https://doi.org/10.5664/jcsm.9822

JCSM | Journal of Clinical Sleep Medicine

SCIENTIFIC INVESTIGATIONS

Sleep Well! An adapted behavioral sleep intervention implemented in urban primary care

Ariel A. Williamson, PhD[1,2]; Chimereodo Okoroji, PhD[1]; Olivia Cicalese, MS[1]; Brittney C. Evans, PhD[3]; Amanda Ayala, BS, COTA/L, CB[1]; Bethany Harvey, BS[1]; Rachel Honore[1]; Amy Kratchman, BA[1]; Rinad S. Beidas, PhD[2,4,5]; Alexander G. Fiks, MD, MSCE[1,2]; Thomas J. Power, PhD[1,2]; Jodi A. Mindell, PhD[1,2,6]

[1]Children's Hospital of Philadelphia, Philadelphia, Pennsylvania; [2]Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania; [3]Chicago Psychotherapy, LLC, Chicago, Illinois; [4]Penn Implementation Science Center at the Leonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, Pennsylvania; [5]Penn Medicine Nudge Unit, University of Pennsylvania Health System, Philadelphia, Pennsylvania; [6]Saint Joseph's University, Philadelphia, Pennsylvania

Study Objectives: To describe the adaptation, feasibility, and initial outcomes of *Sleep Well!*, an intervention for early childhood insomnia and insufficient sleep, designed for families from lower–socioeconomic status backgrounds presenting to large metropolitan primary care sites.

Methods: Fifteen caregiver-child dyads (caregivers: 92.3% mothers, 80.0% Black, 53.3% ≤ 125% US poverty level; children: 73.3% female, 86.7% Black, mean age = 3.0 years) participated in this multimethod, single-arm trial. A family advisory board of caregivers (n = 4) and a clinician advisory board of sleep experts, primary care clinicians, and psychologists (n = 13) provided intervention feedback throughout the pilot. Most adaptations were related to intervention delivery methods, with some related to sleep strategies. At postintervention, caregivers completed surveys on intervention acceptability and cultural humility (primary outcomes) and completed semistructured interviews. Caregivers also reported on child sleep pre- and postintervention.

Results: Thirteen (86.6%) families completed *Sleep Well!* and 12 (80.0%) completed pre- and postintervention measures. Caregivers reported strong intervention acceptability and cultural humility. There were preintervention to postintervention reductions in child sleep problems, bedroom electronics, sleep onset latency, and night awakening frequency and duration. Nighttime sleep duration and overall insufficient sleep also improved. Qualitative data also showed strong intervention acceptability and perceived flexibility, with few participation barriers.

Conclusions: A brief, early childhood behavioral sleep intervention delivered in primary care with families from primarily lower–socioeconomic status backgrounds and/or racially minoritized backgrounds is feasible to implement, with strong retention rates, acceptability, and perceptions of cultural humility. Child sleep improvements are positive and warrant replication in a randomized controlled trial.

Clinical Trial Registration: Registry: ClinicalTrials.gov; Name: Implementing Behavioral Sleep Intervention in Urban Primary Care; URL: https://clinicaltrials.gov/ct2/show/NCT04046341; Identifier: NCT04046341.

Keywords: pediatric, insomnia, sleep health, health disparities, intervention, primary care

Citation: Williamson AA, Okoroji C, Cicalese O, et al. *Sleep Well!* An adapted behavioral sleep intervention implemented in urban primary care. *J Clin Sleep Med.* 2022;18(4):1153–1166.

BRIEF SUMMARY

Current Knowledge/Study Rationale: Very few evidence-based behavioral sleep interventions have been tested with families from lower–socioeconomic status backgrounds. We used community-engaged research methods to iteratively adapt and test *Sleep Well!,* an intervention for early childhood insomnia and insufficient sleep, designed for families from lower–socioeconomic status backgrounds presenting to large metropolitan primary care sites.

Study Impact: Findings suggest that *Sleep Well!* is highly feasible to implement in primary care and acceptable to families, with evidence of cultural humility and child sleep improvements in a sample of caregiver-child dyads from primarily lower–socioeconomic status and/or racially minoritized backgrounds. Thus, *Sleep Well!* is a promising method for increasing access to sleep treatment and promoting pediatric sleep health equity.

INTRODUCTION

Up to 30% of young children experience behaviorally based sleep problems, including insomnia and insufficient sleep,[1–3] which are associated concurrently and prospectively with poor emotional, behavioral, and neurocognitive functioning.[4,5] Fortunately, these sleep problems are highly treatable, with robust evidence for brief, family-based approaches.[6–8] These approaches typically involve psychoeducation about children's sleep needs and healthy habits along with behavioral strategies, such as implementing a consistent bedtime routine and sleep schedule, caregiver limit-setting and differential reinforcement at bedtime, and interventions to promote independent child sleep onset.[9] Empirical reviews show that behavioral sleep interventions significantly improve early childhood sleep, including caregiver-perceived child sleep problems and bedtime resistance, reduced sleep onset latency, fewer nighttime awakenings, and longer nighttime sleep duration.[6–9] In addition, behavioral sleep treatments result in improved child behavior and caregiver mood.[10,11]

Despite this strong evidence base, there are critical gaps in behavioral sleep intervention research. Primarily, the vast majority of this work has been conducted with families of higher educational or socioeconomic status (SES) backgrounds.[9,12] A systematic review[12] of behavioral sleep intervention studies identified that among those reporting family sociodemographic information, most caregivers had completed college or postsecondary education, with 78% of intervention participants identifying as White. Although the efficacy of sleep health education has been examined with families from lower-SES backgrounds attending Head Start,[13] families in transitional housing,[14] and through a bed provision charity program,[15] this research has not focused on treating behavioral sleep problems. Addressing this research gap is especially important given that there are well-documented sleep health disparities beginning in infancy and extending through childhood, with children from lower-SES and/or racially minoritized backgrounds exposed to increased social and environmental contributors to poor sleep.[2,16–19]

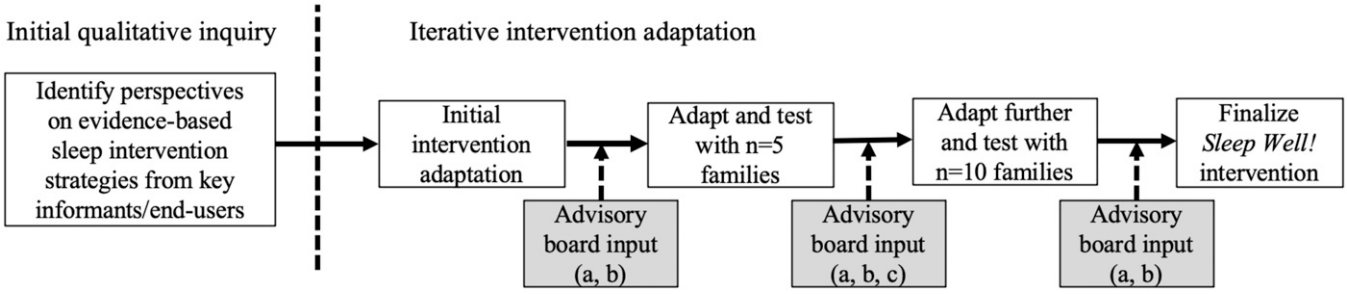
There is also a notable research gap in designing, implementing, and evaluating evidence-based behavioral sleep interventions in usual care settings, especially in practices serving racially minoritized families or those marginalized as a function of socioeconomic disadvantage, contributing to a broad research-to-practice gap in sleep medicine.[20] This research is necessary to ensure that interventions are feasible, acceptable to families, and equitable and that they can be scaled for dissemination across clinical settings. One such setting, pediatric primary care, is accessible for almost all families, particularly during early childhood, when well-child visits and vaccinations occur more frequently.[21] For example, 1 study found that implementing a sleep screening tool followed by behavioral sleep recommendations provided by integrated psychologists was feasible in an urban primary care site and acceptable to clinicians and families, but the resulting impacts on sleep were not assessed.[22] Compared to research with adults, in which cognitive behavioral therapy for insomnia has been adapted for and tested in primary care,[23] pediatric research is lacking.

Collectively, these research gaps raise questions about the extent to which behavioral sleep interventions require adaptations to enhance both their cultural and their contextual fit across populations and settings. Previously, we qualitatively explored these questions by soliciting perspectives on evidence-based behavioral sleep intervention strategies[6–8,24,25] from a sample of caregivers of young children with insomnia or insufficient sleep who were primarily from lower-SES and/or Black/African American (hereafter, "Black") backgrounds and practicing urban primary care clinicians (physicians, nurse practitioners, social workers, psychologists).[26] Converging views from both the caregiver and the clinician groups highlighted the need for culturally adapted intervention strategies and new intervention approaches to benefit family acceptability and engagement, intervention feasibility and efficacy, and effective intervention delivery in primary care. Caregiver- and clinician-identified intervention barriers included challenging family work schedules, shared sleep spaces because of family preference or limited resources, and the need to rely on multiple family members to regulate child sleep. Both groups also endorsed the importance of flexible strategies tailored to the family and broader sociocultural context, empowering and collaborative care, and technologically enhanced intervention delivery (eg, text messages, emails, videos). These findings align with a recent National Institutes of Health report on sleep health disparities that underscores the need for culturally tailored sleep interventions.[19]

Current study

The overall objective of this study, to bridge these research gaps, was to adapt and test the acceptability, cultural humility, and initial sleep outcomes of *Sleep Well!*, an early childhood behavioral sleep intervention designed for implementation with families from lower-SES backgrounds presenting to primary care. We applied a community-engaged research approach[27] to undertake multiple phases of iterative intervention adaptation with feedback from intervention participants and external family and clinician advisory boards. The Cultural Adaptation Framework[28] was used to categorize modifications to evidence-based strategies as being "peripheral" (changes to intervention delivery methods and materials) or "core" adaptations (changes to intervention strategies and mechanisms). We additionally incorporated methods from implementation science to promote equitable health care service delivery,[29] including designing our intervention with the end users and implementation settings in mind, to avoid exacerbating disparities when interventions are scaled up and delivered in settings serving racially

Figure 1—Overview of study design.



See Williamson et al[26] for initial qualitative inquiry results. See **Table S1** for a description of each advisory board. (a) = clinician advisory board, (b) = family advisory board, (c) = expanded clinical advisory board.

Table 1—Family sociodemographic information at preintervention (n = 15 caregiver-child dyads).

Variables	Mean (SD) or %
Child age (y)	3.00 (1.36)
Child female sex	73.3%
Child race*	
Black/African American	86.7%
White	13.3%
Child Hispanic/Latinx ethnicity*	6.7%
Caregiver age (y)	
18–29	46.7%
30–39	33.3%
40–49	13.3%
≥ 50	6.7%
Caregiver relationship to child	
Mother	92.3%
Grandmother	7.7%
Caregiver race*	
Black/African American	80.0%
White	13.3%
Other or multiple races	6.7%
Caregiver Hispanic/Latinx ethnicity*	13.3%
Caregiver occupational status	
Employed full time	80.0%
Employed part time	6.7%
Not employed	13.3%
Single-caregiver household	40.0%
Married	40.0%
Unmarried, cohabitating	20.0%
Caregiver highest level of education	
≤ High school/secondary school	60.0%
Some college/junior college	20.0%
College/university degree or more	20.0%
Number of children living in the home	1.93 (0.96)
Number of adults (aged 18 years or older) living in the home	2.20 (0.94)
Annual household income	
≤ $25,000	46.7%
$25,001–$35,000	13.3%
$35,001–$50,000	20.0%
≥ $50,001	20.0%
≤ 125% US poverty level	53.3%

*Race and ethnicity are included as sociopolitical constructs, not as biological indicators. SD = standard deviation.

minoritized families or those marginalized because of lower SES.[29] We hypothesized that *Sleep Well!* would be feasible in a large metropolitan primary care context and be acceptable to families, with evidence of cultural humility and improved child sleep outcomes.

METHODS

Overview of study design and setting

Figure 1 illustrates the multimethod, single-arm study design used to iteratively adapt and test *Sleep Well!*, with sleep outcomes assessed at pre- and postintervention. The study was conducted at 2 pediatric primary care sites affiliated with a large children's hospital located in a large metropolitan area (hereafter, "urban")[30] serving predominantly Black families, the majority of whom were Medicaid-insured.[31]

Participants

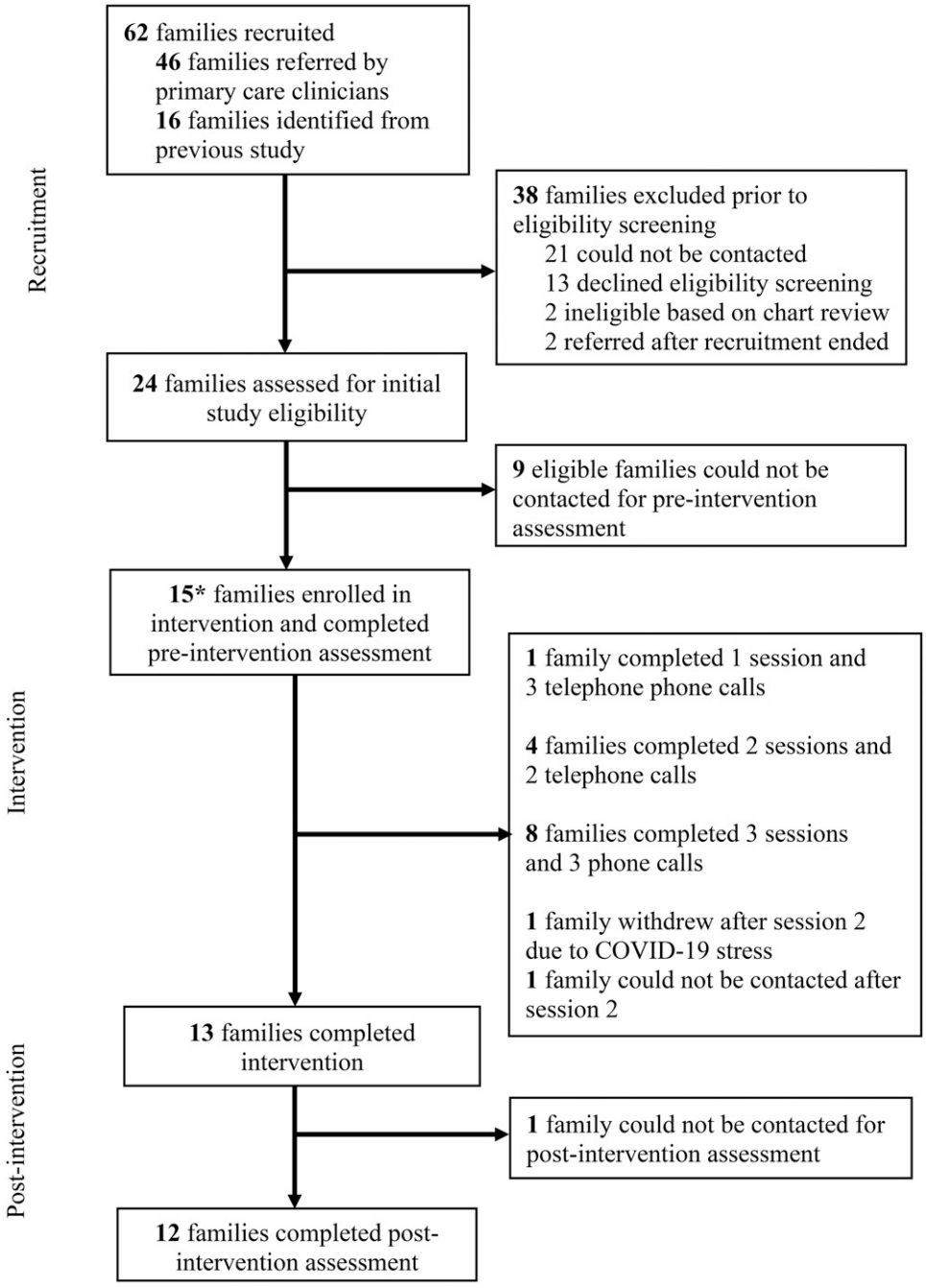
A total of 15 caregiver-child dyads participated in *Sleep Well!* (see **Table 1** for sociodemographic information). The sample size was based on prior feasibility study research[32,33] and guidelines for qualitative data saturation (12–15 interviews).[34] All dyads were consecutively recruited from the 2 urban primary care sites, using a combination of study flyers, primary care clinician referrals, and review of children's electronic health records for families scheduled for well-child care. We also offered intervention participation to caregivers who participated in the phase 1 qualitative study.[26] **Figure 2** provides additional referral, recruitment, and retention data. Inclusion criteria were as follows: (1) English-speaking caregiver, aged 18 years or older, who was the legal guardian of a child aged 1–5 years receiving care at the urban primary care sites; (2) a caregiver-reported "small" to "severe" child sleep problem[10]; (3) child met diagnostic criteria (per the *International Classification of Sleep Disorders,* third edition)[35] for pediatric insomnia or insufficient sleep; and (4) child did not have a diagnosed medical (eg, sickle cell disease, cancer) or neurodevelopmental (eg, autism, Trisomy 21) condition that would impact sleep. All participants provided informed consent. This study was approved by the hospital's Institutional Review Board and registered at ClinicalTrials.gov (NCT04046341).

Intervention adaptation procedures

As shown in **Figure 1**, the caregiver and primary care clinician feedback from our initial qualitative inquiry[26] was used to guide the multistep intervention development and adaptation process. Drawn from the extant literature,[6–8,24,25] strategies included (1) psychoeducation (sleep duration guidelines and importance of sleep for young children), (2) sleep hygiene (consistent bedtime routine; bedtime before 9:00 PM; avoidance of caffeine; avoidance of electronic items 30–60 minutes before bedtime, at sleep onset, and overnight), (3) differential reinforcement for bedtime tantrums (ignoring minor misbehaviors, praise and/or tangible rewards for good bedtime behaviors), and (4) methods to promote independent child sleep onset (gradually reducing caregiver presence at bedtime). We made preimplementation adaptations to these strategies based on previous qualitative input,[26] resulting in the initial *Sleep Well!* adaptation.

For the second step of this process, we presented initial intervention adaptations to (1) a clinician advisory board consisting of 3 clinical research team members with content expertise (A.G.F., J.A.M., T.J.P.) and (2) a family advisory board that included the director (A.K.) and 3 caregivers (A.A., B.H., R.H.)

Figure 2—Participant recruitment, enrollment, and retention.

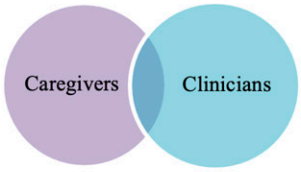


*One family participated in the previous qualitative study.[26] COVID-19 = coronavirus disease 2019.

from the children's hospital's Family Partners program, which provides a mechanism for families to consult on clinical research and practice. The 3 caregivers (100% female, 66.7% non-Latinx Black, 33.3% non-Latinx White) each had 1 or more children receiving care at the broader children's hospital and primary care network and lived in the communities surrounding the 2 primary care sites where intervention occurred. See **Table S1** in the supplemental material for advisory board descriptions. After feedback was received, the third step involved making additional intervention adaptations (described in the following 2 sections) and implementing the intervention with 5 families (**Figure 1**). For the fourth step, we presented the adapted intervention materials, approach, and deidentified quantitative and qualitative outcome data from pre- and postintervention to both advisory boards noted above along with an expanded clinician advisory board of sleep experts, primary care clinicians, integrated psychologists working at the primary care sites at which the intervention occurred, and early childhood psychologists/clinicians (n = 9; 22.2% [n = 2] did not provide data; 80.0% female, 22.2% non-Latinx Black, 55.6%

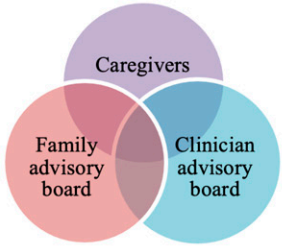
Figure 3—Summary of peripheral and core adaptations made throughout intervention adaptation and testing.

Initial qualitative inquiry



Peripheral adaptations	Core adaptations
• Offer intervention service in primary care • Increase visual aids and reduce literacy level of intervention materials (hand-outs, educational strategies) • Ensure graphics depict families of similar racial/ethnic backgrounds and use culturally relevant examples in materials • Provide intervention content via text messages and e-mails with infographics, reminders, and educational Internet links • Apply flexible, collaborative, and empowering approach, with family as expert on their child and family-centered goals • Directly address potential clinician bias in interventionist materials by including information and training about cultural humility and implicit bias	• Eliminate 9:00 PM bedtime recommendation to prioritize sleep schedule consistency and duration instead of timing • Emphasize sleep duration education • Reframe eliminating electronics usage at bedtime as reducing electronics at bedtime/overnight • Add strategies to address shared sleeping arrangements and/or multiple sleep locations/available caregivers at bedtime

Iterative intervention adaptation



Peripheral adaptations	Core adaptations
• Increase number of intervention sessions from 2 to 3 • Increase number of intervention phone calls from 2 to 3 • Provide services via telephone only or telephone + video due to COVID-19 pandemic • Ensure intervention materials provide consistent messaging with family as expert on their child • Include encouraging caregiver-directed messages • Include content from the American Psychiatric Association's Cultural Formulation Interview at intake	• Provide additional education and infographics related to caffeine consumption (example beverages; tips for locating nutritional labels) • Add anticipatory guidance component to explicitly address potential changes in future caregiver work, childcare/school, and family schedules/arrangements

COVID-19 = coronavirus disease 2019

non-Latinx White; **Table S1**). Step five involved making additional adaptations (described in the following 2 sections) and implementing *Sleep Well!* with 10 families. The sixth and final step was to present the intervention approach, materials, and deidentified participant outcome data to the smaller clinician advisory board and the family advisory board. At this step, we finalized the intervention approach and materials because feedback indicated that no further adaptations were needed.

These preimplementation and iterative intervention adaptations were organized within the Cultural Adaptation Framework's[28] designations of peripheral (intervention delivery methods and materials) and core (intervention strategy) adaptations (see **Figure 3**).

Peripheral adaptations (intervention delivery)

In line with the brief nature of behavioral health services integrated into primary care[36] and previous evidence-based behavioral sleep interventions,[10] we initially developed a 2-session intervention with sessions occurring approximately 2 weeks apart, with a follow-up telephone call 1 week after each session (2 calls total). However, after implementation with the first 5 families, converging feedback from the intervention participants and advisory board members indicated that an additional session and phone call were needed to further generalize intervention strategies. As such, we expanded the program to 3 sessions and 3 telephone calls. For the final 5 families, with the onset of the coronavirus disease 2019 (COVID-19) pandemic, we shifted from in-person visits to HIPAA (Health Insurance Portability and Accountability Act)-compliant video visits or longer telephone calls in place of sessions for families without Internet access.

We designed intervention handouts with increased informational graphics and a reduced literacy level. Intervention materials, including program flyers, were developed with images of Black families to align with the sociodemographics of the majority of patients seen at the urban primary care sites.[31] Based on advisory board feedback, intervention handouts were also developed to be contextually relevant, referencing multiple caregivers who may be involved in the child's bedtime routine (eg, siblings, relatives, babysitters) and methods to address different child sleep locations during the week (eg, another caregiver's or relative's home, babysitter's home). Using language derived from caregivers' qualitative feedback,[26] we created handouts related to "Getting everyone on board" in the family around sleep routines and "Saying goodnight to electronics," instead of eliminating bedtime electronics altogether (see "Core Adaptations" below). Consistent with caregiver preferences in the initial qualitative inquiry,[26] we integrated automated text messages between sessions and telephone calls, which were sent via the HIPAA-secure platform Twilio. Messages consisted of intervention strategy reminders, tailored family-set intervention goal reminders, Internet links to evidence-based early childhood sleep information (https://www.babysleep.com), and informational graphics.

The therapeutic approach was conceptualized as being flexible and highly collaborative, with explicit references to the family being the source of expertise regarding their child. Central to this approach was an emphasis on cultural humility,[37] particularly given the likelihood that interventionists and referring

pediatricians were of different racial, ethnic, SES, or educational backgrounds relative to families and the potential for implicit racial bias in the health care setting.[38] As such, interventionist training and supervision included activities (eg, taking an implicit association test based on race) to promote awareness and discussion of these topics. Family advisors emphasized the need to ensure that messages to families throughout the intervention were consistent with this therapeutic approach. During the adaptation process, family advisors recommended altering the bedtime routine information graphic to ensure that it was inclusive and highlighted families as being the experts on their child (see **Figure S1** in the supplemental material). In addition, after our initial adaptation, family advisors suggested that interventionists explicitly address cultural fit between interventionists and families. To respond to this feedback, we integrated content from the American Psychiatric Association's cultural formulation interview[39] to initiate interventionist-family discussions about this important topic.

Core adaptations (intervention strategies)

In our initial phase of intervention development and adaptation (**Figure 2**), we eliminated explicit references to an "early" bedtime before 9:00 PM[8,24] based on qualitative feedback that altering bedtime was challenging for caregivers with rotating/shift work schedules or competing child care demands.[26] Instead, we emphasized education about the importance of total (24-hour) sleep duration and sleep time regularity across weekdays and weekends. Information about establishing independent child sleep onset latency, which typically assumes an independent child sleep space,[8] was altered to ensure responsivity to caregiver-child bed- and/or room-sharing because of family cultural preferences or economic need. As noted above with regard to intervention handouts, instead of indicating that families should avoid any electronics usage for their child before bedtime,[8] we revised the recommendations to account for family norms around electronics, particularly in shared sleep spaces,[26] and to support families in limiting electronics at sleep onset and overnight.

During the iterative intervention development and adaptation phase (**Figure 2**), intervention families requested support in identifying the caffeine content in popular beverages to help reduce child caffeine intake. We added an informational graphic about this topic with specific references to beverage labels and education about caffeine and child sleep. Our other core adaptation during this phase was to include anticipatory guidance about how sleep may change in early childhood because of normative developmental progress (eg, dropping daytime naps) or social and environmental changes (eg, changes in caregiver work schedules, family structure, sleep arrangement, and school context, including transition to kindergarten). Psychoeducation in this regard was added to session 3, with accompanying informational graphics sent to families. The finalized intervention structure and content of each session, telephone call, and automated text message are summarized in **Figure S2** in the supplemental material.

Intervention implementation procedures

Participating caregiver-child dyads completed preintervention measures approximately 2 weeks before the first session. The lead investigator, a licensed psychologist boarded in behavioral sleep medicine (A.A.W.), served as the study interventionist for the first 5 participating caregiver-child dyads. Two predoctoral psychology interns (C.O., B.E.) served as interventionists for the remaining 10 caregiver-child dyads. Interventionists received intensive training before taking cases, followed by direct observation of sessions by A.A.W. with performance feedback for fidelity purposes. All intervention-related contact was documented in the hospital's electronic medical records and shared with the child's primary care clinician to align with the existing integrated behavioral health procedures in the primary care network. Postintervention measures and caregiver qualitative interviews were completed approximately 2 weeks after the final intervention telephone call.

Measures

Primary trial outcomes were feasibility, acceptability, and cultural humility metrics. Secondary outcomes were selected child sleep parameters, described further in "Child Sleep" below.

Family sociodemographic information

We abstracted child sociodemographic information (age, sex, race, ethnicity) from the hospital's electronic medical record. Caregivers completed a sociodemographic survey at preintervention to report on the caregiver's age, sex, race, ethnicity, educational level, employment status, and relationship status, along with details about family income and the number of adults and children in the home.

Feasibility

Feasibility outcomes included intervention retention and family engagement.[32] Retention was assessed by examining the proportion of dyads who completed all *Sleep Well!* components. The proportion of intervention sessions and telephone calls completed to those planned was used to reflect family engagement.

Acceptability

Caregiver acceptability of the sleep intervention was assessed at postintervention using the Treatment Evaluation Inventory-Short Form,[40] adapted for *Sleep Well!* (eg, "I found the sleep intervention strategies to be acceptable."). The 7 items from this form were rated on a 5-point Likert scale ranging from "strongly disagree" to "strongly agree."

Cultural humility

Based on feedback from the family advisory board after the initial 5 families participated in the study, we included the caregiver-rated Multicultural Therapy Competency Inventory-Client Version[41] at postintervention to assess perceived cultural humility. The 5 Multicultural Therapy Competency Inventory-Client Version items are rated on a 5-point Likert scale ("strongly disagree" to "strongly agree") and include questions about whether the caregivers felt they were treated with respect and the extent to which the interventionist was open to and understanding of the caregivers' beliefs.

Child sleep

At pre- and postintervention, caregivers completed the Brief Child Sleep Questionnaire,[42,43] a widely used and well-validated measure of early childhood sleep patterns (bed- and wake times, sleep onset latency, nighttime and daytime sleep durations), problems (difficulty falling asleep, bedtime resistance), and aspects of the sleep environment (use of a bedtime routine, sleep arrangements/locations). Details about the Brief Child Sleep Questionnaire items and psychometric validity are reported elsewhere.[42,43] Two additional items[24] were included to assess daily child caffeine consumption and the presence of electronics in the child's bedroom.

A priori child sleep outcomes were selected to align with prior behavioral sleep intervention research[6,10,11,15] and included sleep onset latency, number and duration of night awakenings, nighttime sleep duration, total (24-hour) sleep duration, the presence of a caregiver-endorsed child sleep problem, child bedtime resistance, bedtime routine consistency, caffeine consumption, and presence of bedroom electronics. Insufficient sleep duration was calculated by adding caregiver-reported total nighttime sleep to daytime sleep and comparing the sum against age-based guidelines for sleep duration (ie, minimum of 11 hours total for ages 1–2 years and 10 hours total for ages 3–5 years).[44] A child sleep problem was dichotomized in line with previous intervention research, denoted by a "small" to "severe" child sleep problem.[10,11] Bedtime resistance and the presence of a bedtime routine 5 or more nights per week were similarly dichotomized according to prior research.[26] Although bedtimes and wake times were assessed using the Brief Child Sleep Questionnaire, we did not include these as potential intervention outcomes because our qualitative work[26] indicated that family work and child care schedules were unlikely to change to accommodate child sleep timing.

Postintervention caregiver interview

We followed COREQ guidelines[45] for qualitative data. Caregivers participated in a 30-minute semistructured postintervention interview with the female study coordinator (O.C.), who was trained in interview methods by A.A.W. Interviews were conducted individually in person at the primary care site or by telephone and were audiorecorded. Open-ended questions were designed and piloted to solicit perspectives about the acceptability and utility of the intervention strategies and the need for additional adaptation or improvement (see Appendix S1 in the supplemental material). No field notes were recorded.

Statistical analyses

Descriptive statistics were used to summarize the sample and to examine feasibility, acceptability, and cultural sensitivity outcomes. Independent-samples *t* tests (continuous variables) and chi-square tests (dichotomous variables) were used to examine whether study completion was systematically linked to any sociodemographic characteristics. We conducted paired *t* tests (continuous variables) and McNemar tests (dichotomous variables) to assess pre- to postintervention change in a priori child sleep outcomes. We also calculated Cohen's *d* to examine *t* test effect sizes, adjusted for the paired nature of the data.[46]

Audiorecorded qualitative interviews were transcribed and checked for accuracy. An integrated approach[47] was used to analyze qualitative data, with both a priori intervention-related codes and grounded theory codes that emerged from the data. Three study researchers (A.A.W., C.O., B.E.) iteratively developed the code book by independently reviewing and comparing 4 successive transcripts (kappa = 0.83). Once a stable code book was developed, 2 researchers (C.O., B.E.) separately coded the remaining interviews and then reviewed them conjointly. Any coding disagreements were resolved through discussion among the 3 researchers (A.A.W., C.O., B.E.). Qualitative results were presented to family advisors but were not reviewed by participants.

RESULTS

Sociodemographic information for the sample is shown in **Table 1**. Most participating caregivers were Black (80.0%) mothers (92.3%) with a young child aged 3.00 years, on average (standard deviation = 1.36 years). The majority of the children were Black (86.7%) girls (73.3%). Most (60.0%) caregivers had a high school education or less, with half (53.3%) of the families living at or below 125% of the US poverty level.

Feasibility

Of the 15 caregiver-child dyads who initiated *Sleep Well!*, 13 completed all intervention components, yielding an intervention retention rate of 86.6% (see **Figure 1**). As noted, after implementing the intervention with 5 families, the number of sessions and telephone calls was increased from 2 to 3 each. Family engagement was strong. Of the 13 families who completed the intervention, 100% completed all planned sessions and telephone calls (see **Figure 1** for details). Because of COVID-19 restrictions, 3 families completed intervention sessions via HIPAA-compliant video or telephone. We lost contact with 1 family after session 2, and another family withdrew from the study, citing COVID-19–related stress (**Figure 1**).

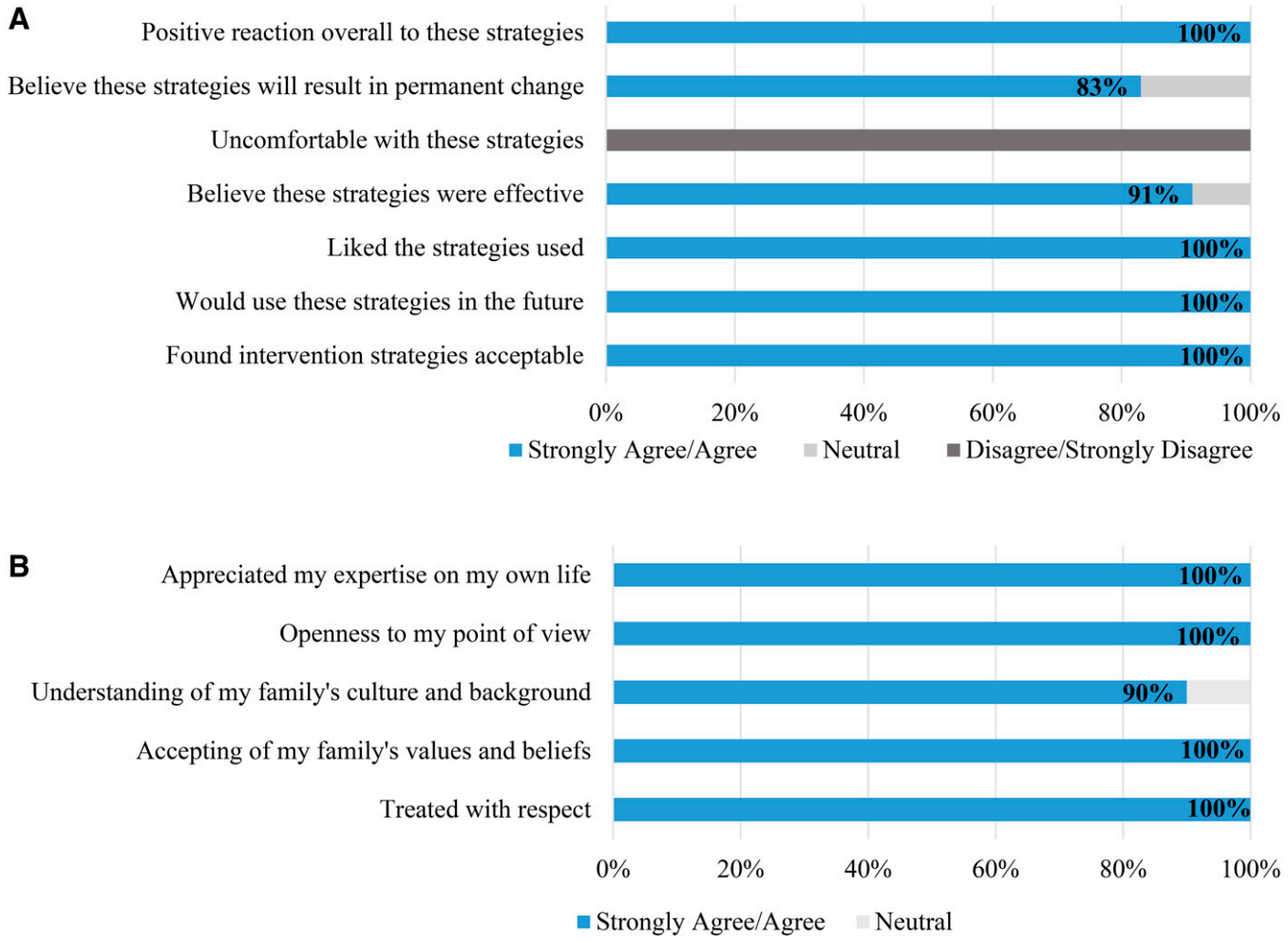
Acceptability

Postintervention ratings of intervention acceptability were strong (**Figure 4A**). All (100%) caregivers agreed or strongly agreed that the intervention was acceptable and that they liked the strategies, would use them in the future, and felt positively about the strategies overall. No families reported feeling uncomfortable with the strategies, and most agreed or strongly agreed that the strategies would result in permanent change (83.0%) and were effective (91.0%).

Cultural humility

Caregiver-reported cultural humility ratings (n = 10, **Figure 4B**) revealed that all (100%) caregivers agreed or strongly agreed that they were treated respectfully, that their family's values and beliefs were accepted, that there was openness to the caregiver's point of view, and that there was appreciation of the caregiver's expertise. Most (90.0%) agreed or strongly that their family's culture and background were understood.

Figure 4—Intervention acceptability and cultural humility ratings.



(A) Intervention acceptability ratings at postintervention (n = 12). **(B)** Cultural humility ratings at postintervention (n = 10).

Sleep outcomes

At the onset of COVID-19 we lost contact with 1 of the 13 families who completed the intervention, resulting in no postintervention data. In total, 12 families (80.0%) who initiated *Sleep Well!* completed both the pre- and postintervention assessments. There were no sociodemographic differences between families who completed the study and those who did not. Descriptive child sleep information and pre- to postintervention change in sleep outcomes are summarized in **Table 2**. There were significant improvements in many sleep parameters and behaviors. Sleep onset latency decreased by an average of 43.17 minutes ($t = 2.93$; $P = .014$), and duration of night awakenings decreased by 103.75 minutes ($t = 2.96$; $P = .013$), with large effect sizes (1.17 for sleep onset latency, 1.35 for night awakening duration). The proportion of families with frequent (≥ 3 times/week) night awakenings also improved from pre- (100%) to postintervention (8.3%; $P = .001$). Nighttime sleep duration significantly improved by > 2 hours from pre- to postintervention ($t = –4.45$; $P = .001$), with a large effect size (1.54), but the improvement in total (24-hour) sleep duration did not reach statistical significance. However, compared to preintervention, fewer children were obtaining insufficient sleep according to age-based guidelines at postintervention (25.0% vs 75.0% at preintervention; $P = .031$). The overnight sleep extension likely resulted from the reductions in sleep onset latency and night awakening duration, given that bed- and wake times did not change substantially from pre- to postintervention.

Having an overall caregiver-perceived child sleep problem decreased from pre- (100%) to postintervention (33.3%; $P = .008$), although changes in perceived child bedtime resistance did not reach statistical significance (91.7% at preintervention vs 41.7% at postintervention; $P = .070$). The proportion of children with electronics items in their bedroom significantly decreased from 66.7% at preintervention to 8.3% at postintervention ($P = .016$). There were no significant improvements in the other sleep health behaviors, although more children followed a consistent bedtime routine (≥ 5 times/week) at postintervention (75.0% vs 33.3% at preintervention; $P = .053$) and fewer consumed caffeine (25.0% at preintervention vs 16.7% at

Table 2—Descriptive statistics for caregiver-reported child sleep variables and pre- to postintervention comparisons (n = 12).

	Preintervention, Mean (SD) or %	Postintervention, Mean (SD) or %	Paired Comparisons (*P*)	ES
Sleep arrangement and patterns				
Sleeps in own room, own bed	16.7%	58.3%		
Shared room with caregiver(s), shared bed	66.7%	25.0%		
Shared room with sibling(s), shared bed	16.7%	8.3%		
Other	0%	8.3%		
Bedtime	9:06 PM (95 min)	9:10 PM (47 min)		
Wake time	7:41 AM (128 min)	7:41 AM (61 min)		
Takes naps	66.7%	66.7%		
Nap duration (min)	125.00 (158.14)	46.25 (60.50)		
Intervention outcomes				
Sleep-onset latency (min)	69.00 (50.41)	25.83 (10.62)	.014	1.17
Night awakenings ≥ 3 times/wk	100%	8.3%	.001	
Duration of nighttime awakenings (min)*	131.25 (121.55)	27.50 (58.56)	.013	1.35
Nighttime sleep duration (h)	6.63 (1.99)	9.21 (1.21)	.001	1.54
Total (24-h) sleep duration (h)	8.71 (3.28)	9.98 (1.03)	.209	0.51
Insufficient sleep for age	75%	25%	.031	
Child sleep problem	100.0%	33.3%	.008	
Child bedtime resistance	91.7%	41.7%	.070	
Bedtime routine ≥ 5 nights/wk	33.3%	75.0%	.063	
Consumes ≥ 1 caffeinated beverage/d	25.0%	16.7%	.100	
Electronic items in bedroom	66.7%	8.3%	.016	

*n = 7 because of data collection error. Paired comparisons are *t* tests for continuous outcomes. McNemar tests were used for categorical outcomes. ES = effect size (Cohen's *d* for paired *t* tests), SD = standard deviation.

postintervention; $P = .100$). Bed-sharing with a caregiver (66.7%) or sibling (16.7%) was common at preintervention, with some dyads setting goals to transition to an independent child sleep space, such that bed-sharing was reduced at postintervention (25.0% with a caregiver; 8.3% with a sibling).

Qualitative feedback

Qualitative themes and representative caregiver quotations are shown in **Table 3**. Themes included "overall program acceptability and satisfaction" and "acceptability of the research procedures" (electronic pre- and postintervention questionnaires). Many caregivers described *Sleep Well!* participation as being "easy" and "fun." Within the theme of "intervention benefits and strategies," caregivers referenced improved child sleep habits and related caregiver sleep health knowledge, particularly regarding beverages with caffeine. Several caregivers also described feeling reassured by information that normalized the high prevalence of sleep problems in young children. Caregivers additionally referenced personalization and flexibility, with 1 caregiver citing the example of the family changing their goals for independent child sleep during the program. There were also references to family empowerment, with caregivers noting the benefits of the intervention approach being designed to prioritize family views. "Additional intervention benefits" emerged as a salient theme, with caregivers reporting improvements in daytime child behavior, caregivers' own sleep and parenting, and an enhanced understanding of linkages between child sleep and daytime behavior.

"Delivery strategies," including the intervention implementation in primary care and the use of text messages and emails for intervention content delivery, were also well received by caregivers, although 1 caregiver noted the challenge of balancing her work schedule with commuting to the primary care site. Caregivers who conducted the intervention sessions by telephone or video reported satisfaction with these methods, and many endorsed the utility of future video sessions. Some caregivers noted the impact of continued barriers to intervention participation and strategies, especially around the impact of overnight or inflexible caregiver work schedules or multiple sleep environments (eg, different caregiver homes, babysitter's home) and, as a result, having multiple nighttime caregivers. A few caregivers also referenced some continued postintervention child sleep issues, primarily night awakenings. Other than initial recommendations to extend the program duration, there were few recommendations for additional adaptations to the intervention. One caregiver highlighted the need for enhanced family communication to support intervention engagement, and another referenced the need to consider insurance coverage if the intervention was implemented as part of usual care.

Table 3—Qualitative themes and selected quotations from postintervention semistructured interviews (n = 12; IDs used for confidentiality).

Theme	Subthemes and Representative Caregiver Quotations
Overall acceptability	Program satisfaction: • "I would recommend this program for anybody who has a kid that don't sleep." (ID 19) • "I'm actually very pleased with how everything went. You know, we got the initial information about the program by expressing our doctor our pediatrician some of the issues we had, which you know were causing the entire family let's say to have a lack of sleep and impacting some of the things that we did in our normal life, you know, trying to get that. So, I'm very appreciative of the program." (ID 52) Ease of participation: • "It [*Sleep Well!*] was very easy to me, everything like y'all explained it out and had the calendar and made it fun so fun. […] Again, like I said, y'all made it fun for the kids, it wasn't like a punishment like you were in trouble or something. Last time, she [interventionist] gave us stickers and we drew pictures and stuff like that. So yeah, would definitely recommend." (ID 13) • "I didn't expect it to be so easy honestly. I went into it with like a closed mind. I'm like 'it's not gonna work, it's not going to make things any different than me telling her to go to her room.' But it made a big difference." (ID 22)
Intervention benefits and strategies	Benefits to sleep habits, routines, and knowledge: • "She's been doing really good. It's a big, it's a really big improvement going from 3 o'clock and 4 o'clock in the morning, to you know falling asleep by 9 or 10 o'clock." (ID 23) • "I liked how easy it was to transition her to her bed. I didn't think it would be that easy to do that. But the steps that the therapist recommended were very effective." (ID 22) • "One thing she [interventionist] did teach me that I am very grateful of, she told me that iced tea had caffeine in it. I never knew that and that was my main drink for them." (ID 19) Normalization of child sleep problems: • "She [interventionist] had text me like 'you know this is not just you, it's [sleep] a problem with everyone, everybody takes it step by step.'" (ID 19) • " … And I know sometimes when parents feel like they fail, like you fail as a parent because your child doesn't sleep. … Like I felt that way, I felt like I was being a horrible parent because my child did not sleep. It wasn't until I started this study when I realized my child is not the only child that doesn't sleep." (ID 35) Personalization and flexibility: • " … We thought we wanted her in her own sleep space, and then after trying it for a while we decided that wasn't something we wanted to do. So then we talked to the sleep therapist about it again. She was really supportive of us just being like we wanting to keep her in her bed, but we just came up with another game plan for keeping her in our bed … ." (ID 20) • " … So she [interventionist] was like 'totally get it, you know I'm not trying to make you change anything, we want to help you, so you are literally like the boss of what's going on.' So she understood the goal that I was working, that I wanted to work on, and it kind of fit in and not like push me or pressure me to have her sleep in her room in her own bed." (ID 28) Family empowerment: • " … It was a great program because it's like, you know, you are pretty much getting like ideas from the parent and going off that. Rather than like, you know, constantly trying to tell us how to do." (ID 33) • "I feel like the program really helped because it gave me strength that maybe I didn't realize as a parent, you know?" (ID 35)
Additional intervention benefits	Improvement in child daytime behavior and awareness of sleep-behavior linkages: • "Behavior, her attitude, everything. It's like a whole—like I told you somebody came in at night and gave me a different kid. […] because I couldn't sleep because she wasn't sleep, if she was up, I was up. So now that she sleeps, mommy gets up and she ready to go … . It's a big difference, everybody just happy." (ID 19) • "I think the program kind of reinforced what we already wanted to do and knew what to do. And it also provided awareness for us. Like, she's cranky in the morning because she's not getting enough sleep 'cuz we allow her to stay up a little late." (ID 28) • " … She [child participant] just wanted to find another way to entertain herself when she couldn't watch the TV, so we've been reading a lot more books and she's been playing with her toys a lot more." (ID 20) Caregiver sleep and parenting: • "It [*Sleep Well!*] helped a lot. I feel much more, like rested cause before like being sleep and then you know not really being able to be sleep because I have to keep an eye on her because she's not falling asleep. Now I get to sleep at night." (ID 23) • "I'm becoming more patient, more patient, about her behavior … ." (ID 40)
Delivery strategies	Benefits and limitations of implementation in primary care: • " … Not even just that it's in here [primary care], it intertwines with the doctors, the specialists, everybody gets on board. You don't gotta go over here and get this paperwork, you don't gotta do this, everything is right together which is perfect." (ID 19) • "It's not anything like that I didn't like about the program, it was just me having to go out of the way to XXX [primary care] so it was more traveling. […] would have been better if I didn't have to lose time from work … that's the only thing." (ID 28) Endorsement of text messages and emails for delivering additional intervention content:

(continued on following page)

Table 3—Qualitative themes and selected quotations from postintervention semistructured interviews (n = 12; IDs used for confidentiality). (*Continued*)

Theme	Subthemes and Representative Caregiver Quotations
	• "The little sleep information texts, they were actually helpful with a lot of tips to add in at bedtime for like stuff to do … . It was a lot of helpful tips in the text messages." (ID 20) • "Yes, yes and it was like text messages, like your child's bedtime is getting you know close and that really helped because I just had a baby so like I was like all over the place … so the text messages really helped … ." (ID 23) • "We [caregiver and child's father] kind of talked about it, and then the text messages that were coming like the screenshots [infographic] one, I would share with him [father]. So he would actually see those. But like the handouts and stuff, we would just talk about it. Like today, this is what we talk about this is the email that was sent." (ID 28) Benefits of telephone and video sessions: • " … I was worried about the sessions getting canceled all-in-all because we couldn't come in, but it was very helpful that we were able to switch to the phone calls instead." (participant who faced transportation issues prepandemic, ID 20) • "I like the intervention over the phone because it was easy, it was convenient, I was still able to work. […] Either [video or telephone] or would have been fine, but I would like the video because then everybody would have gotten to meet everyone. Like I know your voices." (participant who received remaining intervention sessions via telephone because of pandemic, ID 40)
Barriers	Caregiver work and family schedules: • "I was working overnight. So … he's not sleeping at home, so I can't really keep track of when he's going to sleep, you know, when he's up. So, yeah at first. But then I had got you know, the babysitter kind of like on board … so once we were on the same page it wasn't as difficult as it was before." (ID 42) Remaining sleep issues to target: • "We're just still trying to focus on her sleeping through the night. But I think if XXX [child name] is not taking naps when she's supposed to it affects her at night when it's time to go to bed." (ID 33) • "Since we started getting rid of sodas, just trying a lot of little different things, she only has it now where she wakes up like one time a week when she's not sleeping all through the night. So that we're still working on that. I'm still working on that, but she sleeps throughout the night now." (ID 40)
Additional adaptations	Optimal program duration: • "I thought it [*Sleep Well!*] could be extended a little longer." (participant who received 2 sessions and 2 telephone calls, ID 13) • "I wouldn't have wanted more." (participant who received 3 sessions and 3 telephone calls, ID 22) Ensure family engagement: • "I think the program overall works well, the recommendations are awesome, but it's also important to have, you know for anyone else that may need the assistance for parents, engagement is key. It cannot be done without that communication." (ID 52) Future insurance considerations: • " … Yeah, we got directed to the program because apparently our insurance can cover therapy though XXX [primary care office], so like that's a benefit … . If your insurance doesn't cover therapy, apparently … so umm, you know, I don't know how the plan is for it to be delivered to people without insurance or whatever … ." (ID 34)
Research methods acceptability	Questionnaires: • "I didn't have a problem with the surveys … it was really very easy cause it took you right to the link and when you were done it you know just click right off, so it wasn't bad at all." (ID 23) • "That was actually, for me, the easiest part. They would send you one … . So even if you didn't fill it out that moment they would send it to you again to make sure you do fill it out. So I did like that … ." (ID 35)

ID = identification.

DISCUSSION

There are persistent pediatric sleep health disparities, with few behavioral sleep interventions tested with families who are marginalized because of lower SES or with families of racially minoritized backgrounds. Drawing upon methods from community-engaged research,[27] health equity, and implementation science,[29] we iteratively adapted and tested *Sleep Well!*, an intervention for early childhood insomnia and insufficient sleep, designed primarily for families from lower-SES backgrounds presenting to urban primary care sites, which in this study served predominantly Black families. Study results indicated strong feasibility and caregiver perceptions of intervention acceptability, cultural humility, and efficacy. There were also child sleep improvements from pre- to postintervention, with reductions in caregiver-rated child sleep onset latency, night awakenings, and sleep problems, and improvements in sleep health, including reduced bedroom electronics and insufficient sleep.

In line with previous research, adaptations made to *Sleep Well!* on the basis of advisory board and qualitative participant feedback were primarily related to the intervention delivery strategies (ie, peripheral adaptations within the Cultural Adaptation Framework),[28] although there were some adaptations to core intervention content. These adaptations included eliminating the recommendation of a bedtime before 9:00 PM[8,24] in favor of emphasizing a consistent sleep schedule and adequate duration, reframing the presentation of electronics recommendations, and adjusting methods to promote

independent sleep onset in the context of co-sleeping because of family preferences or resource limitations. These adaptations highlight the need for future research that examines the importance of sleep regularity and duration, rather than sleep timing, on sleep-related child outcomes.[48] Other core adaptations included increased psychoeducation about caffeine and sleep duration, along with enhancing anticipatory guidance.

Beyond the strong caregiver acceptability and cultural humility ratings, postintervention interviews highlighted the benefits of a highly flexible and family-centered approach. Families described flexibility with regard to both core intervention strategies (eg, independent sleep onset) and peripheral delivery methods (eg, shifting to telephone sessions when needed). In line with our peripheral intervention adaptations to enhance collaboration and family empowerment, families referenced being the drivers of the intervention goals and strategies, with the interventionist playing a supportive role. A flexible delivery strategy with the option for both in-person and telephone visits prepandemic may have benefited intervention retention, which was 86.6%. This retention rate was higher than the rate in a study of families from lower-SES and/or minoritized backgrounds seeking early childhood behavioral health services (70.7%).[49] A school-based randomized trial of a similar brief, behavioral sleep intervention in Australia yielded an intervention retention rate of 98.1%,[10] although it should be noted that the study was conducted with a more economically advantaged sample, with potentially fewer treatment barriers, and our attrition occurred during the onset of the COVID-19 pandemic. The recent national addition of telehealth as a common delivery model also provides flexibility for families.

Many pre- to postintervention sleep improvements were clinically meaningful, based on experimental research showing that a 30-minute extension in child sleep is associated with improved daytime functioning.[50] In our study, there was a reduction in child sleep onset latency of > 40 minutes on average and in the frequency and duration of night awakenings by > 100 minutes. Although total (24-hour) sleep duration did not significantly improve, there was a significant improvement in nighttime sleep duration, likely because of reductions in sleep onset latency and nighttime awakening duration, and the proportion of children obtaining sufficient sleep increased by 50%. Overall, effect sizes were large for child sleep improvements and larger than previously reported small effect sizes in randomized trials of pediatric insomnia interventions.[6,10] Although our findings require replication in a controlled trial, it is notable that untreated early childhood sleep problems can persist in at least 20% of young children.[51]

Collectively, the findings suggest that *Sleep Well!* is a promising approach for treating behavioral sleep problems in young children from primarily lower-SES and/or Black backgrounds presenting to urban primary care. These results are limited to a specific sample of families and cannot be extended to all families from similar sociodemographic backgrounds. Future research is needed to examine whether the intervention is acceptable to and yields child sleep improvements in families of other racial/ethnic, socioeconomic, and linguistic backgrounds. Broadening the intervention to include young children with neurodevelopmental concerns is also an important future direction. In addition to the need to conduct a fully powered randomized controlled trial of *Sleep Well!* with a more generalizable sample, a critical next step is to examine whether trained interventionists can successfully implement the intervention; in this study a psychologist with advanced sleep training and 2 highly trained trainees implemented the intervention. Although *Sleep Well!* is based on a brief treatment model, includes easily accessible handouts and psychoeducation, and was designed to mirror existing models of integrated behavioral health in primary care, it still requires evaluation with social workers, counselors, and other clinicians as interventionists in this context.

Future research should include additional assessment methods, including quantitative measures of caregiver mood and daytime child behavior, which could help identify moderators of intervention outcomes. A future intervention trial could also include an objective measure of child sleep duration as a secondary outcome to complement the primary intervention outcome of a caregiver-perceived child sleep problem. It would also be useful to quantitatively assess whether caregivers opened text messages and emails with intervention content to supplement the qualitative feedback we received on these methods. Interactions with the study coordinator before the qualitative interview[45] and the small scope of the interview questions may have limited our qualitative results. More in-depth, mixed-methods approaches should also be applied in future research on this intervention. Although relevant implementation science theory[29] informed our research approach, additional research is needed to ascertain key implementation outcomes, including the reach, adoption, fidelity, and utility of this and many other sleep interventions when evaluated in usual care settings with practicing clinicians.[20]

CONCLUSIONS

Sleep Well!, an iteratively adapted brief behavioral sleep intervention for early childhood insomnia and insufficient sleep, is feasible to implement in an urban primary care setting, with positive child sleep outcomes. Especially important in the context of persistent sleep health disparities,[16,17,19] participating caregivers from primarily lower-SES and/or Black backgrounds reported strong intervention acceptability and cultural humility. Although a larger randomized controlled trial is needed to evaluate its effectiveness, *Sleep Well!* may be a method to increase access to sleep treatment and to promote pediatric sleep health equity in young children and their families.

ABBREVIATIONS

COVID-19, coronavirus disease 2019
SES, socioeconomic status

REFERENCES

1. Mindell JA, Sadeh A, Kwon R, Goh DY. Cross-cultural differences in the sleep of preschool children. *Sleep Med.* 2013;14(12):1283–1289.
2. Peña M-M, Rifas-Shiman SL, Gillman MW, Redline S, Taveras EM. Racial/ethnic and socio-contextual correlates of chronic sleep curtailment in childhood. *Sleep.* 2016;39(9):1653–1661.

3. Williamson AA, Mindell JA, Hiscock H, Quach J. Child sleep behaviors and sleep problems from infancy to school-age. *Sleep Med.* 2019;63:5–8.
4. Matricciani L, Paquet C, Galland B, Short M, Olds T. Children's sleep and health: a meta-review. *Sleep Med Rev.* 2019;46:136–150.
5. Reynaud E, Vecchierini MF, Heude B, Charles MA, Plancoulaine S. Sleep and its relation to cognition and behaviour in preschool-aged children of the general population: a systematic review. *J Sleep Res.* 2018;27(3):e12636.
6. Meltzer LJ, Mindell JA. Systematic review and meta-analysis of behavioral interventions for pediatric insomnia. *J Pediatr Psychol.* 2014;39(8):932–948.
7. Mindell JA, Kuhn B, Lewin DS, Meltzer LJ, Sadeh A; American Academy of Sleep Medicine. Behavioral treatment of bedtime problems and night wakings in infants and young children. *Sleep.* 2006;29(10):1263–1276.
8. Allen SL, Howlett MD, Coulombe JA, Corkum PV. ABCs of SLEEPING: a review of the evidence behind pediatric sleep practice recommendations. *Sleep Med Rev.* 2016;29:1–14.
9. Meltzer LJ, Wainer A, Engstrom E, Pepa L, Mindell JA. Seeing the Whole Elephant: a scoping review of behavioral treatments for pediatric insomnia. *Sleep Med Rev.* 2021;56:101410.
10. Quach J, Hiscock H, Ukoumunne OC, Wake M. A brief sleep intervention improves outcomes in the school entry year: a randomized controlled trial. *Pediatrics.* 2011;128(4):692–701.
11. Mindell JA, Du Mond CE, Sadeh A, Telofski LS, Kulkarni N, Gunn E. Efficacy of an internet-based intervention for infant and toddler sleep disturbances. *Sleep.* 2011; 34(4):451–458B.
12. Schwichtenberg AJ, Abel EA, Keys E, Honaker SM. Diversity in pediatric behavioral sleep intervention studies. *Sleep Med Rev.* 2019;47:103–111.
13. Wilson KE, Miller AL, Bonuck K, Lumeng JC, Chervin RD. Evaluation of a sleep education program for low-income preschool children and their families. *Sleep.* 2014;37(6):1117–1125.
14. Labella MH, Kalstabbakken A, Johnson J, et al. Promoting resilience by improving children's sleep: feasibility among families living in supportive housing. *Prog Community Health Partnersh.* 2017;11(3):285–293.
15. Mindell JA, Sedmak R, Boyle JT, Butler R, Williamson AA. *Sleep well!:* A pilot study of an education campaign to improve sleep of socioeconomically disadvantaged children. *J Clin Sleep Med.* 2016;12(12):1593–1599.
16. Guglielmo D, Gazmararian JA, Chung J, Rogers AE, Hale L. Racial/ethnic sleep disparities in US school-aged children and adolescents: a review of the literature. *Sleep Health.* 2018;4(1):68–80.
17. Smith JP, Hardy ST, Hale LE, Gazmararian JA. Racial disparities and sleep among preschool aged children: a systematic review. *Sleep Health.* 2019;5(1):49–57.
18. El-Sheikh M, Bagley EJ, Keiley M, Elmore-Staton L, Chen E, Buckhalt JA. Economic adversity and children's sleep problems: multiple indicators and moderation of effects. *Health Psychol.* 2013;32(8):849–859.
19. Jackson CL, Walker JR, Brown MK, Das R, Jones NL. A workshop report on the causes and consequences of sleep health disparities. *Sleep.* 2020;43(8): zsaa037.
20. Parthasarathy S, Carskadon MA, Jean-Louis G, et al. Implementation of sleep and circadian science: recommendations from the Sleep Research Society and National Institutes of Health workshop. *Sleep.* 2016;39(12):2061–2075.
21. Honaker SM, Meltzer LJ. Sleep in pediatric primary care: a review of the literature. *Sleep Med Rev.* 2016;25:31–39.
22. Honaker SM, Saunders T. The Sleep Checkup: sleep screening, guidance, and management in pediatric primary care. *Clin Pract Pediatr Psychol.* 2018;6(3): 201–210.
23. Troxel WM, Germain A, Buysse DJ. Clinical management of insomnia with brief behavioral treatment (BBTI). *Behav Sleep Med.* 2012;10(4):266–279.
24. Mindell JA, Meltzer LJ, Carskadon MA, Chervin RD. Developmental aspects of sleep hygiene: findings from the 2004 National Sleep Foundation Sleep in America poll. *Sleep Med.* 2009;10(7):771–779.
25. Mindell JA, Williamson AA. Benefits of a bedtime routine in young children: sleep, development, and beyond. *Sleep Med Rev.* 2018;40:93–108.
26. Williamson AA, Milaniak I, Watson B, et al. Early childhood sleep intervention in urban primary care: caregiver and clinician perspectives. *J Pediatr Psychol.* 2020; 45(8):933–945.
27. Key KD, Furr-Holden D, Lewis EY, et al. The continuum of community engagement in research: a roadmap for understanding and assessing progress. *Prog Community Health Partnersh.* 2019;13(4):427–434.
28. Chu J, Leino A. Advancement in the maturing science of cultural adaptations of evidence-based interventions. *J Consult Clin Psychol.* 2017;85(1): 45–57.
29. Baumann AA, Cabassa LJ. Reframing implementation science to address inequities in healthcare delivery. *BMC Health Serv Res.* 2020;20(1):190.
30. Ingram DD, Franco SJ. 2013 NCHS urban-rural classification scheme for counties. *Vital Health Stat 2* 2014;166:1–73.
31. Pediatric Research Consortium. CHOP Care Network Information. https://perc.research.chop.edu/sites/default/files/CHOP-Care-Network-Information-for-grants-2017.pdf. Accessed December 19, 2020.
32. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res.* 2011;45(5):626–629.
33. Goldstein NE, Kemp KA, Leff SS, Lochman JE. Guidelines for adapting manualized interventions for new target populations: a step-wise approach using anger management as a model. *Clin Psychol N Y.* 2012;19(4): 385–401.
34. Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. *Field Methods.* 2006;18(1): 59–82.
35. American Academy of Sleep Medicine. *International Classification of Sleep Disorders.* 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.
36. Stancin T. Commentary: integrated pediatric primary care: moving from why to how. *J Pediatr Psychol.* 2016;41(10):1161–1164.
37. Tervalon M, Murray-García J. Cultural humility versus cultural competence: a critical distinction in defining physician training outcomes in multicultural education. *J Health Care Poor Underserved.* 1998;9(2):117–125.
38. Maina IW, Belton TD, Ginzberg S, Singh A, Johnson TJ. A decade of studying implicit racial/ethnic bias in healthcare providers using the implicit association test. *Soc Sci Med.* 2018;199:219–229.
39. DeSilva R, Aggarwal NK, Lewis-Fernandez R. The DSM-5 Cultural Formulation Interview and the Evolution of Cultural Assessment in Psychiatry. Psychiatric Times. https://www.psychiatrictimes.com/view/dsm-5-cultural-formulation-interview-and-evolution-cultural-assessment-psychiatry. Published 2015. Accessed December 21, 2021.
40. Kelley ML, Heffer RW, Gresham FM, Elliott SN. Development of a modified treatment evaluation inventory. *J Psychopathol Behav Assess.* 1989;11(3): 235–247.
41. Cole E, Piercy F, Wolfe E, West J. Development of the Multicultural Therapy Competency Inventory-Client Version. *Contemp Fam Ther.* 2014;36(4): 462–473.
42. Kushnir J, Sadeh A. Correspondence between reported and actigraphic sleep measures in preschool children: the role of a clinical context. *J Clin Sleep Med.* 2013;9(11):1147–1151.
43. Sadeh A. A brief screening questionnaire for infant sleep problems: validation and findings for an Internet sample. *Pediatrics.* 2004;113(6): e570–e577.
44. Paruthi S, Brooks LJ, D'Ambrosio C, et al. Recommended amount of sleep for pediatric populations: a consensus statement of the American Academy of Sleep Medicine. *J Clin Sleep Med.* 2016;12(6):785–786.
45. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care.* 2007;19(6):349–357.
46. Dunlap WP, Cortina JM, Vaslow JB, Burke MJ. Meta-analysis of experiments with matched groups or repeated measures designs. *Psychol Methods.* 1996;1(2): 170–177.

47. Bradley EH, Curry LA, Devers KJ. Qualitative data analysis for health services research: developing taxonomy, themes, and theory. *Health Serv Res.* 2007;42(4): 1758–1772.
48. Meltzer LJ, Williamson AA, Mindell JA. Pediatric sleep health: it matters, and so does how we define it. *Sleep Med Rev.* 2021;57:101425.
49. Ofonedu ME, Belcher HME, Budhathoki C, Gross DA. Understanding barriers to initial treatment engagement among underserved families seeking mental health services. *J Child Fam Stud.* 2017;26(3):863–876.
50. Gruber R, Cassoff J, Frenette S, Wiebe S, Carrier J. Impact of sleep extension and restriction on children's emotional lability and impulsivity. *Pediatrics.* 2012; 130(5):e1155–e1161.
51. Byars KC, Yolton K, Rausch J, Lanphear B, Beebe DW. Prevalence, patterns, and persistence of sleep problems in the first 3 years of life. *Pediatrics.* 2012;129(2): e276–e284.

ACKNOWLEDGMENTS

The authors thank the network of primary care clinicians, their patients, and families for their contribution to this project and clinical research facilities through the Pediatric Research Consortium at the Children's Hospital of Philadelphia. We also thank the Children's Hospital of Philadelphia Family Partners Program and the Children's Hospital of Philadelphia Reach Out & Read program, which donated bedtime books for us to give to participating families.

SUBMISSION & CORRESPONDENCE INFORMATION

Submitted for publication May 27, 2021
Submitted in final revised form December 1, 2021
Accepted for publication December 2, 2021
Address correspondence to: Ariel A. Williamson, PhD, Roberts Center for Pediatric Research, Room 8202, 2716 South Street, Children's Hospital of Philadelphia, Philadelphia, PA 19146; Tel: (267) 425-1301; Email: williamsoa@chop.edu

DISCLOSURE STATEMENT

Dr. Williamson was supported by the Sleep Research Society Foundation and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (K23HD094905). Dr. Fiks is the co-inventor of decision support software known as the Care Assistant; he has earned no income and does not hold a patent from this invention. In the past, Dr. Fiks received an independent research grant from Pfizer that supported his research team but did not support his salary. Dr. Beidas receives royalties from Oxford University Press, has served as a consultant to the Camden Coalition of Healthcare Providers, currently serves as a consultant to United Behavioral Health, and serves on the Clinical and Scientific Advisory Committee for Optum Behavioral Health. The remaining authors report no conflicts of interest.