

NIH Public Access

Author Manuscript

J Autism Dev Disord. Author manuscript; available in PMC 2015 January 01.

Published in final edited form as:

J Autism Dev Disord. 2014 January ; 44(1): . doi:10.1007/s10803-013-1866-z.

Parent-Based Sleep Education for Children with Autism Spectrum Disorders

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Abstract

This study provided sleep education to parents of children with autism spectrum disorder (ASD) to determine whether an individual or group format was more effective in improving sleep and aspects of daytime behavior and family functioning. Eighty children, ages 2-10 years, with ASD and sleep onset delay completed the study. Actigraphy and parent questionnaires were collected at baseline and one month after treatment. Mode of education did not affect outcomes. Sleep latency, insomnia subscales on the Children's Sleep Habits Questionnaire, and other outcomes related to child and family functioning improved with treatment. Parent-based sleep education, delivered in relatively few sessions, was associated with improved sleep onset delay in children with ASD. Group vs. individualized education did not affect outcome.

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There have been no changes in author affiliation subsequent to the time of study.

Conflict of Interest The authors declare that they have no conflict of interest.

Keywords

insomnia; actigraphy; Children's Sleep Habits Questionnaire; Repetitive Behavior Scale-Revised; Child Behavior Checklist

Sleep difficulties, particularly insomnia, are common reasons why parents seek medical intervention in children with autism spectrum disorders (ASD; Coury 2010). Approximately 50 - 80% of parents of children with ASD report sleep problems (Couturier et al. 2005; Krakowiak et al. 2008; Souders et al. 2009; Goldman et al. 2012). The most commonly reported parental sleep concern is sleep onset insomnia, which may be due to a variety of causes including neurotransmitter abnormalities (e.g., melatonin), medical conditions (e.g., gastrointestinal disturbance, epilepsy), psychiatric conditions (e.g., anxiety, resistance to transitions), or medications (e.g., stimulants, stimulating antidepressants) (Reynolds and Malow 2011). Behavioral causes of insomnia (e.g., poor sleep habits) have been less emphasized—however, the core behavioral deficits associated with ASD may impede the establishment of consistent bedtime behaviors and routines. For example, children with ASD may have difficulty with emotional regulation (e.g., ability to calm self) or transitioning from preferred or stimulating activities to sleep. Due to deficits in communication skills, children with ASD may not readily understand the expectations of parents related to going to bed and falling asleep. Adjusting the sleep environment to promote sleep and conveying sleep expectations in an effective way may be particularly challenging for parents of children with ASD dealing with multiple other priorities and stressors. Therefore, teaching parents of children with ASD to practice strategies which promote sleep represents an important avenue to improve insomnia in this population.

Impairments related to distrupted sleep in children are often acted out behaviorally (e.g, hyperactivity; Owens, 2009). In ASD, disordered sleep may exacerbate symptoms of autism, including social skills deficits, attention deficit/hyperactivity symptoms, and repetitive behaviors (Schreck, 2004; Gabriels, 2005; Malow, 2006; Goldman, 2011). Therefore, interventions to improve sleep in children with ASD have potential wide-ranging benefits.

Apart from improvements in a child's daytime behavior, family functioning may also benefit from improved sleep in the child. Sleep disturbance in children with ASD and other neurodevelopmental disorders has been associated with parenting stress (Richdale et al., 2000; Doo et al., 2006; Goldman et al., 2011), perhaps mediated by the quality of parent sleep. Parents of children with ASD have poorer sleep quality than parents of typically developing children (Lopez-Wagner et al., 2008; Meltzer et al., 2008), and the quality of a child's sleep predicts the quality of the mother's sleep (Meltzer et al., 2007). In turn, competence in a caretaking role is defined as perceived parenting self-efficacy, and has been related to parenting stress in mothers of children with ASD (Kuhn and Carter, 2006).

While a practice pathway advocates behavioral sleep interventions as an initial approach to insomnia in ASD (Malow et al. 2012), relatively few large-scale studies of behavioral sleep interventions have been performed, with most of the published literature consisting of case reports or case series. In particular, research is needed to determine which modes of sleep education are effective, easily accessible to parents, and cost-effective-- ranging from materials available for download from internet sites, to more formal individual and group education sessions. Group learning situations provide multiple interpretations of the shared experience, thereby enhancing the potential for learning that is more meaningful to each individual (Marienau and Segal 2006). Individualized learning situations provide more attention and coaching regarding the needs of the specific child/family.

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We previously published 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 (Reed et al. 2009). Sleep-onset latency, measured by actigraphy, improved with treatment from 62.2 minutes to 45.6 minutes. We carried out a subsequent controlled randomized clinical trial in 36 children with ASD to determine if distribution of a sleep pamphlet could help parents assist their child to have better sleep (Adkins et al. 2012). This trial did not show a benefit of the pamphlet over placebo, as measured by actigraphy. Parents reported that while the material in the pamphlet contained good information, they indicated that it might have been more useful to have specific ideas of how to take the information and put it into practice. Given these results, we proceeded with a randomized trial of individualized or group parentbased sleep education in 80 children with ASD in which parents met with a trained educator who followed a manualized curriculum. Our primary goals were to determine whether the group vs. individualized mode of education would be superior in reducing sleep-onset latency, as measured by actigraphy. Secondary goals were to determine if: (1) Additional measures of sleep, as measured by actigraphy or parent questionnaire, would show treatment-related improvements, and whether these improvements would be influenced by mode of education; (2) Measures of parent-reported outcomes in child behavior, quality of life, or parenting sense of competence would show treatment-related improvements, and whether these improvements would be influenced by mode of education; and (3) Parents found the educational sessions effective and whether they indicated a preference for group vs. individual education. We also performed a secondary analysis to examine whether sleep latency and questionnaire-based measures improved after treatment compared to baseline within our combined cohort (those receiving group or individual education). We interpreted our results in relation to our previously published findings from a cohort receiving a sleep education pamphlet.

Methods

The study was conducted among parents and their children with autism spectrum disorders (ASD) participating in the Autism Speaks Autism Treatment Network (AS-ATN). The AS-ATN is a network of 17 sites across North America dedicated to improving 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 three AS-ATN sites. Participants were screened from those enrolled in the AS-ATN to identify parents who reported prolonged sleep latency on the Children's Sleep Habits Questionnaire (CSHQ; Owens et al. 2000). These parents were called by telephone to ask specifically if their child took at least 30 minutes to fall asleep on three or more nights a week.

Institutional Review Board approval was received at all three sites. All parents of children with ASD provided informed consent. Study inclusion criteria included: (1) Ages 2-10 years. (2) Diagnosis of ASD, based on a interview conducted by a psychologist or developmental pediatrician with expertise in ASD that incorporated DSM –IV-TR criteria (American Psychiatric Association 2000) with confirmation by the Autism Diagnostic Observation Schedule (Lord et al. 2000). (3) Sleep onset latency (time to fall asleep) of at least 30 minutes on three out of seven 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. Children with other sleep difficulties (e.g., night wakings) were also included as long as difficulty falling asleep was identified as a problem by the parent. (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 on the part of the child to tolerate actigraphy and willingness of parent(s) to complete the corresponding sleep diary. (6) The

family's primary language being English as the sleep curriculum was written in English. (7) Screening by a developmental pediatrician to identify medical and behavioral comorbidities that affect sleep, such as sleep apnea, epilepsy, gastrointestinal reflux disease, and depression (Reynolds and Malow 2012). Those children found to have untreated cooccurring conditions were not enrolled into the study until after these co-occurring conditions were addressed. Our rationale for screening for these medical comorbidities was that it followed the established practice pathway within the AS-ATN (Malow et al. 2012), as these conditions can contribute to significant sleep disruption rendering behavioral sleep interventions less effective.

Randomization

Eligible participants were entered into a database managed by the Data Coordinating Center (DCC), the EMMES Corporation. The database software randomly assigned participants in a 1:1 block within each site to either group or individualized sleep education at the time of enrollment. The randomization was done in real time to allow the sites to notify the parents of their treatment assignment.

Study Intervention

The study intervention consisted of administration of a sleep education curriculum to parents by trained educators at each of the three sites. The curriculum was developed in pilot work (Reed et al. 2009) for a group setting and modified for individual sessions. The format and content of the sessions are presented in Table 1. Parents were randomly assigned to one of two interventions: a group education program (two 2-hour sessions conducted one week apart over two weeks with two follow-up phone calls) or an individualized program (one 1hour session with two follow-up phone calls). The rationale for greater hours in the group education session was to ensure sufficient time to address each family's needs as well as provide time for the families to interact with each other and the educator in discussing sleep challenges and strategies for improvement. Each site had one educator who conducted all parent education sessions using a manualized curriculum. An educational assistant helped the educator conduct the group sessions. All educators were trained in both sleep interventions and met fidelity criteria training using mock education sessions prior to providing the intervention. Education sessions were video recorded to assure that the sleep curriculum was being followed across all sites, with 73% of the sessions reviewed for fidelity by a single centralized independent rater. The fidelity criteria used to score each education session spanned four domains including session integrity, adherence to the manual, characteristics of the educator and educator interaction with parent. Fidelity was fully achieved in all sessions.

The group sessions ranged from 2-4 parents. The parent who put the child to bed on a regular basis was asked to attend; this parent was also asked to complete the baseline and treatment questionnaires. The content presented in the individual and group sessions was similar -- the major differences related to format. In the individual sessions, parents were engaged one-on-one with the educator. In the group sessions, parents interacted with each other as well as the educator to share successes and challenges with the curriculum and "pearls" they had gained from the sessions. In group sessions involving more than three parents, concurrent breakout sessions were used to ensure that parents received sufficient time and attention from the educator. While parents received education encompassing many aspects of sleep, the sessions also emphasized the sleep concerns relevant to the participants. To accomplish this, in preparation for the educational sessions, the educator targeted specific areas based on the parent's responses to the CSHQ and Family Inventory of Sleep Habits (FISH; Malow et al. 2009) (e.g., a child with sleep onset delay who was engaging in stimulating activities before bedtime). At the beginning of the session, the parent was asked

to state their major sleep challenge and what they hoped to achieve from the session to assure that the parent's identified sleep challenges were the focus of the session. The major areas covered in the sessions were:

- Sleep hygiene, including daytime and evening habits and the sleep environment
- Sleep amount/timing/regularity, including teaching parents that putting a child to bed too early to ensure that a certain number of hours of sleep is achieved may contribute to sleep onset insomnia).
- Bedtime routine, including completion of a worksheet labeling activities as stimulating or relaxing, and hard or easy for the child and ordering them into a schedule.
- Strategies related to minimizing bedtime resistance, night wakings, and cosleeping, including graduated extinction (having parents sit in a chair with their back to their children, limiting interactions, and gradually moving the chair closer to the door and out of the room) and the bedtime pass (laminated card that child surrenders to parents for visits during the night, similar to a token system), which we modified from the literature (Friman et al. 1999). We modified the bedtime pass protocol to include a reward in the morning if the pass was not used. In addition, we provided a social story about the bedtime pass and also individualized bedtime passes to the preferences of the child (e.g., favorite cartoon or video character).
- Homework, including a written datasheet to complete each night that included elements discussed in the session (e.g. strategies for bedtime resistance that were implemented).
- Educational phone calls-- the educator called the parents at one and two weeks to review homework and answer any questions the parents might have.

Actigraphy and Sleep Diary Data Collection

All children wore the AW Spectrum Actiwatch® device (Phillips Respironics, Bend, OR). The device was configured using a one-minute epoch with medium threshold, and a validated software algorithm (Phillips Respironics, Bend, OR) was used to estimate sleep parameters, based on thresholds for wake and sleep, as described in prior work (Kushida et al. 2001; Lichstein et al. 2006).

As carried out in prior work, our protocol was designed to maximize accuracy and consistency in the collection of actigraphy data through parent education and hands-on training, as well as feedback to parents based on an initial data collection phase (Malow et al. 2012). Parents were introduced to the actigraphy device procedures via a structured training session using a hands-on demonstration with visual supports that included both graphic and descriptive details. Parents were required to demonstrate understanding of the methods by successfully completing a written quiz regarding details of the actigraphy device and the accompanying daily sleep diary. During the training session, the parent and child were introduced to the actigraphy device for placement on the non-dominant 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 non-dominant shoulder location (Adkins et al. 2012).

Once the device placement procedure was established, the parents were given two devices and asked to complete sleep diary forms to collect at least 21 days of continuous sleep data. The first device was programmed for seven days of continuous data collection with parental instruction to mail the device to the site on the morning of day 8. Once the devices were received by the study investigators, the parents were contacted by phone, and feedback was

provided to parents to optimize accuracy of sleep data collection. The parent was instructed to place the second device on their child on the morning of day 8 for collection of an additional 14 days of sleep data. The 14 days of sleep data closest to randomization were used for analysis. Four weeks after the intervention was completed, all parents were asked to have their child wear the actigraphy device (and complete the accompanying sleep diary) for an additional 1-2 weeks of post intervention [average post-intervention collection period of 12.2 days (standard deviation of 3.1 days)]. In most participants, 2 weeks of actigraphy data were collected. The actigraphy watch was worn less than 2 weeks post-intervention in 31 children, with the most common reasons related to illness or watch-related issues (for example, the watch was either configured to stop data collection prematurely or the parent did not place the watch on the child at the appropriate time and therefore data collection stopped early). All of the available post actigraphy data was averaged for each individual participant. All children wore the device for this final post-intervention collection period in the same manner (non-dominant wrist versus non-dominant shoulder pocket) that was tolerated in the initial weeks of actigraphy data collection. 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.

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 standard recommendations (Buysse et al. 2006). 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. 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 efficiency 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.

Study Measures

Cognitive measures—To determine whether intellectual disability was present and ensure comparability of the groups, each child received a standardized cognitive/ developmental measure based on the child's clinical needs. This was part of the ATN protocol and was administered by a psychologist with expertise in ASD. The following measures were used: Mullen Scales of Early Learning (Mullen 1995), the full or abbreviated Stanford-Binet Intelligence Scales– 5th Ed (Roid 2003), the Bayley Scales of Infant and Toddler Development (Bayley 2005), the Differential Abilities Scale, Second Edition (DAS-II; Elliot 2007), or the Wechsler Intelligence Scale for Children, Fourth Edition (WISC-IV; Wechsler 2003).

Family socioeconomic status (SES)—SES was quantified using the Hollingshead Four-Factor Index (Hollingshead 1975). This tool includes the four factors of education, occupation, sex and marital status. The SES is calculated using a rating scale that correlates to points for the education and occupation of each employed parent living in the home.

Children's Sleep Habits Questionnaire (CSHQ) (Owens et al 2000)—The CSHQ is a validated parentally-completed questionnaire that has been used to examine sleep behavior in toddlers, preschool and school-aged children with a variety of conditions,

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including ASD (Goodlin-Jones et al 2008; Malow et al 2012). Subscales of the CSHQ measure insomnia-related dimensions such as bedtime resistance, sleep anxiety, sleep onset delay, sleep duration, and night wakings, as well as other dimensions such as daytime sleepiness, sleep disordered breathing, and parasomnias. The CSHQ was included because we felt that some of the domains it measured, such as bedtime resistance, were important aspects of sleep behaviors not captured by actigraphy. In addition, we wanted to ensure that we also measured insomnia-related dimensions captured by actigraphy from the parent perspective. The CSHQ was scored by applying a scale of 1-3 (1= rarely, 0-1 times a week; 2 = sometimes, 2-4 times a week; 3 = usually, 5-7 times a week) to each of the 33 questions on the CSHQ, following the recommendations of Dr. Owens (personal communication) and our prior work.

Family Inventory of Sleep Habits (FISH)—The FISH, developed by Malow and colleagues (2009) provides a quantitative scale of sleep habits, including bedtime routine, sleep environment, and parental interactions. It has been validated as a 12-item scale, although a full version contains 22 items (Reed et al. 2009). In prior work, the FISH has demonstrated improvement with a parental behavioral intervention.(Reed et al. 2009). A higher score indicates better sleep hygiene.

Child Behavior Checklist (CBCL)—The parentally-completed CBCL has two modules, one for ages 1 ½ to 5 years and one for ages 6-18 years (Achenbach and Rescorla 2001a, b). Several subscales are common to both modules although specific items differ. We selected subscales for analysis that were common to both modules and showed improvements in prior interventional studies (e.g., scales including anxious/depressed, withdrawn and withdrawn/depressed, attention, and DSM-Oriented Scales attention-deficit hyperactivity; Malow et al. 2011; Reed et al. 2009) A higher score indicates more difficulty with behavior. We analyzed our data using T-scores as these are used in clinical practice.

Repetitive Behavior Scale-Revised (RBS-R)—The parentally-completed RBS-R consists of 6 subscales (stereotyped, self-injurious, compulsive, ritualistic, sameness, and restricted behaviors) and a total scale (Bodfish et al. 2000). The RBS-R has been validated in children (Lam and Aman, 2007). We selected subscales for analysis that showed improvements in our prior interventional studies (e.g., stereotyped, compulsive, and restrictive behaviors). A higher score indicates more difficulty with behavior.

The Parent Proxy-Report of the Pediatric Quality of Life Inventory (PedsQL)— The parentally-completed PedsQL is a 23-item instrument designed for children ages 2-18 and encompasses four domains of functioning—physical, emotional, social and school with subscores for these domains as well as a total scale score and a psychosocial health summary score (Varni et al. 1999). The total score was used for analysis.

Parenting Sense of Competence Scale (PSOC)—The PSOC is a self reported 17item scale developed to assess parents' self esteem. Two subscales provide a measure of *s*elfefficacy, indicative of the parent's sense of his/her own problem-solving ability and capability as a parent, and a measure of satisfaction with parenting that reflects frustration, anxiety and motivation with the parenting role (Johnston and Mash 1989).

End of Education Session Survey—At the end of the education session, parents were asked to complete an anonymous survey. In this survey, they reported on a four-point scale (a) their general satisfaction with the program and the educator, (b) whether they would recommend it to others, (c) whether the program helped them improve their child's sleep habits, (d) whether they would have preferred the alternative (group vs. individual)

education program, and (e) how much they would be willing to pay out-of-pocket for the program.

Data Analysis

Actigraphy and questionnaires were compared at baseline and after intervention. Given that our main objective was to determine if one education strategy performed better than the other, the primary outcome variable and basis for power calculations, was change in sleep latency, as measured by actigraphy. Secondary outcome variables were change in sleep efficiency, wake time after sleep onset, and total sleep time (as measured by actigraphy). Additional outcome variables were the total CSHQ and insomnia-related subscales, and total FISH scores, which provided the parents' perspective of improvement. Additional outcomes of child behavior, quality of life, and family functioning (CBCL anxiety and attention subscales, RBS-R, PedsQL, and PSOC) were also compared at baseline and after intervention. When data were missing from questionnaires, subscales were calculated even if the total score could not be calculated.

Initially, baseline values between the two arms were compared for each actigraphic and questionnaire parameter using either independent t-tests (for continuous variables) or Fisher's exact tests (for categorical variables). The baseline comparisons of categorical variables of more than 2 groups used the Freeman and Halton (1951) extension of the Fisher's Exact test. The change from baseline in each parameter was calculated and compared for the two arms using independent sample t-tests. As the arms did not significantly differ at baseline or in change with treatment, for each parameter, paired t-tests were used to compare change scores combining both arms. Significance was set at p < 0.05 but adjusted for multiple comparisons (0.05/number of comparisons) for the primary analysis (change in sleep variables with intervention, as measured by actigraphy). As the secondary outcome measures were exploratory, significance was not adjusted for in the analysis, although we interpreted these conservatively. Via an anonymous survey compiled separately for the two arms, we examined parental satisfaction with the group vs. individualized sessions and whether they would select the alternative session if given the choice.

The sample size of 80 children was determined to have 99% power to detect a difference in the change in mean sleep latency of at least 30 minutes assuming that the common standard deviation is 30 (derived from our pilot data) using a two group t-test with a 0.05 two-sided significance level. This sample size also allowed us to examine secondary outcome variables.

Results

One hundred-fourteen participants were enrolled in the study, and 80 completed all study procedures. Of the 34 children who did not complete the study, they were unable to complete all study procedures for the following reasons: twelve parents withdrew because the protocol was too time-consuming; eight did not have their inclusion criteria of sleep onset latency of 30 minutes or longer confirmed by actigraphy, six children could not tolerate the actigraphy device, four children started new medications, and four parents chose to address behavior issues through other avenues.

Of the 80 children completing all study procedures, 41 participants were randomized to the individual arm and 39 subjects were randomized to the group arm. Six of the subjects randomized to the group arm received individual education instead of group education due to logistical issues with scheduling of sessions (e.g., after a group was scheduled some families needed to reschedule due to illness or other conflicts, and the investigative team felt

delaying parent education until another group was formed would be burdensome to the family). To account for potential bias introduced by switching educational arms in these six participants, actigraphy results were analyzed with and without these six participants and results were comparable. Therefore, we elected to present the actigraphy results including these six participants below. All participants who were randomized to the study were able to tolerate the actigraphy device. Demographics and other characteristics of the study population are listed in Table 2. There were no significant differences between the participants randomized to the two arms in terms of age, gender, race, SES, diagnosis, IQ, or medication classification (p-value > 0.10 for each comparison).

Actigraphy Results

Actigraphy results were compared for the primary outcome measure, sleep latency, and also for other commonly reported sleep parameters (sleep efficiency, wake after sleep onset, and total sleep time). None of the sleep parameters differed at baseline between the two arms. The change in sleep parameters with treatment did not differ between the two arms (Table 3). Given that the mode of parent education did not affect results, group and individual education results were combined and the change in sleep parameters before and after treatment was analyzed for the complete dataset (Table 4). Improvement was observed in sleep latency, with a combined mean (SD) reduction from 58.2 (29.1) minutes to 39.6 (21.4) minutes with treatment (p < 0.0001). In 36% percent of children after treatment, sleep latency was less than 30 min on 5 or more nights per week. Sleep efficiency also improved with treatment, although the change of 2.9% was clinically modest. Wake time after sleep onset and total sleep time did not improve with treatment.

Questionnaire Results-- CSHQ

Results of the CSHQ were compared initially between the two arms, with no significant differences at baseline. The change in CSHQ parameters with treatment did not differ between the two arms. Given that the mode of parent education did not affect results, group and individual education results were combined, and the change in questionnaire parameters with treatment was analyzed for the complete dataset (Table 5). Improvement was noted in all of the insomnia-related parameters. Of note, the subscales that would not be expected to improve with behavioral sleep education did not improve (e.g., sleep disordered breathing, daytime sleepiness), suggesting that parents were not answering indiscriminately that sleep difficulties had improved.

Questionnaire Results-- Behavior and Family Questionnaire Parameters

Results of other questionnaires (CBCL, FISH, RBS-R, PedsQL, PSOC) were compared initially between the two arms, with no significant differences at baseline. The change in questionnaire parameters with treatment did not differ between the two arms. As with the other analyses, given that the mode of parent education did not affect results, group and individual education results were combined and the change in questionnaire parameters with treatment was analyzed for the complete dataset (Table 6). Improvement was noted in sleep habits as well as behavioral parameters related to anxiety/depression, withdrawal, attention, repetitive behaviors, parenting efficacy and satisfaction, and pediatric quality of life.

End of evaluation

There were no differences between responses in the "end of evaluation" survey based on the mode of parent education. Parents reported a high level of satisfaction with the program and educator, with all agreeing the information covered was relevant and useful (75% of those in the group sessions and 86% of those in the individual sessions responding "strongly agree"). All agreed that they would recommend the program to others (83% of those in the group

sessions and 92% of those in the individual sessions responding "strongly agree"). In terms of improvement in sleep habits, 65% of those in the group and 65% of those in the individual sessions responding "strongly agree" with an additional 26% of those in the group and 26% of those in the individual sessions responding "agree." When asked if they would have preferred the alternative format (e.g., those participating in group were asked if they would have preferred the individual format and vice-versa), only 21% of those in the group sessions and 9% of those in the individual sessions stated that they would have preferred to receive the alternative format. When asked what they would be willing to pay for the program if not covered by research or insurance, those in the group session stated \$75 (37.7) on average (SD) and those in the individual session stated \$70 (38.8) on average.

Discussion

In this study, parents of 80 children with ASD were randomized to receive either individual or group education with a trained educator implementing a manualized curriculum. Both modes of education were delivered in relatively few sessions (one, 1-hour session for the individual education and two, 2-hour sessions for the group education). Both were followed by two brief follow-up phone calls and were relatively efficient in terms of educator time, with minimal parent burden. Mode of education (individual and group) did not differ in the effects of treatment on sleep parameters or behavioral measures, and parents stated they were satisfied with both modes of education. Improvements were observed in both sleep parameters and behavioral measures in the sample overall, with a combined mean (SD) reduction in sleep latency from 58.2 to 39.6 minutes with treatment (p < 0.0001). This improvement is substantial compared to a previous study conducted within the AS-ATN with comparable study criteria that provided either an educational pamphlet without formal teaching or no intervention in which the mean sleep latency went from 56.7 to 49.5 minutes with treatment in the pamphlet arm (p = 0.16) and from 52.1 to 61.5 minutes in the no pamphlet arm (Adkins et al. 2012). Our trial is the largest study performed to date of behavioral intervention for sleep in children with ASD. Previous studies have been largely limited to single case reports, or case studies, with only a few larger studies, as summarized in a recent review (Vriend et al. 2011). Apart from sample size and randomization to two discrete arms, our study has several additional unique strengths. First, we used a welldefined sample with precise diagnostic procedures to confirm the diagnosis of ASD. Second, we ensured that our sample has been screened for medical co-occurring conditions. Third, we included actigraphy as an objective outcome measure of sleep in addition to parent report, as these measures provide complementary information.

Parent sleep education was associated with improved aspects of child behavior (including repetitive behavior, a core symptom of ASD), pediatric quality of life, and parenting sense of competence. These findings are consistent with prior work and those of others showing that sleep interventions, including behavioral interventions and also treatment with supplemental melatonin, can contribute favorably to child and family health in ASD (Reed et al. 2009; Malow et al. 2012; Paavonen et al. 2003). The mechanisms whereby parent sleep education may improve daytime behavior require further study. One explanation is that improvements in sleep quantity are directly mitigating challenging behaviors, given that impairments related to disrupted sleep are often manifested behaviorally in children (Owens, 2009). For example, a child who is tired may not appear sleepy but instead have difficulty staying focused on a task. An alternative hypothesis is that the calming techniques that parents teach their children as a result of the parent sleep education program mitigate hyperarousal in the evening and promote more restorative sleep, with downstream benefits on daytime behavior. Evidence for this hypothesis is provided from the cortisol literature. Dysregulation of the cortisol rhythm, with diminished reduction of the expected fall in cortisol in the evening, has been observed in insomnia (Buckley and Schatzberg, 2005) and

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also in ASD (Corbett et al. 2008) in association with daytime stressors (Corbett et al. 2009). In turn, sleep fragmentation has been associated with higher morning cortisol levels and behavioral dysregulation (less inhibitory control) in children (Scher et al. 2010). Incorporating measures of sleep fragmentation beyond those provided by actigraphy, as well as biological markers of hyperarousal into future work will be necessary to determine how interventions that improve sleep in children with ASD may mediate improved daytime behaviors. Regardless of mechanism, a decrease in repetitive behaviors and improvements in attention has broad-reaching effects, as children may then be more amenable to therapies that enhance social communication. In a similar fashion, parents who experience a higher sense of parenting competence (satisfaction and efficacy) as a result of educational sessions may be more empowered to advocate for their children in other settings, such as individualized education programs in the school setting.

Both actigraphy and parent report measures related to sleep latency showed improvements with parent education. In contrast, night wakings and sleep duration were reported to be improved by parents after treatment, while actigraphy did not show improvement in wake time after sleep onset (WASO) or total sleep time. The reasons for these discrepancies are not clear. Our study was not powered to detect a significant difference in night wakings, and study criteria did not stipulate that night wakings be present for inclusion in the study. It is also possible that a parent's perception of a child's night wakings are different than the amount of wake time that a child with ASD experiences, especially if the parent is not alerted to the child's awakening. Furthermore, actigraphic measurements of WASO are based on movement, rather than actual waking, and prior work has indicated that actigraphy may have limitations in the detection of night wakings (Sitnick et al. 2008). Finally, interventions to improve night wakings may require multiple educational sessions to show improvements as compared to sleep onset delay. While parent-reported daytime sleepiness did not improve, sleepiness in young children may manifest differently than in older children or adults. As mentioned earlier, impairments related to sleepiness in children often are expressed in terms of challenging daytime behaviors rather than characteristic manifestations of sleepiness (Owens 2009).

Our study has several weaknesses. First, we did not include a control group (parents not receiving formal sleep education), instead randomizing parents to either group or individual modes of education. However, we had obtained data on the effects of sleep latency of either a pamphlet or no intervention in our prior work (Adkins et al. 2012). Our rationale for including these arms in our prior work rather than in the current study was that had the pamphlet shown clinically significant improvements in sleep latency, we would have not pursued the more time-intensive and personnel-intensive sleep education. It should be noted that the control data obtained in an earlier phase of our project were collected from a similar population of children with comparable study criteria (e.g., ages 2-10 years, participating in the AS-ATN, clinical diagnosis of ASD with confirmatory ADOS and screening for medical co-occurring conditions, and a sleep latency of at least 30 minutes on three out of seven 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). A second weakness is that while we performed fidelity checks to ensure that educators carried out the sessions in a consistent fashion and included all key points, we did not assess the extent to which parents implemented the education provided. We have begun measuring parent implementation through a series of open ended questions in our ongoing work. Third, while sleep measures included both objective (actigraphy) and subjective (parent report) variables, the behavioral variables were all based on parent report. In future work, objective measures of daytime behavior, such as the continuous performance test or formal neuropsychological assessments, will be important to document improvements in aspects of daytime behavior, such as attention. Fourth, our results reflect a cohort of families who made the commitment

to participate in a clinical trial, and therefore may have been more likely to comply with recommendations than those treated in a clinical setting. Finally, we recognize that while the group vs. individual modes of education did not differ in terms of actigraphy parameters, questionnaire results, or parent evaluations of the program, a much larger sample size would be required to determine if specific families may preferentially benefit from one mode of education compared to another (or if acceptability of the group vs. individual format might differ based on family characteristics). For example, the emotional support provided in a group setting by other parents of children with ASD might facilitate learning in a single parent who does not have the benefit of a supportive marital relationship.

Future work will also be needed to determine the role of sleep education in relation to pharmacological treatments for insomnia in ASD. While behavioral sleep interventions are considered a first line treatment for insomnia (reviewed in Malow et al. 2012), some families may have difficulty implementing educational strategies and pharmacological alternatives would be preferred. In these cases, implementing behavioral interventions in conjunction with pharmacological interventions may be more successful than either intevention alone, although further controlled studies will be necessary to establish this.

In summary, our work supports that parent sleep education is beneficial in improving sleep and aspects of daytime behavior and family functioning in children with ASD. Future work is needed to determine (1) the most efficacious and practical modes of providing sleep education to families, including those related to telemedicine and internet-based technologies, (2) the mechanisms that underlie these improvements, and (3) the role of sleep education in relation to pharmacological interventions in children with ASD.

Acknowledgments

We acknowledge the efforts of our study coordinators including Deborah Wofford, Amanda Wyatt, Harriet Austin, Bonnie Chan, Ester Hsueh, and Pam Green, educators Kim Frank, Kay Artibee, and Cathy Petta, and the families who generously participated in this project. This work was presented in part at the 2012 International Meeting for Autism Research, Toronto, Canada and the 2012 Meeting of Associated Professional Sleep Societies, Boston, Massachusetts.

Financial support: This research was conducted as part of the Autism Speaks Autism Treatment Network. Main support came from a cooperative agreement (UA3 MC 11054) from the U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Research Program, to the Massachusetts General Hospital. The views expressed in this publication do not necessarily reflect the views of Autism Speaks, Inc. or the Maternal and Child Health Bureau. Additional support was provided by CTSA award No. UL1TR000445 from the National Center for Advancing Translational Sciences. Its contents are solely the responsibility of the authors and do not necessarily represent official views of the National Center for Advancing Translational Sciences or the National Institutes of Health.

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Table 1

Parent Education Curriculum

1	Introducti	ons		1 Introductions			
2	Parent stat	tes major sleep cor	ncerns	2	Parents st	ate major sleep co	ncerns
3		nt presentation		3		nt presentation	
	a.		n with ASD do not sleep well		a.	•	n with ASD do not
	b.		successful sleep—sleepeducator ed on parent responses to the FISH		b.		ucational workshop
		and CSHQ	ed on parent responses to the 14511		о. с.	Components of	*
		i.	Daytime habits (e.g., caffeine, bedroom use, exercise)		ι.	i.	Daytime habits (e.g.,
		ii.	Evening habits (e.g., limit light, create calm routines)				caffeine, bedroom use, exercise)
		iii.	Sleep Environment (e.g., temperature, sound, light)			ii.	Evening habits (e.g., limit light, create calm routines)
		iv.	Bedtime routine (e.g., rituals, responses)			iii.	Sleep Environment (e.g., temperature,
	c.	Sleep needs for a	children (amount, regularity)				sound, light)
	d.	Timing of bedtir	ne (is bedtime is too early?)			iv.	Bedtime routine (e.g rituals, responses)
	e.	The importance	of bedtime routines		d.		children (amount,
	f.	Examples of visi	ual schedules			regularity)	
4	Complete	bedtime routines v	vorksheet		e.	Timing of bedtin early?)	me (is bedtime is too
5	Video illu	strating successful	bedtime routine	4	Breakout	session—sleep edu	ucators target areas
6	Constructi	ion of visual bedtin	ne routine		basedon parent responses to the F Half theparticipants meet with on		the FISH and CSHQ.
7	PowerPoint presentation			discuss sleephabits and environment while the other group meets with the educational assistant to			
	a.	Causes for sleep	resistance		discuss slo	eep amount,timing	, and regularity. After
	b.	Strategies for sle	ep resistance	_	15 minutes participantsswitch gro5 Complete bedtime routines works		0
	c.	Strategies to mir extinction paired	imize parent interactions(graduated l with rewards)	5		strating successful	
	d.	"Begin at bedtin	he" ⁴² discuss the importanceof	7	Construct	ion of visual bedti	me routine
		falling asleep ind		8	Complete	worksheet on slee	p resistance
	e.		keep interactions to aminimum, , use visualschedules, safety)	9	PowerPoi	nt presentationa	
	f.		limits parent interactions; provides		a.	Causes for sleep	resistance
		comfort and rein			b.	Strategies for slo	eep resistance
	g.	Early morning a waking; strategie	wakening (difference fromnight es to address)		с.		nimize parent duated extinction paire
8		e key recommenda			-	with rewards)	
9	Provide vi schedules		, bedtime passes and visual		d.	"Begin at bedtin importance offa independently	ne ^{"42} discuss the lling asleep
10	Distribute	and explain home	work	10	Summariz	ze kev recommend	ations Parents share 1
11	Confirm p	oost education phot	ne call appointments			s from the worksho	
				11	Provide v	isual supports (vis	ual schedule)
				12	Distribute	and explain home	ework

Individual Curriculum	Group Curriculum-1st Session
	1 PowerPoint presentation
	a. Goals for the workshop
	b. Review homework—presentation by each parentabout challenges and successes
	c. Reasons children with ASD do not sleep well
	d. Night wakings (keep interactions to a minimum, provide rewards, use visual schedules, safety)
	e. Bedtime pass ¹⁵ (limits parent interactions;provides comfort and reinforcement)
	 Early morning awakening (different fromnight waking)
	g. Ways to handle night waking (delay bedtime,eliminate naps, teach children what to do whenthey are awake, provide rewards
	2 Summarize key recommendationsParents share 1 or 2 pearls from the workshop
	3 Provide visual supports (bedtime passes)
	4 Distribute and explain homework
	5 Confirm post education phone call appointments

	Individual Education N = 47	Group Education N = 33	p-value
Age in years (SD)	5.6 (2.6)	5.9 (2.8)	0.59
Male	39 (83%)	25 (76%)	0.57
White ¹	37 (80%)	26 (84%)	0.77
SES mean (SD)	44.3 (13.5)	44.7 (10.6)	0.90
Diagnosis			0.64
Autism	32	26	
Asperger's	11	5	
PDD-NOS	4	2	
$IQ > 70^2$	27 (64%)	15 (45%)	0.16
Medication Type ³			0.99
Psychotropic	7	6	
Melatonin	7	5	
Stimulants	8	6	

 Table 2

 Demographics and Study Population Characteristics

SD = standard deviation

SES = socioeconomic status from Hollingshead Four Factor Measure of Social Status

 I Three participants did not provide racial information; percentages corrected for missing data

²Five participants did not have IQ information (not able to cooperate with testing); percentages corrected for missing data

 3 Some children were on more than one medication

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Table 3

Actigraphy Parameters --Individual vs. Group Comparison

	Indi	Individual	6	Group	p-value ^I
Sleep Parameter	Baseline (mean, SD)	Baseline (mean, SD) Treatment (mean, SD) Baseline (mean, SD) Treatment (mean, SD)	Baseline (mean, SD)	Treatment (mean, SD)	
Sleep Latency (min)	59.8 (31.6)	39.5 (21.6)	56.0 (25.2)	39.7 (21.5)	0.63
Sleep Efficiency, %	76.2 (6.2)	78.7 (5.1)	76.4 (8.0)	79.8 (6.0)	0.56
WASO (min)	63.8 (28.4)	59.3 (27.3)	60.4 (22.1)	58.3 (23.7)	0.37
Total Sleep Time (min)	486.9 (48)	481.1 (49.5)	482.4 (56.7)	488.3 (50.3)	0.37

SD = standard deviation; min = minutes, WASO = wake time after sleep onset

¹Comparison of individual vs. group education. The change in each actigraphy parameter from baseline to treatment was compared between groups (independent samples t-test).

	Table 4
Actigraphy Parameters-	Combined Comparison

		All Participants		p-value ¹
Sleep Parameter	Baseline (mean, SD)	Treatment (mean, SD)	Change (mean, SD)	
Sleep Latency (min)	58.2 (29.1)	39.6 (21.4)	18.6 (26.9)	< 0.001
Sleep Efficiency, %	76.3 (6.9)	79.2 (5.5)	-2.9 (5.0)	< 0.001
WASO (min)	62.4 (25.9)	58.9 (25.7)	3.5 (17.0)	0.07
Total Sleep Time (min)	485.0 (51.5)	484.0 (49.7)	1.0 (40.6)	0.82

SD = standard deviation; min = minutes, WASO = wake time after sleep onset

 I Comparison of change in actigraphy parameters in baseline and treatment phases (combining participants receiving group and individual education).

		All Participants		p-value ¹
Sleep Parameter	Baseline (mean, SD)	Treatment (mean, SD)	Change (mean, SD)	
Total Score	55.5 (8.1)	49.3 (8.2)	6.2 (8.0)	< 0.001
Sleep Onset Delay	2.7 (0.5)	1.8 (0.8)	0.8 (0.9)	< 0.001
Night Wakings	5.7 (1.7)	4.9 (1.7)	0.8 (1.6)	< 0.001
Sleep Duration	5.9 (1.8)	4.7 (1.7)	1.1 (2.2)	< 0.001
Bedtime Resistance	10.9 (3.6)	8.9 (3.1)	2.0 (2.6)	< 0.001
Sleep Anxiety	7.2 (1.9)	6.3 (1.8)	0.9 (1.6)	< 0.001
Parasomnias	10.0 (2.0)	9.6 (2.0)	0.5 (1.9)	0.042
Daytime Sleepiness	13.8 (3.1)	13.0 (3.1)	0.7 (3.3)	0.08
Sleep Dis. Breathing	3.6 (0.8)	3.5 (1.0)	0.1 (0.9)	0.39

 Table 5

 Children's Sleep Habits Questionnaire- Combined Comparison

Dis. = Disordered; SD = standard deviation

¹Comparison of change in CSHQ parameters in baseline and treatment phases (combining participants receiving group and individual education).

		All Participants		p-value ¹
Parameter	Baseline (mean, SD)	Treatment (mean, SD)	Change (mean, SD)	
CBCL Anxious/Depressed	59.9 (8.9)	57.7 (7.9)	2.2 (6.8)	0.006
CBCL Attention	65.2 (8.4)	61.9 (8.3)	3.3 (9.4)	0.003
CBCL ADHD	64.7 (8.5)	65.2 (8.3)	-0.54 (8.1)	0.56
CBCL Withdrawn	68.0 (10.5)	65.2 (9.5)	2.8 (8.5)	0.006
RBS-R Total	33.7 (19.4)	28.1 (16.3)	5.6 (10.8)	< 0.001
RBS-R Compulsive	4.8 (4.2)	4.0 (3.3)	0.79 (3.0)	0.023
RBS-R Restricted	4.5 (2.7)	3.6 (2.6)	0.86 (2.2)	0.001
RBS-R Stereotyped	6.1 (4.0)	5.2 (3.7)	0.91 (2.7)	0.004
FISH Total	45.5 (6.7)	50.2 (5.4)	-4.8 (5.1)	< 0.001
Peds-QL Total Score	61.6 (13.4)	66.9 (14.6)	-5.3 (10.3)	< 0.001
PSOC- Efficacy	28.4 (6.1)	30.4 (5.4)	-2.0 (4.6)	< 0.001
PSOC- Satisfaction	37.7 (8.6)	39.5 (7.4)	-1.8 (6.0)	0.011

 Table 6

 Behavior and Family Questionnaire Parameters- Combined Comparisons

CBCL = Child Behavior Checklist; ADHD = attention deficit hyperactivity scale; RBS-R = Repetitive Behavior Scale-Revised; FISH = Family Inventory of Sleep Habits; Peds-QL = Pediatric Quality of Life Scale; PSOC = Parenting Sense of Competence Scale.

¹Comparison of change in parameters in baseline and treatment phases (combining participants receiving group and individual education). For the CBCL and RBS-R, a higher score indicates more problems. For the FISH, Peds-QL, and PSOC, a higher score indicates fewer problems.