Effects of a Standardized Pamphlet on Insomnia in Children With Autism Spectrum Disorders

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KEY WORDS

sleep, education, actigraphy, sleep latency

ABBREVIATIONS

ASD—autism spectrum disorder
ATN—Autism Treatment Network
CSHQ—Children's Sleep Habits Questionnaire
SES—socioeconomic status

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abstract

OBJECTIVE: Sleep difficulties are common reasons why parents seek medical intervention in children with autism spectrum disorders (ASDs). We determined whether a pamphlet alone could be used by parents to help their child's insomnia.

METHODS: Thirty-six children with ASD, ages 2 to 10 years, were enrolled. All had prolonged sleep latency confirmed by actigraphy showing a mean sleep latency of 30 minutes or more. Parents were randomly assigned to receive the sleep education pamphlet or no intervention. Children wore an actigraphy device to record baseline sleep parameters, with the primary outcome variable being change in sleep latency. Actigraphy data were collected a second time 2 weeks after the parent received the randomization assignment and analyzed by using Student's *t* test. Parents were also asked a series of questions to gather information about the pamphlet and its usefulness.

RESULTS: Although participants randomized to the 2 arms did not differ statistically in age, gender, socioeconomic status, total Children's Sleep Habits Questionnaire score, or actigraphy parameters, some differences may be large enough to affect results. Mean change in sleep-onset latency did not differ between the randomized groups (pamphlet versus no pamphlet). Parents commented that the pamphlet contained good information, but indicated that it would have been more useful to be given specific examples of how to take the information and put it into practice.

CONCLUSIONS: A sleep education pamphlet did not appear to improve sleep latency in children with ASDs. *Pediatrics* 2012;130:S139–S144

Children with autism spectrum disorder (ASD) have a neurologic developmental disability with impairments in social interaction and communication that may also be accompanied by restrictive, repetitive, and stereotypical behaviors. Current statistics estimate that on average, 1 of 110 children in the United States have an ASD diagnosis.[1] Approximately 40% to 80% of parents of children with ASD report sleep problems compared with 9% to 50% of parents of typically developing children.[2–5] The most common reported parental concern is insomnia, defined as having difficulty falling asleep. Behavioral and pharmacologic interventions have been advocated to address these parental sleep concerns[6,7]

In an earlier study, we reported success in an open-label study of 20 children with ASD with parent-based sleep education workshops using a small-group format with 6 hours of education. Sleep-onset latency, measured by actigraphy, improved with treatment from 62.2 minutes to 45.6 minutes.[8] The objective of the current study was to further evaluate the efficacy of sleep education for parents of children with ASD within a controlled randomized clinical trial. The specific objectives were to determine if distribution of a sleep pamphlet, developed within a large autism patient network, could help parents assist their child to have better sleep. We believe that testing the efficacy of a pamphlet, before more interactive education, is important given the costs associated with providing interactive education. Educational pamphlets have been developed for other aspects of medical care for children with ASD, including phlebotomy.[9] Sleep pamphlets have been developed for infants and toddlers with typical development.[10] Our review of the literature did not identify an ASD-specific pamphlet for sleep.

METHODS

The study was conducted in parents and their children with ASD to determine the efficacy of parental use of a sleep education pamphlet to help their child improve sleep latency (time to fall asleep). The Autism Speaks Autism Treatment Network (ATN) is a network of 17 sites across North America dedicated to developing standards of care for children with ASD that includes standardized collection of data, such as autism diagnosis, diagnostic history, and comorbid conditions associated with ASD. The children were recruited for this study at 2 different sites, Vanderbilt University Medical Center and Cincinnati Hospital Children's Medical Center, by screening ATN participants whose parents reported prolonged sleep latency on the Children's Sleep Habits Questionnaire (CSHQ) (one of the standardized questionnaires in the ATN protocol). These parents were called to specifically ask if their child took at least 30 minutes to fall asleep on 3 or more nights a week, and actigraphy was used to verify parental report.

Participants and Study Criteria

Institutional review board approval was received at both sites. All parents of children with ASD provided informed consent. Study criteria included the following: (1) ages 2 to 10 years; (2) diagnosis of ASD, based on a interview that incorporated *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* criteria[11] with confirmation by the Autism Diagnostic Observation Schedule[12]; (3) sleep-onset latency (time to fall asleep) of at least 30 minutes on 3 of 7 nights a week based on parent report and confirmed by 14 scorable days of actigraphy showing a mean sleep latency of 30 minutes or more; (4) medication-free or on a stable dose of medications (no change within 30 days of enrollment in the trial) with parents agreeing to avoid changes in current medications or the start of new medications during the time of study participation; (5) ability for the child to tolerate actigraphy and willingness of parent(s) to complete the corresponding sleep diary; (6) English as the family's primary language as the pamphlet is in English.

All children were screened by a developmental pediatrician to exclude medical and behavioral comorbidities that affect sleep, including sleep apnea, epilepsy, gastrointestinal reflux disease, depression, anxiety, and attention-deficit/hyperactivity disorder. Those children found to have untreated comorbid conditions were excluded from the study.

Intervention: Sleep Education Pamphlet

The main study intervention was the provision of a sleep education pamphlet to parents. The pamphlet is 4 pages in length and written at an eighth-grade reading level. It is available at www.autismspeaks.org/atn. It was developed by the ATN Sleep Committee for use in ATN clinical settings. It includes information about 6 areas relevant to promoting sleep among children with ASD: (1) providing a comfortable sleep setting; (2) establishing regular bedtime habits; (3) keeping a regular schedule; (4) teaching your child to fall asleep alone; (5) avoiding naps (in children who have outgrown the need for a daytime nap); and (6) encouraging daytime activities that promote a better sleep/wake schedule.

At the end of the intervention, parents who received the pamphlet were asked for feedback about what was most useful about the pamphlet and what might have been more useful. The primary intent of asking this question was to ensure that parents had read the pamphlet; the secondary intent was to learn what the pamphlet might be contributing to help their child sleep.

Actigraphy and Sleep Diary Data Collection

Actigraphy is a low-cost, well-validated methodology for measuring sleep parameters, particularly sleep-onset latency, including change with intervention, in children with ASD.[8,13,14] The parental report of sleep latency of at least 30 minutes on at least 3 of 7 nights was confirmed using actigraphy devices for sleep data collection. All children wore the AW Spectrum Actiwatch device (Phillips Respironics, Bend, OR). The device was configured by using a 1-minute epoch with medium threshold, and a validated Mini-Mitter software (version 5.9, Phillips Respironics) algorithm was used to estimate sleep parameters, based on thresholds for wake and sleep, as described in previous work.[15–17]

Parents were introduced to the actigraphy device procedures via a structured training session that included hands-on demonstration with visual supports that include both graphic and descriptive details. Parents were required to demonstrate understanding of the methods by successfully completing a written examination regarding details of the actigraphy device and the accompanying daily sleep diary. Parents were asked to record sleep/wake details on the sleep diary each day of the trial and have their child wear the device for at least 21 days.

During the training session, the parent and child were introduced to the actigraphy device for placement on the nondominant wrist. Children who had difficulty tolerating the device on the wrist were allowed to use an alternate validated method, which consisted of placing the device on a nondominant shoulder location.[5,18]

Once the device placement procedure was established, the parents were given 2 devices and the corresponding daily diary forms to collect at least 21 days of continuous sleep data. The first device was programmed for 7 days of continuous data collection with parental instruction to mail the device to the site on the morning of day 8. The parent was instructed to place the second device on the child in the same manner (wrist or shoulder) on the morning of day 8 for collection of an additional 14 days of sleep data. Once the devices were received by the study investigators, the parents were contacted by phone and feedback was provided to parents regarding accuracy of sleep data collection and a report of the number of scorable days of the device and sleep diary data. All actigraphy data were uploaded to a database housed at the Vanderbilt site for centralized scoring, by a single individual, as a validity measure. As an additional validity measure, the centralized scoring staff member had no other contact with participants or their families.

Additional Study Measures

CSHQ

The total sleep score was derived from the CSHQ, a parental questionnaire describing sleep behaviors in children. The CSHQ has been validated in children ages 2 to 10 years[19] and has been used widely in the ASD literature.[20–22] Additional data documenting socioeconomic status (SES) (4-factor Hollingshead Index of Social Status) were collected to ensure that our groups randomized to the pamphlet or no pamphlet arm did not differ.[23] We also assessed the IQ for each child using the Stanford-Binet 5 or the Mullen Scales of Early Learning .

Randomization

Simple randomization stratified by age group (2–5 years and 6–10 years) and participating site were used to assign treatment groups. Stratification by age was done to ensure that no 1 age group was overrepresented in either arm of the study. Participants were assigned equally to the pamphlet or no-pamphlet groups.

Those parents who were randomized to the pamphlet arm received a copy of the pamphlet and were instructed to read it without further instructions from study staff. The staff did not answer questions regarding the pamphlet. Parents randomized to the no-pamphlet arm were notified that they would be receiving the pamphlet at the end of the study, after they had completed all study procedures. Two weeks after randomization, all parents were asked to have their child wear the actigraphy device and record on the daily sleep diary for an additional 2 weeks of postintervention (pamphlet versus no-pamphlet) data collection. All children wore the device for these final 2 weeks in the same manner (nondominant wrist versus nondominant shoulder pocket) that was tolerated in the initial weeks of actigraphy data collection. Once postintervention actigraphy data were received by the site, those parents randomized to the pamphlet arm were asked a series of questions to collect parent feedback on pamphlet use. Those parents randomized to the no-pamphlet arm received a copy of the pamphlet for review after receipt of their postintervention actigraphy.

Data Analysis

Data from the actigraphs were downloaded to a centralized computer where all sleep intervals were manually placed on the actogram for visual representation of the actigraphy data. The sleep measures of sleep-onset latency (primary outcome variable), total sleep time, sleep efficiency, and wake after sleep onset were calculated based on the recommendations of Buysse and colleagues.[24] Total sleep time was defined as actual time slept, which is the sum of all sleep epochs, measured in minutes, within the interval between the time set on the actogram for nighttime sleep and morning wake

time. Sleep-onset latency was defined as the number of minutes it took the child to fall asleep when the parent turned the lights out and expected the child to fall asleep. This time was documented by the parent using the device event marker and the sleep diary. Sleep efficiency was defined as percentage of total sleep time/time in bed. Wake after sleep onset was defined as the total time the child was awake during the night after the sleep-onset latency was excluded. Wake after sleep onset was measured as the sum of all wake epochs during the sleep period. Fragmentation index, which captures all movement regardless of the intensity of the movement, was also included, as previous work has shown an association with poor sleep continuity,[17] and in children with ASD. Fragmentation index is a measure of nocturnal movement that is calculated by using the following formula: (number of mobile epochs lasting 4 epochs + number of immobile epochs < 1 minute duration/number of immobile epochs > 1 minute duration) × 100. The participants in our study got out of bed for the day on awakening, with this time designated by the parent pushing the event marker and documenting this same information onto the sleep diary form. Wake after sleep onset did not include wake time in bed before the final arising and we did not encounter terminal wakefulness.

The primary analysis was to determine if change in actigraphically measured sleep-onset latency from baseline to treatment differed among participants randomized to the pamphlet versus no pamphlet study group. We also analyzed the change in sleep-onset latency for individual participants and compared this change between the 2 randomization groups (pamphlet versus no-pamphlet study group).

The study was designed to enroll 36 participants (18 subjects per arm) to provide at least 80% power to detect a difference in mean change in time to fall asleep of at least 30 minutes, assuming a common SD of 30 minutes using a 3-group *t* test with a .05 2-sided significance level and a 10% loss to follow-up rate. This 30-minute difference was chosen to represent a clinically meaningful result.

Secondary analyses were conducted to determine whether other actigraphic variables, including total sleep time, sleep efficiency, wake time after sleep onset, and fragmentation, differed among participants based on randomization. Finally, we wanted to confirm that actigraphy placement (wrist versus shoulder) did not affect change in sleep-onset latency with an intervention by examining differences between sleep-onset latency before and after intervention. Our previous published work had shown comparable results for the 2 devices worn simultaneously.

For the primary analysis, mean change in sleep-onset latency (baseline value – treatment value for each participant) between the 2 arms and the secondary analyses of mean change in total sleep time, sleep efficiency, wake time after sleep onset, and fragmentation (baseline value – treatment value for each participant) between the 2 arms were compared by using Student's *t* test. Independent analyses of the baseline characteristics and actigraphy placement were also conducted by using the Student's *t* test.

RESULTS

The study population consisted of 36 children, of whom 24 (67%) were male. The age of the children was 6.4 ± 2.6 years (mean ± SD). Eighteen participants were randomized to the pamphlet arm and 18 subjects were randomized to the no-pamphlet arm. Of the 16 children on medications, melatonin was the most commonly used (in 8 children). Other medications used were risperidone, aripiprazole, sertraline, lamotrigine, and fluoxetine. Demographics and other characteristics of our study population are listed in Table 1. All participants who were consented to the study were able to tolerate the actigraphy device.

There were no significant differences between the participants randomized to the 2 arms in terms of age, gender, SES, total CSHQ score, or actigraphy parameters ($P > .05$ for each comparison), although, as Table 1 indicates, some of these differences could have affected response to the intervention in the 2 groups. In addition, no significant differences were found for the change in sleep-onset latency across gender and age strata, and no significant correlations were found on sleep-onset latency in relation to SES score or total CSHQ score (data not shown).

In our primary analysis, subjects randomized to pamphlet or no-pamphlet based on treatment arm were compared. Mean change in sleep-onset latency did not differ between the randomized groups (pamphlet versus no-pamphlet). In addition, the mean change in total sleep time, wake time

TABLE 1 Demographics and Study Population Characteristics

	Intervention	Control
Age, y		
2–5	9	6
6–10	9	12
Male	10	14
Race		
White	15	14
African American	3	3
SES mean (SD)	34.0 (16.7)	41.1 (11.9)
Diagnosis		
Autism	16	13
Asperger's	2	4
PDD NOS	0	1
IQ mean (SD)	75.1 (25.5)	85.6 (27.1)
Medications[a]		
Psychotropic	5	9
Melatonin	3	3
Stimulants	2	2

[a] Some children were on more than 1 medication.

after sleep onset, and fragmentation did not differ between the randomized groups. The only sleep parameter that showed significance with randomized treatment was the mean change in sleep efficiency (Table 2).

Wrist Versus Shoulder Placement

The wrist placement was tolerated by 27 (75%) children, whereas 9 (25%) children required the shoulder placement. There were no significant differences between the wrist and shoulder placements for mean sleep-onset latency or any other actigraphically measured sleep parameters at baseline or treatment. Analysis of the mean change in sleep parameters from baseline to treatment, when compared across actigraphy placement (wrist versus shoulder) did not show significant differences.

Postintervention Feedback About the Pamphlet

Parents commented that the pamphlet was useful in that it contained good information, and cited specifics including "basic rules for sleep," and "importance of consistent bedtime." They indicated that what might have been more useful would have been to have more-specific ideas of how to take the information and put it into practice.

DISCUSSION

In this randomized controlled study in 36 children with ASD, the parents were randomized to receive a sleep pamphlet or no sleep pamphlet. We measured the actigraphy parameters of sleep-onset latency (primary outcome variable), total sleep time, sleep efficiency, wake after sleep onset, and sleep fragmentation before randomization procedures and again after the randomization procedures. We determined that the pamphlet alone, without further instruction for its use, appears insufficient to significantly improve the sleep patterns of children with ASD. Although sleep efficiency showed a statistically significant improvement, a 2-point improvement in sleep efficiency from 75% to 77% is unlikely to be clinically meaningful.

Our study has several strengths. First, we used a well-defined sample with precise diagnostic procedures to confirm the diagnosis of ASD. Second, we randomized parents to receive the pamphlet or no pamphlet, and included a series of questions to ensure that parents who received the pamphlet had reviewed its content. Third, sleep-onset latency was confirmed by the objective measure of actigraphy. Finally, our study was powered to ensure that we had a sufficient sample to determine a difference in mean change in sleep-onset latency of at least 30 minutes between the 2 groups. We recognize that this sample size assumes homogeneity within the groups and that the randomization did not achieve fully similar samples in the experimental and control groups. Thus, it is possible that our study findings were confounded by sample differences. Our small sample size did not permit controlling for these. We set a high bar for the pamphlet, especially given that in a previous study of group parent education, we achieved an improvement of only 17 minutes in sleep-onset latency.[10] We felt it was important, however, to determine whether the pamphlet was able to achieve a clinically meaningful difference, not only a difference consistent with results from a small pilot study, before moving forward with a larger parent education trial.

Study weaknesses included a small sample size that did not allow us to adjust for covariates including age, gender, and SES, although these variables were not significantly different in the 2 groups. We also recognize that children with ASD often have chronic and intractable sleep-related difficulties. They frequently resist changes in their routine and require incremental change for effectiveness. Therefore, a longer follow-up period than 2 weeks might have resulted in more improvement with the pamphlet; however, we were concerned that parents would get discouraged and implement additional treatments, including medications or more intensive educational programs that would confound our results. We also recognize that we could have provided the control group with a different intervention, such as a pamphlet on feeding issues to better blind the study participants.

We also showed that a shoulder placement for actigraphy can be used successfully in an interventional study. We previously published on reliability of shoulder and wrist placement in children with ASD[16] and others have shown similar results in typically developing children.[7] This alternative placement for actigraphy extends the population of children with ASD who can participate in studies using actigraphy. Such

TABLE 2 Group Differences in Pamphlet Versus No Pamphlet for Sleep Parameters

	Pamphlet (n = 19)		No Pamphlet (n = 17)		P value[a]
	Baseline Mean (SD)	Treatment Mean (SD)	Baseline Mean (SD)	Treatment Mean (SD)	
Sleep latency, min	56.7 (27.1)	49.5 (26.7)	52.1 (25.1)	61.3 (47.0)	.16
Sleep efficiency, %	75.5 (6.1)	77.8 (7.0)	76.8 (6.0)	75.1 (6.7)	.04
Wake after sleep onset, min	61.9 (27.4)	60.4 (32.1)	53.2 (20.2)	59.9 (24.2)	.22
Total sleep time, min	465.7 (66.3)	483.0 (67.8)	461.4 (42.4)	470.8 (35.3)	.55
Fragmentation, min	36.8 (9.0)	36.3 (10.9)	32.2 (7.2)	33.3 (7.5)	.52

[a] P values for the sleep parameters were based on paired t test comparing the mean change in the sleep parameter (baseline – treatment) for the 2 groups.

children may include those with tactile sensitivities or other aversions to wearing wrist devices. In this study, the use of the alternative placement allowed us to include participants who might otherwise have screen-failed. The number of children receiving the shoulder placement was small; future larger controlled trials will be necessary to confirm the ability of the shoulder placement to demonstrate change.

Although the pamphlet alone did not result in improved sleep in this sample, it and other educational materials may be worthwhile for parents of children with ASD. The comments that we received from parents illustrated that the pamphlet contained valuable information, but that the parents needed guidance in how to implement the information in the pamphlet for their individual needs. Therefore, it may be that the pamphlet, when given to a parent accompanied by guidance from a health care provider, may be more efficacious than we showed in this study. We are currently conducting a parent-based sleep education intervention to determine the impact of parent training on sleep in children with ASD.

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