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Weighted Blankets and Sleep Quality in Children with Autism Spectrum Disorders: A Single-Subject Design

Abstract

Purpose: The purpose of the single-subject study was to explore the possible relationship between weighted blanket applications and sleep quality in children with autism spectrum disorder (ASD) and behavioral manifestations of sensory processing deficits.

Method: Two 4-year-old participants diagnosed with ASD who also experienced sleep disturbances took part in a single-subject design study. Objective sleep measures and caregiver surveys were tracked for a baseline period of 7 days followed by a 14-day weighted blanket intervention and a 7-day withdrawal phase.

Results: Caregiver reports and objective data were evaluated using visual analysis and the percentage of non-overlapping data methods. The results suggest minimal changes in sleep patterns because of the weighted blanket intervention. Findings included using a weighted blanket intervention enhanced morning mood after night use and a significantly decreased time to fall asleep for one participant.

Conclusion: The converging evidence from a small but growing literature base indicates that weighted blankets may not strongly influence sleep quality in some children with ASD and sensory processing deficits who demonstrate increased sleep disturbances. Future directions include studies replicating the single-subject design with increased participants and updated outcome measures.

Comments

The authors report no potential conflicts of interest.

Keywords

weighted blankets, sensory-based interventions, autism spectrum disorder

Credentials Display

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Autism is a prevalent disorder with 1 out of every 59 children in the United States diagnosed with autism spectrum disorder (ASD) (Center for Disease Control and Prevention [CDC], 2017). The prevalence of this disorder is similar in other developed countries (e.g., Asia, Europe, and North America) with an average prevalence between 1%–2% (CDC, 2017). ASD has been ranked among 1 of the 20 leading causes of disability for children 5 years of age and younger (Baxter et al., 2015). Globally, statistics provided by the World Health Organization (2019) indicate that 1 in 160 children has ASD.

A common challenge faced by individuals with ASD is sleep disturbances (i.e., difficulty falling asleep, staying asleep, lack of deep sleep, decreased sleep duration) (Humphreys et al., 2014; Tumiran et al., 2013). Humphreys and colleagues (2014) reported that children with ASD between 2.5 and 11 years of age slept 17–43 min less per night than their typically developing age-matched peers. Moreover, decreased sleep quality was found to be most pronounced between 18 and 42 months of age. Sleep duration for children with ASD in this smaller age range was shortened because of sleep latency, frequent night wakings, and earlier risings (Humphreys et al., 2014). Malow and colleagues (2006) found that children with ASD who slept poorly showed an average decrease in rapid eye movement (REM) sleep and an increase in non-rapid eye movement (NREM) of sleep Stages 3 and 4 (Stage 1, light sleep; Stage 2, deep sleep preparation; Stages 3 and 4, REM/deep sleep [Younes et al., 2018]). Findings from this body of research suggest that sleep disturbances in children with ASD exacerbates behavioral problems during the day (Malow et al., 2006). In addition, caregivers of adult children with ASD indicated that sleep disturbances exhibited in children as youth persist into adulthood (Tumiran et al., 2013).

The profession of occupational therapy in the United States includes sleep and rest as a part of its scope of practice (AOTA, 2014; 2017) and emphasizes approaches to improve sleep preparation and participation (Fung et al., 2013). Occupational therapists often assist children with ASD by implementing a therapeutic goal targeting adequate sleep via experimenting with different sleep routines, cognitive and behavioral interventions, and/or sensory-based interventions (Foitzik & Brown, 2018; Picard, 2017).

While sleep disturbances are commonplace in children with ASD, there is minimal empirical evidence that examines potential interventions to enhance sleep quality using sensory-based interventions (Gee et al., 2016; Gringras et al., 2014). Parents and caregivers often seek strategies to increase the quality and duration of sleep for their children with ASD (Autism Speaks, 2019; Goldman et al., 2012). Some of the occupational therapy literature has described applying sensory-based intervention to influence a child's level of arousal, behavioral organization, and on-task behavior (Bodison, 2018). One potential sensory-based strategy to enhance sleep patterns in children with ASD is the use of a weighted blanket (Bodison, 2018; Gee et al., 2016).

Sensory integration theory (Miller et al., 2007a; Schaaf & Anzalone, 2001) posits that deep pressure sensory stimulation may create calming effects as a result of the modulation of the central nervous system. Specifically, deep pressure touch influences reticular formation activity and autonomic nervous system function (Fernandez-Gil et al., 2010). Deep pressure touch provided via weighted blankets are believed to offer a feeling of safety, comfort, and being grounded (Chen et al., 2011; Mullen et al., 2008). In some cases, weighted blankets have been used to help individuals stabilize and modulate responsiveness to sensory input to lower anxiety (Mullen et al., 2008) and levels of arousal,

decrease impulsivity, increase attention to tasks, and decrease maladaptive internalizing emotions (Reynolds et al., 2015).

Another facet of sensory integration theory is sensory responsiveness. Schaaf and Anzalone (2001) describe sensory responsiveness as the ability to receive, organize, and interpret sensory stimuli across multiple sensory domains and systems including oral, visual, tactile, vestibular, proprioceptive, auditory, and interoception. Therefore, sensory responsiveness is “the ability to regulate the response to sensory input” (p. 277). Sensory over responsiveness (SOR) is a subtype of sensory processing disorder where the child or individual responds to a cluster of sensations in an extreme or exaggerated manner (Miller et al., 2007b). Reynolds, Lane, and Mullen (2015) found that children with ASD and SOR had more difficulties with sleep compared to children with ASD only.

Shochat et al. (2009) and Vasak et al. (2015) hypothesized that increased sleep disturbances may be associated with increased sensory sensitivity because of a low neurological threshold and use a passive self-regulation strategy (Dunn, 2007). However, when considering the continuum of sensory responsiveness, it is likely that sensory sensitivities are not as severe as SOR (Dunn, 2007; Kirby et al., 2018). More specifically, Vasak and colleagues reported that infants and toddlers demonstrating low neurological threshold required a longer time to settle in order to fall sleep. There is also evidence that links patterns of similar sensory sensitivities with restless behavior and difficulty falling asleep among typical school-age children (Shochat et al., 2009) and adults (Engel-Yeger & Shochat, 2012). This line of evidence is consistent with Foitzik and Brown (2018), who reported some children with and without a diagnosed behavioral or medical condition experience sensory processing related disturbances that also affect their sleep quality.

The evidence for weighted blanket interventions is accumulating with a range of potential applications. Chen and colleagues (2011) investigated the effects of deep pressure touch through a weighed blanket application during routine teeth cleaning in a sample of 15 women without neurological diagnoses. Physiological measurements were collected to monitor for signs and symptoms of anxiety during a dental procedure. The authors objectively measured electrodermal activity and heart rate variability to track autonomic nervous system function. The weighted blanket intervention (blankets were customized to be 10% of the participants’ body weight) had a calming effect on participants during routine dental cleanings (30 min in duration). All participants self-reported mild to medium anxiety during the pretesting phase and yet all reported no anxiety during the treatment (application of the weighted blanket intervention) and posttreatment (withdrawal phase). Physiological measurements corroborated the self-reported perceptions as evidenced by lower normalized heart rate post intervention (0.86 ± 0.11 , $p = 0.001$) and electrodermal response post intervention (0.73 ± 0.25 , $p = 0.009$). In accordance with sympathetic and parasympathetic nervous system functions, lower heart rate and normalized skin conductivity levels were demonstrated during the weighted blanket intervention (Chen et al., 2011).

Studies of weighted blanket interventions for children with ASD are emerging in the literature. Gringras and colleagues (2014) conducted a study with 73 children 5–16 years of age with ASD who had a concomitant report of a sleep disturbance by a caregiver in the previous 5 months. The authors implemented a crossover design toggling weighted blanket application for 2 weeks with a non-weighted blanket. The primary outcome was total sleep time as measured by an actigraph (a wearable device like a watch that continuously measures sleep parameters). Gringras and colleagues’ primary finding for children with a wide range of ASD severity levels was that weighted blankets were not any more

effective than a typical blanket in helping children with ASD improve their total sleep quantity ($t(52) = 0.996, p = .324$).

Despite the finding of no difference between weighted and unweighted blankets, Gringras and colleagues (2014) found that parents and participants reported an improvement in next-day behaviors using a subjective questioner and sleep diaries analyzed via Wilcoxon signed rank test ($ts = 4.763, n = 67, p = .001$). Gringras and colleagues hypothesized that an improvement in next day behaviors may have been because of improved bedtime behaviors (i.e., routines), other study aspects that may have improved overall parent and child interactions, parents wishing to please the study team, or that the parents observed improvements that the objective measures were not sensitive enough to capture.

Gee and colleagues (2016) implemented a 4-week weighted blanket intervention using a single subject ABA design and found minimal changes in sleep duration and morning mood via caregiver report. Gee and colleagues examined whether weighted blankets have had a positive impact on improving time to fall asleep, the number of wakings, duration of sleep, and morning mood for two children with ASD and SOR. Using visual analysis of caregivers' perceptions, the overall findings demonstrated minimal improvement of the measured constructs related to sleep quality. Both of the participants exhibited some evidence of an increase in total amount of sleep per night as well as a slight decrease in time to fall asleep. However, morning mood did not consistently improve with the use of the weighted blanket for either participant, or the study (Gee et al., 2016) lacked a dependent variable that was more objective in tracking sleep activity outside of parental report.

There is limited research available exploring the efficacy of weighted blanket interventions with preschool-aged children with ASD, SOR, and sleep disturbances. The purpose of the current study was to assess weighted blanket application during sleep for young children with ASD with tactile and auditory behavioral manifestations of SOR who experience difficulty with falling and staying asleep.

Method

Design

The current study implemented an ABA research design with pre and posttest phases (Portney & Watkins, 2015). The pretest phase consisted of the participants' caregivers completing subjective measures related to their child's sleep behavioral patterns and sensory processing preferences and challenges. The first phase of the study, labeled A(1) phase, lasted for at least 7 days. During the A(1) phase, the participants' caregivers completed a non-standardized daily caregiver survey that identified the time to fall asleep at night, duration of night sleep, number of times the child woke up during the night, and the child's morning mood (see Table 1). After completing the A(1) phase baseline measures, the participants transitioned to a 14-day weighted blanket intervention B phase. Throughout the intervention B phase, the participants slept with a weighted blanket and the caregivers continued to complete the daily surveys. Following the completion of the B phase, the weighted blankets were withdrawn and the study transitioned into the A(2) post intervention withdrawal phase. During the A(2) withdrawal phase, caregivers continued to complete daily surveys for 8 days. See Table 1 for the research design.

Table 1*P1 and P2 PND Analysis of Daily Caregiver Survey*

Daily Caregiver Survey			
A1 Phase – Baseline	PND Baseline - Low	PND Baseline - High	PND Selected
P1 Time to Fall Asleep (min)	30	120	Low
P1 Sleep Duration	5	10	High
P1 Number of Night Wakings	0	5	Low
P1 Morning Mood	2	5	Low
P2 Time to Fall Asleep (min)	10	120	Low
P2 Sleep Duration	9	11	High
P2 Number of Night Wakings	0	1	Low
P2 Morning Mood	1	3	Low
B Phase – Intervention	Number of days < >PND HIGH	PND% out of 14 or 7 days HIGH	PND Interpretation HIGH
P1 Time to Fall Asleep (min)	3.00	21.43%	Ineffective
P1 Sleep Duration	0.00	0.00%	Ineffective
P1 Number of Night Wakings	0.00	0.00%	Ineffective
P1 Morning Mood	6.00	42.86%	Ineffective
P2 Time to Fall Asleep (min)	12.00	85.71%	<i>Effective</i>
P2 Sleep Duration	1.00	7.14%	Ineffective
P2 Number of Night Wakings	0.00	0.00%	Ineffective
P2 Morning Mood	0.00	0.00%	Ineffective
A2 Phase – Post Intervention	Number of days < >PND HIGH	PND% out of 14 or 7 days HIGH	PND Interpretation HIGH
P1 Time to Fall Asleep (min)	4.00	57.14%	<i>Questionable</i>
P1 Sleep Duration	0.00	0.00%	Ineffective
P1 Number of Night Wakings	0.00	0.00%	Ineffective
P1 Morning Mood	1.00	14.29%	Ineffective
P2 Time to Fall Asleep (min)	7.00	100.00%	<i>Effective</i>
P2 Sleep Duration	0.00	0.00%	Ineffective
P2 Number of Night Wakings	0.00	0.00%	Ineffective
P2 Morning Mood	0.00	0.00%	Ineffective

Method of Recruitment

This study was approved by the Idaho State University's Human Subject Committee. The study participants were recruited via brochures distributed by the first author and primary investigator (PI) to local pediatricians and pediatric occupational and speech therapists in the area. Interested caregivers contacted the PI directly to receive additional study details and ask questions. During the initial phone conversation, the PI asked several questions to determine eligibility (see inclusion criteria). If the participant met the inclusion criteria and demonstrated willingness to participate in the study, written informed consent was obtained. Informed consent was obtained prior to any participant beginning the study.

Inclusion Criteria

The study participants were required to meet the following inclusion criteria to participate in this study. The child needed to: (a) have a medical diagnosis of ASD, (b) demonstrate the behavioral manifestations of sensory over reactivity [*T*-score of 70 or higher on the Sensory Processing Measure-Preschool auditory and/or tactile subtests (SPM-P)] (Parham et al., 2007), (c) have qualitative ratings of “usually” (5 days per week) or higher in multiple aspects of sleep quality on the Children’s Sleep Habits Questionnaire (CSHQ) (Owens et al., 2000), and (d) be between 3 and 6 years of age. The caregiver needed to: (a) be able to report if the child had difficulty falling asleep and/or staying asleep, (b) speak English, (c) have daily access to a reliable internet connection during the study period, (d) be able to complete an online daily caregiver survey for 30 days, and (e) be able to implement a weighted blanket as part of the child’s sleep routine for 14 consecutive days.

Participants

The SPM-P (Parham et al., 2007) and CSHQ (Owens et al., 2000) were administered to ensure the participant met the inclusion criteria of the study. The SPM-P is a judgment-based rating scale to measure distinct sensory processing patterns (tactile, vestibular, auditory, visual, etc.), praxis, and social participation among preschool aged children (3–5 years of age). The SPM-P demonstrates internal consistency of 0.75 across all subdomains and demonstrates strong correlation to the Sensory Profile (Asher, 2014). The CSHQ is a judgment-based rating scale completed by caregivers to measure sleep habits in children 4–10 years of age. The measure has an internal consistency of .78 with sensitivity of 0.80. The classification accuracy of sleep disorders among the targeted age range is 80% (Asher, 2014; Owens et al., 2000).

Participant 1 (P1) was a 4 year, 5-month-old male with a reported diagnosis of moderate ASD that included a cognitive impairment. The findings from the SPM-P (Parham et al., 2007) caregiver report screener indicated a definite dysfunction in the behavioral manifestations of overresponsivity to tactile (*T*-Score of 70), auditory (*T*-Score of 78), and visual sensory (*T*-Score of 75) stimuli. The qualitative results from the CSHQ (Owens et al., 2000) caregiver report ratings indicated he demonstrated poor sleep quality as evidenced by difficulty falling asleep (“always” – 7 days a week), staying asleep (“always” – 7 days a week), wakes up too early (“usually” – 5 days a week), and experiences a poor morning mood (“usually” – 5 days a week).

Participant 2 (P2) was a 4 year, 1-month-old female with a reported diagnosis of moderate ASD. The findings from the SPM-P caregiver report screener indicated a definite dysfunction in the behavioral manifestations of over responsiveness to tactile (*T*-Score of 79), auditory (*T*-Score of 72), and visual sensory (*T*-Score of 70) stimuli. The qualitative results from the CSHQ caregiver report ratings indicated that she demonstrated difficulty staying asleep (wakes more than once at night [“usually” – 5 days a week]), wakes up too early (“always” – 7 days a week), and experiences a poor morning mood (“usually” – 5 days a week).

Dependent Variables

Daily caregiver surveys (delivered online via SurveyMonkey®) were completed throughout all study phases. The non-standardized survey consisted of six subjective questions assessing the participants’ sleep habits from the previous day and mood the morning the survey was completed. Each survey was completed by the caregiver based on their best recollection of the events of the prior night. The survey tracked the caregivers’ perceptions of their child’s sleep latency, number of naps, duration of naps, number of night wakings, sleep duration, and morning mood. Morning mood was operationalized

as feelings, varying in intensity and duration, and usually involving more than one emotion (Lane & Terry, 2000). In this case, the authors identified agitation and calm as one emotion related to mood. The assessment of morning mood (i.e., agitation and calm) allowed for the participants' caregivers to rate the current level of the child's agitation compared to the prior day using a 5-point Likert scale (more agitated, slightly more agitated, no difference, slightly calmer, and more calm).

The Sense (Hello Inc., 2015) sleep app was used in an attempt to objectively track variables, including the participant's overall quality, total hours of sleep, and number of hours of deep sleep. In addition, the Sense sleep app was used because of the low cost (\$150.00) with an eye toward feasibility of replication or in clinical practice. The Sense sleep app included a motion tracker called a "pill" that was attached to the participants' pillowcase or sheet at the head of the bed. The app exported data that were transmitted and stored from the pill and the base each morning. The base component of the tracker sat next to the bed and captured movement-related information from the pill attached to the participants' pillow or sheet. This commercially purchased device has not been used in any peer-reviewed literature. Because of the proprietary nature of the device, information related to reliability and validity of the device were unavailable.

Intervention

During the B phase of the study, the participants used weighted blankets for 14 consecutive nights. These weighted blankets were the SensaCalm® brand, custom made, and were provided by the PI. The weighted blankets were designed to be 10% of each child's body weight adhering to prototypical weighted blanket protocol (Mullen et al., 2008). The SensaCalm® blankets used for the study ranged from 3–7 lbs to accommodate the varying weights of potential participants and ranged in cost between \$40.00–\$80.00 USD. When the weighted blankets were provided, the caregivers were given instructions for how to use them safely and effectively. The caregivers were instructed to use the blankets only at night (i.e., not during naptime or quiet time); to use the blanket only if the child was able to remove it on their own; to cover the child's body, arms, and feet, but not their head or face; check on the child occasionally while using the blanket; adjust other bedding while using the weighted blanket to ensure the child was not too hot; and to contact the PI if the weighted blanket was showing signs of wear.

Method of Analysis

Data were analyzed through visual analysis (level, slope, and data point variability) of repeated measure graphs generated using Microsoft Excel, version 16, as described by Kennedy (2007). The use of visual analysis has been widely accepted as a mechanism to analyze data for single subject designs (Portney & Watkins, 2015). In fact, the literature supports visual inspection as the preferred method of analysis among single subject designs because it is sensitive and able to capture intervention effects that are significant to clinicians working outside research labs in the natural or typical context of clients (Brossart et al., 2006). Moreover, the visual analysis approach is preferred because it has lower error rates and is conservative enough to identify reliable treatment effects (Brossart et al., 2006).

In addition to visual analysis, this study used percentage of non-overlapping data ([PND]; Scruggs & Mastropieri, 2013) as an additional analysis tool. PND is a statistical method widely used in behavioral science research, particularly for analysis of the small data sets that are commonplace with single subject design studies. PND is calculated by identifying the most extreme data point in the baseline phase (either the highest or lowest value depending on whether the intervention is intended to reduce or increase a behavior). The PND is the percentage of data in the intervention phase, which fall above or below this point based on the intended outcome of the intervention.

Results

Visual Analysis

The initial step for data analysis for this study was visual analysis of the data plotted as a figure that composed of the scores and ratings from the outcome measures (daily caregiver survey and the Sense sleep app). The data were evaluated observing changes in level, slope, and variability in data points across each phase for the subjective and objective measures for both participants. Figures 1–4 represent the data from the caregiver survey (sleep onset latency, sleep duration, number of night wakings, and morning mood) and the data from the Sense sleep app (sleep score, sleep duration, and deep sleep) that were significant with the PND analysis (see Tables 1 and 2).

P1's caregiver reported increasingly negative morning moods during the A(1) phase followed by an increase in positive behaviors during the B phase. In the A(2) withdrawal phase, an increase in negative morning behaviors was reported compared to the A(1) phase. There may be two possible reasons for this. First, it may be that parents had a strong predisposition to study phase and were more sensitive to mood changes as the study phases progressed and particularly after the intervention was discontinued. Alternatively, during the 28-day process of tracking and reporting morning mood the caregiver may have become more sensitive to the severity or variations in morning mood behaviors. In addition to the caregiver reported changes in morning mood, there were notable changes from the Sense sleep app's recording of sleep duration. P1 demonstrated an increase in sleep duration up to 9–10 hr in the B phase compared to phase A(1) followed by an observed decrease to below 9 hr that switched to above 10 hr of sleep as phase A(2) progressed. Normative sleep data for typically developing children aged 3–5 years is an average of 11–12 hr per night (Paruthi et al., 2016; Tremblay et al., 2017). P1 demonstrated an approximate sleep duration of 9–10 hr with the weighted blanket intervention and 8–9 hr when it was withdrawn. In addition, a spike on day 6 and/or 7 was observed and may be attributed to treatment latency effect or environmental changes or demands that were not reported or observed by the caregiver.

Analysis of P2's data through visual analysis resulted in notable changes in the caregiver's reporting of sleep onset latency, the number of night wakings (see Figure 10), and reported morning mood. Changes were observed during the A(1) phase for sleep onset latency with a decrease in the time it took to fall asleep from a maximum of 120 min to less than 20 min. It is interesting to note that during the B phase, the time to fall asleep remained lower than the A(1) phase (between 60 and 15 min). In addition, time to fall asleep remained low (between 40–20 min) during the A(2) phase. P2's caregiver reported a highly variable frequency count of night wakings influencing the direction and slope of the trend lines. An increase in number of wakings occurred as the A1 phase progressed, but a flat trend line during the B phase was noted with no night wakings reported for the majority of the nights with the weighted blanket intervention. During the A(2) phase, however, an increased number of night wakings occurred (particularly between night 1 and 2). The final notable observation of the data was found in the caregiver's report of morning mood. The caregiver observed and reported behavior that was mostly typical for their child through the duration of the A(1) phase. During the B phase, P2's caregiver reported better than normal morning mood with the weighted blanket intervention followed by moods that are either more typical or difficult for the participant during the A(2) withdrawal phase. No other observable changes indicated that the weighted blanket was having an influence over the measures used to track sleep quality. Using the benchmark of 11–12 hr of sleep per night from a normative data sample in the literature (Paruthi et al., 2016; Tremblay et al., 2017) as a comparison, P2 appears to have

experienced increased variability of sleep duration across the study. P2's results included periods of sleep duration of 5–14 hr of sleep with the weighted blanket intervention and 3–11 hr when the weighted blanket intervention was withdrawn.

Figure 1
P1 Caregiver Reported Sleep Onset Latency

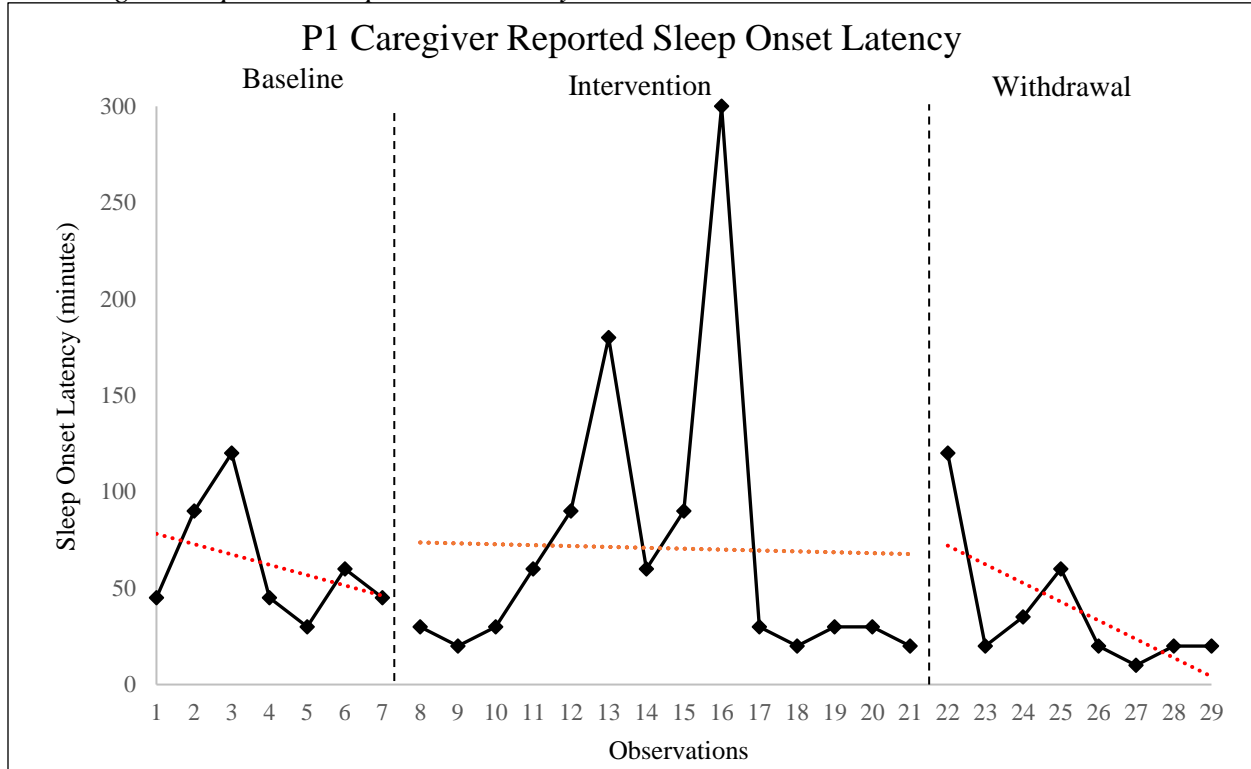


Figure 2
P2 Caregiver Reported Sleep Onset Latency

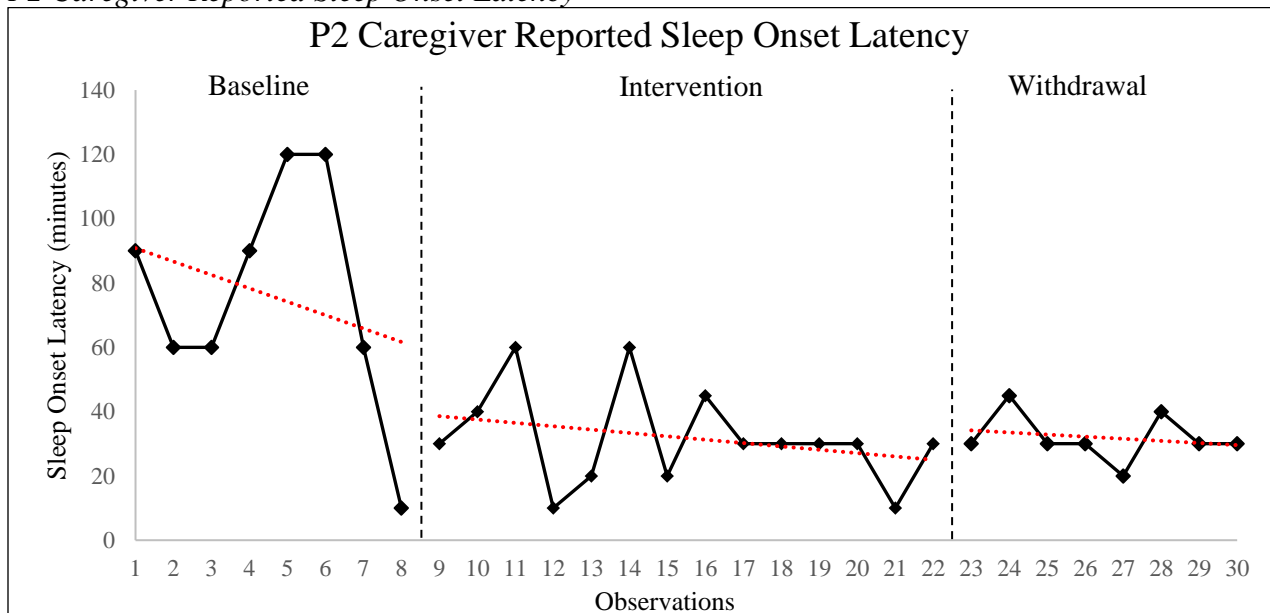


Figure 3
P1 Sense Sleep Deep Sleep Duration

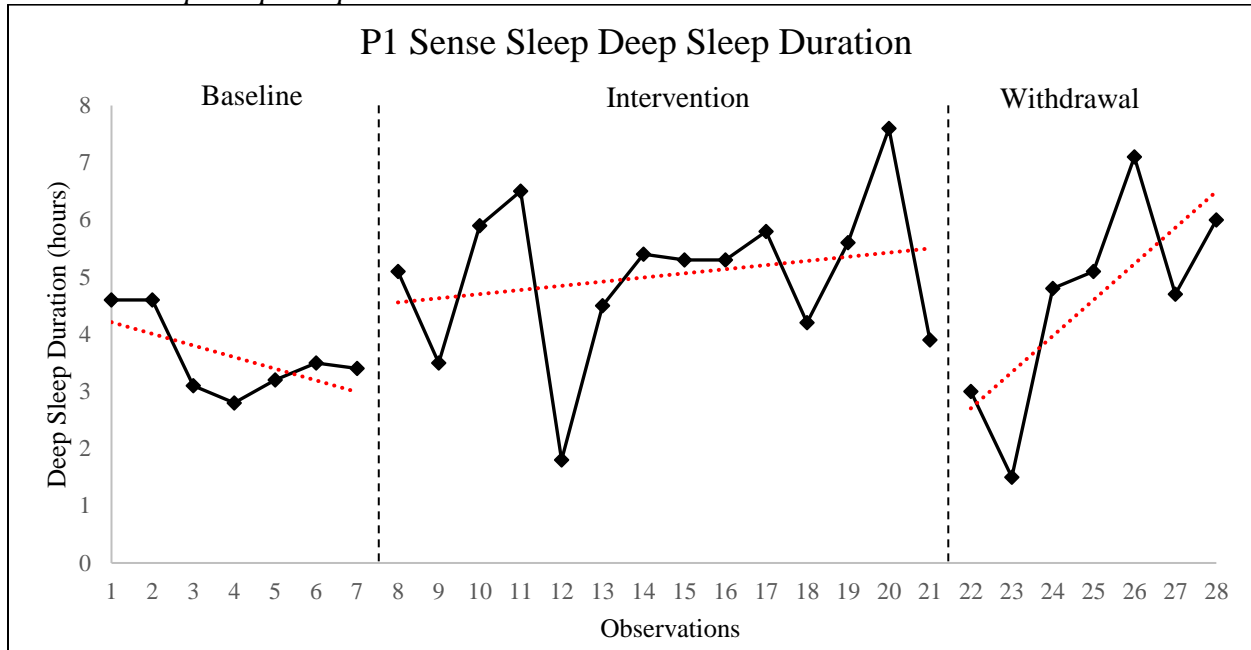
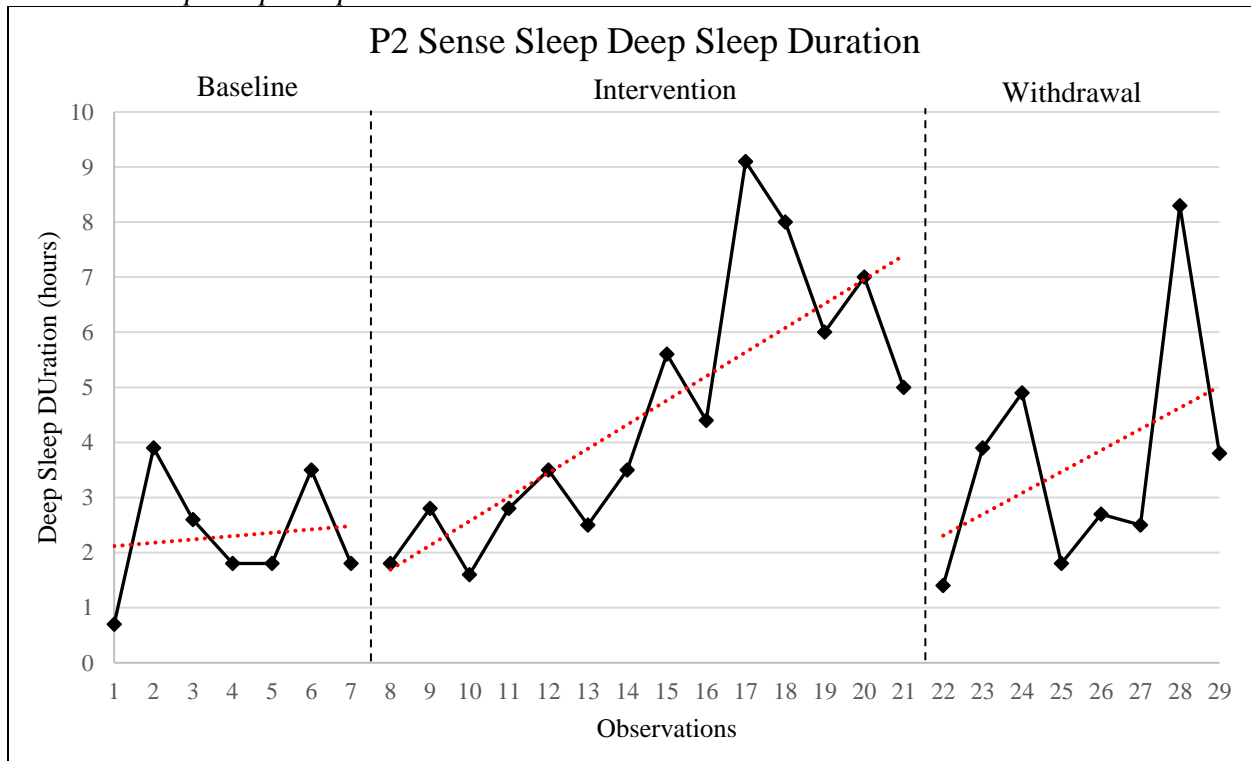


Figure 4
P2 Sense Sleep Deep Sleep Duration



Quantitative Analysis

The percentage of non-overlapping data (PND) statistic was used to assess treatment effectiveness. Scruggs and Mastropieri (2013) provide evaluative criteria for the implementation of this frequently used method of analysis for single-case research. The index of treatment effectiveness is

based on the percentage of non-overlapping data using the following criteria: PND \geq 90% = very effective, PND 70%–90% = effective, PND 50%–70% = questionable effectiveness, and PND $<$ 50% = ineffective. When applying these methods in the current study, the only factor categorized as effective was the time to fall asleep for P2.

Table 1*P1 and P2 PND Analysis of Daily Caregiver Survey*

Daily Caregiver Survey			
A1 Phase – Baseline	PND Baseline - Low	PND Baseline - High	PND Selected
P1 Time to Fall Asleep (min)	30	120	Low
P1 Sleep Duration	5	10	High
P1 Number of Night Wakings	0	5	Low
P1 Morning Mood	2	5	Low
P2 Time to Fall Asleep (min)	10	120	Low
P2 Sleep Duration	9	11	High
P2 Number of Night Wakings	0	1	Low
P2 Morning Mood	1	3	Low
B Phase – Intervention	Number of days < >PND HIGH	PND% out of 14 or 7 days HIGH	PND Interpretation HIGH
P1 Time to Fall Asleep (min)	3.00	21.43%	Ineffective
P1 Sleep Duration	0.00	0.00%	Ineffective
P1 Number of Night Wakings	0.00	0.00%	Ineffective
P1 Morning Mood	6.00	42.86%	Ineffective
P2 Time to Fall Asleep (min)	12.00	85.71%	<i>Effective</i>
P2 Sleep Duration	1.00	7.14%	Ineffective
P2 Number of Night Wakings	0.00	0.00%	Ineffective
P2 Morning Mood	0.00	0.00%	Ineffective
A2 Phase – Post Intervention	Number of days < >PND HIGH	PND% out of 14 or 7 days HIGH	PND Interpretation HIGH
P1 Time to Fall Asleep (min)	4.00	57.14%	<i>Questionable</i>
P1 Sleep Duration	0.00	0.00%	Ineffective
P1 Number of Night Wakings	0.00	0.00%	Ineffective
P1 Morning Mood	1.00	14.29%	Ineffective
P2 Time to Fall Asleep (min)	7.00	100.00%	<i>Effective</i>
P2 Sleep Duration	0.00	0.00%	Ineffective
P2 Number of Night Wakings	0.00	0.00%	Ineffective
P2 Morning Mood	0.00	0.00%	Ineffective

Table 2
P1 and P2 PND Analysis Sense Sleep App

Sleep Sense App Analysis			
A1 Phase – Baseline Testing	PND Baseline - Low	PND Baseline - High	PND Selected
P1 Sleep Score	58	85	High
P1 Sleep Duration	6.5	9.7	High
P1 Deep Sleep Duration	2.8	4.6	High
P2 Sleep Score	51	81	High
P2 Sleep Duration	3.3	11.7	High
P2 Deep Sleep Duration	0.7	3.9	High
B Phase – Intervention	Number of days < >PND HIGH	PND% out of 14 or 7 days HIGH	PND Interpretation HIGH
P1 Sleep Score	1.00	7.14%	Ineffective
P1 Sleep Duration	5.00	35.71%	Ineffective
P1 Deep Sleep Duration	9.00	64.29%	<i>Questionable</i>
P2 Sleep Score	3.00	21.43%	Ineffective
P2 Sleep Duration	1.00	7.14%	Ineffective
P2 Deep Sleep Duration	7.00	50.00%	<i>Questionable</i>
A2 Phase – Post Intervention Testing	Number of days < >PND HIGH	PND% out of 14 or 7 days HIGH	PND Interpretation HIGH
P1 Sleep Score	2.00	28.57%	Ineffective
P1 Sleep Duration	3.00	42.86%	Ineffective
P1 Deep Sleep Duration	4.00	57.14%	<i>Questionable</i>
P2 Sleep Score	2.00	28.57%	Ineffective
P2 Sleep Duration	0.00	0.00%	Ineffective
P2 Deep Sleep Duration	2.00	28.57%	Ineffective

Discussion

The purpose of this study was to assess weighted blanket application during sleep for young children with ASD with sleep difficulties and tactile and auditory behavioral manifestations of SOR. The findings for the two cases included in this report indicate that the weighted blanket application was a feasible treatment intervention but that it resulted in different sleep quality patterns for each participant. For P1 the total duration of sleep was increased, and for P2 there was a reduction in the time it took to fall asleep. Occupational therapy professionals working with children who have ASD, SOR, and sleep disturbances have options regarding intervention to support improved sleep quality. These interventions include sensory based (massage), sensory strategies (weighted items), environmental supports, modifications (lighting and sound modifications) (Bodison, 2018), and implementation or enhancements to sleep hygiene and routines (AOTA, 2017). Future studies are needed to assess the use of each of these specific interventions and the potential combination of interventions in order to enhance clinical practice guidelines.

Limitations

The participants were obtained through convenience sampling methods and were comprised of caregiver-child dyads who volunteered to take part in the study via recruitment brochures. Given that the findings originate from a small sample for pilot data and feasibility purposes, generalization of these

results is limited and tailored to individuals with co-occurring diagnoses of ASD and SOR. The results are preliminary in nature; however, they do align with prior findings from Gringras and colleagues (2014) and Gee and colleagues (2016) and demonstrate the feasibility of using weighted blanket interventions with a preschool age clinical population. An additional study limitation was the application of self-report measurement tools. The daily caregiver survey lacked psychometric analysis; however, a critical component of the current study was to provide caregivers an opportunity to offer sleep quality perceptions and rate their child's mood throughout the study. Though the survey ratings offered a caregiver-friendly approach, there may have been inconsistencies in how the caregivers evaluated each participant's sleep habits, particularly as the caregivers could not be blinded to the study phases.

The Hello Sense sleep app was a proprietary tool, and unfortunately, the researchers were not provided with its validity and reliability properties despite multiple requests. Several limitations with the Hello Sense sleep app, such as possible removal or dislodging of the tracking device from the pillow or sheet, may have impacted data collection. Furthermore, the tracking device was typically attached to the participant's pillow, yet if the participant left their bed to co-sleep with their parent, a gap in the data collection would be introduced. This highlights a challenge between finding an objective measure that can track sleep outcomes but not cause additional difficulty in the area of tactile SOR that could be caused by a wearable sleep tracking device. There is a need to replicate this study with different and potentially more reliable wearable sleep tracking devices appropriate for pediatric populations with tactile SOR.

A final study limitation included the length of each phase of the study. The total duration of the study was 28 days with 14 days of intervention, similar to Gringras et al. (2014), but it may not have been long enough to allow for possible functional or stable changes. The rate at which the participants habituate to having a new/weighted blanket may have been slower than what the study could have objectively or subjectively captured. In addition, the baseline phase lacked sufficient duration to ensure a stable baseline prior to the implementation of the intervention (weighted blanket). This limitation may point to a broader challenge for empirically evaluating sleep and sleep interventions, especially with children with ASD and SOR. A stable baseline might be very difficult to achieve because of the high level of variability in sleep patterns for this clinical population. Future studies may need to account for longer study durations in order to achieve stable baseline measurements prior to the intervention phase. Extending the baseline phase could impact study participation if a definitive timeline for the study duration could not be provided during the informed consent process.

Lessons Learned

From a preliminary standpoint, the current findings from this pilot study may generate positive perceptions that weighted blankets may improve sleep quality for young children with ASD. However, in addition to the reported study limitations, this study reveals a number of critical lessons to be considered when conducting single subject sleep related research among young children with ASD. The prominent issue with this study is the small *n* of two subjects. In addition to this, the lack of a stable baseline on the outset of the study further complicates how the results are interpreted. If this study is to be replicated or a study with similar methodology is planned using a weighted blanket intervention for young children with ASD, clinical researchers should consider the following strategies:

- Ensure the research design endorsed by a human subjects committee allows for flexibility in the baseline and intervention phases in order to achieve a stable baseline prior to the initiation of the intervention.

- Identify wearable technology that can aid in objective tracking of sleep quality parameters (e.g., heart rate variability), can account for movement, and provide options for children who may have a reduced tolerance for wearing a device while sleeping. At the time of publication, a few tracking devices are available for purchase at a relatively low cost (e.g., Garmin HR Jr.).
- Exploring sleep quality among young children with both ASD and behavioral manifestations of SOR entails a multifaceted approach. Future research could include: (a) a pre-study phase that helps to identify wearable technology that is amenable to the participant prior to study onset, (b) increase caregiver education and training to accommodate the unpredictable nature of achieving a stable baseline, (c) include a longitudinal component for caregivers who elect to continue the intervention following study completion, (d) expand the caregiver reported measure to include open-ended queries to supplement the caregiver reported ratings, and (e) increase the total number of participants (i.e., preschool, school-age, severity of ASD, and range of behavioral manifestations) to increase the potential for generalization of results.

Implications for Clinical Practice

Occupational therapists considering the use of weighted blankets should pay close attention to the underlying factors contributing to the child's sleep disturbances (behavioral, biological, environmental, sensory, cultural, etc.) and use those to guide clinical hypotheses of whether to trial weighted blanket use to improve sleep quality among children diagnosed with ASD and experience the behavioral manifestations of SOR. Historically, occupational therapy professionals prescribe weighted blankets, vests, etc., at 10% of the child's body weight, though there is no empirical data to support this practice. For this study it was difficult to determine if the weight of the blankets used were adequate, too light, or too heavy. Future studies could incorporate an array of weighted blanket options with a range of weights in order to address this open question in current clinical practice.

Occupational therapists should collaborate with a pediatric client's medical provider and caregiver to address potential underlying mechanisms of the reported and observed sleep disturbance (biological, behavioral, or sensory processing related). The converging evidence from this and other studies (Gee et al., 2016; Gringras et al., 2014; Reynolds et al., 2015) indicates that weighted blankets may be a feasible and caregiver-friendly intervention. However, using weighted blankets may not result in predictable increases in sleep quality with children who demonstrate increased sleep and sensory processing deficits (auditory and tactile domains) across the spectrum of ASD (mild to severe). Sleep disturbances (i.e., difficulty falling asleep, staying asleep, lack of deep sleep, decreased sleep duration) are commonplace for individuals with ASD (Humphreys et al., 2014; Tumiran et al., 2013), and additional studies are needed to examine the efficacy of weighted blanket interventions to increase sleep quality for the ASD population.

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