Pilot and Feasibility Studies

STUDY PROTOCOL

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Optimizing Attention and Sleep Intervention Study (OASIS): a protocol for a pilot randomized controlled trial to compare parent behavioral interventions with and without sleep strategies delivered in pediatric primary care for preschool-aged children at risk of childhood ADHD

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Abstract

Background Attention-deficit/hyperactivity disorder (ADHD) is a prevalent neurodevelopmental disorder that presents as early as preschool. Inattention and hyperactivity in childhood interfere with developing social and preacademic skills, leading to lifelong impairment. Evidence-based treatments for children with ADHD exist, including parent behavioral interventions (PBIs). However, current treatments have failed to substantially change the long-term trajectory of symptoms and impairment for individuals with ADHD, suggesting the need to enhance treatment approaches and intervene earlier. Given that sleep is a modifiable factor linked to ADHD symptom persistence and exacerbation, it may be a useful target in addressing ADHD among preschool children (ages 3–5 years). The most common sleep problems among preschoolers are behavioral and amenable to PBIs. However, sleep strategies have not been included within PBIs to address ADHD symptoms in young children. Thus, this pilot trial aims to assess the feasibility, acceptability, and appropriateness of a novel sleep-focused PBI (SF-PBI). Moreover, given the barriers to accessing care for sleep-related issues, this pilot trial aims to increase access to evidence-based care by partnering with behavioral health therapists embedded in pediatric primary care to deliver intervention.

Methods A pilot randomized clinical trial is being conducted in 5 pediatric primary care offices by embedded behavioral health therapists with 50 families of 3- to 5-year-old children with elevated ADHD symptoms and behavioral sleep problems. Families are randomized (1:1) to six sessions of either standard PBI or SF-PBI, informed by focus groups with caregivers, therapists embedded in pediatric primary care, and pediatric providers. Primary outcomes at post-intervention will be therapist and caregiver report on the intervention's acceptability, appropriateness, and feasibility.

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Discussion Primary outcomes will inform the decision to transition to a definitive trial testing SF-BPI targeting sleep among preschool-aged children at elevated risk for ADHD via accessible, primary care-based intervention that harnesses parenting strategies. Ultimately, the SF-PBI has the potential to improve outcomes for children at risk for ADHD by increasing access to early intervention for behavioral sleep issues to reduce the prevalence, symptoms, and associated impairments of ADHD among children and families.

Trial registration ClinicalTrials.gov NCT05683756 (prospectively registered, date registered 4 January 2023): https://clinicaltrials.gov/study/NCT05683756

Keywords ADHD, Sleep, Preschool, Parenting training, Pediatrics/primary care

Background

Attention-deficit/hyperactivity disorder (ADHD) is a highly prevalent neurodevelopmental disorder with lifelong impairment [1]. Children with ADHD followed longitudinally have higher rates of high school dropout, lower college entry or completion, greater employment challenges, more interpersonal conflicts, more substance misuse, higher rates of comorbid mental and physical health disorders, and an elevated risk for suicide [2]. The social, educational, and health impairments due to ADHD are estimated to result in an economic burden of hundreds of billions of dollars worldwide annually [1]. Although most often identified for treatment at school age, ADHD symptoms including inattention, hyperactivity, and impulsivity are often present as early as preschool age [3–5]. An estimated 2.4% of preschool-aged children in the USA exhibit ADHD symptoms, equaling approximately 388,000 2 to 5 years old [6]. Children with elevated ADHD symptoms at age 3 have a high likelihood of meeting diagnostic criteria for ADHD in adolescence, demonstrating that even subthreshold ADHD symptoms during preschool age are prognostic of later ADHD [7]. The presence of early ADHD symptoms interferes with the development of social and preacademic skills that can initiate the path to the lifelong impairments [8, 9]. Thus, effective, sustainable, and accessible interventions early in life are critical to altering the trajectory of symptoms and ADHD-related impairments for children at risk of developing childhood ADHD.

The American Academy of Pediatrics has called for behavioral treatments as first line among preschool-aged children with ADHD [10]. Parent-focused behavioral interventions (PBIs) focus on modifying parenting practices to increase desired and reduce disruptive behaviors of the child and are considered the gold standard behavioral treatment for ADHD. PBIs can include techniques for managing challenging child behaviors that manifest from underlying executive dysfunction among children with ADHD. Such PBIs have been effective in acutely improving child ADHD symptoms [11]. Yet, traditional PBIs have not been found to substantially alter the trajectory of symptoms and impairment for children with ADHD. A recent systematic review of the limited studies on the longitudinal effects of traditional PBIs for preschool-aged children found that only a marginally significant effect on ADHD symptoms 3 to 12 months after the intervention.[11] There are multiple reasons that traditional PBIs for ADHD may be insufficient. One important reason may be that existing PBIs fail to address the sleep difficulties that are highly common in this population [12].

Sleep is a modifiable factor strongly linked with ADHD symptom persistence and exacerbation. Sleep problems are present among as many as 70% of children with ADHD as compared to 20–30% of typically developing children [13]. Such sleep disturbances include difficulties falling asleep and frequent night awakenings, as well as poor sleep health, including shortened sleep duration [13]. Additionally, numerous studies have identified that insufficient (i.e., less sleep than age-based recommendations [14] or short sleep duration is linked to impaired executive functioning skills and behavioral control, both of which resemble and partially overlap with childhood ADHD symptoms (for review, see Beebe, 2011). Experimental studies have found that relative to a sleep extension condition, when youth are sleep restricted, they tend to exhibit increased symptoms of ADHD [15] and neurobehavioral impairments [16–18]. Similarly, insomnia symptoms (difficulty falling asleep, frequent night wakings) are linked to executive functioning challenges [19]. Behavioral sleep interventions for school-aged children, adolescents, and adults are effective in improving sleep onset and duration and have been associated with improvement in ADHD symptoms [20]. However, earlier intervention is warranted given that sleep disturbances can begin as early as toddlerhood and can set the stage for sleep impairment through adolescence [21–23]. In addition, there is a robust evidence base for treating early childhood behavioral sleep disturbances, although few studies have examined intervention effectiveness among children with ADHD and/or behavior problems, or in accessible settings, such as primary care [24–26].

Sleep problems in early childhood may be a mechanism through which inattention and hyperactivity increase,

in turn leading to childhood ADHD. The most common sleep problems among children 3–5 years old are difficulty falling asleep, including bedtime resistance and a prolonged sleep onset latency, and nighttime awakenings [22, 27]. These problems result in shortened sleep duration and can contribute to daytime behavioral problems [28]. For preschool-aged children with ADHD symptoms, sleep disturbances may both result from ADHD symptoms themselves and worsen subsequent daytime behaviors. Thus, addressing early sleep disturbances may reduce ADHD symptoms and prevent future impairment. Parent factors (e.g., lax parenting and inconsistent bedtime routines) have been identified as risk factors for behavioral disruptors of sleep [29]. Therefore, parent-focused interventions are ideal given the critical role that parents play in shaping child health behaviors and contributing to optimal child sleep health [30]. Targeting and improving sleep among preschool-aged children can favorably impact child behavioral and affective regulation, reducing ADHD symptoms and possibly disorder onset.

Rationale

Pediatric primary care was selected as the delivery setting because pediatricians are frontline in identifying early concerning behaviors. Pediatricians have regular contact with children across development with yearly visits recommended during the preschool period. Most families have access to primary care with the CDC estimating that 97.1% of children in the USA have a usual place to seek care [31]. Additionally, medical home models with behavioral health providers embedded in pediatric primary care centers continue to increase in prevalence across the country as a means to improve access to behavioral health care for children [32]. Moreover, PBIs have been successfully implemented in pediatric primary care settings [33, 34] with emerging evidence for the feasibility of implementing early childhood sleep intervention in this context [35]. Thus, the Optimizing Attention and Sleep Intervention Study (OASIS) was designed to increase the impact and accessibility of PBIs for ADHD among preschool children by (1) adapting an existing PBI for parents of children with ADHD to include strategies for improving sleep and (2) translating the intervention for delivery within pediatric primary care by embedded behavioral health therapists. The aim of the present report is to describe the OASIS study protocol and the intervention content and delivery methods for the standard PBI and SF-PBI.

Objectives

The overall objective of the OASIS study is to leverage the primary care setting and evidenced-based sleep strategies to enhance a PBI to address sleep problems among preschoolers at high risk for ADHD to change the trajectory of ADHD symptom development. Project aims are as follows:

- Aim 1: Demonstrate the acceptability, feasibility, and appropriateness of the sleep-focused PBI (SF-PBI) delivered in pediatric primary care for preschool-aged children (3–5 years old) at elevated risk for ADHD.
- Aim 2: Examine change in target engagement (sleep) and ADHD symptoms among preschool-aged children at elevated risk for ADHD receiving SF-PBI compared to standard PBI.

Trial design

The OASIS study is a randomized controlled pilot trial to test the feasibility, acceptability, and initial efficacy of the SF-PBI compared to standard PBI. The study is projected to last 2 years with 50 families enrolled and each participating for 8 months. Half of the families will be randomized to the SF-PBI, and half will be randomized to the standard PBI. The intervention will be delivered by behavioral health (BH) therapists embedded in pediatric primary care offices. Figure 1 is the study flow diagram, and Table 1 outlines the study timeline including enrollment, assessment, randomization, and intervention.

Methods

Study setting

Five pediatric primary care practices, and the six behavioral health therapists at these locations, were selected to participate in the study. These practices act as a primary medical home and are part of a larger network of 55 pediatric offices, which have an integrated behavioral health clinician. Offices range from Western to Central Pennsylvania and were selected based on regional diversity (rural vs. urban), sociodemographic characteristics of the patient population, and offices in which the integrated clinician tends to get frequent referrals for children under the age of 5. The integrated therapist spearheads collaboration between the pediatrician and family, provides assessment of behavioral health concerns, and provides brief evidenced-based interventions all within the patient's primary medical home.

Eligibility criteria

Inclusion and exclusion criteria can be found in Table 2. Fifty children 3–5 years old at elevated risk for ADHD (4+symptoms) and with behavioral sleep disturbances (bedtime resistance and/or nighttime awakenings) along with their primary caregiver will be enrolled in the

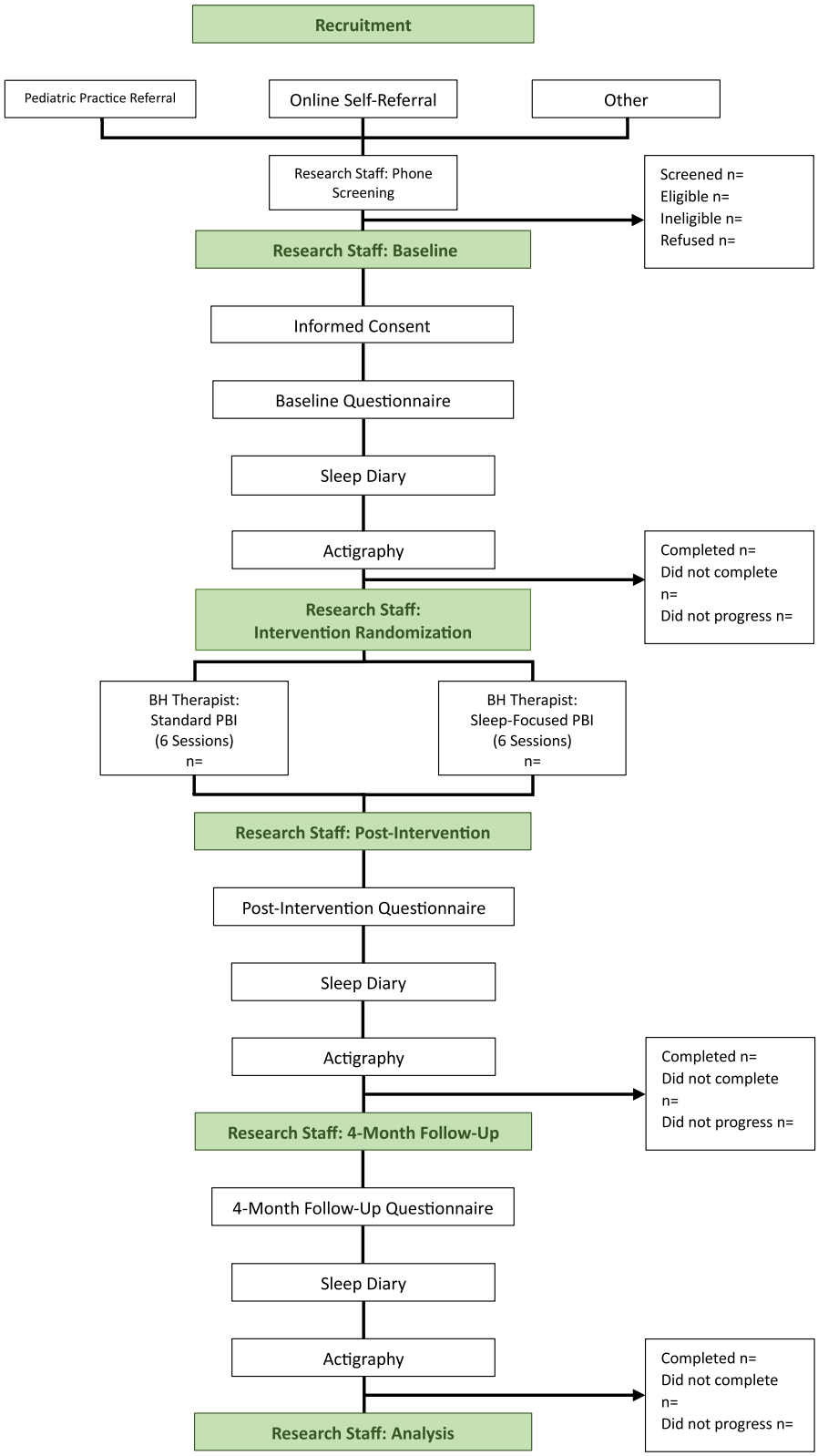

Fig. 1 Study flow diagram

Table 1 Study timeline

	Study period				
Timepoint	**Enrollment**	**Baseline (0 month)**	**Intervention**	**Post-intervention (4 months)**	**Follow-up (8 months)**
Enrollment					
Eligibility screening	X				
Informed consent	X				
Assessments					
ADHD RS-IV-PV		X		X	X
BCSQ		X		X	X
AIM				X	
IAM				X	
FIM				X	
Actigraphy		X		X	X
Sleep diary		X		X	X
Randomization		X			
Intervention					
Standard PBI			X		
Sleep-focused PBI			X		

Note: ADHD Rating Scale-IV-Preschool Version (*ADHD RS-IV-PV*) [36], Brief Child Sleep Questionnaire (*BCSQ*) [37], acceptability of intervention measure (*AIM*), intervention appropriateness measure (*IAM*), feasibility of intervention measure (*FIM*) [38]

Table 2 Participant eligibility criteria

Inclusion	Exclusion
1. Child is between 3 and 5 years old	1. Child has sleep interfering medical diagnosis (e.g., narcolepsy, obstructive sleep apnea)
2. Caregiver reports child has four or more ADHD symptoms	2. Child has severe neurodevelopmental disorder
3. Caregiver reports child's sleep as a "moderate" or "serious problem"	
4. Child receives care from participating pediatric primary care office	
5. Caregiver is at least 18 years old	
6. Caregiver reads and speaks English	
7. Child is English speaking	

OASIS study. Frequency of ADHD symptoms over the past 6 months will be assessed by caregiver report using the ADHD Rating Scale-IV-Preschool Version (ADHD RS-IV-PV). Items on the ADHD RS-IV-PV are considered symptoms if the caregiver rates them as 2 (often) or 3 (very often). Severity of a caregiver-perceived sleep problem will be determined by caregiver report using the Brief Child Sleep Questionnaire (BCSQ), a rating of either 4 (a moderate problem) or 5 (a serious problem) will meet inclusion criteria, similar to inclusion criteria for other behavioral sleep intervention studies [39, 40].

Practice referrals

Therapists and pediatric providers at participating pediatric primary care offices are encouraged to introduce the study to caregivers with potentially eligible children. After receiving verbal consent, the practice will send a referral to a dedicated study email or study phone maintained by a research specialist. Referrals include the child's name and date of birth. Contact information for the child's caregiver will be obtained through online medical records. The caregiver will be contacted via phone or email by the study team to confirm interest and schedule the screening call.

Self-referrals

Online self-referrals will be submitted through a university-based research participant registry. The registry provides a brief description of study activities and potential compensation for completion. Interested caregivers will provide their preferred contact method (phone number or email) and sociodemographic information on their

child, including name, date of birth, race, and ethnicity. A research specialist will be notified of their inquiry and will reach out via the caregiver's preferred contact method to schedule the screening call.

Brochures will be distributed to the participating pediatric primary care practices. A study website is listed in the brochures and provides additional details about the study for potentially interested participants. Both sources encourage caregivers to contact the study team via email or phone if interested in determining eligibility or if they have additional questions. A member of the research team will monitor the email and phone number, provide study details, and schedule screening calls.

Screening

For all referral sources, the screening call will begin with a synopsis of study procedures and allow the caregiver to express any questions or concerns. If the caregiver decides to continue with the call, they must provide verbal consent for the research team to ask screening questions. Once consent has been provided, the research team continues to ask questions about contact information, sociodemographic information, child ADHD symptoms, and child sleep problems.

Consent to participate

If the caregiver and their child are eligible to participate in the study, research team will facilitate the enrollment process. A link to the online consent form will be sent to the caregiver's provided email address. The online consent form also requires the caregiver to provide assent for the child, as both will be participants in the study. The caregiver must complete the online consent before continuing with baseline study procedures. If the caregiver fails to complete the online consent, they will be excluded from the study. Consent completion will be checked by research team.

Randomization and blinding

Each participant will be randomly assigned by the research team to standard PBI (an abbreviated, modified version of COPEing with ADHD, Cunningham et al., 2009) [41] or SF-PBI (modified integration of COPEing with ADHD and SleepWell!, Williamson et al., 2022) [35]. Randomization will be conducted at the patient level, with each behavior therapist randomly assigned to deliver standard PBI or SF-PBI with their first enrolled patient. Therapists will then alternate intervention conditions with each of their subsequent participants. Half of the trained therapists will start with standard PBI, and half will begin with SF-PBI. As participants are enrolled in the protocol, they will receive the next preset randomized condition for their associated therapist. The research team developed the allocation sequence prior to enrollment of any research participants. The research team member who records the randomization will keep it concealed until baseline assessment is complete. The behavioral therapist assigned to the participant will then be notified of the assignment. Masking for this study is single blind such that participants are never informed of their randomized assignments. There is no limit to how many participants can be enrolled at each pediatric practice. As such, there may be unequal numbers enrolled across the five participating practices.

Interventions

Participants in this protocol are randomly assigned to receive one of two modified evidence-based interventions designed to support caregivers in managing preschool behavioral and/or sleep difficulties. Both conditions will include six, audio-recorded, virtual, or in-person sessions with a licensed, embedded behavioral therapist in the participant's pediatric primary care office. Sessions are designed to be delivered in the allotted 45–60-min clinical appointment and are encouraged to be scheduled 1 to 2 weeks apart. Both the caregiver and child will attend the sessions; however, the child only needs to be present for a brief check-in with the therapist.

Participants assigned to standard PBI will participate in an abbreviated, developmentally appropriate version of *COPEing with ADHD* [41]. Session topics will include social reinforcement for positive behavior and relationship building (attending and praise), planned ignoring of minor inappropriate behavior and associated parental coping techniques for skill implementation, strategies designed to improve transitions and increase compliance such as transitional warnings and when-then techniques, and use of effective commands, time out from positive reinforcement to address behaviors that cannot be ignored, and the planning, creation, and implementation of incentive systems to motivate positive change. The *COPEing with ADHD* session format includes a success-oriented homework review designed to reinforce parental efforts, enhance self-efficacy, and curtail short-term expectations of change, presentation of brief video vignettes depicting exaggerated parenting errors designed to initiate caregiver discoveries of the short- and long-term impacts of effective and ineffective parenting, opportunities for therapist modeling and caregiver role-playing of session-specific strategies, and opportunity to develop and plan individualized, specific application of each skill between sessions [41].

With the exception of time out from positive reinforcement, participants assigned to sleep-focused PBI will participate in sessions that include the identical caregiver management techniques. The format of the standard PBI

sessions will be altered slightly with the elimination of strategy modeling and roleplay to preserve time for the delivery sleep content from *SleepWell!*, a brief, evidence-informed early childhood intervention for insomnia and insufficient sleep that was developed using community-engaged methods and optimized for primary care delivery [35]. A comprehensive sleep assessment, development of optimal bedtime routines, and appropriate individualized application of specific strategies to address common preschool sleep disturbances will enhance the standard PBI content (see Table 3).

To further inform the initial sleep assessment for participants assigned to SF-PBI, the participant's BH therapist is also provided with data collected from the baseline survey and an auto-generated graph based on the completed sleep diary prior to the family's first OASIS session. This information will be communicated to the BH therapist via an informational encounter in the child's electronic medical record (Epic). Those participants assigned to standard PBI will also have an informational encounter placed in the electronic medical record; however, that note will be restricted to demographic and behavioral information and will not reference data related to the participant's sleep.

While participants in the standard PBI will not be prevented from identifying skill application at bedtime, bedtime parenting strategy application will not be targeted or solicited. For the SF-BPI, however, homework planning worksheets have been designed to identify the

Table 3 OASIS session content

Session	Standard PBI	Sleep-focused PBI
1	Behavioral assessment Case conceptualization Goal setting Social reinforcement (attending, praise)	Behavioral assessment Sleep assessment Case conceptualization Goal setting Social reinforcement (attending, praise) Introduction to sleep diary
2	Goal review Planned ignoring Keeping your cool	Goal review Orientation to developmental sleep norms Sleep onset associations Establishing a bedtime routine Bedtime fading (if indicated) Removal of electronics (if indicated) Planned ignoring Keeping your cool
3	Transitional warnings When-then Effective commands	Enhancing the bedtime routine Transitional warnings When-then Effective commands
4	Take a break (time out from positive reinforcement)	Optimizing bedtime routine (if indicated) Re-evaluation of goals Individualized sleep intervention (one or more of the following strategies based on family and therapist-identified needs) • Bedtime fading • Predetermined checks • Graduated extinction • Night awakening strategies • Nighttime fear strategies • Bedtime refusal and delay strategies • Early wake strategies
5	Incentive systems • Standard behavioral	Optimizing sleep strategies Incentive systems • Standard behavioral • Bedtime Pass • Sleep Fairy
6	Optimizing incentive system Progress review Review of behavioral strategies Problem-solving daytime behavior Future goal development	Optimizing incentive system Progress review Review of behavioral strategies Review of sleep strategies Problem-solving daytime and sleep behavior Future goal development

application of each parenting skill or strategy at bedtime and during the day.

Each intervention arm has been manualized, and each condition also has six, session-specific PowerPoints created to maximize consistency of intervention delivery across therapists. Participating caregivers will be provided with a bound, color-coded folder that contains all session PowerPoints and homework sheets that they may use to follow along with the therapists. Sessions including vignettes have developmentally appropriate video clips imbedded in the presentation to facilitate the session's flow. Therapists will also be provided with a packet of each participant's worksheet to record planned parental skill application that the therapist may reference in later sessions. Sample clinical note text for documentation and sleep assessment tools will also be provided to therapists to decrease therapist burden. The naming of each intervention and their color-coded materials have been designed to preserve parental blinding of intervention assignment while serving as a visual cue to therapist who will be delivering both arms of the intervention.

At any time during the study, participants may receive resources and referrals for families of preschool-aged children with disruptive behaviors that are standard to pediatric primary care, except active sleep-focused treatment. These may include brief interventions that providers deliver as part of a medical visit (e.g., sleep education) or referral for treatment of a psychiatric disorder. We will track the resources and referrals that participants receive. We will also track medication changes to measure whether and how these changes are associated with changes in sleep.

Therapist training

The content for each training was informed by the study design and a therapist survey completed before the first training. Therapists were asked to indicate their experience and comfort with the primary behavioral and sleep intervention strategies included in the OASIS interventions. While all therapists rated their experience and comfort with caregiver training in general and the specific behavioral strategies highly, they reported feeling less comfortable with sleep assessment and intervention. Thus, while both interventions were covered in each training, the education and training were weighted toward the sleep-focused intervention to build therapist knowledge, skill, and comfort in sleep assessment and treatment.

Therapists participated in 10 and half hours of structured training to prepare for the delivery of the OASIS study interventions. This training included an initial half-day training focused on providing critical background information and introduction to the study interventions. The first 90 min of the training included a presentation that focused specifically on the assessment and management of sleep problems in preschool-aged children. This introduction provided core background in the basics of sleep, sleep in early childhood, assessment of sleep problems, and treatment of early childhood sleep problems — an expressed need uncovered in a therapist pre-survey. After a brief break, therapists then participated in a second 2-h and 15-min training session that was comprised of a 30-min overview of the OASIS protocol, a 90-min review of the specific session content for both intervention conditions, and a 30-min brainstorming session to plan future collaboration and discuss logistical issues. The presentations were a blend of instruction, demonstration, and discussion. Therapists were provided with a training binder that included both structured presentations, the six standard PBI sessions, the six SF-PBI sessions, all associated session materials, and contact information for the OASIS team members for reference during the training and to use in their clinical practice. This training session was recorded so that the therapists could review the material as needed and to ensure comparable training for future therapists. Therapists were encouraged to use the materials with their current patients to familiarize themselves with the materials and to generate questions.

The next 1-h training occurred 1 month later after the therapists had the opportunity for self-study and piloting the strategies as part of their regular clinical work, as appropriate. This follow-up provided the opportunity for important review and therapists questions after they had the opportunity to digest the material and practice delivery. The study team also conducted a case series with three families to finalize our study procedures. Recorded pilot sessions were uploaded to a secure shared study site for the BH therapists to access as models for the study intervention (SF-PBI).

A third, 1-h training offered 2 weeks later provided advanced instruction in the conduct of pediatric sleep assessments and the development of bedtime routines, core components of the OASIS Blue intervention. Therapists observed a recorded sleep assessment conducted by a study investigator who is an expert in behavioral sleep medicine. This example was also uploaded to the therapist's shared drive for future access.

Open virtual drop-in hours were offered once a month for the next 2 months to address individual therapist questions related to intervention delivery and piloting.

Just over 4 months after the initial training, therapists reconvened to participate in a 3-h enhanced sleep training. Several case studies depicting common preschool sleep and behavior problems were presented and discussed. Important components of assessment, problem-identification, and sleep strategy selection were discussed

and reviewed with active participation and solutions generation by the attending therapists. The research team developed a PowerPoint slide with a menu of possible sleep strategies for each presenting sleep problem to help guide the therapist in their decision-making.

One-on-one consultation was offered during the training period and is available throughout study implementation.

Therapists were offered continuing education credit for each training. Meals and parking were also provided for the in-person training.

As noted above, therapists had access to several resources for self-training including electronic and paper versions of the session PowerPoints, recorded modeled sleep assessments, and video-taped pilot cases.

Continuing supervision is offered at monthly drop-in hours and via 24–7 access to the principal investigators by e-mail or chat on a Microsoft Teams page.

Outcomes

Feasibility outcomes

- *Intervention acceptability* (post-intervention): Therapist and caregiver report of intervention acceptability will be assessed using the 4-item acceptability of intervention measure (AIM), rated from 1 (completely disagree) to 5 (completely agree), with scores greater than or equal to 16 indicating good acceptability (see Table 4).
- *Intervention appropriateness* (post-intervention): Therapist and caregiver report of intervention appropriateness will be assessed using the 4-item intervention appropriateness measure (IAM), rated from 1 (completely disagree) to 5 (completely agree), with scores greater than or equal to 16 indicating good appropriateness (see Table 4).
- *Intervention feasibility* (post-intervention): Therapist and caregiver report of intervention feasibility will be assessed using the 4-item feasibility of intervention measure (FIM), rated from 1 (completely disagree) to 5 (completely agree), with scores greater than or equal to 16 indicating good feasibility (see Table 4).

Table 4 Feasibility outcome, measure, and measure items

Feasibility outcome	Measure	Measure items
Intervention acceptability	AIM	OASIS meets my approval OASIS is appealing to me I like OASIS I welcome OASIS
Intervention appropriateness	IAM	OASIS seems fitting OASIS seems suitable OASIS seems applicable OASIS seems like a good match
Intervention feasibility	FIM	OASIS seems implementable OASIS seems possible OASIS seems doable OASIS seems easy to use

Clinical outcomes

- *Problematic sleep* (change from baseline up to 8 months): As in other behavioral sleep problem treatment evaluations [39, 40], caregivers will report on their perception of their child's sleep as problematic (rate 1 — not at all to 5 — a serious problem) using a single item (item 25) from the Brief Child Sleep Questionnaire.
- *ADHD symptoms* (change from baseline up to 8 months): Caregiver report on their child's ADHD symptoms using the 18-item ADHD Rating Scale-IV-Preschool Version, with symptoms rated from 0 (rarely) to 3 (very often).

Secondary outcomes

- *Nighttime awakenings* (change from baseline up to 8 months): Caregiver report of how many times their child typically wakes during the night, using item 17 on the Brief Child Sleep Questionnaire.
- *Sleep onset latency* (change from baseline up to 8 months): Caregiver report of how long it typically takes their child to fall asleep (number of minutes), using item 12 on the Brief Child Sleep Questionnaire.
- *Consistency of bedtime routine* (change from baseline up to 8 months): In caregiver report of the number of days, in a typical week, they regularly put their child to bed at the same time (within 15 min), using item 10 on the Brief Child Sleep Questionnaire.

Data collection and management

Physical copies of the completed screening packets will be stored in a locked filing cabinet accessible only to research team.

Intervention acceptability, feasibility, and appropriateness data will be collected from therapists through an online fidelity survey completed twice over the course of the study: first after delivering the SF-PBI to two participants and at the end of the study. Primary and secondary outcome data relying on caregiver reports will be collected digitally via the post-intervention and 4-month

follow-up surveys. Study surveys for both therapists and participants will be distributed via email through the website Qualtrics, a web-based platform for developing and distributing surveys. The survey flow and results can only be viewed by those who are a "collaborator" on the survey, which is an invite-only role delegated to the research team. For exploratory analyses, actigraphy and sleep diary data will be collected at baseline, post-intervention, and 4-month follow-up. Actigraphy data from the child participant will be collected using an ActiGraph CPW01 device for 10 days, beginning on a Friday so that the data collection period includes two weekends. Caregivers will be instructed to place the actigraphy on the child's wrist and keep it in place continuously for the 10-day monitoring period at the baseline, post-intervention, and follow-up assessments. The actigraphy devices use CentrePoint, a software dedicated to collecting, processing, and managing actigraphy data. An online sleep diary link will be sent to the caregiver via text message or email in the morning and evening daily for 10 days. The sleep diary will be programmed by a research assistant to be delivered after the child's typical waking time in the morning and after their typical bedtime in the evening at the time of the caregiver's choosing. The sleep diary is maintained by a department that builds and manages research applications for data collection.

All used file servers and workstations will be behind a firewall, restricting access. The database server and file servers will not be accessible from outside of the firewall. No local accounts will be used, and access to all files and databases will be restricted. Login procedures for data entry and access will be restricted to designated research team members through database software protection.

Sample size

As this is a feasibility study, the sample size is not meant to obtain a desired level of statistical power to detect effects on clinical outcomes [42–44]. Rather, our sample size $N=50$ (25 in each of the 2 interventions) will provide sufficient data for describing the acceptability, appropriateness, and feasibility of the intervention. A sample of 25 in the SF-PBI arm is sufficient to assess 80% therapist and parent-reported feasibility (rating of 16 or greater on the AIM, IAM, FIM measures of intervention feasibility) with 95% CI of 59–93%.

Data analysis

CONSORT guidelines for reporting randomized pilot and feasibility trials will be followed [44]. This feasibility study is not powered for inferential analyses. Therefore, our primary goal is to evaluate whether the magnitude and direction of effect sizes are consistent with our hypotheses, rather than to determine statistical significance.

Aim 1: Demonstrate the acceptability, feasibility, and appropriateness of the sleep-focused PBI

Summary statistics will be used to describe BH therapist and caregiver-reported measures of acceptability, appropriateness, and feasibility of the SF-PBI. The proportion and frequency of participants reporting good acceptability, appropriateness, and feasibility as indicated by scores > 16 will be reported. BH therapist data collected after each intervention session will be aggregated to assess total dose administered and compliance (provider and caregiver) with the intervention. Descriptive statistics will be used to describe caregiver strategy utilization post-intervention. Point estimates will be reported along with 95% confidence intervals where appropriate to quantify the extent of the potential error surrounding the estimate.

Aim 2: Examine change in target engagement (sleep) and ADHD symptoms among preschooler-aged children at elevated risk for ADHD receiving the SF-PBI compared to those receiving standard PBI

We will implement our analytic strategy that is envisioned in a future fully powered RCT, with the goal of honing the analytic approach for this future study. In preliminary analyses, we will visually examine distributions and trajectories over time to assess linearity and normality and to determine the functional form of time in the model. Patterns of missing data and potential reasons for missingness will be examined, and stratified sensitivity analyses will be conducted when appropriate; these analyses will be reported with transparency. Analyses will use an "intent-to-treat" approach such that all participants randomized will be included in the analyses, regardless of fidelity to the treatment. We will use linear mixed-effects models to regress the repeatedly measured outcome (sleep and ADHD symptoms) on group (SF-PBI vs. Standard PBI), time, their interaction, and covariates selected a priori based on the literature. Random intercept and, if appropriate, random slope terms will be included. Effect sizes and confidence intervals for within-group changes and between-group differences at post-treatment and 4-month follow-up will be estimated based on post hoc comparisons. Correlations between change in sleep and ADHD symptoms from pre- to post-treatment will also be examined.

Transition to a definitive trial

Scores greater than or equal to 16 by 80% of therapists and participants on the feasibility outcomes

(acceptability, appropriateness, and feasibility) will indicate good feasibility and support progression to a definitive trial. A lesser percentage by therapists or parents will suggest modifications are needed to improve feasibility of the intervention including implementation in primary care settings.

Human ethics

All study consent forms, recruitment materials, intervention materials, and necessary modifications were submitted to, and approved by, the University of Pittsburgh Institutional Review Board (IRB; STUDY22070096). IRB approval is based on compliance with regulations regarding human subjects and scientific content. The principal investigator will continue to submit progress reports to the IRB throughout data collection, including the number of participants enrolled, to ensure continued compliance.

Patient and public involvement

Patient, provider, and administrative input was solicited and integrated into the development of the OASIS intervention. The behavior health program director for the pediatric network (AG) began meeting with the research team during the initial planning stages for this research project to ensure that proposed intervention could be integrated into the existing behavioral health model of care. Further involvement included ensuring the study followed best practices for integrated behavioral health care in pediatric primary care while continuing to uphold the financial billing model for sustainability [45, 46]. Before developing the intervention materials, three separate focus groups were held with caregivers ($n=12$) of children 3–5 years old with elevated ADHD symptoms (4+) and moderate to severe sleep problems, behavioral health therapists ($n=9$) working in pediatric primary care offices, and pediatric providers ($n=5$) that represented each of the five practices enrolled in the study. These focus groups were held to identify areas of concern around preschoolers' sleep and behavior, understand how children in need of this intervention are typically identified in pediatric primary care, determine the preferred content and format of the intervention, and assess provider knowledge and experience with preschool sleep assessments and use of sleep strategies as well as standard parent behavioral intervention strategies for young children. Three of the caregivers who participated in the focus group expressed interest in receiving the treatment and were enrolled in a case series. Members of the research team (H. J., H. K., J. L.) delivered the intervention using the materials developed for the study. Iterative refinements were made to the intervention materials based on the caregiver and research team feedback. The study team will continue to communicate with the behavioral health program director and the five pediatric providers representing each of the practices throughout the research study for consultation if challenges arise, to ensure clear communication between the research team and the clinical staff, and to support recruitment of research participants from their clinic.

Discussion

Symptoms of ADHD interfere with preacademic and social skills even before school entry. Importantly, sleep disturbances including insomnia symptoms (difficulty falling and/or staying asleep) and poor sleep health (insufficient sleep) are critical, modifiable contributors to core ADHD symptoms, including to worsening inattention, hyperactivity, and impulsivity [15–18, 28]. Given that 70% of children with ADHD experience sleep disturbances, effective, sustainable, and accessible interventions early in life are necessary to alter the trajectory of symptoms and ADHD-related impairments for young children at risk of developing childhood ADHD. To date, no interventions have been designed to target both daytime and nighttime disruptive behaviors of preschool-aged children presenting with both ADHD symptoms and sleep problems. Thus, the OASIS intervention combines elements of a traditional parent behavioral intervention for young children with ADHD and evidence-based strategies for treating child sleep disturbances in preschoolers. To enhance downstream implementation and intervention uptake [26], the six-session program was designed with thoughtful input from caregivers, behavioral health therapists, and pediatric providers to be implemented via telehealth in the pediatric primary care setting. In addition, the behavioral sleep intervention strategies included in OASIS were developed and tested using community-engaged methods to prioritize feasibility in primary care and cultural humility in the intervention implementation [35, 47].

The initial pilot effectiveness trial was designed to test the acceptability, feasibility, and appropriateness of the OASIS intervention and to begin to examine changes in both child sleep and ADHD symptoms. Results from this study will inform a larger randomized controlled trial and will shed light on whether addressing sleep disturbances can benefit ADHD symptoms, providing a foundation for larger-scale mechanistic research focused on understanding longitudinal change in ADHD symptom trajectories following early childhood treatment.

The OASIS intervention has many strengths including adaptation from an evidence-based PBI for ADHD and an evidence-informed behavioral sleep intervention [35, 41], formatting to fit the brief assessment and treatment model of behavioral health embedded in pediatric primary care, and easy to use materials (a therapist

manual, PowerPoints with notes for each session, video vignettes, and parent homework handouts). However, there are some notable limitations of this research. The providers delivering this intervention in the pilot effectiveness trial are trained as licensed professional counselors or licensed clinical social workers. Thus, generalizability is limited as behavioral health therapists are not routinely embedded in pediatric primary care offices. While medical home models are increasing, many pediatric primary care offices lack access to a behavioral health provider. Given the small sample size and single geographic region in which this study will be conducted, generalizability may be limited, particularly regarding sociodemographic factors. Considering sleep and behavioral health disparities begin in early childhood, additional, larger-scale research is needed to identify whether access to, engagement in, and outcomes of the OASIS intervention are equitable across sociodemographic factors, including racial, ethnic, and socioeconomic characteristics [48, 49]. Families' perceived cultural humility in intervention delivery should also be examined in this future work.

Another notable limitation is the potential need for training on sleep assessment and sleep strategies for preschool-aged children for behavioral health therapists in pediatric primary care. Although the OASIS intervention materials clearly describe the sleep strategies and their indications, we are aware that (1) not all sleep strategies are applicable to every child or family (i.e., some children may not exhibit bedtime resistance or do not obtain insufficient sleep), and (2) selecting and flexibly applying the sleep strategies take practice. Although the OASIS intervention and related trainings incorporated information about the flexible use of strategies, more training may be needed for effective intervention delivery. The study team will examine fidelity surveys and review the audiotapes of each session to better understand which strategies were selected for each presenting problem. The study team is also interested in considering additional, scalable training programs and materials for behavioral health therapists working with young children. Scalable, high-quality training to ensure clinicians can implement OASIS with fidelity is an important future direction that should be examined in subsequent hybrid effectiveness-implementation trials. In addition to evaluating OASIS effectiveness in a larger sample of families and across sociodemographic groups, future research should focus on understanding the most effective implementation therapist training and implementation strategies. Despite these limitations, the OASIS study will provide much-needed preliminary data to support subsequent research aimed at effectively and equitably addressing sleep disturbances in young children as a method to reduce ADHD symptoms and improve development longitudinally.

Trial status

At the time of submission (March 2024) recruitment for this clinical trial was ongoing with the initial research participant having been enrolled on 12–1-2023.

Abbreviations

ADHD	Attention-deficit/hyperactivity disorder
ADHD RS-IV-PV	Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Preschool Version
AIM	Acceptability of intervention measure
BCSQ	Brief Child Sleep Questionnaire
BH	Behavioral health
FIM	Feasibility of intervention measure
IAM	Intervention appropriateness measure
OASIS	Optimizing attention and sleep intervention study
PBI	Parent behavioral intervention
RCT	Randomized controlled trial
SF-PBI	Sleep-focused-parent behavioral intervention

Supplementary Information

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Supplementary Material 1.

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Authors' contributions

HJ contributed to the study conception and study design and drafted the manuscript. JL and RC contributed to the study conception and study design and substantively revised the manuscript. KM drafted the manuscript. HK contributed to the study design and drafted the manuscript. AG, MW, and AW each contributed to the study design and substantively revised the manuscript. All authors read and approved the final manuscript.

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Data availability

The datasets generated during the current study will be available in the NIMH National Data Archives repository, https://nda.nih.gov/edit_collection.html?id=4690.

Declarations

Competing interests

The authors declare that they have no competing interests.

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