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ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	Adverse Event
BCSQ	Brief Child Sleep Questionnaire
BMI	Body Mass Index
COVID-19	Coronavirus
DSMB	Data Safety and Monitoring Board
IRB	Institutional Review Board
EMR	Electronic Medical Record
OSA	Obstructive Sleep Apnea
PHI	Protected Health Information
PI	Principal Investigator
PriCARE	Child Adult Relationship Enhancement in Pediatric Primary Care
REC	Recruitment and Enhancement Core
REDCap	Research Electronic Data Capture
SES	Socio-Economic Status
WCV	Well Child Visit

ABSTRACT

Context: (Background)

Behavioral sleep problems such as insomnia and insufficient sleep are common in toddlers and preschoolers and disproportionately impact lower socioeconomic status (SES) children. Despite a robust evidence base, behavioral sleep interventions are rarely tested with lower-SES children or in primary care, an accessible service delivery setting.

Objectives:

The primary objective of this study is to determine the feasibility of recruitment, randomization, and measurement procedures; intervention acceptability; and intervention engagement and adherence for the Sleep Well! brief behavioral sleep intervention.

Secondary objectives are:

- To compare Sleep Well! to enhanced usual care on objective and caregiver-reported child sleep outcomes over post-intervention and follow-up
- To explore the effects Sleep Well! on child behavior outcomes over post-intervention and follow-up.

Study Design:

This is a randomized controlled trial (RCT). Caregiver-child dyads will be assigned to the intervention group, in which they participate in the Sleep Well! behavioral sleep intervention, or to an enhanced usual care control group, in which they are provided with an evidence-based sleep education handout.

Setting/Participants:

The study will be conducted at two sites: CHOP, outpatient setting, and University of Oregon, outpatient setting.

At CHOP, caregiver-child dyads (child ages 1-5 years with a sleep problem) will be recruited from 3 CHOP urban primary care sites (South Philadelphia, Cobbs Creek, Karabots). A maximum of 100 caregiver-child dyads will participate.

No study recruitment or data collection will occur at University of Oregon. Only data management, analysis, and interpretation will occur at University of Oregon.

Study Interventions and Measures:

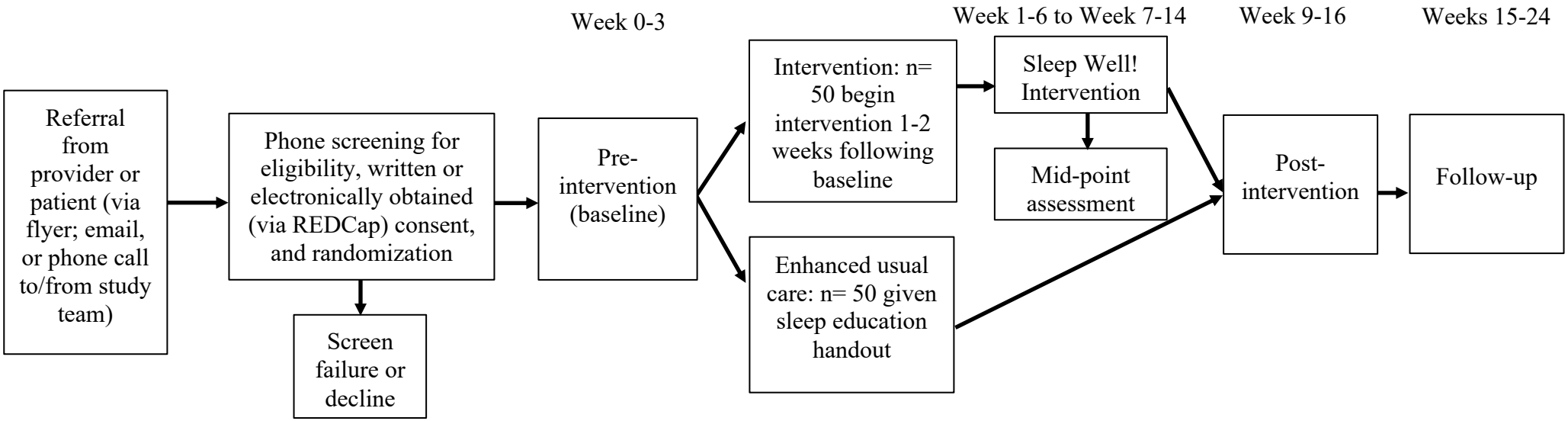
Sleep Well! is a brief, behavioral sleep intervention for toddlers and preschoolers who have a caregiver-reported sleep problem or who are not getting enough sleep. The intervention includes evidence-based behavioral sleep approaches and strategies to engage and empower families. The primary study outcomes are the feasibility of recruitment, randomization, and measurement procedures; intervention acceptability; and intervention engagement and adherence. Secondary outcomes are the direction and magnitude of objective and caregiver-report child sleep and behavior at post-intervention and follow-up.

TABLE 1: SCHEDULE OF STUDY PROCEDURES

	Procedure	Screening/ Eligibility	Pre-intervention (baseline)	Intervention Phase	Mid-point assessment	Post-intervention	Follow-up (2-3 months)
Measures to Determine Eligibility							
Screening eligibility measure	Caregiver-reported	X					
Measures of Treatment Feasibility and Acceptability							
Screening rate	Study team-documented	X	X				
Recruitment rate	Study team-documented		X				
Retention rate	Study-team documented		X	X		X	
Intervention usability	Study-team rated					X	
Family engagement*+	Student-team documented			X			
Intervention adherence*+	Study-team rated			X			
Treatment acceptability: Treatment Evaluation Inventory—Short Form+	Caregiver-reported					X	
Treatment acceptability: Multicultural Therapy Competency Inventory-Client Version (MTCI-CV)+	Caregiver-reported					X	
Goal attainment+	Caregiver-reported					X	X
Treatment acceptability: Caregiver interview+	Caregiver-reported					X	
Services interview#							X
Assessment process	Study-team documented		X			X	X
Demographic and Parent and Child Measures							
Child demographic information	Study team- abstracted from EMR		X				
Caregiver demographic and family information	Caregiver-reported		X				
Previous service use	Caregiver-reported		X			X	X
Review of services	Study team- abstracted from EMR		X				
Brief Child Sleep Questionnaire	Caregiver-reported		X		X	X	X
Child Behavior Check List	Caregiver- reported		X			X	X
Center for Epidemiological Studies Depression Scale-Revised (CES-D-R)	Caregiver- reported		X			X	X
PROMIS Sleep Disturbance Short Form	Caregiver-reported		X			X	X
COVID-19 and Life Stressors Measure	Caregiver-reported		X			X	X
Daily sleep diary (7 days)	Caregiver-reported		X			X	X
Actiwatch (objective sleep monitor, 7 days)	Objective		X			X	X

* = Completed at each intervention session and phone follow-up; + = intervention group only; # = control group only

FIGURE 1: STUDY DIAGRAM



1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Behavioral sleep problems, including insomnia and insufficient sleep, are associated with adverse physical,[1] neurobehavioral,[2,3] and social-emotional outcomes.[4] Sleep problems impact 20-30% of young children[5] and disproportionately impact lower-SES children[6-8]. There is little research on behavioral sleep interventions with lower-SES youth, and no studies have examined these interventions in primary care, an accessible setting. This project will examine the feasibility and acceptability of a behavioral sleep intervention for lower-SES toddlers and preschoolers that is implemented through primary care.

1.2 Name and Description of Investigational Product or Intervention

Sleep Well!, a behavioral sleep intervention for toddlers and preschoolers, is being tested. The program includes standard behavioral sleep treatment approaches (caregiver education about healthy sleep habits; development of bedtime routine and sleep schedule; behavioral management of bedtime tantrums) with adaptations (see 1.3, below) for the target population (lower-SES caregivers) and context (pediatric primary care).

1.3 Relevant Literature and Data

Treating early childhood behavioral sleep problems is a key strategy for health promotion. Given the rapid neurobehavioral growth in toddlers and preschoolers,[9] early childhood sleep problems may be especially detrimental. Early behavioral sleep problems predict concurrent and subsequent neurobehavioral (inattention; poor response inhibition)[2-4] and social-emotional[10-12] problems, which can impair school outcomes.[13,14]

Behavioral sleep problems are more prevalent in lower-socioeconomic status (SES) children.[6,8,15] Behavioral sleep problems including pediatric insomnia (bedtime problems; night awakenings) and insufficient sleep are found in 20-30% of young children.[16,17] Lower-SES children show greater insomnia symptoms,[7,15,18] shorter sleep duration, and worse sleep quality,[3,6,8] even when controlling for other factors such as child race/ethnicity.[7,18,19]

Although there are robust behavioral treatments for child sleep problems, studies rarely examine these treatments in lower-SES children with sleep problems.[17,20,21] Brief interventions result in improvements in child sleep and behavior.[22,23] Intervention content generally involves caregiver education about child sleep needs and healthy habits and implementing behavioral interventions, such as a consistent bedtime routine and sleep schedule, parental limit-setting, and reducing caregiver presence in the child's bedroom at bedtime.[17,20,24] Two studies have tested sleep health promotion for lower-SES children without sleep problems.[25,26] A randomized trial with Head Start families[26] found that one session of sleep education and a 2-week classroom curriculum resulted in increased preschooler sleep duration. We[25] randomly assigned lower-SES children receiving a bed from a charity program to sleep education or a dental hygiene control, and found reductions in electronic items in the bedroom and increased child sleep duration in the sleep education condition.

Behavioral sleep treatments have not been implemented in primary care. Primary care is an accessible and widely used service setting,[27,28] especially in early childhood when there is increased need for well child visits and vaccinations.[29] Receiving care in this setting may be more feasible for lower-SES families, who may lack access to specialty care.[30-32] However, sleep problems are under-treated in primary care,[27,33,34] and there is a nationwide shortage of behavioral sleep specialty care providers.[35] The 2015 NIH and Sleep Research Society Workshop emphasized the need to translate evidence-based sleep interventions into practice settings.[36] **During the past 20 years, there has been a major emphasis on integrating behavioral health services into primary practice.**[28] To be responsive to this important practice shift, which has incorporated behavioral health clinicians into primary care, **research is needed to identify *how* evidence-based interventions can be implemented in an integrated primary care context.**[37]

Adaptations to behavioral sleep intervention are needed for effective implementation in urban primary care. Previous research[38] indicates a high need to adapt the **content** and **service delivery methods** of early childhood sleep interventions for a lower-SES sample and for implementation in the primary care context. **Content adaptations** include developing intervention materials for lower health literacy and education in lower-SES caregivers.[39] Shift-work and single parenthood, which are both common in lower-SES families, are each linked to increased parenting stress,[40-43] which can make intervention components such as consistent bedtime routines difficult to implement.[7] Other intervention components, such as reducing parent presence in the bedroom, may also need adaptation to accommodate socio-cultural variation in beliefs about sleep[18,44] and increased bed- and room-sharing in lower-SES families.[45] Other modifications may be needed, such as tailoring parenting strategies for mothers with depressed mood, as previous studies[15,46,47] show that caregiver depression and child sleep problems are significantly associated across different levels of SES.

Service delivery method adaptations include enhanced engagement, empowerment, and retention strategies may be needed, as attrition is common in lower-SES families facing multiple stressors (e.g., housing instability, childcare and transportation issues).[48-52] Additionally, pre-intervention motivational strategies[53] to increase engagement may be needed. Supplemental methods to provide content to families, such as via text messages, may also be appropriate. A trauma-informed approach may also need to be integrated due to high rates of violence exposure in lower-SES contexts.[54-56]

1.4 Compliance Statement

This study will be conducted in full accordance all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46 and the Good Clinical Practice: Consolidated Guideline approved by the International Conference on Harmonisation (ICH). All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in

accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

The purpose of the study is to test the feasibility and acceptability, as well as the magnitude of intervention effects, of Sleep Well!, a behavioral sleep intervention for toddlers and preschoolers presenting to primary care telehealth or in-person visits.

2.1 Primary Objective (or Aim)

The primary objective of this study is to determine the feasibility of recruitment, randomization, and measurement procedures; intervention acceptability; and intervention engagement and adherence for the Sleep Well! brief behavioral sleep intervention.

2.2 Secondary Objectives (or Aim)

The secondary objectives are to:

- Compare Sleep Well! to enhanced usual care on objective and caregiver-reported child sleep over post-intervention and follow-up
- Explore the effects Sleep Well! on child behavior outcomes over post-intervention and follow-up.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This is a randomized control trial of Sleep Well!, a behavioral sleep program for toddlers and preschoolers. As shown in Figure 1, following referral, potentially eligible families will be screened by phone for intervention eligibility. Eligible and interested participants will be scheduled for a pre-intervention (baseline assessment) visit that occurs in-person or by electronically and includes informed consent (or e-consent), random assignment to the intervention condition or an enhanced usual care condition, and completion of baseline measures. The baseline assessment will occur 0-3 weeks post-screening. Those assigned to the intervention group will start receiving the intervention 1-3 weeks following baseline assessment. Those in the control condition will be given a Parent-Family Education Manual handout about healthy sleep in early childhood and directed to follow-up with their pediatrician. The Sleep Well! intervention phase includes 3 sessions conducted in-person, by HIPAA-compliant video conferencing platform, or by telephone, as well as 3 telephone check-ins over a 6- to 8-week period (study weeks 1-6 to 7-14). A mid-point assessment of child sleep will occur electronically for the intervention condition 2 weeks into the intervention phase. The post-intervention assessment will occur at week 9-16 (1-3 weeks post last intervention session for intervention group). The follow-up assessment will occur 6-8 weeks after the post-intervention assessment, or at week 15-24.

Outcomes related to intervention feasibility and acceptability will be assessed throughout the duration of the study period (see Table 1, above). Caregiver participants will complete baseline demographic information and ratings of their child's sleep. Actigraph devices will be used to objectively measure sleep. At post-intervention, caregiver participants will also provide ratings of their child's sleep, their own sleep, mood, and stress, and those who were in the intervention condition will participate in a qualitative interview to provide intervention content and delivery feedback. Similar measures will be administered at post-intervention. At this time, caregivers in the control condition will also complete an interview to identify perspectives about their enhanced usual care experience.

3.1.1 Screening Phase and Baseline Assessment

Potential participants will be recruited for study eligibility screening through multiple methods.

First, providers (physicians, nurses, social workers, and psychologists) practicing at the South Philadelphia, Cobbs Creek, and Karabots primary care locations will identify potentially eligible families of young children with sleep problems for this study. The study team will also post a flyer for participants (see uploaded recruitment document) in providers' office to remind them of the study and to encourage referrals. This flyer will also be emailed to all of the providers. A smartphrase in Epic will be made available to providers practicing at these sites to facilitate recruitment and to provide families with information. Families who have sleep concerns and are potentially eligible will be asked if they would be interested in participating in an intervention program to improve child sleep. The providers will then provide the child's name and either the date of birth and/or medical record number (MRN) of interested families to the study team, or provide the smartphrase to families in the After Visit Summary. The study team will also activate an EPIC alert for the Sleep Well! Study in the electronic medical record for 1- to 5-year-old patient well-visits that providers can use to refer patients and their caregivers to the study team. If submitting a referral via e-mail or phone, the referring provider will collect and provide potential subject contact information to a study team member.

Second, the study team will also identify possible participants by reviewing providers' schedules for basic eligibility criteria (child ages 1-5 years presenting for a primary care visit), and will contact the possible participant by telephone.

Third, the study team will also use printed flyers and tear pads, which will be posted in the providers' waiting rooms, will be handed out to families, and will be displayed for potential families to take.

Fourth, the Recruitment Enhancement Core (REC) will provide in assistance with recruitment plan development and may assist in identifying and contacting potential participants using the CRU, the CHOP Recruitment Registry, social media and internal communication resources. Please see the REC e-mail uploaded with this protocol for further information. The REC also engages community partners and facilitates outreach on behalf of the research Institute and CHOP research studies. Any recruitment materials distributed by REC, such as tear pads and recruitment flyers, will first be submitted to the IRB for review and approval prior to use. Of note, we have included the REC e-mail, tear pads, and

recruitment flyers with this submission. Any additional recruitment materials, such as social media posts, will be submitted to the IRB for review prior to any use of these materials.

Fifth, due to an overlap in the target study population, Sleep Well! and another CHOP primary care-based study team, PriCARE, will have a shared EPIC alert for children ages 1-6 at three of the participating primary care sites. When referring patients, clinicians will indicate on the alert whether the referral is for Sleep Well!, PriCARE, or both. The two study teams will collaborate on contacting the caregivers who were referred to both programs and if the caregiver is interested in participating, they will be asked to decide which program they'd like to participate in first. If Sleep Well! is chosen, the Sleep Well! team will screen for eligibility and proceed with the consent process if the caregiver is eligible and interested. If PriCARE is chosen, the PriCARE team will screen for eligibility and proceed with the consent process if the caregiver is eligible and interested. Each team will be responsible for screening, enrolling, and data collection for their own study. All call attempts and contact information will be securely stored in each team's respective REDCap databases and cross-team communication will occur via CHOP's secure e-mail system and embedded REDCap messaging features.

For these methods we are requesting a waiver of HIPAA authorization to screen medical records in the EHR to ensure that families that are contacted for the study meet basic eligibility criteria available in the child's medical record.

For potentially eligible families, the study team will contact families by telephone and, for interested families, screen them for the study using inclusion/exclusion criteria and an associated eligibility screening survey, and schedule eligible and interested families for informed consent procedures. The study team is also requesting an **alteration of documentation of HIPAA authorization to screen** given that the study team is located in the Roberts building or in an alternative work arrangement (in the case of coronavirus restrictions) and will not have in-person contact with the families at the primary care sites. It would therefore not be feasible to obtain written documentation of HIPAA authorization for screening from these families. In addition, this method will reduce any burden to participants in traveling to complete in-person eligibility screening.

The phone screening will include requesting that parents/legal guardians respond to questions to determine whether exclusion criteria are present. If families are eligible, they will be scheduled for a study visit at their child's CHOP primary care practice to obtain written consent for the main study and collect baseline data. Families will also be provided the option to complete electronic informed consent procedures via REDCap (see below). During the screening phone call, families will be informed of their choice to participate or not. If families decide not to participate, they will be referred to their pediatrician for further follow-up care, consistent with the current standard of care for behavioral sleep problems.

Given that the CHOP urban primary care sites see approximately 49,600 children per year, we believe that we will be able to recruit a sufficient number of participants to meet the goals for this objective. In addition, this recruitment strategy has been discussed with the primary care sites for this study, and has been approved by the Pediatric Research Consortium.

3.1.2 Study Treatment Phase (start of the study intervention)

Sleep Well! is a brief, behavioral sleep intervention. The intervention was originally comprised of healthy sleep advice and tested in the context of a sleep health education campaign for impoverished children.[25] Based on our preliminary research regarding the need for sleep intervention in primary care,[38] we have expanded the intervention to more comprehensively address poor sleep health behaviors (e.g., use of electronics at bedtime; inconsistent and variable sleep schedules; lack of a bedtime routine) as well as insomnia (difficulty falling and staying asleep; the need for caregiver presence at bedtime) and insufficient sleep in toddlers and preschoolers who are living in disadvantaged contexts. Intervention components are based on effective pediatric behavioral sleep treatments.[21,22,24,57]

Adaptations to the program content and delivery have been made based on preliminary results from our previous studies (IRB 18-015041; IRB 19-016482) with primary care providers in the target urban primary care context and caregivers of young children with sleep problems who are reflective of the target intervention population. For example, interventionists will use strategies to engage with and empower families, such as motivational interviewing and collaborative problem-solving.[53] In-person session content will be reinforced via phone calls from interventionists. We will also send families intervention session appointment reminders and information about intervention content (e.g., reminders to follow a bedtime routine), using Twilio, which is integrated with REDCap. No PHI will be transmitted via text message, and families will be asked to contact the study team or interventionist by phone if they have any questions or concerns during the study assessments or intervention phase. Consistent with standards of clinical care for behavioral health services in the CHOP primary care network, progress notes for intervention-related patient contact (sessions; phone calls) will be documented in the electronic health record.

3.1.3 Enhanced Usual Care Phase (start of the control condition)

The control condition will be usual care enhanced by the provision of evidence-based guidelines for addressing sleep problems in early childhood. This is consistent with usual care in the CHOP system. Please see section 4.3.3 below for further information.

3.1.4 Follow-up Phase (post-intervention and follow-up assessments)

Caregivers in both study conditions will complete post-intervention measures at study week 9-16, depending on the timing of their baseline assessment and, for intervention participants, depending on the timing of their final Sleep Well! interventionist contact. Caregivers in both study conditions will also complete a follow-up visit approximately 6-8 weeks following the post-intervention assessment, or at study weeks 15-24 depending on the timing of earlier visits. Please see Table 1 for a summary of study measures at these assessment periods.

If the participant had originally been referred to both the Sleep Well! and PriCARE programs via the EPIC alert, once they have completed study participation in either Sleep Well! or PriCARE (whichever they chose to do first), they will be asked if they are interested in joining the other program and will be referred to that study team accordingly. Additionally, embedded in the consent form is the option for participants to give permission to be contacted by other study teams in the future; therefore, if a caregiver was only referred

to Sleep Well!, for example, at the onset but gives permission to be contacted by other teams, then once they have finished Sleep Well! the PriCARE team may contact them to assess for interest and eligibility.

3.2 Allocation to Intervention Groups and Blinding

Participants will be randomly assigned to the intervention or enhanced usual care condition at the baseline assessment. Please see section 8.1.1 for further information. It will not be possible to conceal intervention condition from the PI, study coordinator, and members of the intervention team, but research assistants involved in data collection will be blind to study condition.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

The study duration per subject will be up to 6 months (24 weeks), to accommodate families needing to reschedule any assessments or intervention sessions. After screening and, for eligible families, enrollment, a baseline assessment will occur within 0-3 weeks. One to 3 weeks following the baseline assessment, the enrolled family randomized to the intervention condition will participate in Sleep Well! over 6-8 weeks. The post-intervention will occur 1-2 weeks after the end of the intervention phase for those randomized to Sleep Well!, or at weeks 9-16 for those in the control condition. The follow-up assessment condition will occur 6-8 weeks after the post-intervention assessment. Thus, the duration of study participation is between 15 and 24 weeks.

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

CHOP and the University of Oregon are the two sites involved in this study. All participant procedures, including recruitment and data collection, will occur at the 3 CHOP-affiliated urban primary care sites in Pennsylvania (South Philadelphia, Cobbs Creek, and Karabots). No study recruitment, data collection, or other participant procedures will occur at University of Oregon. Only data management, analysis, and interpretation will occur at University of Oregon.

3.4 Study Population

3.4.1 Inclusion Criteria

1) Parental/guardian permission (informed consent)
2) Caregiver participant is the parent or legal guardian of the child subject
3) Caregiver/legal guardian ≥18 years of age.
4) Child between the ages of 1 and 5 years.
5) Presence of caregiver-reported child sleep problem determined by a Brief Child Sleep Questionnaire item[58,59] included in an eligibility screening questionnaire (see below) or child meets American Academy of Sleep Medicine[51] diagnostic criteria for either pediatric insomnia or insufficient sleep, assessed through an eligibility screening questionnaire.
6) English-speaking.

3.4.2 Exclusion Criteria

1) Caregiver is not parent or legal guardian of child participant.
2) Presence of a child neurodevelopmental (e.g., autism spectrum disorder; Trisomy 21) or chronic medical condition or concern (e.g., sickle cell disease, cancer) in which the disorder or treatment of the disorder impact sleep.
3) Caregivers/guardians or subjects who, in the opinion of the Investigator, may be non-compliant with study schedules or procedures.

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Screening Phase

Procedures for screening referred and potentially eligible participants are described in detail above (section 3.1.1). The screening phase will be completed by a study team member and will include:

- EMR review by a study team member
- Phone screening using eligibility screening questionnaire (section 5.1.2), after completing verbal HIPAA authorization
- Scheduling of informed consent and baseline assessment (completed in person or electronically)

4.2 Baseline Assessment (Pre-Intervention)

The baseline assessment will be conducted by a study team member and will be completed in person or electronically. It will include:

- Informed consent
- Abstraction of child demographic information and previous behavioral health or sleep services (EMR)
- Caregiver completion of caregiver demographic and family information questionnaire, previous treatment questionnaire, Brief Child Sleep Questionnaire, and Child Behavior Checklist
- Caregiver completion of the Center for Epidemiological Studies Depression Scale, Revised (CES-D-R), PROMIS Sleep Disturbance Short Form, and coronavirus (COVID-19) and Other Life Stressors questionnaire
- Randomization to study condition (see 3.1 and 8.1 for further information)
- 7-day daily sleep diary questionnaire via text messages delivered via REDCap and its integration with Twilio
- 7-day actigraphy

If a caregiver has difficulty completing measures independently, a research assistant will read the items and provide assistance as needed. If a caregiver is unable or unwilling to

receive the 7-day diary via text messages, we will offer to (a) e-mail the daily diary to the caregiver for 7 days or (b) have a research assistant call the caregiver by phone to administer the daily diary verbally for 7 days, with the research assistant entering caregiver responses into a REDCap database.

4.3 Study Treatment Phase

4.3.1 Intervention condition

Sleep Well! will be provided over approximately 6-8 weeks, to allow for families to reschedule sessions as needed, and will include 3 sessions. Intervention sessions will typically last about an hour, but session length may vary. Content is delivered in a modular format based on family goals and the child's sleep concern (e.g., using electronics before bedtime; an inconsistent bedtime routine; etc.). To ensure high-quality care, intervention providers will receive regular supervision. Providers will also contact families by phone between sessions (3 times total) to (a) promote attendance, engagement,[53] and implementation of Sleep Well! strategies, (b) assist in resolving barriers to treatment, and (c) guide families to community resources as needed. As noted above (3.1.2), text messages about the intervention will also be sent to families via Twilio and its integration with REDCap. For ethical reasons, families will be informed that they have the right not to participate in the study. If they choose not to participate, they will be referred to their pediatrician, who may provide the family with additional referrals to the CHOP Sleep Center or other behavioral health services, consistent with the current standard of care at CHOP.

Intervention sessions that occur in-person, via HIPAA-compliant video, or by telephone will be audio-recorded to monitor fidelity. Telephone check-in calls will not be audio-recorded. After each intervention session and intervention-related phone call, the interventionist will document which intervention contents were used using an intervention-specific fidelity checklist. The study interventionist will also document any feedback regarding the intervention as a method to assess intervention feasibility and usability. In addition, approximately 2 weeks into the intervention phase caregivers will complete a brief survey about their child's sleep electronically via REDCap (mid-point assessment).

4.3.2 Procedures for training Sleep Well! interventionists

Dr. Ariel Williamson, a licensed psychologist who is also a Diplomat in Behavioral Sleep Medicine, will train and supervise all study interventionists, who are doctoral-level or post-doctoral level clinical psychology trainees at CHOP. Dr. Williamson will provide each interventionist with approximately 8 hours of training prior to intervention. Interventionists will be trained to implement the treatment manual and attend to process variables, including establishing trust, listening actively, and re-directing tangential comments. All interventionists are mandated child abuse reporters and will be trained to identify and report child abuse and any other concerns related to participant safety. Consultation and peer supervision related to intervention delivery will occur weekly with Dr. Williamson's mentor, Dr. Jodi Mindell, Associate Director of the CHOP Sleep Center and Diplomat in Behavioral Sleep Medicine.

4.3.3 Control (enhanced usual care) condition

The enhanced usual care condition will occur for between 6 and 8 weeks. At randomization to this condition, participants will be provided with an evidence-based sleep guidelines for young children. These guidelines are summarized in the CHOP Parent Family Education manual and have been reviewed and approved by pediatric sleep experts (including study Co-I Dr. Williamson and co-I Dr. Mindell) and CHOP primary care physicians. Participants in this condition will also be able to consult with their primary care physician for management of child sleep. Consistent with usual care in the CHOP system, the primary care physician may manage the sleep concern or choose to make a referral to the CHOP sleep center or to other behavioral health services internal or external to the CHOP system. Of note, the CHOP Parent Family Education handouts provide contact information for the CHOP Sleep Center and direct readers to follow-up with their primary care provider for further guidance.

4.4 Post-intervention assessment

The post-intervention assessment will be completed approximately 1-2 weeks following the end of the intervention phase for Sleep Well! participants or following the end of the control phase for the enhanced usual care condition participants. Post-intervention will be conducted by a study team member and will be completed in person or electronically (questionnaires) and via telephone (interview for Sleep Well! participants). It will include:

- Caregiver completion of the Brief Child Sleep Questionnaire, Child Behavior Checklist, previous treatment questionnaire, Center for Epidemiological Studies Depression Scale, Revised (CES-D-R), PROMIS Sleep Disturbance Short Form, and COVID-19 and life stressors questionnaire
- 7-day daily sleep diary questionnaire via text messages delivered via REDCap and its integration with Twilio
- 7-day actigraphy
- EMR review of any behavioral health or sleep services
- For Sleep Well! intervention participants only:
    - Caregiver completion of the Treatment Evaluation Inventory—Short Form,[60] Multicultural Therapy Competency Inventory- Client Version (MTCI-CV),[61] and Goal Attainment measure
    - Audio-recorded caregiver interview on intervention content and acceptability

If a caregiver has difficulty completing measures independently, we will follow procedures as outlined above in section 4.2.

4.5 Follow-Up Phase

The follow-up assessment will be conducted approximately 6-8 weeks after the end of the intervention phase. The assessment will be conducted by a study team member and will be completed in person or electronically (questionnaires) and via telephone (interview for enhanced usual care participants only). It will include:

- Caregiver completion of the Brief Child Sleep Questionnaire, Child Behavior Checklist, Center for Epidemiological Studies Depression Scale, Revised (CES-D-

R), PROMIS Sleep Disturbance Short Form, and COVID-19 and life stressors questionnaire
- EMR review of any behavioral health or sleep services
- 7-day daily sleep diary questionnaire via text messages delivered via REDCap and its integration with Twilio
- 7-day actigraphy
- For enhanced usual care participants only:
    - Caregiver interview about sleep services

If a caregiver has difficulty completing measures independently, we will follow procedures as outlined above in section 4.2.

4.6 Unscheduled Visits

We do not anticipate any unscheduled visits, although unscheduled phone contact may occur with some participants (e.g., concern related to participant safety reported by caregiver or study interventionist; issue with actigraph).

Participant safety concern. Please see sections 7 and 8.4.1 for information about safety monitoring throughout this study.

Actigraph issue. If there are any issues with the actigraph device, families will be encouraged to contact a member of the study team by phone. Any issues will be handled primarily via phone, although an in-person visit may occur if the family must be provided with a replacement actigraph.

Clinically significant mood, behavior, or safety concern. At baseline, study participants will be provided with handout that lists resources obtaining mental health services, crisis intervention resources, and domestic violence/sexual abuse or assault/broad safety resources. This resource has been uploaded with this IRB submission. If a participant spontaneously reports significant concerns related to caregiver or child mood, behavior, or safety to a member of the study team, that team member will notify Dr. Williamson, who will then contact the family within 3 business days. During an unscheduled phone call, Dr. Ariel Williamson will provide the family with appropriate community referrals for mental health services and direct the family to follow-up with their primary care clinician. Dr. Ariel Williamson will also conduct a risk assessment over the phone. This risk assessment will contain questions about caregiver homicidal and suicidal ideation, and the presence of any homicide/suicide plan or intent, consistent with CHOP behavioral health risk assessment practices. Should there be an imminent safety risk, Dr. Williamson will contact emergency services (911 or Pennsylvania mobile crisis services) for further suicide/homicide/risk assessment. All information obtained during the risk assessment will be used only for the purposes of determining appropriate follow-up care. Information about child safety concern or mandated reporting of any child abuse or neglect will be documented in the child's medical record, and will not be stored with study data, or used for any study-related data analysis. For caregiver risk assessment procedures, risk assessment will be documented in a Note to File coded by the participant ID and will be stored separately from the consent form and in a separate REDCap database used for tracking purposes only.

Other follow-up issue. If caregiver-child dyads that participated in the study contact the study team by phone to request follow-up, any issues will be handled via phone by Co-I Dr. Ariel Williamson, without an in-person visit.

4.7 Subject Completion/Withdrawal

Caregiver-child dyads may withdraw from the study at any time without prejudice to their care, education or employment. They may also be discontinued from the study at the discretion of the investigators for lack of adherence to the study and/or the emergence of exclusionary criteria. Children will be withdrawn from the study if any exclusionary criteria emerge during the study. Child well-being will be monitored by the interventionists and the caregiver throughout the study. If any adverse events occur that require clinical intervention during the course of study participation, a PI or co-investigator who is a licensed clinician will conduct a risk and safety assessment and make clinically appropriate referrals. If the investigators become aware of any serious, related adverse events after a participant completes or withdraws from the study, the event will be recorded in a separate, coded REDCap database used to track study attrition and any adverse events.

4.8 Early Termination Study Visit

We will attempt to contact all participants who withdraw from the study during the intervention phase so that we may complete any remaining assessment procedures with these participants and offer any clinical referrals if needed.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening Measures

5.1.1 Medical Record Review

Medical record review for eligibility purposes and abstraction for child demographic data (baseline assessment, section 4.2, above) will occur for child participants and will include the following items. PHI marked with a * are entered into the separate, password-protected Study ID and MRN database in REDCap used for maintaining confidentiality and storing family contact information needed for screening, enrollment, intervention procedures, and follow-up.

- Child name*
- Age at time of enrollment
- Sex
- Race
- Ethnicity
- BMI
- Current medications
- Current diagnoses
- Current problem list
- Insurance at time of enrollment
- All family addresses on file, including zip code*

- Caregiver names, e-mail addresses, and telephone numbers*
- The child medical record will also be reviewed at baseline, post-intervention, and follow-up assessment periods to identify whether the child has received any behavioral health or sleep services at CHOP. We will exclude content of mental health progress notes that are not reviewable by all providers and are marked as "sensitive" (i.e., segregated mental health records). Information abstracted from the medical record in this regard will include:
    - Number of visits related to sleep concerns
    - Sleep treatment plan/recommendations
    - Sleep treatment strategies
    - After visit summary content (treatment strategies and follow-up recommendations or referrals)

5.1.2 Eligibility Screening Questionnaire

Caregivers will be asked questions to identify whether dyads are eligibility for the study. These questions are related to child medical or neurodevelopmental conditions, medications, and the presence of child sleep problems.

5.2 Measures of Treatment Feasibility and Acceptability (Primary Outcomes)

- *Screening rate (feasibility):* The study team will track the number of potentially eligible participants screened of those referred per month.
- *Recruitment rate (feasibility):* The study team will track the number of potentially eligible participants enrolled of those screened per month.
- *Retention rate (feasibility):* The study team will track the number of caregiver-child dyad participants who complete all study procedures following enrollment.
- *Assessment process (feasibility):* The study team will track the number of proportion of participants who complete all assessments (pre-intervention and post-intervention) that were planned.
- *Intervention usability (feasibility):* Study interventionists will keep records of barriers to and facilitators of the intervention content and procedures.
- *Family engagement and adherence (feasibility):* Study interventionists will keep records of family intervention attendance, including the number of sessions that the family attended, rescheduled, and no-showed, and the number of phone calls that families completed, as well as session ratings of engagement. Study interventionists will also keep records of families' usage of intervention strategies, based on feedback from families in-session.
- *Intervention fidelity (feasibility):* Intervention fidelity, or the extent to which the Sleep Well! intervention is delivered as intended, will be assessed using the following two methods.
    1. Intervention sessions conducted in person, via a HIPAA-secured video platform, or via telephone will be audio-recorded and coded by a study team member. <u>No video-recording will occur.</u> Audio data will be provided to the Co-I/interventionist supervisor, Dr. Ariel Williamson, who will use this in her supervision of study interventionists. The study team will also code sessions

for fidelity purposes. Telephone check-ins between families and interventionists will not be recorded.

2. Interventionists will complete fidelity checklists[62] that include items corresponding to the core components of Sleep Well! and to process items, including establishing trust, listening attentively, and re-directing tangential comments.

- *Treatment acceptability:* Treatment acceptability for Sleep Well! will be assessed using the following methods:
    1. Caregivers will complete the Treatment Evaluation Inventory—Short Form,[60] a widely used measure of treatment acceptability that has been adapted for the purposes of the Sleep Well! intervention. We have also added two questions about telehealth visits to assess acceptability related to remote telephone and video intervention procedures. There will be an attention check item placed randomly within the questionnaire, which is designed to detect individuals who are quickly responding to survey questions without sufficient attention to item content. Previous research has demonstrated that the inclusion of an attention check item can increase the reliability of survey completion.[75]
    2. Caregivers will complete the Multicultural Therapy Competency Inventory-Client Version (MTCI-CV)[63] to assess patient's perceptions of the Sleep Well! therapist's cultural sensitivity during discussions about safe sleep.
    3. Caregivers will complete a 3-item goal attainment measure developed by the study team. Caregivers will answer each item on a 5-point Likert scale. Questions are related to caregiver perceptions of goal attainment and intervention success.
    4. Caregivers will complete an audio-recorded, open-ended qualitative interview (15-20 minutes) with questions related to aspects of the intervention that were helpful/unhelpful, how the intervention could be improved, and the acceptability of the measurement process (see interview guide uploaded with study measures).

5.3 Demographic and Parent and Child Behavior Measures (Secondary Outcomes and Covariates)

- *Child Demographic Information:* Child demographic information will be abstracted from the EMR (see section 5.1.1).
- *Caregiver Demographic and Family Questionnaire:* Caregivers will complete a caregiver and family demographic questionnaire at baseline. Child data will include CHOP primary care site where child receives care, whether the child attends daycare/preschool, and where the child typically sleeps. Caregiver/family data will include age, sex, race, ethnicity, highest educational level obtained, relationship to child, income, employment status, relationship status, number of times the family has moved in the last year, and information about children and adults living in the home.
- *Previous Service Use Form:* At each assessment, caregivers will complete a form related to any previous treatment for child sleep or behavior problems.
- *Brief Child Sleep Questionnaire (BCSQ):* Caregivers will complete the BCSQ[58,59] to report on child sleep habits (sleep time, total sleep durations, night wakings, aspects

of the sleep environment, etc.) and the severity of any caregiver-perceived sleep problems. The BCSQ is appropriate for children ages 1-5 years and has shown good reliability and moderate correspondence with actigraphic recordings of child-sleep.[59] There will be an attention check item placed randomly within the questionnaire, which is designed to detect individuals who are quickly responding to survey questions without sufficient attention to item content. Previous research has demonstrated that the inclusion of an attention check item can increase questionnaire reliability.[75]

- *7-Day Daily Child Sleep Diary:* Items drawn from the BCSQ will be used to track regularity in child bedtime routines, bedtime activities, and 24-hour sleep schedule over 7 days at baseline (pre-intervention) and follow-up (post-intervention).
- *Actigraphy:* Objective child sleep will be assessed using a Philips Respironics, Inc., Actiwatch Spectrum,[63] which is a water-resistant accelerometer device. Consistent with guidelines for the reliable and valid use of actigraph devices in children,[64] caregivers will be instructed to keep the actigraph on their child's wrist continuously for the 7-day period at baseline and the 7-day period at follow-up, with the exception of bath time or swimming, to ensure that at least 5 days of data (to account for 2 days of missing data) are obtained.[64] Caregivers will be asked to press an event marker at lights-off and lights-on. Actigraph data show an 85.1-88.6% agreement with polysomnography, which is the gold standard for objectively assessing sleep.[64] Actigraph data will be analyzed using Philips Actiwatch software and scored using guidelines for young children.[64] Actigraphs will generate daily total estimates of child sleep onset, offset, and sleep time variability. If the participant loses an Actiwatch or has difficulties with the device, the study team may choose to have the family discontinue engagement with actigraphy for subsequent data collection time points. Families will be given three options to return the actigraph to the study team after each assessment: 1) the study team will provide families with a pre-paid UPS envelope, 2) the family can coordinate a time with the study team to drop off the actigraph, or 3) the family can schedule a pick-up time with a delivery/courier service.
- *Center for Epidemiological Studies Depression Scale-Revised (CES-D-R):* Caregivers will report on their own depressed mood using the 10-item CES-D-R short form. This indicator may used as a control variable in study analyses. The CES-D-R has shown good reliability and validity in diverse adult samples.[71-72] There will be an attention check item placed randomly within the questionnaire to increase reliability in participant responses.[75]
- *Child Behavior Checklist (CBCL):* Caregivers will complete the 99-item problem items of the Achenbach System of Empirically Based Assessment CBCL for children ages 1.5 to 5 years to report on child internalizing, externalizing, and attention problems. The CBCL has shown strong reliability and validity in large validation studies and is a widely used measure of child behavior[73]. The CBCL will be administered via REDCap. Data will then be entered into the Achenbach System of Empirically Based Assessment (ASEBA) website for scoring, with no PHI entered into the scoring website.
- *PROMIS Sleep Disturbance Short Form:* Caregivers will report on their own perceptions of sleep quality, sleep depth, and restoration associated with sleep. This

includes perceived difficulties and concerns with getting to sleep or staying asleep, as well as perceptions of the adequacy of and satisfaction with sleep.

- *COVID-19-Related and Non-COVID-19-Related Stress Measure:* Caregivers will be asked 9 questions related to life stressors. Four questions were drawn from a measure developed by the Center for Pediatric Traumatic Stress to evaluate the impact of COVID-19 on parent and child distress. Five additional questions were developed by the study team to include non-COVID-19-related life stressors.
- *Enhanced usual care qualitative interview:* Caregivers in the enhanced usual care condition will complete an audio-recorded, semi-structured qualitative interview (15-20 minutes) at follow-up to identify their perceptions about this condition assignment and the study procedures. This information will inform future randomized trials on the intervention and the comparison condition.

5.4 Safety Evaluation

Participant safety will be monitored by adverse events throughout the study. Please see the Data Safety and Monitoring Plan (section 8.4.1) for further information.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoints

The primary endpoints are overall ratings of intervention feasibility and acceptability.

6.2 Secondary Endpoints

Secondary endpoints include the magnitude and direction of change in child sleep and behavior outcomes.

6.3 Control of Bias and Confounding

As a convenience sample, our participants may differ in important ways from those who choose not to participate in the study, which will limit the generalizability of our findings. We will mention this as a limitation of our study in any publications. In addition, in order to ensure that the subjects recruited from the study sites are representative of primary care patients presenting to these sites, we will monitor the demographics of our samples from each site to the CHOP Pediatric Research Consortium data on the demographics of patients at each site and to the demographics of primary care providers. Finally, although we will attempt to recruit subjects evenly throughout the study period, recruitment during different times of the year (i.e., various seasons) could potentially impact child sleep. We will note this as a limitation in any study publications.

6.4 Statistical Methods

We will examine the following primary feasibility, acceptability, and engagement and adherence outcomes through the use of descriptive statistics, which include means for continuous variables and proportions for categorical variables.

Feasibility of the research process (metrics for monitoring by internal study team):

- Screening (number of caregiver-child dyads referred and screened/month)

- Recruitment (number of caregiver-child dyads enrolled/month)
- Randomization (number of dyads eligible who enroll and are randomized/month)
- Intervention usability (interventionist-rated perceptions of intervention manual and strategies)
- Intervention adherence (interventionist-rated checklist)
- Intervention fidelity (a: interventionist self-reported checklist; b: review of the implementation of audio-recorded intervention sessions and phone calls)

Feasibility of intervention:

- Retention (number of dyads who complete intervention condition of those enrolled and number of intervention sessions/phone calls completed)
- Family engagement (interventionist-rated perceptions of family engagement in sessions and phone calls)
- Intervention acceptability (caregiver-rated Treatment Evaluation Inventory – Short Form and the Multicultural Therapy Competency Inventory- Client Version [cultural humility])
- Assessment process (number of planned assessments that are completed)

Prior to quantitative data analysis, we will examine baseline equivalency of the randomized groups, attrition and missing data. Baseline equivalence will consist of chi-square and grouped t-tests analyses comparing randomized groups on demographic characteristics and baseline outcomes. We will conduct an attrition analysis consisting of chi-square and grouped t-tests comparing the proportion of participants who fail to complete surveys; the independent variables will include intervention condition and demographic characteristics. We will also explore missing data due to item non-response among participants who completed the surveys. If missing data due to item non-response is non-trivial (greater than 5%), we will conduct a missing data analysis using the same analytic approach for the attrition analysis.

For qualitative interview data, transcribed interviews will be coded by study team members using an iterative process that begins with open coding, codebook development and refinement, and consensus regarding the codes. We will use an integrated approach,[65] with a priori codes based on prior work and themes emerging from the data. Once a stable codebook is developed, approximately 20% of the data will be double coded for reliability purposes (weighted kappa). Separate codebooks may be developed for the Sleep Well! participant interviews and for the enhanced usual care condition interviews. We will also explore how themes from the intervention group vary by quantitative caregiver-reported outcome data (e.g., sleep problem perception) and family factors (e.g., shiftwork). We will also examine variation using this method for the usual care group interviews.

Data analysis for the secondary sleep outcomes (below) will include (1) the application of mixed effects growth models, and (2) generating effect sizes, as follows.

(1) Mixed effects linear growth models will also be applied to compare overall change in continuous outcomes between groups from pre-intervention to follow-up using an intent to treat approach with maximum likelihood estimation. Individual variability in the outcomes from pre-intervention through the follow-up assessments will be predicted by a two-level fixed effect condition variable (coded 0 for enhanced usual

care and 1 for intervention), a time variable with the intercept defined as the pre-intervention assessment and weeks between this assessment and last follow-up, and the group × time interaction. Models will account for random effects (intercept, time) and fixed effects (group, and time by group). The time by intervention group interaction identifies whether there is a significant between-group difference in change since pre-intervention. Categorial outcomes will be modeled as mixed-effects growth models with maximum likelihood and a logit link. Model parameters include those described for the continuous models and a threshold parameter at each timepoint. Any sleep and behavior outcomes that are significantly different by group at pre-intervention will be included as covariates in all models.

(2) Effect sizes for the magnitude of group differences will be drawn from the mixed effects models. The effect size for the condition × time interaction is equivalent to Cohen's d-statistic.[66, 67] For categorical outcomes, percent change in the odds for the condition × time interactions are provided as a measure of effect size.

Secondary sleep outcomes for these analyses will be drawn from the caregiver-rated Brief Child Sleep Questionnaire (BCSQ)[58] and actigraphy (objective sleep measurement) and will include:

- Child sleep problems (BCSQ)
- Child bedtime resistance (also called "bedtime difficulties" BCSQ)
- Child sleep onset latency (BCSQ)
- Child night awakenings (frequency and duration BCSQ)
- Child sleep quality (BCSQ)
- Child total (BCSQ) and nighttime sleep duration (BCSQ and sleep onset to offset for actigraphy)

To examine secondary child behavior outcomes, we will examine change by group over time from pre-intervention to to follow-up, exactly as described for the sleep outcomes (see above).

Secondary behavior outcomes drawn from validated the following validated clinical measures include:

- Child externalizing problems composite T-score (Child Behavioral Checklist for ages 1.5-5 years)[68]
- Child internalizing problems composite T-score (Child Behavioral Checklist for ages 1.5-5 years)[68]

Additional exploratory analyses

Using the above growth model methods for secondary child sleep and behavior outcomes, we will also explore change in other sleep outcomes (BCSQ), including child bedtime routine consistency and sleep health behaviors (caffeine, fussy morning mood, bedtime fears, insufficient sleep) on the BCSQ and caregiver mood (CES-D) and sleep (PROMIS). Exploratory analyses included tests of moderating effects for age of the child, whether the caregiver reported shift work, pretest measure of parent mood (CES-D), and pretest measure

of parent sleep (PROMIS). Moderation models will be run separately for each moderator and include main effects of the moderator and all higher order interaction terms with condition, time, and condition × time.

6.5 Sample Size and Power

As is appropriate for a pilot study,[69] the primary goal of this study to estimate effect sizes to fully power a future large-scale randomized controlled trial of the adapted behavioral sleep intervention through a subsequent R01 submission. However, we will have adequate power to detect the expected medium effects (found in similar efficacy and effectiveness trials[57,70,71] for sleep) between groups on sleep outcomes. Based on previous primary care behavioral intervention research studies conducted at CHOP, we expect an approximate attrition rate of 15% at follow-up.[72] A final sample size of 68 participants yields >80% power[73] to detect medium (0.5 SD) between-group effects using linear regression and adjusting for covariates (pre-intervention scores; socio-demographic variables) to evaluate change in sleep outcomes. The proposed sample of 80 dyads is thus sufficient for detecting medium intervention effects and accounts for potential attrition. Medium effects for relevant child sleep outcomes are equivalent to a ~10-minute reduction in sleep onset latency, a 30 to 40-minute increase in sleep duration, and a reduction of ~1 night awakening—all clinically meaningful results.[22]

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

7.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

8 STUDY ADMINISTRATION

8.1 Treatment Assignment Methods

8.1.1 Randomization

Participants will be randomly assigned to the intervention or enhanced usual care condition at the baseline assessment. The randomization sequence will be generated by a study statistician. Randomization will be maintained by keeping a separate, password-protected list in REDCap that lists subject ID and group assignment.

8.1.2 Blinding

Families and Sleep Well! interventionists will not be blinded to condition assignment. In addition, it is not possible for the Co-I Dr. Williamson or the Study Coordinator to be

blinded to condition assignment. However, all other members of the study team involved in data collection will be blinded to intervention group assignment. Blinding will be maintained by keeping a separate, password-protected list in REDCap that lists subject ID and group assignment. This database will be accessible only to the Co-I (Dr. Williamson) and the Study Coordinator.

8.1.3 Unblinding

As the PI and Study Coordinator will not be blinded, and will review any adverse events, it is not necessary to unblind the other study team members during the conduct of the study.

8.2 Data Collection and Management

The data collection and management plan described below is consistent with CHOP Policy A-3-9: Acceptable Use of Technology Resources that defines the requirements for encryption and security of computer systems.

Confidentiality: A separate, password-protected REDCap database will be used as a master list linking PHI and study ID numbers. This master list will contain the child name, MRN, the contact information for the family (caregiver name, family address, phone number, e-mail addresses) for communicating with participants, and whether the family agrees to be contacted by other study teams at CHOP for future research. This master list database will be accessible only to members of the study team. All paper consent forms will be stored separately, in locked filing cabinets in the Roberts Center for Pediatric Research. Any electronically completed consent forms will be entered by participants into a separate, password-protected REDCap database with consent documents only identified by child and caregiver names. These electronic consent forms will be printed out from REDCap and stored with paper consent forms in the same locked filing cabinets in the Roberts Center for Pediatric Research.

Participants will complete study questionnaires by entering responses electronically and directly into REDCap databases. Daily sleep diary information will be administered to participants via Twilio and its integration with REDCap. The REDCap databases are password-protected, accessible only to members of the study team, and only contain subject ID numbers and questionnaire responses. For scoring of the CBCL, CBCL item responses entered into REDCap will be entered into the ASEBA scoring platform using only participant IDs and the age and gender of the child, for norm-referenced scoring purposes. No identifying information, such as date of birth, will be entered into the scoring database. Once scored, the ASEBA files will be downloaded and saved in a secured and password-protected CHOP network drive.

Actigraphy data will be identified via unique participant ID. These coded data will be stored in a password-protected CHOP network drive accessible only to study team members for actigraphy analysis. Once data have been downloaded from the actigraph device, data on the actigraph will be destroyed.

Intervention sessions conducted in-person, via HIPAA-secure video platform, or by telephone will be audio-recorded for fidelity purposes. No video-recording will occur. Brief check-in telephone calls between sessions will not be recorded. For the qualitative

interviews that occur at post-intervention or follow-up, participants' responses will be audio-recorded in person or by telephone. All audio files for intervention sessions and study interviews will also be password-protected and temporarily saved on the secure CHOP computer network drive. Transfer of audio files from the audio device to the secure CHOP computer network drive will occur via a flash drive that is encrypted and password-protected per CHOP IT standards. Once the audio file is transferred from the audio-recording device, it will be deleted from the flash drive and from the audio-recording device. For audio-recordings made via a HIPAA-secured video platform, audio files will be downloaded from the video platform with no video information included (audio file only) and saved directly to the secure CHOP computer network drive. In the drive on the password-protected computer, all audio files will be labeled according to participants' unique study ID numbers, and no identifying information will be used to label the files. Audio files of the intervention sessions will be analyzed by study team members for the coding of fidelity. Audio files of the interviews will also be transcribed and checked for accuracy. All audio files will be retained for a minimum of 6 years, consistent with CHOP Data Retention Policy A-3-9, after which point they will be destroyed. Audio recordings may be sent to an outside professional transcription agency, ACTS Document Management located in South Point, Ohio. All files are securely stored, transmitted, and encrypted. The agency will remove all identifying information from the transcripts and destroy their copy of the audio files after transcription is complete. Transcribed interview data will be coded using participants' unique study ID numbers. Any interviewer field notes taken during the interview will be coded using only the participants' unique study ID numbers, and stored in a locked filing cabinet in the Roberts Center for Pediatric Research until the point of transcription. Interviewer field notes will then be destroyed. The transcribed interview and interviewer field note data will be stored in the secure and password-protected CHOP network drive.

For sharing data including PHI with University of Oregon for the purposes of data management, analysis, and interpretation, data will be transferred using a secure file transfer program. Data will be stored on password-protected University of Oregon drives available only to the Co-I Dr. Ariel Williamson. In addition, a data use agreement will be established between University of Oregon and CHOP.

Security: Copies of only coded data (i.e., with participant unique study ID, demographic information, questionnaire responses, the transcribed interview and interviewer field note data) will be downloaded from REDCap for data analysis purposes. These data will be stored on the secure CHOP network drive. No identifying data from the separate, password-protected REDCap dataset that contains the master list linking the participants' identifying information and their unique study ID number will be downloaded, and the database will only be accessible on the secure, password-protected REDCap server. As noted above, for audio files, transfer of files from the audio device to the password-protected computer will occur via an encrypted and password-protected CHOP flash drive, consistent with CHOP IT security procedures. Uploads of audio files to the ACTS Document Management site for transcription purposes will also be encrypted. ACTS Document Management has been vetted by CHOP and is compliant with all CHOP technology transfer policies.

Anonymization: All identifiers that are stored in the separate, password protected REDCap database master list and the separate, password protected REDCap electronic consent

database will be retained for 6 years and then destroyed, consistent with CHOP policy. The coded data will be retained indefinitely through password-protected files on the secure research server and on the REDCap platform.

8.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with CHOP institutional policies and HIPAA on subject privacy. The PI, members of the study team, and other site personnel will not use such data and records for any purpose other than conducting the study.

No identifiable data will be used for future study without first obtaining IRB approval. The investigator will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers (including others at CHOP) before sharing a limited dataset (PHI limited to dates and zip codes).

8.4 Regulatory and Ethical Considerations

8.4.1 Data and Safety Monitoring Plan

The Co-I, Dr. Ariel Williamson, and her co-Investigators and mentors Drs. Alexander Fiks, Jodi Mindell, and Thomas Power will maintain oversight over data integrity and subject safety. The co-Investigators and mentors have extensive experience conducting clinical trials of behavioral interventions with caregivers and children, and will mentor Dr. Williamson on all aspects of data safety and monitoring.

Each member of the research team, including study interventionists, will be instructed about his or her responsibility to maintain data collection integrity and participant safety. Members of the study team meet weekly with the study coordinator and PI to monitor safety and will be in contact by phone during all data collection and intervention periods. In addition, the PI and the co-Investigators are licensed pediatric providers who are experienced in talking with individuals who are under stress due to mood concerns, child behavior concerns, or contextual issues (e.g., poverty, housing instability, work-related stress). In addition, we will work closely with the CHOP Office of Research Compliance to insure data collection integrity, the privacy of data, and participant safety, and to monitor procedural compliance. We will inform the IRB of serious adverse events (SAEs) in a timely manner. Other adverse events (AEs) will be reported annually.

Additionally, a Data and Safety Monitoring Board (DSMB), comprised of a pediatric sleep provider, a pediatric psychologist, and a pediatric primary care provider who work internally at CHOP, will be appointed at the outset of this study, and this board will meet every 6 months and provide feedback to the research team. DSMB members have no conflicts of interest with the study team and are not involved in any study procedures.

8.4.2 Risk Assessment

Risks of participating in this study are not greater than minimal. There are no known physical or legal risks to participating in the study intervention. Potential risks are as follows:

Families will be asked to participate in **actigraphy assessment** at pre- and post-intervention and at follow-up. There are no risks with wearing an actigraph, which is the size and shape of a small wristwatch, though some participants may consider it a minor inconvenience. To ensure that actigraphs are clean and do not increase risk for transmission of COVID-19 and other viruses, each actigraph will be sanitized prior to being provided to families and immediately upon return of the device. We will also provide families with wipes for sanitizing the device upon request.

Families may experience **continued child sleep problems** following the intervention phase or during the enhanced usual care condition. If families who participated in Sleep Well! report continued child sleep concerns at post-intervention, we will refer families to the child's primary care pediatrician for further guidance and potential referral to the CHOP Sleep Center or other behavioral health services, which is the current standard of care for managing child sleep problems. Families in the enhanced usual care condition will similarly be referred to their pediatrician for further guidance and potential referrals if they experience continued child sleep problems.

Although we are not asking caregivers to report on any instances of **child abuse or neglect**, should a caregiver or child spontaneously disclose this information to us during the study procedures or intervention phase, we will file a Department of Human Services report in this regard. Based on standard behavioral health practices within the CHOP system, these procedures are likely to be effective in the case that additional behavioral health treatment and/or risk assessment are necessary.

The study members responsible for data collection and intervention will offer participants an opportunity to reflect on their experience (i.e., 'debrief') after they have completed the study procedures/intervention. In the rare event that a participant necessitates **psychological treatment due to adverse effects of study participation**, or a caregiver spontaneously discloses **low mood or other psychological concerns,** the study team member will contact the PI by phone, and the PI will speak with the participant, provide behavioral health resources, and screen for any suicide/homicide risk in a manner consistent with routine behavioral health practice at CHOP. Resources to mitigate risk (crisis numbers; referral resources) will be provided to participants verbally. Of note, at the baseline assessment, all participating families will be provided with a handout listing resources for obtaining mental health services, crisis services, and other safety-related services (domestic violence, sexual abuse and assault; see handout uploaded with this IRB submission).

All information obtained during any of the risk assessment procedures described above will be used only for the purposes of determining appropriate follow-up care. Information about mandated child abuse reporting or concerns for the child's safety will be documented in the child's medical record, and will not be stored with study data, or used for any study-related data analysis. For any caregiver-related risks (i.e., caregiver homicidal or suicidal risk), risk assessment information will be documented in a Note to File coded by the participant ID and will be stored separately from the consent form and in a separate REDCap database used for tracking purposes only.

There is also the risk related to the **potential loss of confidentiality**. All reasonable safeguards to secure the confidentiality of data will be taken by the study team (section 8.2).

The risk of breach of privacy and confidentiality are greatly reduced by using password-protected REDCap databases, storing data on secure CHOP computers and servers, and de-identification of data when applicable.

Additionally, a **Certificate of Confidentiality (CoC)** will be obtained to protect identifiable research information from forced disclosure. The CoC will allow all individuals who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, the CoC will help achieve the research objectives and promote participation in the study by assuring confidentiality and privacy to participants.

8.4.3 Potential Benefits of Trial Participation

Families in this study may learn information to manage their child's sleep problems. Knowledge gained from this study will inform a larger pilot randomized trial of the Sleep Well! intervention. It is possible that families will not derive any direct benefits from study participation.

8.4.4 Risk-Benefit Assessment

The risks associated with this study are minimal and generally no greater than the risks of receiving the standard of care in the community (i.e., referral to the primary care pediatrician).

8.5 Recruitment Strategy

Potential participants will be recruited from primary care sites for study eligibility screening through multiple methods, including provider referral, review of well child visit schedules and related EMR data, study flyers and tear pads, and recruitment emails to providers and via the REC.

Due to an overlap in target study population and recruitment sites, Sleep Well! and another CHOP primary care-based study team, PriCARE, will have a shared EPIC alert for children ages 1-6 at three of the participating primary care sites (Karabots, South Philly, Cobbs Creek) that will appear during well-visits. When referring patients, clinicians will indicate on the alert whether the referral is for Sleep Well!, PriCARE, or both and the study teams will collaborate on the referrals that are made to both programs. The Sleep Well! and PriCARE teams will alternate weeks for contacting caregivers referred to both programs and alert each other based on the outcomes of the calls. Because Sleep Well! only recruits caregivers of children aged 1-5 and PriCARE only recruits caregivers of children aged 2-6, all one-year-olds will be contacted by the Sleep Well! team and all six-year-olds will be contacted by the PriCARE team, regardless if the referral was made to both programs. Caregivers of children aged 2-5 who were referred to both, will be contacted by a team member from either study and if interested in participating, will select which program they want to attend first. If Sleep Well! is chosen, the Sleep Well! team will screen for eligibility and proceed with the consent process if the caregiver is eligible and interested. If PriCARE is chosen, the PriCARE team will screen for eligibility and proceed with the consent process

if the caregiver is eligible and interested. Once study participation is completed, the participant will have the opportunity to be contacted and screened for the other study they did not select to start first. Additionally, embedded in the consent form is the option for participants to give permission to be contacted by other study teams in the future; therefore, if a caregiver was only referred to one of the programs at the onset but gives permission to be contacted by other teams in the consent form, then once that study is completed, the other study team (either Sleep Well! or PriCARE) may contact that participant to assess for interest and eligibility.

Please see the above section 3.1.1 for additional recruitment information.

No recruitment will occur at the University of Oregon site.

8.5.1 Waiver of HIPAA Authorization to Screen Medical Records

We are requesting a **waiver of HIPAA authorization to screen medical records** in the EHR for children referred to the study or to identify potentially eligible participants via chart review. As described in section 3.1.1., this will ensure that families who are contacted appear to be eligible based on chart review.

8.5.2 Alteration of HIPAA Authorization for Screening

Members of the study team will be responsible for contacting referred, potentially eligible families to initiate the **telephone screening for eligibility**. Study members who contact families will introduce themselves as research team members of the Sleep Center and the Department of Child and Adolescent Psychiatry and Behavioral Sciences at CHOP. We are requesting an **alteration of documentation of HIPAA authorization to screen**. The eligibility screening procedure could not practicably be conducted without a waiver of HIPAA authorization, as the study team members contacting referred families are not located at the primary care sites. This method will also ensure that families do not have to travel to the primary care sites or the main hospital to undergo screening procedures.

8.5.3 Combined Informed Consent-Authorization of HIPAA for Study Procedures

Members of the study team will be responsible for obtaining informed consent for study procedures for all participants. For eligible families, **informed consent using a combined consent-HIPAA authorization will occur either in person or electronically, via a secure REDCap portal, pending caregiver preferences and availability.** Informed consent will be obtained from the child participant's legal guardian. For families who agree to meet with the study team to perform the consent process in person, this meeting will take place at the primary care sites or at the CHOP Main Hospital, in spaces that are semi-private and far enough away from other patients in order to maintain privacy. If the primary care site is too crowded to maintain patient privacy, we will request to use a private room at each primary care site for the consent process. If informed consent is obtained electronically, the participant will receive a link to the secure REDCap portal in which they will be asked to enter their name, their child's name, and the date to indicate their consent. The provision of the caregiver's and child's name will associate the consent document with the enrolled participant. The REDCap portal will contain the exact same information in the same format as the paper consent copy. The study team will email a copy of the completed electronic consent form to the family, with

the instruction to either save or print a copy of this form. See section 8.2 for information about secure maintenance of electronic consent data.

For all consent procedures, families will be given unlimited time to decide their participation. Either in person or by phone with a member of the study team, families will be informed of the nature of this research, study procedures, and its potential benefits and possible risks. Families will be informed that they are free to decline to participate or to withdraw from the study, and that this will not impact any future medical care. Families will be asked to explain back to the investigators the nature of the study, study procedures, and risk and benefits of participants to assure their understanding. A copy of the completed consent form will be provided to participants for their records. For families completing the consent process electronically, we will print a copy of the completed consent from the secure REDCap portal and provide this to the family.

8.5.4 Waiver of Assent

A **waiver of child assent** is requested as all child participants will be between the ages of 1 and 5 years. The capacity of children in this age group is so limited that they cannot reasonably be consulted about their assent and study participation.

8.6 Payment to Subjects/Families

8.6.1 Payments to caregivers for time, effort and inconvenience (i.e. compensation)

The compensation for study participation will be provided to caregivers of the participating child as described below. All payment will be provided either in cash or by ClinCard (for those completing assessments electronically, without an in-person visit). The bonus compensation for completing all measures at each time point will be in the form of an electronic gift card. Caregivers will be given the option of a Wawa gift card or an Amazon gift card.

Baseline assessment: ($70.00 total possible)

- $25.00 for questionnaire completion
- $2.00 for each day that the caregiver completes the daily sleep diary over the 7-day baseline measurement period (7 days x $2.00 = $14.00 total)
- $3.00 for each day that the child wears the actigraph over the 7-day baseline measurement period (7 days x $3.00 = $21.00 total)
- $10.00 for having complete data (i.e., all measurement occasions complete, either diary only or diary + actigraphy) over the 7-day daily baseline measurement period in the form of a gift card.

Post-intervention assessment: ($70.00 total possible)

- $25.00 for questionnaire and (for Sleep Well! participants only) the interview
- $2.00 for each day that the caregiver completes the daily sleep diary over the 7-day follow-up measurement period (7 days x $2.00 = $14.00 total)
- $3.00 for each day that the child wears the actigraph over the 7-day post-intervention measurement period (7 days x $3.00 = $21.00 total)

- $10.00 for having complete data (i.e., all measurement occasions complete, either diary only or diary + actigraphy) over the 7-day daily post-intervention measurement period in the form of a gift card.

Follow-up assessment: ($70.00 total possible)

- $25.00 for questionnaire and (for enhanced usual care participants only) the interview
- $2.00 for each day that the caregiver completes the daily sleep diary over the 7-day follow-up measurement period (7 days x $2.00 = $14.00 total)
- $3.00 for each day that the child wears the actigraph over the 7-day follow-up measurement period (7 days x $3.00 = $21.00 total)
- $10.00 for having complete data (i.e., all measurement occasions complete, either diary only or diary + actigraphy) over the 7-day daily follow-up measurement period in the form of a gift card.

For the daily measures, providing subjects with daily incentives and additional compensation for complete data has been shown to increase measure adherence to ≥ 94%.[74]

The total possible payment for adherence to all measurement strategies (actigraphy included) is $210.00.

8.6.2 Gifts

During the Sleep Well! study, families may be provided with stickers or age-appropriate books to keep and use during their child's bedtime routine.

9 PUBLICATION

We intend to present the results of this project at national and international conferences and to publish project results in peer-reviewed journals.

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