View metadata, citation and similar papers at core.ac.uk

brought to you by CORE

provided by Harvard University - DASH

DIGITAL ACCESS TO SCHOLARSHIP AT HARVARD
DASH.HARVARD.EDU

HARVARD LIBRARY
Office for Scholarly Communication

The development of a clinically relevant sleep modification protocol for youth with Type 1 diabetes.

The Harvard community has made this article openly available. Please share how this access benefits you. Your story matters

Citation	Perfect, Michelle M., Dean W. Beebe, Deborah Levine-Donnerstein, Sara S. Frye, Grai P. Bluez, and Stuart F. Quan. 2016. "The Development of a Clinically Relevant Sleep Modification Protocol for Youth with Type 1 Diabetes." Clinical Practice in Pediatric Psychology 4 (2): 227–240. doi:10.1037/cpp0000145.
Published Version	doi:10.1037/cpp0000145
Citable link	http://nrs.harvard.edu/urn-3:HUL.InstRepos:36642792
Terms of Use	This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Open Access Policy Articles, as set forth at http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#OAP

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

HHS Public Access

Author manuscript

Clin Pract Pediatr Psychol. Author manuscript.

The Development of a Clinically-Relevant Sleep Modification Protocol for Youth with Type 1 Diabetes

Michelle M. Perfect, Ph.D.[1], **Dean Beebe, Ph.D.**[2], **Deborah Levine-Donnerstein, Ph.D.**[3], **Sara S. Frye, M.A.**[1], **Grai P. Bluez, M.A.**[1], and **Stuart F. Quan, M.D.**[4,5]

[1]Disability and Psychoeducational Studies, University of Arizona, Tucson, AZ

[2]Department of Pediatrics, Cincinnati's Children's Hospital Medical Center, Cincinnati, OH

[3]Educational Psychology, University of Arizona, Tucson, AZ

[4]Arizona Respiratory Center, University of Arizona, Tucson, AZ

[5]Division of Sleep Medicine, Harvard Medical School, Boston, MA

Abstract

Findings from type 2 diabetes research indicate that sleep is both a predictor of onset and a correlate of disease progression. However, the role sleep plays in glucose regulation and daytime functioning in youth with type 1 diabetes mellitus (T1DM) has not been systematically investigated. Nonetheless, preliminary findings have supported that various sleep parameters are strongly correlated to health-related and neurobehavioral outcomes in youth with T1DM. This suggests that improving sleep might reduce morbidity. A critical step in developing evidence-based guidelines regarding sleep in diabetes management is to first determine that sleep modification in natural settings is possible (i.e., instructing youth to have a healthy sleep opportunity leads to more total sleep time) and that an increased sleep duration impacts disease and psychosocial outcomes in these youth. This article describes the background, design, and feasibility of an ongoing randomized clinical trial that aims to examine if increasing sleep relative to youth's own sleep routines affects glucose control and daytime functioning.

Type 1 diabetes mellitus (T1DM) affects approximately 1 in every 400 children and adolescents (American Diabetes Association, 2011). T1DM is an autoimmune disease whereby beta cells in the pancreas cease to produce of the insulin needed for natural regulation of blood sugar (glucose). In the absence of naturally secreted insulin, blood sugar levels are controlled by self-administration of exogenous insulin, adjustments for diet, and engagement in physical activity (Johnson, Perwien, & Silverstein, 2000; Haugstvedt, Wentzel-Larsen, Roken, & Graue, 2011). Well over 2/3 of youth with T1DM struggle to achieve optimal glucose control, placing them at enormous risk for morbidity (e.g., organ damage, blindness) and premature death (ADA, 2011; Johnson et al., 2000; Haugstvedt et al., 2011). Thus, a pressing need exists to develop innovative and sustainable approaches to improve glucose regulation in youth with T1DM.

Address correspondence to: Michelle M. Perfect, Ph.D., 1430 E. 2nd St., Tucson, AZ 85719, ; Email: mperfect@email.arizona.edu

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Diabetes and Sleep Insufficiency

Current recommendations for sleep duration are that school-age youth through age 13 should obtain 9–11 hours per night and older adolescents (14+ years) should obtain 8–10 hours of sleep per night for optimal health and wellbeing (Hirshkowitz et al., 2015). Tarokh, Carskadon, and Achermann (2012) demonstrated that adolescents have a biological need for at least nine hours of sleep per night. However, nearly 2/3 of youth fail to obtain the recommended sleep duration (Perfect, Levine-Donnerstein, Archbold, Goodwin, & Quan, 2014). Higher rates of sleep disturbances in youth with T1DM may be evident as early as the preschool years (Monaghan, Herbert, Cogen, & Streisand, 2012) and continue into adolescence (Caruso et al., 2014). With regard to sleep duration, studies have supported that high rates of inadequate total sleep time (TST) exist amongst youth with T1DM (Estrada, Danielson, Drum, & Lipton, 2012; Jaser & Ellis, 2016; Perfect, 2014). Although Monaghan found that the average TST (11.69 hours inclusive of naps) for 24 preschoolers with T1DM fell within the recommended range (10 to 13 hours), considerable variability existed and most children did not achieve the upper limit. Very few studies have reported objectively measured sleep duration in school-age youth with T1DM relative to those without diabetes; studies using polysomnography (PSG) revealed that youth with T1DM had shorter sleep duration than healthy peers/controls (Matyka, Crawford, Wiggs, Dunger, & Stores, 2000; Perfect et al., 2012; Pillar et al., 2003). Using actigraphy, we have previously reported that the average weekly sleep duration was less than seven hours for a sample of 10 to 16 year olds with T1DM (Perfect et al., 2012).

Despite some evidence of insufficient sleep, it is unclear whether sleep has a direct impact on glycemic control. One study (Jaser & Ellis, 2016) did not yield a significant correlation between TST and glucose control, but sleep quality and HbA1c were related among male adolescents. Our previous cross-sectional study supported that shorter sleep duration related to higher HbA1c levels in 10 to 16 year olds (Perfect, 2014). The mechanisms may be due to sympathetic activation, increased stress hormones (cortisol), or increased inflammation. Beyond the physiological underpinnings of shortened sleep, sleep insufficiency may impact adherence in diabetes management. Effective management of diabetes requires day-to-day decision making, emotional and behavioral regulation, attention, planning, comprehension, and memory (McNally, Rohan, Pendley, Delamater, & Drotar, 2010). Data from healthy populations have indicated that insufficient sleep has been associated with impairment in these skills (Dewald, Meijer, Oort, Kerkohof, & Bögels, 2010; Perfect et al., 2014; Steenari et al., 2003). In this regard, Jaser and Ellis (2016) did find a significant association between sleep duration and blood glucose checks.

Experimental Manipulation of Sleep

Despite the plausibility of sleep's role in glucose regulation and skills that foster adherence to treatment, the American Diabetes Association's (ADA, 2016) current standards of care in the management of T1DM are devoid of recommendations for sleep, most likely because of the lack of evidence demonstrating a causal relationship between better sleep and improved outcomes for youth with T1DM. In contrast, the potential impact of insufficient sleep on glucose and insulin sensitivity (body's response to insulin; Matsuda & DeFronzo, 1999) has

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

been demonstrated within *adult* experimental protocols employing a moderate sleep restriction condition (generally 4 to 5 hours ranging from one night to multiple weeks; Buxton et al., 2010; Buxton et al., 2012; Reynolds et al., 2012; Spiegel, Leproult, & Cauter, 1999; van Leeuwen et al., 2010) and adults with T1DM (Donga et al., 2010). Furthermore, clinical trials with adult samples have demonstrated that extending sleep over six weeks to twelve months in natural environments is feasible (Cizza et al., 2011; Leproult, Deliens, Gilson, & Peigneux, 2015). Further, in non-obese adults, the additional sleep contributed to improved insulin sensitivity and glucose levels (Leproult et al., 2015) as well as neurocognition (Lucassen et al., 2014).

No such experimental sleep manipulation studies have been published on youth with T1DM. However, healthy youth and youth with asthma can follow a home-based sleep modification protocol, including sleep extension instructions (Beebe et al., 2008; Beebe, Rose, & Amin, 2010; Beebe et al., 2013; Fallone, Acebo, Seifer, & Carskadon, 2002; 2005; Gruber, Cassoff, Frenette, Wiebe, & Carrier, 2012; Meltzer et al., 2015; Sadeh, Gruber, & Raviv, 2003; Jiang et al., 2011). These studies found that within a short timeframe, decreases in sleep duration demonstrated negative effects on cognition, behavior, and diet (Beebe, et al., 2010; Beebe et al., 2013; Fallone et al., 2005; Gruber et al., 2012; Jiang et al., 2011; Sadeh et al., 2003). Such sleep *restriction* studies have merit in that they establish that changing sleep duration results in adverse physiological or psychological outcomes. However, because youth with T1DM are frequently sleep deficient, a more clinically important question is whether *increasing* sleep duration produces measureable positive outcomes. In this regard, new studies have highlighted potential benefits of youth obtaining additional sleep (i.e., recommending a specific 'healthy sleep opportunity,' or time in bed, in anticipation that a participant will increase TST), including improvements with attention, memory, problem-solving, emotional regulation, and depression (Dewald-Kaufman, Oort, & Meijer, 2013; 2014; Gruber et al., 2012; Sadeh et al., 2003).

Study Aims

Although there is a relative lack of knowledge pertaining to the association between T1DM and sleep, a number of studies have suggested that an adverse relationship exists. There is evidence of a causal link between inadequate sleep and endocrine functioning in *adults* with and without diabetes and neurobehavior in non-medically involved youth, but due to maturational changes that occur during adolescence, the burden of a complex medical regimen, and the physiological underpinnings of T1DM, successful execution and benefit in this pediatric population remains to be determined. Thus, to truly determine the causal contribution of sleep in the health and functioning of youth with T1DM, it is necessary to perform a randomized control trial (RCT) to demonstrate that a sleep intervention results in a change in a T1DM outcome. The ultimate goal of this line of research is to demonstrate improvements in Hemoglobin A1c (HbA1c), which is the "gold standard" measurement of glucose control and a metric of average glucose over approximately a three month period (ADA, 2016). This would necessitate a sleep intervention that is unprecedented in pediatric diabetes research. Given the costs and complexity of multi-site, large scale-RCTs, particularly ones that are of longer duration, we undertook a RCT to examine a brief pediatric sleep extension intervention to establish a well-developed set of procedures,

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

ascertain perceptions of youth with T1DM and their families regarding the intervention, and obtain preliminary evidence of effect (i.e., short-term efficacy). This paper describes the design and feasibility of data collected in the context of this RCT. We address considerations including (1) the sufficiency in the number of youth who evidenced inadequate sleep duration and were willing to participate; (2) the development of the study procedures and adherence to our sleep modification consultation instructions; and (3) feedback reported by study participants.

Method

Participants

This study reports data from 79 participants who were enrolled as part of a larger, ongoing RCT examining the efficacy of a brief sleep extension intervention on glucose control and neurobehavioral functioning in youth with T1DM. Participants, between the ages of 10–16 with a confirmed diagnosis of T1DM as defined by the ADA, were recruited exclusively from one pediatric endocrinology clinic in the Southwest region of the United States. To be included, child participants were required to speak, read, and understand English, and have at least one caregiver willing to participate. Exclusion criteria included (1) psychiatric, cognitive, genetic (e.g., Down syndrome, Prader-Willi syndrome, Fragile X), or neurological conditions (e.g., epilepsy) that could significantly impact sleep, neurobehavioral performance, glucose control, or participation; and (2) hospitalization within one month of enrollment. Based on recommended sleep durations, participants were eligible for randomization if they slept <9.5 hours for 10 to 13 year olds and <9 hours for 14+ year olds (Hirshkowitz et al., 2015; Tarokh et al., 2012).

Measures

To show the depth of the overall protocol in the context of all study procedures, including a comprehensive neurobehavioral evaluation, we provide a Supplemental online table that includes the measures we administered, including the respondent perspective, and descriptions of the information yielded from them. Continuous glucose monitors (CGMs) were used to assess glucose levels and variability as these devices are recognized for capturing short-term, day-to-day fluctuations in glycemic control. We used the iPro-CGM (Medtronics, Minneapolis, MN), which is an FDA-approved blinded device, validated for use with children under 18 to track glucose levels every 5 minutes (Agus, Alexander, Wolfsdorf, 2010; Al-Ansary et al., 2011; Alleyn et al., 2011). Retrospective CGM recordings have the benefit of not influencing diabetes management during clinical trials (Muchmore, Sharp, & Vaughn, 2011). It is placed subcutaneously with the recorder attached to the sensor. Youth were instructed to continue with their diabetes regimen, but for CGM calibration purposes, asked to obtain finger-stick blood glucose levels at least four times a day with the provided meter and strips. Using the glucose logs, participants were asked to record their carbohydrate intake, exercise intensity, insulin adjustments, and meter readings. The self-reported meter values were used as a backup in case of meter failure or in instances when an alternative meter had been used for which values were not available. During one night of the Naturalistic Sleep Period, each child underwent a home-based PSG. The PSG was recorded using the Compumedics Somté system (Abbotsford, Victoria, Australia). PSG

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

allows for ascertainment of sleep stages (N1, N2, N3, REM) via electroencephalogram (EEG), sleep-disordered breathing via respiratory channels, sleep quality, and sleep duration (Iber, Acoli-Israel, Chesson, & Quan, 2007). Concurrent with the CGM, participants wore an actigraph (Actiwatch-Spectrum, Philips Respironics), which is a wristwatch-sized device that records the frequency of movement to estimate sleep-wake patterns in 30 second intervals. Actigraphy data have been found to correlate with PSG data (Iber, Ancoli-Israel, Chesson, & Quan, 2007; Ancoli-Israel et al., 2003; Meltzer, Montgomery-Downs, Isana, & Walsh, 2012), be valid for use with children and adolescents (Ancoli-Israel et al., 2003; Meltzer, et al., 2012), and allow for continuous serial data collection over several days.

At the final study visit (Neurobehavioral Evaluation #2), participants and caregivers were asked to complete an exit survey and provide the study team with feedback about their experience. Questions inquired about the ease of the child extending his/her sleep (sleep extension condition only), how successful the child was perceived to be at extending or maintaining his/her sleep, how helpful the sleep consultation was in modifying the child's sleep, and how likely the child was to continue the assigned sleep schedule after the study ended.

Procedure

The study was approved by the local human subject protection program. Prior to initiating the RCT, we ran nine participants through all the anticipated procedures to solidify the sleep extension intervention components, determine potential barriers to implementation, and select viable study endpoints. To collect data using a multi-setting, multi-informant, and multi-method approach, the study typically involved three clinic visits, one home visit, and two school visits during the 12-day participation. These occurred in the following order: (1) consent; (2) home-based sleep study; (3) school visit #1; (4) end of Naturalistic Sleep period/Neurobehavioral Evaluation #1/start of Sleep Modification period; (5) school visit #2; and (6) end of Sleep Modification period/Neurobehavioral Evaluation #2. Participants' baseline, referred to as the Naturalistic Sleep period, involved tracking sleep and glucose for approximately six days as well as a battery of neurobehavioral measures. For the Sleep Modification period, also lasting approximately six days, participants were randomly assigned to one of two conditions: Sleep Extension or Fixed Sleep Duration.

Recruitment—Our primary method of recruitment occurred at potential participants' regularly scheduled clinic visits in which they were given information about the study. Participants were initially asked by clinic staff if they would grant permission for a research team member to describe the study. Patients were given the option to decline, schedule, provide information for follow-up, or participate immediately if an opening existed. If a research team member was not available, clinic staff asked the potential participant to leave contact information. As this study was occurring over multiple years and to preserve privacy, no identifying information was retained for patients who did not provide contact information. Clinic staff or research team members recorded basic demographic information and patient-provide reason for refusal for families who opted not to meet with a researcher, give contact information, or enroll after hearing about the study.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Initial intake (consent visit)—Enrollment began with a consent visit during which participants provided written assent, had an actigraph placed on their non-dominant wrist, and had a CGM inserted. Guardians signed a consent document and a release of information for school data. They were also provided meters and strips (50), a glucose log, and a sleep diary.

Naturalistic Sleep period (baseline)—We instructed participants to follow their typical school week and weekend sleep schedules, but to wake up at the time they would for school if they were absent. At the end of the Naturalistic Sleep period, participants returned their devices, completed forms, and underwent Neurobehavioral Evaluation #1. This evaluation lasted approximately 3.5 hours during which a parent spent about 30 to 45 minutes completing questionnaires. The evaluator, trained on neurobehavioral assessments as part of a doctoral program of study, was blinded to the Sleep Modification condition until after the evaluation was completed. We strived to balance team members in the number of Naturalistic and Sleep Modification evaluations they completed; no team member completed both evaluations for any participant.

Sleep Modification period (intervention)—After completing the neurobehavioral measures, a research team member computed average Naturalistic sleep duration using data from the sleep diary and actigraphy. As with other sleep modification studies (Beebe et al., 2008; Fallone et al., 2002; Gruber et al., 2012; Leproult, Deliens, Gilson, & Peigneux, 2015; Lucassen et al., 2014) that have incorporated both methods of assessing sleep duration, we established a protocol to use a combination of the two to mitigate inaccuracies in actigraphy due to variability in children's motoric activity and the unknown credibility of the sleep diary (Short, Gradisar, Lack, Wright, & Carskadon, 2012). We also focused on time in bed increases (considering the light data from actigraphy to determine whether an adolescent attempted to follow the instructions (i.e., modify their sleep/comply with sleep schedule). In the small number of cases for which the diary and actigraphy were widely discrepant, the research team member conferred with another team member and/or PI to determine if the actigraphy data should be used for TST (Ashworth et al., 2015).

The team member then provided a newly initialized actigraph and CGM, as well as a new sleep diary, glucose log, and more glucose strips. At that time, the evaluator learned the assignment of the participants' Sleep Modification condition (e.g., Sleep Extension or Fixed Sleep Duration) and revealed to the participant and caregiver. To increase power, efficiency, and reduce bias, random assignment included stratification based on Tanner Stage Groups [pre-pubertal (Stage I), early puberty (Stages II–III), and late puberty (Stage IV–V; Kernan, Viscoli, Makuch, Brass, Horwitz, 1999; Kahan & Morris, 2012)]. The groupings are consistent with research on insulin resistance and pubertal circadian rhythm changes (Moran et al., 1999).

The consultation intervention, which lasted approximately 20 minutes, was delivered by the same individual who completed the evaluation. For both conditions, interventionists reviewed actigraphy and diary data with the student in the presence of at least one caregiver. The review included patterns, bedtimes and wake-times plus sleep onset and offset, sleep disruptions (e.g., longer latency and frequent/long awakenings), and light exposure (e.g.,

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

blue light suggesting technology usage). At the end of the Sleep Modification week, the interventionist met with families to review data. Once again, if the veracity of the diary was in question, the interventionists used discretion and/or consulted with the supervising PI to determine what information should be conveyed to families about their child's estimated TST change from one week to the next.

Sleep extension—To improve the likelihood of obtaining a healthy sleep opportunity, the research team member and family worked collaboratively to address factors that interfere with sleep onset and quality sleep. Table 1 provides the general target areas of the consultation for the Sleep Extension participants, which involved instructing participants to increase their time in bed to up to 10 hours or one hour more than their Naturalistic Sleep, whichever was greater (Beebe et al., 2008; Fallone, et al., 2002). At the consultation, the trained research team member asked participants about their daily routines (particularly afterschool/evening) and focused on behaviors/conditions that were relevant for the child. This consultation was based on procedures used in previous sleep modification studies with children and adolescents (Beebe et al., 2008; Beebe et al., 2013; Fallone et al., 2002; Jiang et al., 2011; Sadeh et al., 2003) and research demonstrating factors that contribute to sleep disturbances and sleep habits that interfere with daytime functioning, (Dworak, Schierl, Bruns, & Strüder, 2007; Jones, Owens, & Pham, 2013; Paterson, Nutt, Ivarsson, Hutson, & Wilson, 2009; Perfect et al., 2012). This "prescription" was individualized, reviewed by the adolescent/family, and considered barriers to implementation.

Fixed sleep duration condition—In contrast with other sleep modification studies in natural settings, we did not want to include a 'sleep restriction condition' as research has shown that less sleep is harmful and would be problematic while participants are attending school. Therefore, as most youth were already getting insufficient sleep, we prescribed a duration anchored to their average baseline TST (Naturalistic) to reduce the chances of them getting more sleep during the Sleep Modification period. To balance time with research team members, the consultation was neutral and focused on obstacles to being compliant with the prescribed number of hours.

Mid-week check-in—A mid-week check was conducted in both sleep modification conditions during the six day intervention period. The interventionist (i.e., graduate research assistant who delivered the intervention) called the family to inquire about compliance with the instructions and to determine if any difficulties with the prescribed sleep schedule occurred. If needed to increase adherence to the sleep schedule, the interventionist worked with the family over the phone to troubleshoot problems, reminding them of the strategies discussed in the consultation.

Results

Recruitment and enrollment data

Three-hundred and eighty-eight recruitment attempts (i.e., clinic staff asked the patient permission for a research team member to approach or to provide contact information when a team member was not available) resulted in 180 participants providing contact

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

information, of whom 79 enrolled. These patient inquiries were not necessarily unique cases; some patients may have been informed of the study multiple times. Recruitment for the year stopped due to summer break; thus, there were many potentially eligible participants who could not be scheduled prior to the end of the school year. Additionally, 6.74% of patients who had a scheduled consent visit cancelled or no showed. Among the 79 participants, 34 (44.74%) participants identified as Latino/Latina. Nearly half (48.68%) are females. HbA1c ranged from 5.4% [6 mmol/L) to 12.90% (17.9 mmol/L; mean=9.04% (11.8 mmol/L), SD= 1.91% (.4 mmol/L)]. Sixty participants (76.92%) out of 78 with available HbA1c had values above 7.5%. The mean age of participants was 13.14 years. These characteristics mirror the clinic patient population.

Sleep sufficiency

The overall mean sleep duration of the sample at baseline, as recorded by actigraphy and diary, was 7.46 (SD = .73) and 8.21 (SD = .91) hours, respectively. Although the difference in objectively-measured and self-reported sleep duration constituted a 40 minute difference, the mean actigraphy sleep period (onset to offset) was 8.05 hours (*SD* = 1.24 hours), which more closely mirrored the diary data. Based on the averaged TST between actigraphy and diary above our TST cutoff, three participants were not randomized (3.80%).

Completion data

None of the 79 participants withdrew from the study. More than 90% of participants were able to use all the equipment following exact study procedures and without any equipment malfunctions for both Naturalistic and Sleep Modification periods. Four participants (5.1%) had missing CGM data during the Naturalistic Sleep period as a result of: replacing the study device with their own CGM device; CGM falling out and participant refusing reinsertion; and not performing enough finger-sticks to calibrate the CGM. During the Sleep Modification period, CGM data were missing for five participants (6.3%) for the following reasons: continuing to use their own CGM (same participant from baseline), continued without reinsertion (same participant from baseline), not enough finger-sticks to calibrate CGM (same participant from baseline), and problems retrieving the data from the CGM. Two participants (2.5%) had missing or insufficient (<3 days) Naturalistic Sleep actigraphy data due to taking off the watch for an extended period of time. In the Sleep Modification period, one participant (1.3%) again, removed the watch resulting in insufficient actigraphy data. We redid two out of four PSGs (prior to the intervention) due to insufficient data.

Sleep modification compliance

Nearly 80% of participants assigned to the Sleep Extension condition obtained at least 15 minutes additional sleep each intervention night than during their Naturalistic Sleep period, with 1/3 of them increasing their sleep duration by over an hour. The average increase in TST was 40.95 (SD = 47.93) minutes; actigraphy showed 28.61 (SD = 37.61) minutes increased from baseline, and diary showed 47.75 (SD = 75.31) minutes increased. In contrast, participants assigned to the Fixed Sleep Duration condition had negligible overall change in sleep duration (3.69 minutes increase for actigraphy and 10.38 increase in diary), with an average of 6.39 minute difference between TST during the Naturalistic and Sleep Modification periods. Collectively, youth in the Sleep Extension condition slept

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

significantly longer than their own baseline and significantly more minutes than youth in the Fixed Sleep Duration condition. Even so, one in five youth in the Sleep Extension condition failed to increase their sleep by at least 15 minutes, whereas one in four in the Fixed Sleep Duration condition ended up increasing their sleep by at least that long (See Table 2).

Participant feedback

Table 3 provides comments regarding facilitators and barriers to modifying sleep schedules. For youth participants randomized to the Sleep Extension condition and their parents, 60–66% reported that it was somewhat to very difficult to extend their sleep, respectively. When asked how likely participants were to continue with the sleep schedule used for the study, 55% of youth in the control condition said they were very likely to somewhat likely to continue, 22.5% were somewhat to very unlikely to continue, and 15% were unsure if they would continue. The sleep extension group was less likely to endorse a desire to continue their prescribed sleep schedule as 45.5% reported being very likely to somewhat likely; 23.8% being somewhat to very unlikely, and 17.9% were unsure if they would continue. Caregivers also answered a question asking how helpful they perceived the sleep consultation to in successfully modifying their child's sleep. Overall, most of the caregivers in the Sleep Extension group felt the sleep consultation was somewhat or very helpful (25.6% and 51.3%, respectively). The control group did not differ greatly in their viewing of the sleep consultation as helpful.

Discussion

Given that 60% to 80% of youth with T1DM experience suboptimal control (Moore, Hackworth, Hamilton, Northam, & Cameron, 2013), a critical need exists to improve standard clinical care and interventions in this population. The current study demonstrates that it is possible to implement a sleep extension intervention in a cohort of youth with T1DM who participate in a RCT. Our primary objective of the overarching study was to determine the role that sleep had in health and psychosocial outcomes in youth with T1DM. We propose that sleep should be an integral part of diabetes management; and therefore, studies are needed to demonstrate that *increasing* sleep duration produces measureable, positive outcomes reversing the effects of prior self-imposed sleep restriction.

The data presented in this article pertained to the feasibility of implementing a sleep extension intervention in youth with T1DM, a population known to have difficulty with adherence to health behaviors. Overall, similar to prior sleep extension studies in natural environments, 80% of youth with T1DM followed the sleep extension instructions for one week. They did so despite the fact that the majority reported that the prescribed sleep schedule was 'somewhat' or 'very' difficult. One caution is that only 45.5% indicated they would be at least somewhat likely to continue the sleep schedule. It is possible that it could become easier as youth acclimate to the earlier bedtimes over time. Nonetheless, researchers employing interventions with the intention to impact glycemic control and daytime functioning should determine exactly what strategies are needed to ensure sustainability.

The data show that youth are willing to monitor and extend their sleep, at least in the short term. If youth increased sleep by as little as 15 minutes per night, they would obtain 7.5

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

hours additional sleep per month, and 90 more hours of sleep in a year. The benefit of different "doses" of additional sleep has not been tested. However, put in perspective, certain pharmacological treatments deemed to be clinically efficacious to target sleep problems produce a ~15 minute increase in TST (Cizza, Piaggi, Rother, & Csako, 2014; Roth, Hull, Lankford, Rosenberg, & Scharf, 2008).

Design Considerations, Future Interventions, and Consideration of Sustainability

The study components were developed based on previously published studies (Beebe et al., 2008; Fallone et al., 2002; Gruber et al., 2012; Meltzer et al., 2015; Sadeh et al., 2003). One distinction for some of those studies is that their primary aim was to experimentally manipulate sleep (both restricted and extended) to show contrasting effects of sleep on outcomes of interest. However, very few studies aimed to use sleep as an intervention that is meant to be long lasting.

Data from the Fixed Sleep Duration (control) group suggest that instructions to maintain consistent sleep duration may effectively prevent inadvertent additional sleep during a sleep modification study, though some may experience less sleep and others may exhibit an increase. As responses to our exit surveys indicated, one possible explanation for this finding is that these families were expecting to find out how their adolescents could get more sleep (even though we did not state this as the purpose). The impact of participants' expectations entering a sleep extension study was illustrated in another recent trial in which adults with obesity experienced improvements in overall health even prior to randomization (Cizza, Piaggi, Rother, & Csako, 2014). One solution may be to not prime participants that the sole focus of the study is related to sleep or to do a full cross-over design in which all participants experience both experimental conditions. Further, obtaining more consistent sleep, albeit still below recommendations for the age group, may have some benefit. Thus, a control group in a study of longer duration (i.e., 3 months to mirror quarterly visits typical of youth with T1DM) may be further differentiated if youth were allowed to maintain their natural sleep patterns.

As we refine the sleep modification condition and move toward sustainability, we are considering the tools that might help participants change their lifestyle to allow for more sleep opportunity and quality, such as training or referrals to engage in basic mind-body techniques (e.g., self-hypnosis, mindfulness, yoga; Perfect & Smith, 2016) that have been shown to be helpful in reducing stress and/or insomnia. Further, we may need to employ motivational interviewing techniques to work with participants to adopt healthier sleep habits (Cassoff, Rushani, Gruber, & Knauper, 2014). In addition, an alternative approach to sleep extension, as employed by other investigators, (Dewald et al., 2013; 2014), would be to instruct adolescents to increase their sleep in 5-minute increments rather than increased time in bed all at once. This may be necessary for "treatment-resistant" youth who need to gradually adjust their circadian rhythm. However, many youth show day-to-day fluctuations in sleep that far exceed five minutes, suggesting that less cautious adjustments produce change. We found the bigger challenge was modifying routines to enable youth to spend more time in bed rather than with how long it took them to fall asleep.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Another consideration is the method of measuring sleep duration. The PSG data provide an objective metric of sleep duration but does not capture night-to-night variability in TST (Perfect et al., 2012). The actigraphy is a validated measure in children, but has previously been reported to potentially underestimate adolescent sleep (Short et al., 2012). However, sleep diary relies on the adolescent both being compliant with completing it as well as being accurate in the information provided. Some adolescents may also overestimate as well. In this regard, the rest interval (i.e., time in bed) may more closely align with the self-reported sleep times. Thus, our determination of sleep duration at each time point and the difference between the two may be less precise than polysomnography. Consequently, for studies that examine sleep duration change as the outcome or as a mediating or moderating effect on an outcome (e.g., glucose), use off multiple methods of time in bed, sleep duration, and self-reported data should be considered.

Conclusions

At the present time, scarce information exists about sleep and its potential impact on diabetes disease progression or morbidities in youth with T1DM. Yet, youth should spend a significant portion of their day sleeping. Our long-term goal is to determine the role that sleep has in health and neurobehavioral outcomes of youth with T1DM. It is anticipated that the data from the parent RCT will establish the short-term efficacy of providing a healthy sleep opportunity in youth with T1DM, laying the groundwork for future studies examining longer-term sustainability and impact. The strength in our sleep modification consultation approach is that it is relatively brief (~20 minutes for the initial discussion), straightforward, acceptable to most families, and could be integrated into diabetes education. Thus, this study lays the foundation for a large scale RCT to empirically examine if consistently achieving or obtaining close to recommended amounts of sleep leads to clinical improvements in youth with T1DM.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

This study was co-sponsored by the American Diabetes Association (7-13-CE-32) and the Order of the Amaranth Diabetes Foundation and preparation of the manuscript was supported by HL62373.

References

Agus MS, Alexander JL, Wolfsdorf JI. Utility of immediate hemoglobin A1c in children with type I diabetes mellitus. Pediatric Diabetes. 2010; 11:450–454. [PubMed: 20070556]

Al-Ansary L, Farmer A, Hirst J, Roberts N, Glasziou P, Perera R, Price CP. Point-of-care testing for HbA1c in the management of diabetes: A systematic review and meta-analysis. Clinical Chemistry. 2011; 57:568–576. [PubMed: 21368238]

Alleyn CR, Laffel LMB, Volkening LK, Anderson BJ, Nansel TR, Wysocki T, Weissberg-Benchell J. Comparison of longitudinal point-of-care and high-performance liquid chromatography HbA1c measurements in a multi-centre trial. Diabetic. 2011 http://doi.org/10.1111/j.1464-5491.2011.03404.x.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

American Diabetes Association. Standards of medical care in diabetes-2016. Clinical Diabetes: A Publication of the American Diabetes Association. 2016; 39:S107–S108. DOI: doi: 10.2337/dc16-S018

American Diabetes Association. Diabetes Statistics. 2011 Jan 26. Retrieved from http://www.diabetes.org/diabetes-basics/diabetes-statistics/.

Ancoli-Israel S, Cole R, Alessi C, Chambers M, Moorcraft W, Pollack CP. The role of actigraphy in the study of sleep and circadian rhythms. Sleep. 2003; 26:342–392.

Ashworth DK, Sletten TL, Junge M, Simpson K, Clarke D, Cunnington D, Rajaratnam SW. A randomized controlled trial of cognitive behavioral therapy for insomnia: An effective treatment for comorbid insomnia and depression. Journal Of Counseling Psychology. 2015; 62:115–123. DOI: doi: 10.1037/cou0000059 [PubMed: 25867693]

Beebe DW, Simon S, Summer S, Hemmer S, Strotman D, Dolan LM. Dietary intake following experimentally restricted sleep in adolescents. Sleep. 2013; 36:827–834. DOI: doi: 10.5665/sleep.2704 [PubMed: 23729925]

Beebe DW, Fallone G, Godiwala N, Flanigan M, Martin D, Schaffner L, Amin R. Feasibility and behavioral effects of an at-home multi-night sleep restriction protocol for adolescents. Journal of Child Psychology and Psychiatry. 2008; 49:915–923. DOI: doi: 10.1111/j.1469-7610.2008.01885.x [PubMed: 18564072]

Beebe DW, Rose D, Amin R. Attention, learning, and arousal of experimentally sleep-restricted adolescents in a simulated classroom. Journal of Adolescent Health. 2010; 47:523–525. DOI: doi: 10.1016/jadohealth.2010.03.005 [PubMed: 20970088]

Buxton OM, Cain SW, O'Connor SP, Porter JH, Duffy JF, Wang W, Shea SA. Adverse metabolic consequences in humans of prolonged sleep restriction combined with circadian disruption. Science Translational Medicine. 2012; 4:129ra43–129ra43. DOI: doi: 10.1126/scitranslmed.3003200 [PubMed: 22496545]

Buxton OM, Pavlova M, Reid EW, Wang W, Simonson DC, Adler GK. Sleep restriction for 1 week reduces insulin sensitivity in healthy men. Diabetes. 2010; 59:2126–2133. DOI: doi: 10.2337.db09-0699 [PubMed: 20585000]

Caruso NC, Radovanovic B, Kennedy JD, Couper J, Kohler M, Kavanagh PS, Lushington K. Sleep, executive functioning and behaviour in children and adolescents with type 1 diabetes. Sleep medicine. 2014; 15:1490–1499. [PubMed: 25441750]

Cassoff J, Rushani F, Gruber R, Knauper B. Evaluating the effectiveness of the motivating teens to sleep more program in advancing bedtime in adolescents: A randomized controlled trial. BMC Psychology. 2014; 26:2–10.

Cizza G, Marincola P, Mattingly M, Williams L, Mitler M, Skarulis M, Csako G. Treatment of obesity with extension of sleep duration: A randomized, prospective, controlled trial. Clinical Trials. 2011; 7:274–285. DOI: doi: 10.1177/1740774510368298

Cizza G, Piaggi P, Rother K, Csako G. Hawthorne effect with transient behavioral and biochemical changes in a randomized controlled sleep extension trial of chronically short-sleeping obese adults: implications for the design and interpretation of clinical studies. PLoS ONE. 2014; 9:e104176.doi: doi: 10.1371/journal.pone.0104176 [PubMed: 25141012]

Dewald JF, Meijer AM, Oort FJ, Kerkhof GA, Bögels SM. The influence of sleep quality, sleep duration and sleepiness on school performance in children and adolescents: A meta-analytic review. Sleep medicine reviews. 2010; 14:179–189. DOI: doi: 10.1016/j.smrv.2009.10.004 [PubMed: 20093054]

Dewald-Kaufmann JF, Oort FJ, Meijer AM. The effects of sleep extension on sleep and cognitive performance in adolescents with chronic sleep reduction: an experimental study. Sleep Medicine. 2013; 14:510–517. [PubMed: 23523432]

Dewald-Kaufmann JF, Oort FJ, Meijer AM. The effects of sleep extension and sleep hygiene advice on sleep and depressive symptoms in adolescents: a randomized controlled trial. Journal of Child Psychology and Psychiatry. 2014; 55:273–283. DOI: doi: 10.1111/jcpp.12157 [PubMed: 24252173]

Donga E, van Dijk M, van Dijk JG, Biermasz NR, Lammers GJ, van Kralingen KW, Romijn JA. A single night of partial sleep deprivation induces insulin resistance in multiple metabolic pathways

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

in healthy subjects. The Journal of Clinical Endocrinology & Metabolism. 2010; 95:2963–2968. DOI: doi: 10.1210/jc.2009-2430

Dworak M, Schierl T, Bruns T, Strüder HK. Impact of singular excessive computer game and television exposure on sleep patterns and memory performance of school-aged children. Pediatrics. 2007; 120:978–985. DOI: doi: 10.1542/peds.2007-0476 [PubMed: 17974734]

Estrada CL, Danielson KK, Drum ML, Lipton RB. Insufficient sleep in young patients with diabetes and their families. Biological Research for Nursing. 2012; 14:48–54. [PubMed: 21278167]

Fallone G, Acebo C, Seifer R, Carskadon MA. Experimental restriction of sleep opportunity in children: Effects on teacher ratings. Sleep. 2005; 28:1561–1567. Retrieved from: http://www.journalsleep.org/Articles/281213.pdf. [PubMed: 16408416]

Fallone G, Acebo C, Seifer R, Carskadon MA. How well do school-aged children comply with imposed sleep schedules at home? Sleep. 2002; 25:739–745. Retrieved from http://www.journalsleep.org/Articles/250703.pdf. [PubMed: 12405609]

Gruber R, Cassoff J, Frenette S, Wiebe S, Carrier J. Impact of sleep extension and restriction on children's emotional lability and impulsivity. Pediatrics. 2012; 130:e1155–e1161. DOI: doi: 10.1542/peds.2012-0564 [PubMed: 23071214]

Haugstvedt A, Wentzel-Larsen T, Rokne B, Graue M. Psychosocial family factors and glycemic control among children aged 1-15 years with type 1 diabetes: A population-based survey. BMC Pediatrics. 2011; 11:118–118. DOI: doi: 10.1186/1471-2431-11-118 [PubMed: 22185481]

Hirshkowitz M, Whiton K, Albert SM, Alessi C, Bruni O, DonCarlos L, Hillard PJA. National Sleep Foundation's sleep time duration recommendations: methodology and results summary. Sleep Health. 2015; 1:40–43.

Iber C, Ancoli-Israel S, Chesson AL, Quan SF. The AASM Manual for the scoring of sleep and associated events: rules, terminology, and technical specifications. American Academy of Sleep Medicine. 2007

Jaser SS, Ellis D. Sleep in adolescents and young adults with type 1 diabetes: associations with diabetes management and glycemic control. Health Psychology and Behavioral Medicine. 2016; 4:49–55. [PubMed: 27081578]

Jiang F, VanDyke RD, Zhang J, Li F, Gozal D, Shen X. Effect of chronic sleep restriction on sleepiness and working memory in adolescents and young adults. Journal of Clinical & Experimental Neuropsychology. 2011; 33:892–900. DOI: doi: 10.1080/13803395.2011.570252

Johnson SB, Perwien AR, Silverstein JH. Response to hypo-and hyperglycemia in adolescents with type I diabetes. Journal of Pediatric Psychology. 2000; 25:171–178. DOI: doi: 10.1093/jpepsy/25.3.171 [PubMed: 10780144]

Jones CH, Owens JA, Pham B. Can a brief educational intervention improve parents' knowledge of healthy children's sleep? A pilot-test. Health Education Journal. 2013; 72:601–610. DOI: doi: 10.1177/0017896912464606

Kernan WN, Viscoli CM, Makuch RW, Brass LM, Horwitz RI. Stratified randomization for clinical trials. Journal of Clinical Epidemiology. 1999; 52:19–26. [PubMed: 9973070]

Kahan BC, Morris TP. Reporting and analysis of trials using stratified randomization in leading medical journals: Review and reanalysis. BMJ. 2012; 345:1–8.

Leproult R, Deliens G, Gilson M. Beneficial impact of sleep extension on fasting insulin sensitivity in adults with habitual sleep restriction. Sleep. 2015; 38:663–664. DOI: doi: 10.5665/sleep.4660

Lucassen EA, Piaggi P, Dsurney J, de Jonge L, Zhao X-c, Mattingly MS, et al. Sleep Extension Improves Neurocognitive Functions in Chronically Sleep-Deprived Obese Individuals. PLoS One. 2014; 9:e84832.doi: doi: 10.1371/journal.pone.0084832 [PubMed: 24482677]

Matyka KA, Crawford C, Wiggs L, Dunger DB, Stores G. Alterations in sleep physiology in young children with insulin-dependent diabetes mellitus: Relationship to nocturnal hypoglycemia. The Journal of pediatrics. 2000; 137:233–238. DOI: doi: 10.1067/mpd.2000.107186 [PubMed: 10931417]

Matsuda M, DeFronzo RA. Insulin sensitivity indices obtained from oral glucose tolerance testing: Comparison with the euglycemic insulin clamp. Diabetes Care. 1999; 22:1462–1470. [PubMed: 10480510]

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

McNally K, Rohan J, Pendley JS, Delamater A, Drotar D. Executive functioning, treatment adherence, and glycemic control in children with type 1 diabetes. Diabetes Care. 2010; 33:1159–1162. DOI: doi: 10.2337/dc09-2116 [PubMed: 20215458]

Meltzer LJ, Faino A, Szefler SJ, Strand M, Gelfand EW, Beebe DW. Experimentally manipulated sleep duration in adolescents with asthma: Feasibility and preliminary findings. Pediatric Pulmonology. 2015 [Epub ahead of print]. [PubMed: 25872769]

Meltzer LJ, Montgomery-Downs HE, Insana SP, Walsh CM. Use of actigraphy for assessment in pediatric sleep research. Sleep Medicine Reviews. 2012; 16:463–475. DOI: doi: 10.1016.jsmrv.2011.10.002 [PubMed: 22424706]

Monaghan M, Herbert LJ, Cogen FR, Streisand R. Sleep behaviors and parent functioning in young children with type 1 diabetes. Children's Health Care. 2012; 41:246–259. [PubMed: 25035574]

Moore SM, Hackworth NJ, Hamilton VE, Northam EP, Cameron FJ. Adolescents with type 1 diabetes: parental perceptions of child health and family functioning and their relationship to adolescent metabolic control. Health Quality Life Outcomes. 2013; 11:1–8.

Moran A, Jacobs DR, Steinberger J, Hong CP, Prineas R, Luepker R, Sinaiko AR. Insulin resistance during puberty: Results from clamp studies in 357 children. Diabetes. 1999; 48:2039–2044. [PubMed: 10512371]

Muchmore D, Sharp M, Vaughn D. Benefits of blinded continuous glucose monitoring during a randomized clinical trial. Journal of Diabetes Science and Technology. 2011; 5:676–680. [PubMed: 21722582]

Paterson LM, Nutt DJ, Ivarsson M, Hutson PH, Wilson SJ. Effects on sleep stages and microarchitecture of caffeine and its combination with zolpidem or trazodone in healthy volunteers. Journal of Psychopharmacology. 2009; 23:487–494. DOI: doi: 10.1177/0269881109104852 [PubMed: 19351801]

Perfect MM, Levine-Donnerstein D, Archbold K, Goodwin JL, Quan SF. The Contribution of sleep problems to academic and psychosocial functioning. Psychology in the Schools. 2014; 51:273–295.

Perfect MM. The relations of sleep and quality of life to school performance in youth with type 1 diabetes. Journal of Applied School Psychology. 2014; 30:7–28. DOI: doi: 10.1080/15377903.2013.853718

Perfect MM, Patel PG, Scott RE, Wheeler MD, Patel C, Griffin K, Quan SF. Sleep, glucose, and daytime functioning in youth with type 1 diabetes. Sleep. 2012; 35:81.doi: doi: 10.5665/sleep.1590 [PubMed: 22215921]

M. Perfect M, Smith B. Hypnotic relaxation and yoga to improve sleep and school functioning. International Journal of School & Educational Psychology. 2016; 4:43–51.

Pillar G, Schuscheim G, Weiss R, Malhotra A, McCowen KC, Shlitner A, Shehadeh N. Interactions between hypoglycemia and sleep architecture in children with type 1 diabetes mellitus. The Journal of pediatrics. 2003; 142:163–168. DOI: doi: 10.1067/mpd.2003.66 [PubMed: 12584538]

Reynolds AC, Dorrian J, Liu PY, Van Dongen HPA, Wittert GA, Harmer LJ, Banks S. Impact of five nights of sleep restriction on glucose metabolism, leptin and testosterone in young adult men. PLoS ONE. 2012; 7:e41218.doi: doi: 10.371/jounal.pone.0041218 [PubMed: 22844441]

Roth T, Hull SG, Lankford DA, Rosenberg R, Scharf MB. Intermezzo Study group low-dose sublingual zolpidem tartrate is associated with dose-related improvement in sleep onset and duration in insomnia characterized by middle-of-the-night (MOTN) awakenings. Sleep. 2008; 31:1277–1284. [PubMed: 18788653]

Sadeh A, Gruber R, Raviv A. The effects of sleep restriction and extension on school-age children: What a difference an hour makes. Child Development. 2003; 74:444–455. DOI: doi: 10.1111/1467-8624.7402008 [PubMed: 12705565]

Short MA, Gradisar M, Lack LC, Wright H, Carskadon MA. The discrepancy between actigraphic and sleep diary measures of sleep in adolescents. Sleep medicine. 2012; 13:378–384. [PubMed: 22437142]

Spiegel K, Leproult R, Van Cauter E. Impact of sleep debt on metabolic and endocrine function. The Lancet. 1999; 354:1435–1439. DOI: doi: 10.1016/S0140-6736(99)01376-8

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Steenari MR, Vuontela V, Paavonen EJ, Carlson S, Fjällberg M, Aronen ET. Working memory and sleep in 6-to 13-year-old schoolchildren. Journal of the American Academy of Child & Adolescent Psychiatry. 2003; 42:85–92. DOI: doi: 10.1097/00004583-200301000-00014

Tarokh L, Carskadon MA, Achermann P. Dissipation of sleep pressure is stable across adolescence. Neuroscience. 2012; 216:167–177. [PubMed: 22554778]

van Leeuwen W, Hublin C, Sallinen M, Härmä M, Hirvonen A, Porkka-Heiskanen T. Prolonged sleep restriction affects glucose metabolism in healthy young men. International Journal of Endocrinology. 2010:1–7. DOI: doi: 10.1155.2010/108641

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Table 1

Sleep Intervention Components

1. Knowledge	Review the importance of getting more sleep and potential impact of not sleeping enough Consider sleepiness levels and sleep pressure
2. Nightly Routine	Develop routine consistent with bedtime Begin preparing for bed with enough time to be attempting sleep at set bedtime (nighttime diabetes management)
3. Competing Activities	Discuss competing activities (e.g., homework, dinner time, sports) Adjust timing of activities to accommodate bedtime
4. Environmental Conditions	Limit light in the room at night (e.g., curtain for morning light, turning light off at bedtime) Sibling or pets in the room at night that may be distractions
5. Lifestyle	Limiting moderate to high intensity exercise 2 hours before bedtime No caffeine intake after dinner or 2-3 hours before bedtime
6. Technology	No technology (e.g., TV, video games, etc.) 1-2 hours before bedtime No cell phone in the room at bedtime
7. Stress	Reduce overload of information by breaking down expectations related to sleep schedule Address basic strategies to manage stress
8. Parental Monitoring	Meet with child and parent to establish sleep schedule for week Empower parents with monitoring child's sleep behaviors/schedule

Note: Interventionists inquire about each of these areas, but develop a "prescription" of behaviors that includes recommendations mutually agreed upon between the family and interventionist. The session concludes with a discussion of strategies and barriers to implementation.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Table 2

Differences in Sleep Duration between Naturalistic and Sleep Modification Weeks

	Rando-mized	Less Sleep	0 to 15 Min.	16 to 30 Min.	31 to 45 Min.	46 to 60 Min.	More Than An Hour	Percent Increased/ Not Increase[a]
Sleep Extension	39	5 (12.82%)	3 (7.69%)	5 (12.82%)	6 (15.38%)	7 (17.95 %)	13 (33.33%)	31 (79.49%)
Fixed Sleep Duration	36	18 (50.0%)	8 (22.22%)	4 (11.11%)	2 (5.56%)	2 (5.56%)	2 (5.56%)	26 (72.22%)

Note: The time categories are s based on the difference between the average sleep durations recorded via actigraphy and sleep diary during the Naturalistic and Sleep Modification weeks.

[a]The percent increased (for Extension group) is based on 16 or more minutes across the Sleep Modification Period; the Percent Not Increased (Fixed Sleep Duration group) is based on sleep not exceeding more than 15 minutes from baseline. Four youth were not randomized due to evidencing sufficient sleep duration at baseline (n = 3) or having a preexisting medical condition discovered after enrollment (n = 1).

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Table 3

Exit Survey Responses

	Fixed Sleep Duration		Sleep Extension	
	Barriers to Maintain	***Helped to Maintain***	***Barriers to Extend***	***Helped to Extend***
CHILD	• Homework • Friends • Pain • Did not get enough sleep/tired (2) • Same schedule on weekends as weekdays • Getting to school on time • Watching TV/ movies (2) • Going to bed early • Holiday • Being sick	• Being tired • Parents (2) • Self-discipline • Sleep consultation • Habits • Turning off the lights • Relaxing • Having to stay up later • Alarm	• Homework (4) • Extracurriculars/ Sports (8) • Family activities/chores (3) • School schedule • Habits • Hard to fall asleep • Sleep schedule (3) • No TV/phone (2) • Getting home late (2) • TV shows	• Parent reminder (10) • Music (2) • Doing homework earlier • Going to bed earlier • Setting a bed/wake time (2) • Bonus money (2) • Recording TV shows • No electronics
PARENT	• Weekends were tough • Child “likes” to stay up • Getting less sleep/needs more sleep (2) • Running late getting home • Reminding child • Variable times of falling asleep • Keeping child up later • Not taking naps (2) • Waking up early (2) • Activities • Being home in time for bed • Being sick	• Reminders of sleep schedule (2) • Praying • Monitoring (2) • Self-motivation • Set time for lights out and wake up (2) • Alarm clock • Watching TV • Planning and organized to stay on schedule (2) • Study expectations • No naps	• Earlier bedtime (3) • Family schedule • Homework (4) • Extracurriculars/Sports (6) • Evening activities and daily routine (5) • School start time (3) • Needs TV to fall asleep • Rest of family not ready for bed • Being able to stay asleep	• More time in bed allowed for more sleep time • Skipping sports practice • Planning ahead (2) • Knowing that she was not “missing anything” • Do homework/chores early (2) • Watching the clock (3) • Doing it for science • Siblings letting her relax • Better diet • Monitoring glucose levels • Motivation to complete study (2) • Getting more sleep than usual • Mom or dad stayed in room until fell asleep • No noise

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

	Fixed Sleep Duration		Sleep Extension	
	Barriers to Maintain	***Helped to Maintain***	***Barriers to Extend***	***Helped to Extend***
				• No TV/electronics (3)