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Original Research Article

Pilot Trial of a Sleep-Promoting Intervention for Children With Type 1 Diabetes

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Abstract

Objective To assess the feasibility and acceptability of an educational sleep-promoting intervention (Sleep Coach Jr.) for school-aged children (ages 5–9) with type 1 diabetes (T1D) and their parents. **Methods** Parents and children ($N = 39$ dyads, mean child age = 8 years, 64% girls,) were randomized to either the Sleep Coach Jr. intervention, consisting of educational materials and three individual phone calls ($N = 20$), or the Standard Care condition ($N = 19$). Data were collected at enrollment and 3 months later. Children and parents wore actigraphy devices to obtain an objective measure of sleep characteristics, and parents completed questionnaire measures of sleep quality and psychosocial outcomes. Clinical data (i.e., hemoglobin A1c, glucose data) were obtained from children's medical records. **Results** Feasibility and acceptability of the study were demonstrated to be high; all three sessions were completed by 80% of parents randomized to the Sleep Coach Jr. intervention, and 90% of parents completed follow-up data at 3 months. Parents reported high levels of satisfaction with the study and identified barriers to participation. No changes were observed in children's sleep or diabetes outcomes, but parental sleep quality and well-being improved. **Conclusions** A brief, behavioral sleep-promoting intervention is feasible and acceptable for school-aged children with T1D and their parents. A larger trial is needed to evaluate efficacy of the intervention.

Type 1 diabetes (T1D) affects 1 in every 400 individuals under the age of 20, and the prevalence of T1D in school-aged children (ages 5–9 years) is increasing in the United States (Dabelea et al., 2014). In this age group, diabetes care is primarily parents' responsibility, and parents describe high levels of stress related to the "constant vigilance" of diabetes management (Sullivan-Bolyai et al., 2003). In a recent national study, only 20% of children ages 6–12 were meeting the target of hemoglobin A1c (HbA1c) <7.5% (Miller et al., 2015), and with new recommended glycemic targets (<7.0%, American Diabetes Association, 2020), it is likely that an even smaller percentage will meet treatment goals. Thus, novel interventions are needed to help children achieve and maintain optimal glycemic control and reduce parental distress. One of the most significant but potentially modifiable sources of stress described by parents is children's sleep disturbances, and therefore, sleep may represent an important target for intervention.

Approximately 20–30% of children in the general population experience sleep disturbances (Mindell et al., 2006), which includes bedtime resistance or difficulty initiating sleep, night wakings, and insufficient sleep (Owens, 2008). A recent meta-analysis found that children and adolescents with T1D obtained significantly less sleep than youth without diabetes (Reutrakul et al., 2016). In addition, parents reported that children with T1D had more issues around sleep initiation and maintenance, the sleep–wake transition, and daytime sleepiness (Caruso et al., 2014), and they were more likely to exhibit bedtime resistance and co-sleeping with their parents (Herbert et al., 2015). Children with T1D may be especially vulnerable to sleep disruptions, as parents may delay bedtime if blood glucose levels are out of the target range, and parents often wake children during the night for nighttime blood glucose monitoring and treating episodes of hypoglycemia or hyperglycemia (Monaghan et al., 2009). A recent study found that parental fear of hypoglycemia was associated with poorer sleep quality in children (Jaser et al., 2017), and parents of children with T1D identify sleep disturbances as one of the most salient sources of stress (Sullivan-Bolyai et al., 2003; Van Name et al., 2018).

Accumulating evidence points to short sleep duration and poor quality sleep as contributing to problems with glycemic control in people with T1D (Perfect et al., 2012; Van Cauter, 2011). In a sample of children with T1D aged 2–12, both poor sleep quality and shorter sleep duration were related to higher HbA1c, and poor sleep quality was linked to an increased likelihood of experiencing severe hypoglycemia and diabetic ketoacidosis (Jaser et al., 2017). In addition to the direct, physiological impact of sleep disturbance on glycemic control, insufficient and poor quality sleep likely has an indirect, behavioral impact on diabetes management. Sleep disturbances, including bedtime resistance and night waking, have been associated with greater behavioral problems in school-aged children (Stein et al., 2001) and these behavior problems, in turn, may interfere with diabetes management and escalate parent stress (Hilliard et al., 2011). Improving sleep may reduce these problems; extending sleep time by 30 min results in improved neurobehavioral functioning in school-aged children (Sadeh et al., 2003), and an increase of just 15–20 min of sleep has been associated with an additional daily blood glucose check and insulin bolus in adolescents with T1D (McDonough et al., 2017). Thus, improving sleep quality has the potential to address both the physiological and behavioral aspects of diabetes management.

This study builds on prior sleep-promoting interventions for children and adolescents that have demonstrated the feasibility and efficacy of brief, behavioral interventions (e.g., Malow et al., 2014), as well as pilot trials of sleep-promoting interventions for adolescents with T1D (Jaser et al., 2020; Perfect et al., 2016). Interventions that can be delivered remotely by lay health professionals are needed to reach the children and families that may benefit the most. To our knowledge, however, no studies have tested sleep-promoting interventions in school-aged children with T1D. This study targeted sleep as a novel approach to improve diabetes management and reduce parental distress. We conducted a pilot randomized trial to assess the feasibility and acceptability of a sleep-promoting intervention in school-aged children with T1D and their parents.

Materials and Methods

This study was a pilot randomized controlled trial of an educational sleep-promoting intervention with a parallel design. Participants were randomized to receive either the active intervention (Sleep Coach Jr.) or standard care.

Sample

Children were eligible for the study if they (a) were between the ages of 5 and 9 years; (b) were diagnosed with T1D for at least 12 months at the time of enrollment; (c) had no interfering health problems or sleep issues (other than insufficient sleep or insomnia); and (d) were not enrolled in any other intervention studies at the time of the study. Insufficient child sleep duration was not required to participate in the study. Parents were eligible to participate with their child if they lived with the participating child and read and spoke English. We aimed for a sample of 20 per intervention arm, as we would expect to target small effect sizes in a larger trial (Bell et al., 2018).

Children who met the criteria for age and duration of diagnosis were approached during regularly scheduled outpatient diabetes clinic visits at an academic medical center in the Southeastern United States between July 2018 and April 2019. A trained research assistant (RA) described the study to the child and his/her parents and answered their questions. Interested families completed informed consent, in line with the protocol approved by the University Institutional Review Board. The study was registered as a clinical trial (NCT03397147, Pilot Sleep Intervention to Improve Diabetes Management in School-Aged Children).

Of the 72 families approached, 41 enrolled in the study (57%), and 31 declined participation. The most common reasons for refusal were lack of interest ($N = 15$), no reported sleep issues ($N = 9$), and time commitment ($N = 2$). There were no significant differences in demographics (i.e., age, sex, or race/ethnicity) or clinical factors (i.e., HbA1c and duration of diabetes) between the children who enrolled and those who did not. After completing baseline data, participants were randomized to either Standard Care or the Sleep

Coach Jr. intervention. The randomization allocation was determined by the study biostatistician and uploaded into the study database. Children were stratified by treatment type (insulin pump vs. injections) in blocks of 4–6 to avoid confounding with differences related to treatment regimen.

Interventions

Standard Care

Children randomized to the Standard Care condition completed data at baseline and 3 months. They were mailed a report summarizing their sleep characteristics from the baseline data after follow-up data were collected, including recommendations for sleep time (i.e., 9–12 hr/night for school-aged children; Paruthi et al., 2016). They continued with regular outpatient clinic visits (quarterly) and had telephone access to the medical team 24 hr/day, 7 days/week. Sleep education is not routinely part of standard care, and it is typically discussed in outpatient visits only if the patient or caregiver brings it up as a problem.

Sleep Coach Jr.

Building on materials used in a sleep-promoting intervention for children with ASD developed by a member of the research team (Malow et al., 2014) and our intervention for adolescents with T1D (Jaser et al., 2020), we adapted the examples to reflect sleep-related disturbances described by parents of school-aged children with T1D. After developing an initial version of intervention materials, with input from the pediatric endocrinologist on the team, we recruited a small sample of caregivers and solicited their feedback. Seven caregivers (five mothers, one father, and one aunt) reviewed the materials and answered a short survey. Most caregivers were familiar with one or more common sleep disturbance, including television use, co-sleeping, and waking for blood sugar monitoring. Several caregivers also reported awareness of or experience implementing some of the bedtime strategies included in the materials. In general, caregivers assessed the intervention materials favorably; all of the caregivers surveyed reported that the information was presented clearly and that there were enough illustrations. Caregivers' suggestions for improvements were incorporated into the final versions of the materials.

Parents of children randomized to the Sleep Coach Jr. intervention were mailed a binder with educational information on the benefits of healthy sleep, common barriers to sleep in school-aged children, and ways to modify routines and habits in order to promote better sleep in children. A trained RA ("Sleep Coach") scheduled three individual phone calls with parents (see Supplementary Table). During the first call, lasting about 30 min, the Sleep Coach discussed the importance of good sleep habits and routines and prompted the parent to identify specific ways to improve their child's sleep. Parents identified their most significant problems surrounding their child's sleep and bedtime, and they chose one of three individualized strategies to try: Relaxation and Mindfulness, Setting a Bedtime, or Bedtime Resistance and Nighttime Waking.

Parents whose children had problems "winding down" for bed were encouraged to select the "Relaxation and Mindfulness" module, in which they were given age-appropriate resources for mindfulness practices, breathing exercises, and guided meditations. A progressive muscle relaxation script was also included as a component of this module, which parents were instructed to read to their child. Breathing exercises and progressive muscle relaxation scripts have been incorporated into previous sleep hygiene interventions for children of similar ages, with clinically meaningful results (Zupanec et al., 2017). If parents identified problems with enforcing a consistent bedtime, they were prompted to select the "Setting a Bedtime" module. In this module, the Sleep Coach advised parents on recommendations for setting an appropriate bedtime. Finally, parents who identified problems with their child going to bed or waking frequently throughout the night group were encouraged to select the "Bedtime Resistance and Nighttime Waking" module. In this module, parents were given suggestions for ways to address resistance at bedtime and nighttime waking. These strategies included remaining calm, being consistent, and introducing changes around bedtime slowly. Instructions for creating and using a "bedtime pass" were also included. The child could use this pass to leave the bed, but if it was not used during the night, it could be exchanged for a special treat the next morning.

The educational components of the sleep manual were addressed over the first phone session (mean call time was 40 min). The second session included a decisional balance exercise (To Sleep or Not to Sleep) to validate the challenges associated with changing sleep behavior and highlight the benefits of new sleep habits (mean call time was 19 min). The third phone session consisted of a "booster" session in which the parent described their experiences implementing new sleep strategies. In this session, the parent had the opportunity to discuss any difficulties or successes they experienced, and to work with the Sleep Coach to plan for future setbacks (mean call time was 19 min).

Interventionists were post-bac trainees who received training in diabetes management and manualized interventions, as well as weekly supervision from a clinical psychologist. All phone sessions were recorded, and 20% were randomly selected for a fidelity check by an objective rater. Fidelity scores ranged from 89.3% to 100%, with an average of 98%, indicating that the interventionists closely adhered to the material included in the manual.

Measures

Questionnaire measures were completed by parents using REDCap, a secure web-based data collection platform. Parents were compensated for data collection with $20 gift cards, and children chose a small toy.

Demographics

Parents completed a demographic questionnaire during the baseline survey that asked about the race/ethnicity of the parent and child, family income, parental education, and use of diabetes technology, including insulin pumps and continuous glucose monitors (CGMs).

Sleep

Actigraphy data were collected as an objective measure of child and parent sleep characteristics (total sleep time and efficiency). Philips Actiwatch Spectrum Plus^{TM} ($N = 18$ dyads) and Actigraph wGT3X-BT^{TM} ($N = 21$ dyads) devices were used to collect data, with approximately half of each brand used by each intervention group. Participants were instructed to wear the actigraphy watches continuously for 7 days (if this was not possible, we requested that they put the watch on an hour before bed and take it off an hour after waking). Based on earlier work (Goldman et al., 2017), we configured Philips devices for 60-s epochs, with a sleep interval of 10 epochs for sleep onset, and an awake threshold setting of 40 (medium). For the Actigraph devices, we used the Cole–Kripke algorithm to score parent data and the Sadeh algorithm to score child data with 60-s epochs. Due to contracting issues, we needed to switch to a different brand of actigraphy watch after starting enrollment. However, we used the same type of device with each dyad pre- and postintervention to reduce variability related to brand, and no significant differences in parent or child sleep parameters were observed at baseline related to device.

Sleep diaries were completed by parents (separate diaries for themselves and for their children) to aid in scoring of the actigraph watch data at baseline and 3 months. Parents were asked to note any problem with the watches, illness, new medications, or special events that could have influenced sleep data. Diaries were used when bedtime/wake time was not clear from the actigraphy devices (e.g., participants pressed the interval marker multiple times, or not at all, or there was no clear change in activity or light levels).

Child sleep quality was assessed with the Children's Sleep Habits Questionnaire (CSHQ, Owens et al., 2000), completed by the parent to evaluate common sleep problems that children encounter. This measure includes 33 items that ask about bedtime, sleep behavior, waking during the night, morning waking, and daytime sleepiness. Scores range from 33 to 99, and a score of 41 or higher indicates clinically significant sleep disturbances.

Parent sleep quality was assessed with the Pittsburgh Sleep Quality Index (PSQI, Buysse et al., 1989), a self-report measure that assesses seven areas of sleep: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, uses of sleeping medication and daytime dysfunction. Global scores range from 0 to 21, where a higher number indicates a poorer sleep quality, and a score >5 is considered clinically significant.

Parental Distress

Diabetes distress was measured with the Problem Areas in Diabetes: Parent Report version (Tinsley et al., 2018). This scale was created to identify areas that cause distress specifically to a parent of a child with T1D based on their experience in the past month. Score range from 0 to 72, where a higher score indicates greater diabetes distress, and scores of 56 or higher are clinically significant. Reliability in the current sample was $\alpha = .91$.

Parental Fear of Hypoglycemia was assessed with the Worry Subscale of the Parent Hypoglycemia Fear Survey (Cox et al., 1987). This measure consists of 15 statements concerning different worries or concerns that a parent of a child with T1D may have Scores range from 0 to 60, and higher scores indicate more diabetes-related concern and worry. Reliability of the Worry subscale in the current sample was $\alpha = .87$.

The World Health Organization Five Well-Being Index (WHO-5, World Health Organization, 1998) was used to assess parents' emotional well-being. The WHO-5 consists of five statements that identify emotional states that the parent may have experienced in the previous two weeks Raw scores range from 0 to 25 and are multiplied by 4 to produce a percentage score, ranging from 0 to 100, with higher scores indicating higher overall well-being of the parent. Reliability in the current sample was $\alpha = .87$.

Glycemic Control

Glycemic control was assessed with point-of-care HbA1c, obtained as part of children's regularly scheduled diabetes clinic visits. HbA1c is an average of blood glucose levels during the prior 8–12 weeks. The recommended target for children is <7.0% (American Diabetes Association, 2020).

Data Analysis Plan

Feasibility of the study was assessed with percentage of calls completed, with a benchmark of 70%, and

Table I. *Demographics and Baseline Clinical Characteristics by Treatment Group*

Characteristic	SCJ (*N* = 20)	SC (*N* = 19)	Total sample (*N* = 39)
Child age, *M* (SD)	8.4 (1.4)	7.6 (1.5)	8.0 (1.5)
Parent age, *M* (SD)	34.7 (12.7)	32.7 (12.2)	33.7 (12.3)
Duration of diabetes, *M* (SD)	3.0 (1.5)	3.7 (1.8)	3.4 (1.7)
A1C (%), *M* (SD)	8.6 (1.6)	8.5 (1.5)	8.6 (1.5)
Sex			
Male (%)	8 (40%)	6 (32%)	14 (36%)
Female (%)	12 (60%)	13 (68%)	25 (64%)
Race/ethnicity			
White, non-Hispanic, *N* (%)	15 (75%)	14 (74%)	29 (74%)
Non-white, *N* (%)	4 (20%)	4 (21%)	8 (20%)
White, Hispanic, *N* (%)	1 (5%)	0 (0%)	1 (3%)
Not reported, *N* (%)	0 (0%)	1 (5%)	1 (3%)
Annual income (USD)			
<39,000, *N* (%)	2 (10%)	5 (26%)	7 (18%)
40,000–79,000, *N* (%)	7 (35%)	6 (32%)	13 (33%)
>80,000, *N* (%)	11 (55%)	8 (42%)	19 (49%)
Treatment type			
Insulin pump, *N* (%)	12 (60%)	12 (63%)	24 (62%)
Injections, *N* (%)	8 (40%)	7 (37%)	15 (38%)
CGM use, *N* (%)	14 (70%)	10 (53%)	24 (62%)

Note. SCJ = Sleep Coach Jr. intervention; SC = standard care; CGM = continuous glucose monitor.

retention, with a benchmark of 80% of follow-up data completed. Acceptability of the study was assessed with the satisfaction survey, completed by parents at the 3-month data collection. In addition, exit interviews with parents were transcribed and coded using a thematic analysis approach (Braun & Clarke, 2006) to understand participants' experiences in the study. We calculated effect sizes (Cohen's *d*) by comparing the mean differences in change scores between groups and reported 95% Confidence Intervals (CIs).

Results

Participant Characteristics

As seen in Table I, mean age of children was 8 years, 74% of the children in our sample were white, non-Hispanic, and mean Hb1c was 8.6%, which is similar to school-aged children from a national registry of people with T1D (Miller et al., 2015). Mean sleep duration was 7.9 hr in children and 6.7 hr in parents, below the recommended amounts (9–12 hr for school-aged children and 7–9 hr for adults). In addition, 82% of children scored above the clinical cutoff on the CSHQ, and 63% of parents scored above the cutoff on the PSQI. There were no significant differences in baseline sleep characteristics between the two groups.

Feasibility

Of the 41 families who enrolled in the study, 2 withdrew prior to randomization (Supplementary Figure 1); one parent changed her mind about participating after consenting, and one family declined to continue participation after completing baseline data. Of the 20 families randomized to receive the Sleep Coach intervention, 3 withdrew, all due to the time commitment. Sixteen parents in the Sleep Coach Group completed all three calls (80%; one was unable to schedule calls), and follow-up surveys and clinical data were collected from 90% of participants, exceeding our benchmarks. Usable actigraphy data were obtained from 85% of children and 72% of parents at follow-up.

Acceptability

Based on parents' responses to the Satisfaction Survey, the study was viewed favorably. Overall, 91% of parents reported that the study was worthwhile (yes vs. no) and 91% reported that they would recommend it to others (yes vs. no). When asked how helpful the study was, on a scale of 1 (*not helpful*) to 5 (*very helpful*), the mean score was 3.4 (±1.0), with no significant difference between groups. Similarly, when asked how enjoyable the study was, on a scale of 1 (*not enjoyable*) to 5 (*very enjoyable*), the mean score was 3.6 (±1.1), with no difference between groups.

Exit interviews were completed by 31 parent participants (16 from the Sleep Coach group, 15 from the Standard Care group, and 79% of the total sample). In general, parents reported favorable experiences while participating in the study. Many parents (*N* = 11) described learning about sleep, acknowledging the potential to improve not only their child's sleep but also their own. Participants also described greater awareness of their sleep habits.

> Well [the study] makes you kind of look at how your schedule is and everything. It makes you kinda pay more attention to what you're doing. If you're eating late at night or, you know, keeping a good schedule. It kinda makes you aware of what you're actually doing (parent of a 9-year-old boy).

Similarly, another parent of a 9-year-old boy said, "The information we received was enlightening…it caused us to think about our habits."

Although monitoring of sleep via actigraphy and diary were not an explicit part of the intervention, almost a quarter of parents (*N* = 7) reported that they liked having the ability to track their sleep and learn information about their own sleep patterns.

> Tracking it, knowing how many times a night we were getting up, how often she was having a low, kind of just tracking that information was probably the most beneficial for us" (parent of a 6-year-old girl).

Parents described ways in which maintaining the sleep diary and wearing the actigraphy watch made them more aware of their routine, nighttime awakenings, and areas for improvement.

> I was able to catch our bad habits just by writing it down. I have older kids, so our sleep schedule is unpredictable…it helped me realize the things we need to improve upon (parent of a 6-year-old boy).

Few barriers to participation were reported by parents. The most common barriers pertained to wearing or using the actigraphy watch. Some parents (*N* = 9) found the watch uncomfortable and bulky, particularly to wear during the night. Others reported difficulty remembering to put on the watch (e.g., after showering, activities) or to press the tracking button before sleep (*N* = 7). In addition, some parents described difficulty remembering to record or keep up with the sleep diary (*N* = 7). Although less frequent, a few parents noted some confusion related to the format of questions (*N* = 4) and logging blood sugar checks (*N* = 3) in the sleep diary. Despite these barriers, 71% of parents interviewed liked the sleep diary and found it useful. For parents assigned to the intervention group, the most common barrier was scheduling constraints and availability for phone calls (*N* = 8). Parents appreciated the flexibility of the program and that the coach was able to accommodate their schedules (e.g., rescheduling phone sessions if needed).

Parents assigned to the Sleep Coach Jr. intervention (*N* = 16) reflected on favorable aspects of the intervention. More than half of these interviewees commented on positive experiences communicating with the sleep coach (*N* = 9). A parent of a 9-year-old boy described:

> "I liked doing the sleep coaching part where [coach] called. Talking to her made me get an outside perspective and some tips and made me realize thigs I wasn't seeing. Talking to her and going over the things that promoted sleep helped me think. I am thinking 'Ok I'm not screwing up as a parent.' I enjoyed getting to talk to her.

Many parents in the intervention group also favorably described learning several strategies to improve sleep (N = 6), including restricting use of electronics and the use of bedtime passes.

> I liked the tips, keeping the bedtime as close as possible and relaxation time, turning the TV off 30 minutes before bed, and he really likes the bedtime pass" (parent of an 8-year-old boy).

A parent of an 8-year-old girl found the bedtime pass particularly useful and explained:

> I learned about the bedtime passes. That was a very good thing…In general, I got an overall view of how we sleep, and I got better understanding of putting her to bed at a certain time… I learned not to wake up every three hours because that's what I did the most.

Some parents also reflected on improvements to their own sleep as a result of engaging in less nocturnal caregiving behaviors.

> Having the Dexcom (CGM) and knowing that it's going to alarm me if something happens. It improved a lot. At the beginning of the study, I was getting up 3,4,5 times a night, and now there are nights where I don't get up at all. If I do, it's usually once" (parent of a 6-year-old girl).

In addition, most parents (*N* = 12) liked the Sleep Coach materials (binder) and found it useful. Finally, most parents (81%) reported continued use of the Sleep Coach strategies after they completed study participation.

Differences in Change Scores between Groups

As seen in Table II, we observed a moderate effect on parents' sleep quality ($d = -.76$), with parents in the Sleep Coach Jr. group reporting greater improvements in sleep quality than parents in Standard Care over three months. In addition, we found a small effect on parents' well-being, with parents randomized to the Sleep Coach Jr. group reporting greater improvements in well-being ($d = .20$) than those in the Standard Care group. However, we also observed a small effect on fear of hypoglycemia ($d = .38$), with parents in the Sleep Coach Jr. group reporting greater increases in worry as compared with parents in the Standard Care group. The differences in total sleep time and sleep efficiency, as well as child's glycemic control (HbA1c), were minimal. However, when we excluded children who were already meeting recommended targets for HbA1c (<7%, *N* = 4), we observed a small difference in HbA1c (mean HbA1c at 3 months = 8.3% ± 1.5% in the Sleep Coach group versus 8.7% ± 1.4% in the Standard Care condition ($d = .32$, 95% CI = −0.99, 0.35).

Table II. *Summary of Sleep and Diabetes Outcomes at Each Time Point by Intervention Group*

Variable	Baseline (*M* + SD)	3 months (*M* + SD)	Effect size *d* (95% CI)
Mean child TST			
SCJ	7.97 + 0.56	7.91 + 0.81	.07 (−0.56, 0.70)
SC	7.96 + 0.43	7.86 + 0.51	
Mean child efficiency			
SCJ	84.79 + 3.88	84.14 + 8.54	.08 (−0.55, 0.71)
SC	86.33 + 3.36	85.27 + 4.51	
CSHQ			
SCJ	48.69 + 9.51	45.06 + 6.55	−.12 (−0.75, 0.51)
SC	46.50 + 7.64	43.82 + 7.01	
Mean parent TST			
SCJ	6.69 + 0.96	7.02 + 1.15	.08 (−0.55, 0.71)
SC	6.70 + 1.31	6.94 + 1.06	
Mean parent efficiency			
SCJ	87.74 + 5.61	87.32 + 6.01	−.15 (−0.78, 0.48)
SC	86.18 + 8.36	86.72 + 5.23	
PSQI			
SCJ	7.84 + 4.25	4.73 + 2.77	−.76 (−1.41, −0.11)
SC	6.35 + 2.89	5.59 + 2.35	
HbA1c			
SCJ	8.59 ± 1.57	8.23 ± 1.42	−.17 (−0.80, 0.45)
SC	8.53 ± 1.49	8.43 ± 1.46	
WHO			
SCJ	60.00 ± 20.35	60.94 ± 21.19	.20 (−0.42, 0.83)
SC	58.95 ± 17.53	55.56 ± 25.52	
PAID-PR			
SCJ	36.90 ± 10.95	38.82 ± 12.78	−.06 (−0.69, 0.57)
SC	30.74 ± 7.35	33.33 ± 10.96	
PHFS			
SCJ	17.30 + 9.63	18.65 + 11.24	.38 (−0.25, 1.02)
SC	14.84 + 8.26	12.67 + 7.01	

Note. SCJ = Sleep Coach Jr. intervention; SC = standard care; TST = total sleep time; PSQI = Pittsburgh Sleep Quality Index; WHO = World Health Organization Wellbeing; PAID-PR = Problem Area in Diabetes Parent Report; PHFS = Parent Hypoglycemic Fear Survey; *d* = Cohen's *d*.

Discussion

In this study, we developed and pilot tested the first sleep-promoting intervention for school-aged children with T1D. Building on existing, effective interventions to improve sleep quality and duration in pediatric populations, we adapted our materials to include relevant experiences of children with T1D and their parents. This intervention was highly feasible and acceptable to parents, exceeding our benchmarks, and we identified potential barriers to participation and data collection.

Our preliminary work to develop intervention materials highlighted the importance of focusing on the needs of school-aged children with T1D and their parents. Although children in our sample experienced many sleep disturbances common for this age group (bedtime resistance and nighttime waking), they also experienced diabetes-related sleep disturbances, usually related to nighttime caregiving (Van Name et al., 2018). By including examples of both types of sleep disturbances, our intervention materials were aimed at promoting sleep in this high-risk pediatric population, and the individual phone sessions allowed for tailored goals and feedback. Parents in the pilot trial reported high levels of satisfaction with the study, even those randomized to the Standard Care group. Exit interviews revealed that parents appreciated learning more about their child's sleep characteristics, and that tracking their child's and their own sleep helped them to identify patterns.

Parents randomized to the Sleep Coach Jr. intervention group enjoyed the phone sessions, and they reported increases in their own sleep quality and wellbeing. However, we also observed increased fear of hypoglycemia among parents randomized to the intervention. It is possible that the discussion around nighttime glucose checks increased their attention to this fear. In addition, some of the mothers in our study reported during phone sessions that they did not feel comfortable trading off nights with other caregivers, so they would still be up worrying even if it was their night "off." Our preliminary findings suggest that sleep-promoting interventions for this age group may need to explicitly address parents' worry around hypoglycemia. Further, including sleep monitoring may improve parent satisfaction and behavior change.

The minimal changes in child sleep and diabetes outcomes suggests that future trials may screen for participants who are not meeting glycemic targets and/or obtaining sufficient sleep. Parents described some difficulty using the actigraph devices, which resulted in missing data, further limiting the sample size. As a pilot study, the goal was to assess feasibility and acceptability of the intervention, which was demonstrated through participation in intervention calls, satisfaction surveys, and exit interviews with study participants.

Limitations

This study was limited by a small size. However, the demographic and clinic characteristics were representative of our outpatient diabetes clinic and similar to national samples of children with T1D (Miller et al., 2015). Parents and children who participated in this study expressed interest in improving sleep habits, but we did not conduct comprehensive sleep assessments, and findings may not generalize to other populations. In addition, we chose to focus on the Worry subscale of the Parental Fear of Hypoglycemia measure, as this has been associated with sleep in previous studies (e.g., Herbert et al., 2015), but the Behavior scale may have implications for sleep habits. Finally, since not all of the children in our sample were using CGM devices, we were not able to examine nighttime blood glucose stability across participants, which could influence sleep quality (Monzon et al., 2019).

Clinical Implications

Given the rapid increase in CGM use among people with T1D, particularly in this age group (Foster et al., 2019), our findings point to the need to help parents manage blood glucose data, especially overnight. Although some parents described greater peace of mind with a CGM, where they can sleep more, or wake up quickly to check the number on their phone or monitor and go back to sleep, other parents reported frequently being up at night adjusting insulin or trying to get their child to eat to “fix” blood glucose numbers. This is in line with findings from a recent study of children age 2–5, in which CGM use improved sleep in children with T1D but not in their parents (Sinisterra et al., 2020). Children who use CGM may experience fewer sleep disturbances related to nighttime blood glucose checks, but many of their parents are still waking up to check and treat hypo or hyperglycemia. Educational and behavioral support to help parents to manage diabetes overnight with new diabetes technology may be needed to enhance the effects of the current sleep-promoting intervention, but feasibility of billing for such services requires further examination.

Conclusion

This study was the first to test a sleep-promoting intervention in school-aged children with T1D and their parents. We found the Sleep Coach Jr. intervention to be feasible and acceptable for this population, and we identified ways to address barriers to participation (e.g., clearer instructions for actigraph device use). An important strength of the intervention is the ability for lay health professionals to deliver it remotely, increasing the potential for dissemination. The next step is to evaluate efficacy in a randomized clinical trial.

Supplementary Data

Supplementary data can be found at: https://academic.oup.com/jpepsy.

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Conflicts of interest: None declared.

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