Behavioral Effects of a Sleep Intervention in Preschoolers with Sleep Problems: A Randomized Controlled Trial

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<u>Abstract</u>

Sleep has been recognized as an important determinant for healthy development in children, with well documented effects on, not only physical health, but also emotional development. The mechanisms and extent of these relationships have yet to be fully elucidated. Considering that sleep is a modifiable health risk factor with myriad compounding impacts across the lifespan, this area of research is of distinct importance in the sphere of public health. This preliminary study is unique in that it uses a randomized, controlled experimental paradigm to assess the relationship between healthy sleep and emotion processing in children. 12 children with sleep problems, aged 4-to-6.9 years, were enrolled in the study. Roughly 2/3 of the enrolled subjects (n=8) were provided an in-home, 1 month sleep intervention administered by a behavioral interventionist while subjects in the control group were provided an intervention of similar structure and duration which did not pertain to sleep (e.g. health and safety). Parentreport of children's behavior via the Emotion Regulation Checklist was collected pre- and postintervention for both groups. On average, children who received the sleep intervention had a slightly greater increase in scores on the adaptive subscales and slightly greater decrease in scores on scales of negative emotional lability than did subjects in the control group. These differences were not statistically significant as measured by paired or unpaired t-tests, but show trends in the hypothesized direction. These findings help lay the groundwork for increased understanding of the role of sleep in emotional regulation (study data collection is ongoing). They additionally establish the feasibility of a sleep intervention as an effective treatment for children with comorbid sleep problems and emotional dysregulation, although larger-scale studies are needed.

Introduction

It is intuitively apparent to anyone who has spent time around young children that sleep and emotional behaviors are linked – unexplained tantrums are often met with questions about whether a child needs a nap or whether they slept enough the night before. The practical significance of this relationship and its long-term implications are still unfolding at the hands of the scientific community. Academics aside, the general population – including the caregivers who actively affect and are affected by these processes in young children – know surprisingly little about the impacts of poor sleep and what they can do to improve it. Only in the past 20-25 years have clinicians and parents begun to understand the nuances of pediatric sleep problems and the potential long-term consequences of leaving them unresolved¹¹. Sleep habits and behavioral precedents established in early childhood can last a lifetime. Moreover, the impact expands well beyond the realm of sleep. It is now well established that insufficient sleep correlates to hormonal dysfunction; it is considered the third most significant risk factor for obesity right behind activity levels and diet. Mood disorders, type two diabetes, cardiac disease, immune dysfunction, and lower life expectancy are all associated with insufficient sleep¹⁷.

The goal of the present project was to hone in on the relationship between emotional regulation and insufficient sleep in early childhood. It is possible that the relationship between sleep and emotion regulation could be modifiable and causal in nature; if so, elucidating the short-term impact of a behavioral sleep intervention is a significant step towards establishing how sleep problems in childhood could be targeted clinically to reduce the incidence of mood disorders and behavioral problems in the general population. Considering the high prevalence of

mental health problems in the U.S. population and the fact that roughly 30% of parents report their children do not get enough sleep, childhood sleep seems an obvious and potentially highyield target for efforts aimed at improving public health¹⁸.

Literature Review

Data from epidemiological and experimental studies support a relationship between sleep and emotion regulation in adolescents and adults; however, the underlying mechanisms of these associations remain poorly understood²⁰. Central to this project is the relative lack of data on sleep and emotion regulation in children. All-night sleep deprivation and chronic sleep restriction protocols are commonly utilized to investigate similar relationships in adults; however, they are not feasible or ethical in young children. This may help to explain why relatively few studies exist focusing on possible causal relationships between sleep and emotion regulation in children. This is particularly problematic considering that early childhood is a sensitive period for the development of multiple facets of executive functioning and emotion regulation and problems that develop in this sensitive stage of life may have enduring effects on emotional and cognitive functioning and mental health^{2, 6,20}. Understanding how sleep affects children's emotion regulation is an important field of inquiry that needs to be met with alternative experimental approaches.

Although experimental data concerning emotion regulation in young children is sparse, numerous correlational studies have established the relevance and importance of the relationship between sleep and emotion regulation in childhood. One study of 325 five-year-old children concluded that emotion regulation is correlated with better academic outcomes in early education ⁸. Moreover, there is a growing body of literature to support the conclusion that behavioral and emotional problems in children and adolescents are correlated to sleep problems¹⁵. Sleep quality in school-age children is associated with performance on complex executive functioning tasks, as well as with rates of parent-reported behavior problems^{16,19}. There is further evidence that these problems endure beyond early childhood. A longitudinal study of 490 Colorado children published in 2002 indicated that although sleep problems tapered off after 4 years of age, sleep problems during the preschool years predicted behavioral and emotional difficulties in midadolescence, even when controlling for sleep problems among the adolecents⁹. These findings demonstrate the importance of helping families establish healthy sleep patterns in the earliest stages of childhood. In addition, sleep restriction studies in adolescents have confirmed that three weeks of sleep restriction in adolescents is sufficient to significantly increase self-reported anxiety, anger and hostility as well as parent reports of increased irritability and worsened emotional regulation³. These data establish that children's sleep is correlated to emotional regulation both in the short term and longitudinally. Additionally, they suggest that changes in sleep duration over relatively short periods of time (e.g. 1 week) are sufficient for measurable emotional changes to be observed.

Experimental data collected previously by the Sleep and Development Lab indicates that acute sleep restriction (one day of nap deprivation or one night of a three-hour bedtime delay) increases maladaptive emotion expression and a deterioration of self-regulation strategies in young children. Importantly, emotion and self-regulation outcomes were evaluated via objective behavioral coding from videotapes of the children during an unsolvable puzzle task and during a cognitive task with high cognitive load^{5, 14}. This finding is key because it establishes that

insufficient sleep in young children is not only correlated to but likely causal for maladaptive emotion expression and self-regulation. It is unclear how these findings translate to young children who experience chronic insufficient sleep and whether a sleep-focused intervention can effectively alter behavior. In this preliminary project, our aim was to begin to address this gap using a randomized, controlled experimental trial to examine the effects of a behavioral sleep intervention on parent-reported emotion regulation in young children who are experiencing chronic insufficient sleep.

Methods

Participants for this study to date include 12 children aged 4.0-6.9 (5 females) who were reported by their parents to be experiencing chronic insufficient sleep. Insufficient sleep was defined as less than 9 hours of sleep on an average day or significant bedtime resistance, long sleep onset latencies, and/or frequent nighttime awakenings. Two subjects who enrolled but did not complete the full protocol were excluded from this analysis. Families were recruited on a volunteer basis through multiple avenues including clinician referrals, neighborhood canvasing, social media and local community events. Participants lived in Boulder, Jefferson or Denver counties. Children with profound disability or developmental delays were excluded from this study; however, two children with high-functioning ASD were included. Of these 12 children, 4 were identified by their parents as ethnically Hispanic/Latino and 5 (including those 4) were identified by their parents as being racially non-Caucasian. Stratified randomization accounting for sex, SES and 1 week average sleep duration prior to the study start date was used to assign

participants into either control (n=4) or treatment (n=8) groups. Subjects in the control group received a behavioral intervention of a similar format and duration to those in the treatment group, but their intervention focused on health and safety instead of sleep.

The existing primary study examining the sleep intervention (Sleep Health in Preschoolers: SHIP) indicated that the intervention can increase sleep duration by roughly 1 hour in children who sleep less than 10 hours per day on average. The intervention protocol is modular, making it flexible and appropriate for implementation in families with varying organization and socioeconomic status and is also effective in children with various behavioral and temperamental traits. A key part of the program is helping parents to establish a clear and consistent bed time and a healthy, calming bedtime routine. The actual timing and the make-up of the routine is tailored to the needs of the family. For example, families are supported by the interventionist in choosing when their children's bedtime and wake time will be with the sole constraint that it must be consistent for all seven days of the week and provide a sufficient opportunity for sleep. Additionally, families work with an interventionist to formulate a practical bedtime routine tailored to their particular child. For example, an energetic child who struggles to deescalate in the time leading up to bedtime might have more kinesthetic elements in their routine, such as doing "animal yoga", while another child may respond better to reading a story or singing a song. Families work with an interventionist to establish goals in the first intervention meeting and then have three follow-up visits with the interventionist, roughly 7 days apart, to troubleshoot and stay on track.

Actigraphs, watch-like devices that estimate sleep and wakefulness states minute by minute, were used in conjunction with parent-report sleep diaries to assess a child's sleep and related daytime behavior. These data were collected for 2 weeks prior to and 2 weeks following

the 1 month sleep intervention phase. Actigraphy is a practical alternative to polysomnography for long-term, all-day monitoring of sleep timing and duration. It has been established in the field as a reliable way to measure treatment effects for insomnia and other night-to-night variations in sleep disturbance ^{1,4,11}. Preliminary visual analysis of Actigraphy data was conducted for this analysis to examine the efficacy of the sleep intervention in extending sleep.

Multiple parent-report surveys including the Emotion Regulation Checklist (ERC) were completed at the 2 time points. The ERC is a 24-item survey divided into 5 subscales with some items counting towards multiple subscales. The subscales are (1) Positive Regulation, which is a sum of 5 items, including questions like how cheerful the child is or how empathic they are towards other children. (2) Emotion Regulation, which is a sum of scores on 8 items, and includes every item from the Positive Regulation score with the addition of items that ask the parent to rate to what extent their child "can recover quickly from upset", or "responds positively to neutral or friendly overtures," as well as whether the child is generally sad or listless (which is reverse scored as part of the final subscale computation). (3) Dysregulation is a sum of 4 items that query the amount of inappropriate emotional and social behaviors the child presents, for example being overly excited or expressing negative emotions frequently when engaging others in play. (4) Negative Lability 3-factor subscale, which contains 4 items assessing a lack of ability to delay gratification, whether the child is easily frustrated or struggles to switch tasks, etc. and, finally (5) Negative Lability 2-factor contains 15 items and has some items in common with the 3-factor subscale but includes additional elements assessing behaviors like the child being frequently angry or exhibiting disruptive outbursts.

All data were analyzed in R Studio. ERC survey data were scored in R Studio using the standard subscales as described above. Adaptive behaviors are indicated by the positive

regulation 3-factor and emotional regulation 2-factor subscales; maladaptive behaviors are indicated by the remaining subscales. Each subscale is a summed total of 4 to 15 items from the complete survey, and each subscale has been shown to represent a distinct aspect of child emotion regulation behavior⁸. Changes in scores from pre- to post- intervention for each subscale of each subject was then computed. The average change in score for each subscale is presented graphically for the treatment and control groups in **Figure 1**. Paired and unpaired t-tests were run in R Studio.

Results

ERC subscale scores were calculated for each subject for both pre- and post- intervention surveys. The difference between the pre- and post- intervention scores were then calculated for each subject. The treatment group had an increase in adaptive emotional behaviors on average while the control group, on average, had a decrease.

As shown in **Figure 1**, the treatment group showed modest reductions in both Negative Lability subscales and small increases in both of the adaptive behavior subscales (Emotion Regulation and Positive Regulation). The intervention group, on average, did not show any change in dysregulation or inappropriate affect as measured by the subscale Dysregulation. The differences between groups as measured by average change in score were most pronounced in the Positive Regulation and in the Negative Lability 2-factor subscales.

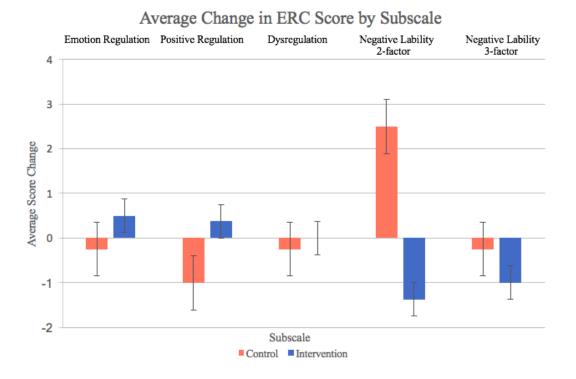


Figure 1. The average change in score from pre- to post-assessment for control and treatment groups. Control n=4, Treatment n=8

Descriptive statistics for ERC subscale scores including standard deviations can be found in **Table 1**. The values presented in **Table 1** reaffirm that average scores for the intervention group increased in Emotion Regulation and Positive Regulation and decreased on both scales of Negative Lability and additionally indicate a trend of reduced standard deviation which suggests that subjects with abnormal scores were approaching the mean score by the end of the intervention.

For a significance level of α = 0.05, the differences between groups were not statistically significant as measured by (1) Emotion Regulation subscale, (2) Positive Regulation 3-factor subscale, (3) Dysregulation, (4) Negative Lability 3-factor or (5) Negative Lability 2-factor subscales (**Table 2; Table 3**). Insufficient power due to the small sample size is a likely contributing factor. We tested with 1-tailed t-tests the hypothesis that the intervention would result in increases in the Emotion Regulation and Positive Regulation scales and decreases on the

Dysregulation, Negative Lability 2-factor and Negative Lability 3-factor subscales (**Table 2**). In addition, 2-tailed t-tests were used to analyze data from the control group, testing the hypothesis that scores for the control condition would not change (**Table 2**).

	Emotion Regulation	Positive Regulation	Dysregulation	Negative lability (2-factor)	Negative lability (3-factor)
Control Group, Pre-intervention	26.5 + 1.0	19.5 + 0.58	7.75 + 0.5	25.25 + 6.95	8.75 + 4.03
Control Group, Post-intervention	26.25 + 0.5	18.5 + 0.58	7.5 + 0.58	27.75 + 2.87	8.5 + 1.91
Intervention Group, Pre-intervention	24.13 + 2.03	17 + 2.83	8 + 1.31	31.38 + 11.61	9.88 + 3.32
Intervention Group, Post-intervention	24.63 + 0.52	17.38 + 1.19	8 + 1.77	30 + 8.91	8.88 + 2.85

Table 1. Descriptive statistics for ERC subscale scores at both time points (control or intervention groups; Mean and standard deviation (M + SD)

For thoroughness, 1-tailed unpaired t-tests were also used to test the hypothesis that the

treatment group should have a greater increase in Emotion Regulation and Positive Regulation

and a greater decrease in Dysregulation as well as 2- and 3- factor Negative Lability (Table 2).

	Emotion Regulation	Positive Regulation	Dysregulation	Negative Lability (2-factor)	Negative Lability (3-factor)
Control Group (2-tail)	p = 0.64	p = 0.18	p = 0.39	p = 0.61	p = 0.89
Intervention Group (1-tail)	p = 0.28	p = 0.35	p = 0.50	p = 0.21	p = 0.11

Results were not statistically significant.

Table 2. P-values for paired t-test, 2-tailed in control group and 1-tailed in intervention group.

Emotion	Positive	Dysregulation	Negative Lability	Negative Lability
Regulation	Regulation		(2-factor)	(3-factor)
p = 0.22	p = 0.12	p = 0.70	p = 0.23	p = 0.35

Table 2. P-values for unpaired t-test, 1-tailed.

In addition, Actigraphy data were collected for 14 days prior to and 14 days after the intervention period for each subject and the total amount of sleep per day – including accidental naps – was recorded. The average amount of sleep per day was then calculated for each subject at each time-point (pre-intervention and post-intervention). The difference between these 2 measurements was recorded for each individual subject and was then averaged across the control group and intervention group to yield 2 means. Based on this preliminary visual analysis, the mean change in sleep duration for the intervention group was 0.6 minutes while the mean change in the control group was -7.3 minutes.

Discussion

The overarching objective of this preliminary study was to clarify the possible causal relationship between insufficient sleep and poor emotion regulation. Using a well-controlled randomized experimental design, the aim was to elucidate whether a sleep intervention and subsequent sleep extension would improve parent-reported emotion regulation in children. Existing literature supports the theory that sleep problems should correlate to more maladaptive, dysregulated and labile affect. Conversely, a sleep intervention which increases the child's average sleep duration, should enhance the opposite: adaptive emotion regulation and positive affect with reduced negative lability and dysregulated emotional behaviors. The visual results of this analysis were largely, albeit superficially, consistent with this theory. Children in the sleep intervention group had slightly increased Emotion Regulation and Positive Regulation alongside decreased Emotional Lability. Notably, the intervention had no effect on Dysregulation.

is possible that intervening variables including poor social skills might mask the impact of a short-term sleep intervention on Dysregulation.

These data fail to reach statistical significance, as is to be expected for a preliminary trial in which the number of subjects is quite small and data collection is ongoing. Nonetheless, average changes in emotion regulation scores between the two groups are consistent with the hypothesis that a 1 month sleep intervention may increase positive and adaptive emotion regulation behaviors in children, as well as reduce maladaptive behaviors (i.e. negative lability). On average, the treatment had no effect on Dysregulation. The changes indicated (**Figure 1**) are small, no more than one point on the survey in most cases. Nonetheless they are grossly consistent with the hypothesis that sleep intervention increases adaptive emotional behaviors and reduces lability.

Preliminary Actigraphy findings raise questions about individual differences in the impact of the SHIP intervention. The average difference in daily sleep duration from the preintervention phase to the post-intervention phase was less than 10-minutes in each individual case, with some intervention subjects actually reducing their average daily sleep duration by as much as 41 minutes. Although these variations between subjects were not found to correlate to changes in any of the ERC subscale scores, it does raise questions about whether a more significant change in average sleep duration may have a more robust effect on emotion regulation. Additionally, none of the subjects involved in this study had an average sleep duration less than 9 hours prior to intervention, as measured by actigraphy. It is possible that there is a ceiling effect at play and that children experiencing more dramatic insufficient sleep would respond more strongly to the sleep intervention. Importantly, sleep efficiency, sleep onset latency and other measures of sleep quality were not included in this analysis and therefore cannot be presented at this time. A comprehensive analysis of all of the Actigraphy variables will be reported at the completion of this study, when data on all subjects have been obtained. Further evaluation with a larger sample size and more robust analysis of Actigraphy data will help to clarify potential areas for further development of the sleep intervention.

Due to the small scale of this study, at the present time no broad conclusions can be drawn; however, these data are promising and reinforce the need for further research in this area and a possible extension of this study protocol. Further subjects are currently in the process of completing the study (total target sample size, n=25) and these data will be updated when the full protocol is completed.

There are data available to suggest the neurobiological basis for these observations. Experimental sleep-deprivation in adults is correlated to greater activation of the amygdala in response to aversive stimuli and interestingly, these subjects also had significantly less connectivity between the amygdala and the regulatory regions of the medial prefrontal cortex, with significantly increased connectivity between the amygdala and the autonomic system¹⁸. In essence, this means that the medial prefrontal cortex could not exert its usual regulatory control over activation of the amygdala, which is involved in anger and fear responses while the propensity for emotional stimuli to activate a fight-or-flight response is enhanced. This is particularly relevant as children are still actively developing their neuronal networks. If similar neurobiological phenomena are occurring in children experiencing insufficient sleep, it is plausible that synaptogenesis and myelination of these pathways could be impacted.

As previously noted, data collection for this study are ongoing and this analysis represents only a portion of the many measures being collected for these subjects. As more subjects complete the protocol, subsequent analyses of this relationship between sleep extension and parent-reports of emotion regulation will have more statistical power. Additional measures including MRI data and behavioral assessments, which have been collected but are not available for analysis at the time of this writing, will allow for more objective analysis of emotion regulation and possible underlying physiological mechanisms in early childhood. Having said this, the findings presented here are encouraging, given that near-significance was achieved even with subjective measurements of emotional regulation in a small sample of children.

Conclusion

The findings of this preliminary study to date reinforce the body of literature indicating a link between emotional regulation and sleep. As previously noted, these data are not sufficient to unequivocally affirm the hypothesis, but given the small sample size the results are promising. This study suggests that extending sleep may help improve emotion regulation in children who have experienced chronic insufficient sleep. This is encouraging as it suggests that sleep interventions and public education about the importance of adequate sleep in childhood may someday give rise to evidence-based preventative measures to reduce the prevalence of emotional problems in young children and, foreseeably, the prevalence of emotional problems in the general population.

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