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ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	Adverse Event
BCSQ	Brief Child Sleep Questionnaire
BMI	Body Mass Index
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
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 whether the Sleep Well! behavioral sleep intervention is feasible and acceptable to families. We will also examine the direction and magnitude of change in child sleep from pre-intervention to post-intervention.

Study Design:

This is a preliminary open trial of the Sleep Well! program with pre-intervention and post-intervention assessments.

Setting/Participants:

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 20 caregiver-child dyads will participate in the intervention.

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 outcomes for this open trial are feasibility (number of caregivers recruited, engaged, and retained in intervention; participant intervention attendance rate) and caregiver acceptability, assessed via a questionnaire and qualitative post-intervention interview. Secondary outcomes are the direction and magnitude in any pre- to post-intervention change in child sleep.

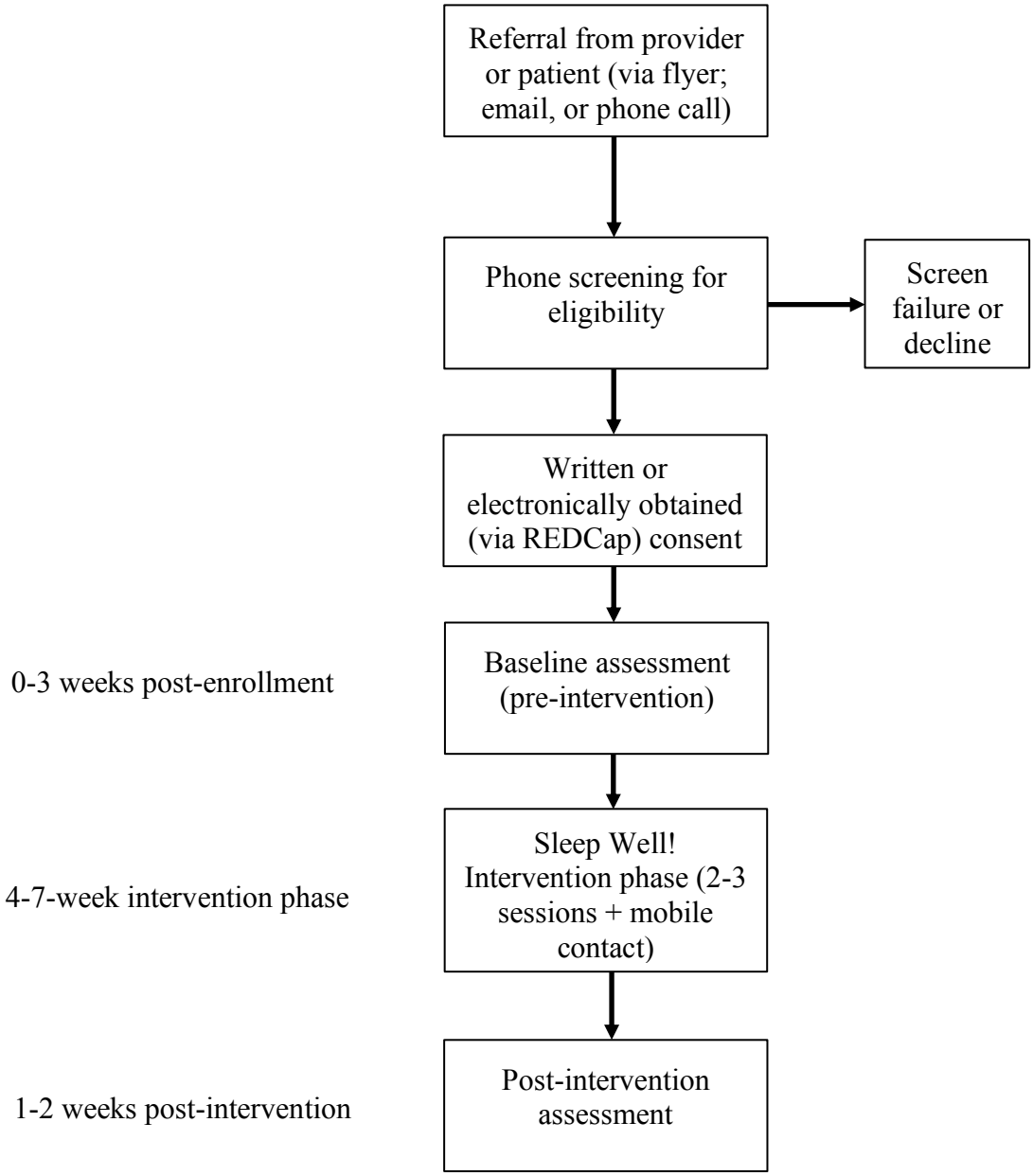
TABLE 1: SCHEDULE OF STUDY PROCEDURES

	Procedure	Screening/ Eligibility	Pre-intervention (baseline)	Intervention Phase	Post-intervention
Measures to Determine Eligibility					
Screening eligibility measure	Caregiver-reported	X			
Measures of Treatment Feasibility and Acceptability					
Screening rate	Study team-documented	X	X		X
Recruitment rate	Study team-documented		X		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	
Intervention fidelity*	Study-team rated			X	
Treatment acceptability: Treatment Evaluation Inventory—Short Form	Caregiver-reported				X
Treatment acceptability: Caregiver interview	Caregiver-reported				X
Assessment process	Study-team documented		X		X
Demographic and Child Sleep Measures					
Child demographic information	Study team-abstracted from EMR		X		
Caregiver demographic and family information	Caregiver-reported		X		
Previous service use	Caregiver-reported		X		
Brief Child Sleep Questionnaire	Caregiver-reported		X		X
Daily sleep diary (7 days)	Caregiver-reported		X		X
Actiwatch (objective sleep monitor, 7 days)**	Caregiver-reported		X		X

* = Completed at each treatment session and phone follow-up

** = Optional; offered to all families who can complete baseline measures in-person.

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 the preliminary feasibility and acceptability of a behavioral sleep intervention for lower-SES toddlers and preschoolers that is implemented in 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, pretreatment 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 preliminary feasibility and acceptability of a behavioral sleep intervention for lower-SES toddlers and preschoolers that is implemented in primary care.

2.1 Primary Objective (or Aim)

The primary objective of this study is to determine the whether the behavioral sleep intervention is feasible and acceptable to families.

2.2 Secondary Objectives (or Aim)

The secondary objectives are to:

- Examine the magnitude and direction of change in child sleep from pre- to post intervention.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This is a small open pilot trial of Sleep Well!, a behavioral sleep program for toddlers and preschoolers that will be implemented at 3 of the CHOP urban primary care sites. Following referral, potentially eligible families will be screened by phone for intervention eligibility. Eligible and interested participants will be consented and scheduled for a pre-intervention (baseline) assessment occurring 0-3 weeks post-enrollment. The intervention consists of 2-3 in-person sessions with periodic phone check-ins over a 4- to 7-week period. The post-intervention assessment will occur 1-2 weeks post-intervention (see Figure 1, above). 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 to objectively measure sleep will also be offered as an optional assessment. At post-intervention, caregiver participants will also provide ratings of their child's sleep and participate in a qualitative interview to provide intervention content and delivery feedback.

3.1.1 Screening Phase

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 below and 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 (see uploaded recruitment document) 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.

Second, the study team will also identify possible participants by reviewing providers' schedules prior to the date of the visit for basic eligibility criteria, and will contact the possible participant by telephone prior to the clinic visit.

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, we have requested approval to use data collected as part of IRB 18-015041 on patient and provider perceptions of early childhood sleep problems. This study was conducted by the principal investigator of this study, Dr. Ariel Williamson. Dr. Williamson will identify potentially eligible participants from IRB 18-015041 and notify the current study team of the patient name and MRN. The current study team will then contact these potentially eligible participants for recruitment in the current study by telephone using the screening procedure and methods identified below.

Fifth, 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.

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 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. If families are unable to meet in-person for baseline procedures, they will 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 the CHOP Sleep Center, 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 Intervention Phase

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 study (IRB 18-015041) 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, sessions will be scheduled in the electronic health record, with progress notes for in-person visits and intervention-related phone calls also documented in the electronic health record.

3.1.3 Follow-up Phase

A follow-up assessment will occur with families either by phone or in-person, pending family availability, 1-2 weeks after the last contact with the Sleep Well! interventionist. The follow-up assessment will include caregiver-complete questionnaires and a brief qualitative interview. The follow-up assessment will be conducted by a research team member.

3.2 Allocation to Intervention Groups and Blinding

All participants will be allocated to the intervention condition, as this is a non-randomized, open trial. Blinding is not applicable.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

The study duration per participant will be up to 3 months, to accommodate families needing to reschedule any assessments or intervention sessions. After screening and, for eligible families, enrollment, a baseline assessment will occur within 3 weeks. The enrolled family will then participate in the Sleep Well! intervention over the course of 4-7 weeks. The follow-up assessment will occur 1-2 weeks after the end of the intervention phase.

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

This study will be conducted at the 3 CHOP-affiliated urban primary care sites in Pennsylvania (South Philadelphia, Cobbs Creek, and Karabots).

It is expected that 80 caregiver-child dyads (total screening N = 160) will be screened to meet the recruitment goal of enrolling 30 caregiver-child dyads (total enrollment N = 60). Based on our previous research with the target population (IRB 18-015041) and intervention attrition rates (20-30%) in similar urban primary care contexts,[58] it is expected that of those 80 caregiver-child dyads screened, 30 will be enrolled in the main study to produce **20 evaluable caregiver-child dyads (total evaluable N = 40).**

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[59,60] 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 diagnosed child neurodevelopmental (e.g., autism spectrum disorder; Trisomy 21) or chronic medical condition (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 after potential participant referral
- 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
- Caregiver completion of caregiver demographic and family information questionnaire, previous treatment questionnaire, and Brief Child Sleep Questionnaire
- 7-day daily sleep diary questionnaire via text messages delivered via REDCap and its integration with Twilio
- Actigraphy for families who are able to conduct the baseline assessment in person (optional)

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

Sleep Well! will be provided over approximately 4-7 weeks, to allow for families to reschedule sessions as needed, and will include 2-3 sessions, depending on family needs. 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 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 the CHOP Sleep Center for management of behavioral sleep problems, consistent with the current standard of care at CHOP.

Intervention sessions will be audio-recorded to monitor fidelity. 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.

4.3.1 Procedures for training Sleep Well! interventionists

The initial Sleep Well! provider for the first 1-4 families enrolled will be the PI, Dr. Ariel Williamson, a licensed psychologist who is also a Diplomat in Behavioral Sleep Medicine. 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. Other study interventionists will be advanced clinical, counseling, school psychology or social work graduate students. Dr. Williamson will provide each interventionist with approximately 4 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. Dr. Williamson will provide the interventionists with weekly supervision based on review of audio-recorded intervention sessions.

4.4 Follow-up Phase (Post-Intervention)

The follow-up assessment will be conducted by a study team member and will be completed in person or electronically (questionnaires) and via telephone (interview). It will include:

- Caregiver completion of Treatment Evaluation Inventory-Short Form, Brief Child Sleep Questionnaire
- Caregiver completion of Multicultural Therapy Competency Inventory- Client Version (MTCI-CV)
- 7-day daily sleep diary questionnaire via text messages delivered via REDCap and its integration with Twilio
- Audio-recorded caregiver interview on intervention content and acceptability
- Actigraphy for families who completed actigraphy assessment at baseline

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.

4.5 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.

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 PI Dr. Ariel Williamson, without an in-person visit.

4.6 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.

4.7 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 the follow-up (post-intervention) assessment 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*

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. 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 intervention is delivered as intended, will be assessed using the following two methods.
    1. Intervention sessions will be audio-recorded and coded by a study team member. This information will be provided to the PI/interventionist supervisor, Dr. Ariel Williamson, who will use the information in her supervision of study interventionists. Telephone contact between families and interventionists will <u>not</u> be recorded.

2. Interventionists will complete fidelity checklists[61] 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 will be assessed using the following two methods.
    1. Caregivers will complete the Treatment Evaluation Inventory—Short Form,[62] a widely used measure of treatment acceptability that has been adapted for the purposes of the Sleep Well! intervention.
    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 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 Child Sleep Measures (Secondary Outcomes)

- *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 baseline, 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[59,60] 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.[60]
- *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.

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 for specific outcomes.

6.2 Secondary Endpoints

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

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

I will examine the following quantitative feasibility and acceptability outcomes through the use of descriptive statistics, which include means for continuous variables and proportions for categorical variables.

- Screening (number of caregiver-child dyads referred and screened/month)
- Recruitment (number of caregiver-child dyads enrolled/month)
- Retention (number of dyads who complete intervention condition of those enrolled)
- Intervention usability (interventionist-rated perceptions of intervention manual and strategies)
- Family engagement (number of intervention sessions/phone calls completed)
- Intervention adherence (interventionist-rated checklist)
- Intervention fidelity (a: interventionist self-reported checklist; b: coding of the implementation of audio-recorded intervention sessions)
- Intervention acceptability (caregiver-rated TEI-SF and MTCI-CV)

- Assessment process (number of planned assessments that are completed)

I will examine the following quantitative child sleep-related outcomes drawn from the caregiver-rated BCSQ and, for families that have it, actigraphy, through descriptive statistics (means; proportions). I will also estimate within-group effect sizes (Cohen's d) with 95% confidence intervals. Effect sizes will be estimated as the ratio of the mean within-person change scores (post-treatment minus pre-treatment) to the standard deviation of change scores. Cohen's d values will be examined to identify the direction and magnitude of effects.

- BCSQ:
    - Child total (24-hour) sleep duration
    - Child sleep onset latency
    - Child night awakenings
    - Child bedtime resistance
    - Child sleep problems

- Actigraphy (for families who have opted to complete it)
    - Sleep onset and offset
    - Sleep time regularity

Interview data analysis will utilize an integrated approach,[65] with both *a priori* codes and grounded theory codes that emerge from the data. We will use QSR NVivo© software for interview data analysis. The study team will create a codebook from the first three transcripts. After establishing a stable codebook, all transcripts will be coded. Every fifth transcript will be double coded to generate an interrater reliability (Kappa) index. Coding disagreements will be resolved through discussion. We will examine each code to identify patterns in the data and key themes.

6.5 Sample Size and Power

This open clinical trial is not designed to have sufficient power to test the efficacy or significance of intervention effects. A power analysis was thus not appropriate. The sample size for this study was identified through a review of the literature on the testing of preliminary behavioral intervention development/adaptation[66-68] and through discussion with my mentors and co-investigators Drs. Alexander Fiks, Jodi Mindell, and Thomas Power.

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

Randomization and blinding procedures are not applicable for this non-randomized, open trial.

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, and the contact information for the family (caregiver name, family address, phone number, e-mail addresses) for communicating with participants. 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.

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 will be audio-recorded in person for fidelity purposes. For the qualitative post-intervention interview, participants' responses will be audio-recorded in person or by telephone. All audio files 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. In the drive on the password-protected computer, 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.

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 PI, 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 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 who are able to conduct the baseline assessment in person may choose to participate in an Actigraphy assessment. 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.

Families may experience **continued child sleep problems** following the intervention phase. If families report continued child sleep concerns at post-intervention we will offer families a referral to the CHOP Sleep Center, which is the current standard of care for managing 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.

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. It will not be stated in the medical record documentation that the child or caregiver are participating in a research study. 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 CHOP Sleep Center).

8.5 Recruitment Strategy

Potential participants will be recruited 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, recruitment emails to providers and via the REC, and participant information from a previous study (IRB 18-015041). Please see the detailed plan for study recruitment and screening described above in section 3.1.1. for further information.

8.6 Informed Consent/Assent and HIPAA Authorization

8.6.1 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.

8.6.2 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.

8.6.3 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 in the waiting room of 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 waiting room at 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.

8.6.4 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.

8.7 Payment to Subjects/Families

8.7.1 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).

- $20.00 (for those completing surveys electronically) for questionnaire completion at the baseline assessment.
- $1.00 for each day that the caregiver completes the daily sleep diary over the 7-day baseline measurement period (7 days x $1.00 = $7.00 total)
- For those participating in actigraphy: $2.00 for each day that the child wears the actigraph over the 7-day baseline measurement period (7 days x $2.00 = $14.00 total)
- $5.00 for having complete data (i.e., all measurement occasions complete, either diary only or diary + actigraphy) over the 7-day daily baseline measurement period.
- $30.00 for questionnaire and interview completion at follow-up (post-intervention).
- $1.00 for each day that the caregiver completes the daily sleep diary over the 7-day follow-up measurement period (7 days x $1.00 = $7.00 total)
- For those participating in actigraphy: $2.00 for each day that the child wears the actigraph over the 7-day follow-up measurement period (7 days x $2.00 = $14.00 total)
- $5.00 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.

For the daily measures, providing subjects with daily incentives and additional compensation for complete data has been shown to increase measure adherence to ≥ 94%.[69]

The total possible payment for adherence to all measurement strategies (actigraphy included) is $102.00.

8.7.2 Gifts

During Sleep Well! intervention participation, families may be provided with small stuffed animals 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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