has passed. If your child's sleep is not improving after 6 weeks, we will refer you and your child to your pediatrician for further care. You will still be allowed to continue the intervention if you would like to, and the primary investigator will be available to support you if you choose to do this.

Appendix B. Sleep Diary

Morning Sleep Diary:

Date:

Wake Time:

How did your child wake up? Self/caregiver/alarm

Did your child go back to sleep after waking?

Nighttime Sleep Diary:

Date

Did Your Child Nap Today?

If your child napped, what time did they fall asleep?

If your child napped, what time did they wake?

What is total time your child spent napping (in hours)

What time did you put your child in bed tonight?

What time did your child fall asleep?

Did your child fall asleep independently?

Did you have to implement response cost and take the child out of bed for 30 minutes?* (do not do this unless you are in the INTERVENTION phase)

If you had to implement response cost, how many times did this occur?

If you had to implement response cost, what was the LAST time your child was put into bed?

Additional Comments (e.g., night waking episodes) can go here:___________

Actigraph Log

1) Was there a period of time in the past 24 hours when your child was not wearing the actigraph?__________________________

2) Describe reason it was removed________

3) EXACT time removed_______________

4) EXACT time it was put back on________

Appendix C. Caregiver Acceptability

Behavior Intervention Rating Scale – Revised (BIRS-R)

Thank you for completing an intervention to improve your child's sleep. Please evaluate the intervention by circling the number which best describes your agreement or disagreement with each statement. Please answer each question.

1 = Strongly Disagree, 2 = Disagree, 3 = Slightly Disagree, 4 = Slightly Agree, 5 = Agree, 6 = Don't Know/Unsure

1. This was an acceptable intervention for my child's delayed sleep onset and night wakings. 1 2 3 4 5 6
2. Most parents would find this intervention appropriate for delayed sleep onset and night wakings as well as other sleep problems. 1 2 3 4 5 6
3. The intervention proved effective in changing my child's delayed sleep onset and night wakings. 1 2 3 4 5 6
4. I would suggest the use of this intervention to other parents. 1 2 3 4 5 6
5. My child's delayed sleep onset and night wakings were severe enough to warrant the use of this intervention. 1 2 3 4 5 6
6. Most parents would find this intervention suitable for delayed sleep onset and night wakings. 1 2 3 4 5 6
7. This was something I was willing to do from home. 1 2 3 4 5 6
8. The intervention did not result in negative side effects for my child. 1 2 3 4 5 6

9. The intervention would be appropriate for a variety of children. 1 2 3 4 5 6

10. The intervention is consistent with those I have used at home before. 1 2 3 4 5 6

11. The intervention was a fair way to handle the child's delayed sleep onset and night wakings. 1 2 3 4 5 6

12. The intervention is reasonable for delayed sleep onset and night wakings. 1 2 3 4 5 6

13. I like the procedures used in the intervention. 1 2 3 4 5 6

14. This intervention was a good way to handle my child's delayed sleep onset and night wakings. 1 2 3 4 5 6

15. Overall, the intervention was beneficial for my child. 1 2 3 4 5 6

16. The intervention quickly improved my child's sleep. 1 2 3 4 5 6

17. The intervention produced a lasting improvement in my child's sleep. 1 2 3 4 5 6

18. The intervention improved my child's sleep to the point that it is not noticeably different from other children's sleep. 1 2 3 4 5 6

19. Soon after using the intervention, I noticed a positive change in my child's sleep. 1 2 3 4 5 6

20. My child's sleep remained at an improved level even after the intervention was discontinued. 1 2 3 4 5 6

21. When comparing my child with a peer that does not have delayed sleep onset before and after the intervention, my child and the peer's sleep were more alike after the intervention. 1 2 3 4 5 6

22. The intervention produced enough improvement in my child's sleep so that sleep is no longer a problem at home. 1 2 3 4 5 6

23. Additional Comments: ____

Appendix D. Parental Stress Scale

Parental Stress Scale

The following statements describe feelings and perceptions about the experience of being a parent. Think of each of the items in terms of how your relationship with your child or children typically is. Please indicate the degree to which you agree or disagree with the following items by placing the appropriate number in the space provided.

1 = Strongly disagree 2 = Disagree 3 = Undecided 4 = Agree 5 = Strongly agree

1	I am happy in my role as a parent	Choose one
2	There is little or nothing I wouldn't do for my child(ren) if it was necessary.	Choose one
3	Caring for my child(ren) sometimes takes more time and energy than I have to give.	Choose one
4	I sometimes worry whether I am doing enough for my child(ren).	Choose one
5	I feel close to my child(ren).	Choose one
6	I enjoy spending time with my child(ren).	Choose one
7	My child(ren) is an important source of affection for me.	Choose one
8	Having child(ren) gives me a more certain and optimistic view for the future.	Choose one
9	The major source of stress in my life is my child(ren).	Choose one
10	Having child(ren) leaves little time and flexibility in my life.	Choose one
11	Having child(ren) has been a financial burden.	Choose one
12	It is difficult to balance different responsibilities because of my child(ren).	Choose one
13	The behaviour of my child(ren) is often embarrassing or stressful to me.	Choose one

14	If I had it to do over again, I might decide not to have child(ren).	Choose one
15	I feel overwhelmed by the responsibility of being a parent.	Choose one
16	Having child(ren) has meant having too few choices and too little control over my life.	Choose one
17	I am satisfied as a parent	Choose one
18	I find my child(ren) enjoyable	Choose one

Appendix E. Children's Sleep Hygiene Scale

		Once in a While	Sometimes	Quite Often	Frequently- if not Always	Always
	Does your child…					
1.	Nap 4 hours before bedtime?					
2.	Have caffeine 4 hours before bedtime?					
3.	Do relaxing things before bedtime?					
4.	Drink lots of liquids before bedtime?					
5.	Play rough before bedtime?					
6.	Do things that are alerting?					
7.	Go to bed about the same time?					
8.	Complain about being hungry at bedtime?					
9.	Do things in bed that keep him/her awake?					
10.	Go to bed in the same place?					
11.	Go to bed feeling upset?					
12.	Sleep alone?					
13.	Have a calming bedtime routine?					
14.	Use bed for things other than sleep?					
15.	Get put to bed after falling asleep?					
16.	Stay up past usual bedtime?					
17.	Get out of bed at same time in morning?					

Appendix F. Children's Sleep-Wake Scale

Appendix

Children's Sleep -Wake Scale

Directions:

Using the choices below, circle how often the following things have happened during the past month.

Never
Once in Awhile
Sometimes
Quite Often
Frequently, if not always
Always

Questions 1 - 5 **only concern** your child **Going to Bed.**		Never	Once in Awhile	Sometimes	Quite Often	Frequently, if not Always	Always
When its *time to go to bed*, your child...							
1.	...goes straight to the bed	N	O	S	Q	F	A
2.	...makes repeated requests (for example: asks for another drink, hug, story)	N	O	S	Q	F	A
3.	...wants to stay up and do other things (for example: read, play, or watch TV)	N	O	S	Q	F	A
Your child...							
4.	...is ready to go to bed at bedtime	N	O	S	Q	F	A
5.	..."puts off" or delays going to bed	N	O	S	Q	F	A
	Write in how long your child usually "puts off" or delays bedtime: ____minutes						
Questions 6 - 10 **only concern** your child **Falling Asleep**.							
When it's *time to go to sleep* (lights-out), your child...							
6.	...is quiet and calm	N	O	S	Q	F	A
7.	...has trouble settling down	N	O	S	Q	F	A
Your child...							
8.	...has trouble going to sleep	N	O	S	Q	F	A
9.	...needs help getting to sleep	N	O	S	Q	F	A
10.	...falls asleep quickly after "lights-out"	N	O	S	Q	F	A

	Write in how long it usually takes your child to fall asleep: ____ minutes

Questions 11 - 15 **only concern** your child **Arousing and Awakening during the night.**

		Never	Once in Awhile	Sometimes	Quite Often	Frequently, if not Always	Always
***During the night*, your child...**							
11.	…tosses and turns in the bed	N	O	S	Q	F	A
12.	…is very restless	N	O	S	Q	F	A
13.	…moans, groans, or talks in sleep	N	O	S	Q	F	A
14.	…arouses, but does not fully awaken	N	O	S	Q	F	A
15.	…awakens more than once	N	O	S	Q	F	A
	Write in how many times your child usually awakens during the night: ____ times						

Questions 16 - 20 **only concern** your child **Returning to Sleep after waking during the night**.

After arousing or awakening, your child…							
16.	…comes out of the bedroom	N	O	S	Q	F	A
17.	…awakens other family members	N	O	S	Q	F	A
18.	…calls out for the caretaker	N	O	S	Q	F	A
19.	…goes into someone else's bed	N	O	S	Q	F	A
20.	…rolls over and goes back to sleep	N	O	S	Q	F	A
	Write in how long it takes your child to go back to sleep after arousing/awakening: ____min						

Questions 21 - 25 **only concern** your child **Waking in the Morning.**

In the morning, your child wakes up...							
21.	…without any help	N	O	S	Q	F	A
22.	…and is ready to get up for the day	N	O	S	Q	F	A
23.	…rested and alert	N	O	S	Q	F	A
Your child...							
24.	…is slow-to-start in the morning	N	O	S	Q	F	A
25.	…is difficult to get out of the bed in the morning	N	O	S	Q	F	A
	Write in how long it takes your child to become alert in the morning: ____ minutes						

Appendix

Children's Sleep Wake Scale (CSWS) Scoring

- The CSWS provides 5 subscale scores and an overall sleep quality score.
- Higher scores indicate better success on each of the dimensions (or sleep quality).
- Response options are scored as follows:

  Never (1 point)
  Once in Awhile (2 points)
  Sometimes (3 points)
  Quite Often (4 points)
  Frequently, if not Always (5 points)
  Always (6 points)

Reverse scoring is needed for some items (1=6, 6=1, 2=5, 5=2, 3=4, 4=3). Reversed items are noted below with an "r" before item number.

Going to Bed Subscale – GTB (Items 1-5)
- Reverse score items 2, 3, 5
- Compute the mean of the following items: 1, r2, r3, 4, r5

Falling Asleep Subscale – FA (Items 6-10)
- Reverse score items 7, 8, 9
- Compute the mean of the following items: 6, r7, r8, r9, 10

Maintaining Sleep Subscale – MS (Items 11-15)
- Reverse score items 11-15
- Compute the mean of the following items: r11, r12, r13, r14, r15

Reinitiating Sleep Subscale –RS (Items 16-20)
- Reverse score items 16-19
- Compute the mean of the following items: r16, r17, r18, r19, 20

Returning to Wakefulness Subscale – RTW (Items 21-25)
- Reverse score items 24, 25
- Compute the mean of the following items: 21, 22, 23, r24, r25

CSWS Total Sleep Quality Score - CSWSTOT
- Compute the mean of each of the subscales (GTB, FA, MS, RS, RTW)

Appendix G. IRB Approval Letter

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board
4N-64 Brody Medical Sciences Building· Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office **252-744-2914** ·
Fax **252-744-2284** · **rede.ecu.edu/umcirb/**

Notification of Amendment Approval

From: Biomedical IRB
To: Marie Rodriguez
CC: Aimee Smith
Date: 6/21/2023
Re: Ame4_UMCIRB 19-001457
UMCIRB 19-001457
Improving Sleep in Young Children

Your Amendment has been reviewed and approved using expedited review on 6/20/2023. It was the determination of the UMCIRB Chairperson (or designee) that this revision does not impact the overall risk/benefit ratio of the study and is appropriate for the population and procedures proposed.

Please note that any further changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a Final Report application to the UMCIRB prior to the Expected End Date provided in the IRB application. If the study is not completed by this date, an Amendment will need to be submitted to extend the Expected End Date. The investigator must adhere to all reporting requirements for this study.

Approved consent documents with the IRB approval date stamped on the document should be used to consent participants (consent documents with the IRB approval date stamp are found under the Documents tab in the study workspace).

The approval includes the following items:

Description:
Extend the deadline of this project to August of 2024.

For research studies where a waiver or alteration of HIPAA Authorization has been approved, the IRB states that each of the waiver criteria in 45 CFR 164.512(i)(1)(i)(A) and (2)(i) through (v) have been met. Additionally, the elements of PHI to be collected as described in items 1 and 2 of the Application for Waiver of Authorization have been determined to be the minimal necessary for the specified research.

The Chairperson (or designee) does not have a potential for conflict of interest on this study.