

A sleep hygiene and yoga intervention conducted in affordable housing communities: Pilot study results and lessons for a future trial

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ABSTRACT

Background: and purpose: Inadequate sleep is highly prevalent among socioeconomically disadvantaged and racial/ethnic minority communities and is often related to maladaptive sleep behaviors and stress. There is scant research investigating the delivery of these interventions in underserved communities. The purpose of this study was to develop and test the feasibility and acceptability of a sleep education and yoga intervention for socioeconomically disadvantaged and racial/ethnic diverse adults.

Materials and methods: We present quantitative and qualitative data from a single-arm sleep education and yoga pilot study (n = 17) conducted in two affordable housing communities, and the multi-modal process we employed to refine the intervention for a future trial.

Results: Participants were age 43.6 years on average (± 19.3 years) and 88.2% were female. Nearly 56% identified as non-Hispanic Black and 19% as Hispanic/Latino. Results showed significant pre/post-intervention improvements in sleep duration (5.4 ± 1.2 h/night vs 6.9 ± 1.7 h/night; $p < 0.01$), sleep-related impairment (-8.15 ; $p < 0.01$), sleep disturbance (-5.95 ; $p < 0.01$), and sleep hygiene behaviors (-5.50 ; $p < 0.01$).

Conclusion: This study indicates intervention acceptability and improvements in sleep and sleep hygiene. Future randomized controlled trials are needed to assess efficacy.

1. Introduction

Short sleep duration and poor sleep quality (termed “inadequate sleep”) are associated with many adverse health conditions including impaired mental health and cognitive functioning, cardiovascular disease, diabetes, and cancer [1–3]. Modifiable sleep-related behaviors (often called “sleep hygiene”) and stress impact sleep duration and quality. As such, interventions that not only educate participants on appropriate sleep health behaviors, but also incorporate stress-reduction techniques, such as yoga, may be especially helpful in improving sleep outcomes [4–6] among adults who report inadequate sleep and who may face high levels of stress.

Individuals of low socioeconomic position and racial/ethnic minority communities (herein referred to as marginalized populations) are

more likely to experience inadequate sleep as well as health disparities compared to non-Hispanic whites and individuals of higher socioeconomic position [7,8]. Because sleep can play an important role in overall health and well-being, sleep interventions targeted towards marginalized populations are of particular salience [9,10]. However, to the best of our knowledge, there are sparse accounts of: (1) behavioral sleep interventions targeting marginalized populations, and (2) behavioral sleep interventions that quantitatively and qualitatively investigate acceptability among marginalized populations.

As part of an NIH funded study (R34 mechanism) to develop an integrated sleep hygiene and yoga intervention, we conducted a pilot study of a sleep hygiene and yoga intervention tailored for racially/ethnically diverse adults residing in affordable housing communities. The goals of the pilot study were to: (1) estimate the impact and (2)

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acceptability of the intervention, as well as (3) obtain quantitative and qualitative data to inform intervention refinement for a future randomized controlled trial (RCT). The intervention goals were to improve participants' sleep-related behaviors and help participants to reduce stress through regular yoga practice, which may then result in improved sleep. Here, we report on the initial impact and acceptability of our pilot study, as well as describe how we subsequently used these data as part of a theory-informed, multi-modal process to systematically refine the intervention. Specifically, we describe our process of incorporating mixed method pilot study data, input from community partners, investigator observations, and an empirically supported behavior change theoretical model (Behavior Change Wheel, described later in this paper) to further improve our intervention.

2. Materials and methods

2.1. Design

We conducted a single-arm study (pre-post intervention) in two different affordable housing communities in Boston, MA. The Partners HealthCare Committee on Human Subject Research approved the study. All participants provided written informed consent.

2.2. Participants

Participants were recruited from affordable housing communities through convenience sampling methods, which included an opt-out letter and phone call from study staff or through direct contact by our community partners with the aid of informational recruitment flyers and letters. Participants were recruited purposively for diversity. Eligibility criteria included English speaking adults aged 18–70 years with self-reported short sleep duration (<6 h/night). Exclusion criteria included known pregnancy and/or major physical limitations that would prevent yoga participation (e.g., limited mobility). The intervention took place in the community spaces at the respective housing facilities.

2.3. Procedures

All participants were preliminarily screened for eligibility by phone with a structured interview. Eligible participants were invited to attend a baseline visit to provide written informed consent and complete baseline assessments.

2.4. Intervention

The six-week intervention consisted sequentially of: one group-based sleep hygiene education session (1-h), one individual telephone coaching session (15-min), and four weekly 1-h beginner level group yoga classes (Table 1). The intervention was conceptually grounded in the Social Contextual Model of Health Behavior change, which examines multi-level factors that can influence health behaviors, in order to optimize intervention accessibility and adherence [11]. To inform the content and delivery of the intervention and promote intervention acceptability, our team also conducted qualitative formative research to investigate perceptions surrounding sleep hygiene and yoga, as well as barriers and facilitators to participating in a sleep hygiene and yoga intervention among our target population [12,13].

2.4.1. Sleep hygiene education

Content for the sleep hygiene education was determined by consensus after reviewing and discussing the extant literature [14,15], input from experts in behavioral sleep medicine (including co-authors SB, SR, and EZ), and the results of formative qualitative interviews with racially/ethnically diverse adults residing in affordable housing communities [12,13]. The hour-long group sleep hygiene education session was conducted in a community room and led by a behavioral

Table 1
Sleep hygiene (SH) intervention session structure.

Session	Content
Week 1. SH group session 1-h	<p>Didactic Component:</p> <ul style="list-style-type: none"> • General recommendations for sleep duration • Consequences of poor sleep on physical and mental health • Review of SH principles: consistent wake time, exposure to light in the morning, limiting daytime naps, reducing caffeine, nicotine, and alcohol consumption in the late afternoon or evening, and encouraged a sleep environment conducive to good sleep (i.e., a dark, and quiet bedroom). <p>Interactive component:</p> <ul style="list-style-type: none"> • Participants identify individual barriers to implementing SH behaviors • Participants set a SH goal for the next week • Participants are given a daily SH diary to complete <p>Motivational Component:</p> <ul style="list-style-type: none"> • Outcomes of improving sleep are connected to social identity • Committing to a small SH goal is framed as a behavioral experiment • Small, achievable goals are emphasized • The group setting fosters social modeling and support • The SH diary promotes accountability and self-monitoring <p>One week between sessions 1 & 2</p>
Week 2. SH check in phone call 15-min	<p>Interventionist offers one-on-one positive reinforcement, troubleshooting, and future planning as needed for implementing sleep hygiene goals.</p> <p>One week between sessions 2 & 3</p>
Weeks 3–6. Yoga 1-h	<p>Yoga class (weekly)</p> <ul style="list-style-type: none"> • Beginner-level yoga asana (poses) and breathing techniques are taught to focus and relax the mind and body to reduce stress/hypervigilance <p>Home practice</p> <ul style="list-style-type: none"> • Participants are encouraged to practice a ~20-min subset of yoga poses and breathing techniques nightly to promote relaxation before sleep. <p>One week each between sessions 3-6</p>

psychologist with expertise in behavioral sleep medicine (EZ). The didactic lecture lasted approximately 45-min and was followed by 15-min of question and answer, and discussion of individual sleep hygiene goals. The overarching goals of the presentation were to communicate information on the importance of sleep for health and well-being and review sleep hygiene behaviors (e.g., maintaining a consistent sleep schedule, avoiding alcohol, caffeine, and nicotine consumption in the late afternoon/evening) [16]. Table 1 details the specific intervention components. Participants were educated on the use of a daily sleep diary to promote self-monitoring and accountability, adapted from the Consensus Sleep Diary [17], and provided a sleep hygiene infographic (Fig. 1), which visually summarized the sleep hygiene recommendations to promote recall.

One week after the group sleep hygiene session, participants received a sleep check-in phone call from the research team (approximately 15-min). The goals of the phone calls were to offer positive reinforcement, troubleshoot barriers to achieving sleep hygiene goals, and to promote accountability and self-efficacy (Table 1).

2.4.2. Yoga intervention

The yoga intervention consisted of four weekly 60-min classes delivered in a community room of the housing community. Participants were also encouraged to practice a 20-min nightly yoga routine at home to reduce stress prior to bedtime. We provided all the necessary supplies to practice yoga in group classes and at home (i.e., mat, strap, blankets, and a written/pictorial yoga home practice manual).

A highly experienced Iyengar yoga instructor (JC) taught all the classes at the beginner-level to ensure safety and accessibility for individuals with varying physical abilities. Sequences of yoga asanas and breathing techniques reflected the Iyengar Yoga theory [18] that active poses can help to self-regulate somatic and mental hyper-arousal, and

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CALYPSO Study

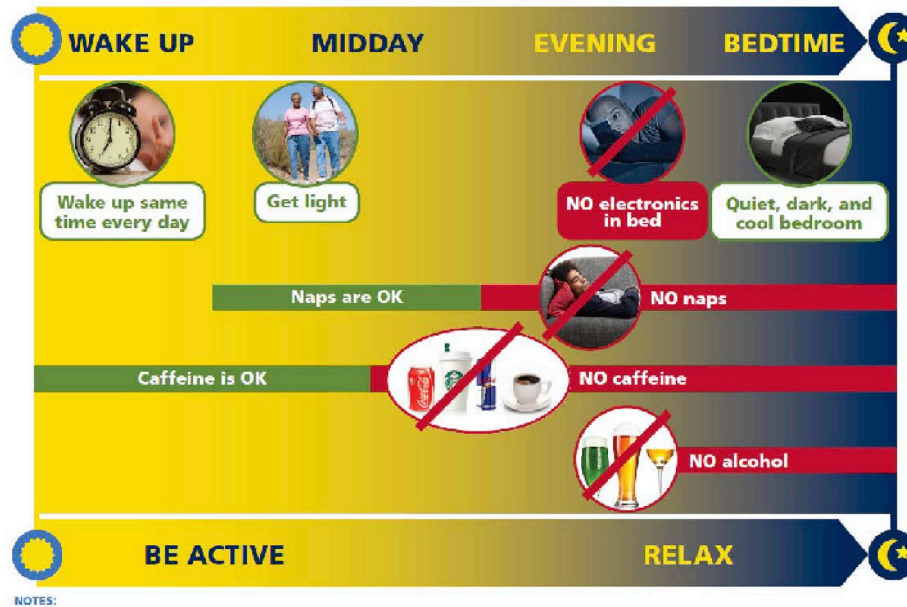


Fig. 1. Sleep health infographic.

then one can successfully transition to restful, calming poses and achieve deeper relaxation. At the beginning of each class, the instructor would check-in with participants and inquire about barriers and facilitators to home practice and implementation of sleep hygiene goals. This was followed by 15-min of active yoga poses, 15-min of resting poses, and concluded with deep breathing and savasana (relaxation pose; see Table 2). We describe the yoga protocol further in the appendix, utilizing the elements described in the “Essential Properties of Yoga Questionnaire.” [19] A high prevalence of trauma was assumed among our target population; therefore, the yoga classes were designed to be trauma-informed, (e.g., minimal physical assists, emphasis on choice, employing a warm and welcoming yoga instructor) [33].

The yoga protocol was initially adapted from a standardized clinical trial protocol examining yoga for back pain among low-income, racial/ethnic minority adults [20]; then further refined based on qualitative formative research [13] and expert input (JC and SBK). The protocol was refined to incorporate Iyengar yoga principles relevant for reducing hyperarousal and enhancing sleep.

2.5. Measures

All assessments were paper-based and completed by participants, in-person, at baseline and post-intervention (six weeks). Research staff were available for assistance as needed by the participants.

2.5.1. Sleep and sleep behavior characteristics

Sleep disturbance and sleep-related impairment were assessed using the NIH Patient Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance (PROM-SDA) and the PROMIS Sleep-Related Impairment (PROM-SRI) scales [21,22]. Raw scores were standardized to T-scores for the PROMIS scales and range from 28.9 to 76.5 (sleep disturbance) and from 30.0 to 80.0 (sleep-related impairment). Higher scores indicate a higher level of sleep disturbance or sleep-related impairment [22]. Sleep duration was calculated as the average of self-reported sleep duration on weekdays and weekends, assessed using the questions assessed at baseline with a single item query: “How many hours of sleep do you usually get per night on weekdays or workdays?” and “How many hours of sleep do you usually get per night on weekends or days off?” Post-intervention sleep duration

Table 2
Example of yoga protocol (Week 3).

Yoga posture- Sanskrit name	Sequence Element	Basic description	Suggested home practice
1) Swastikasana and Introduction	Introduction	Sitting in a comfortable position (on blankets or a chair);	
2) Supta akunchanasana	Introduction	Supine with one knee bent in the chest	X
3) Supta padangusthasana	Introduction	Supine with one leg straight at 90°	X
4) Tadasana	Active	Standing (a.k.a. mountain pose)	X
5) Urdhva hastasana	Active	Raising the arms above the head	X
6) Urdhva baddhanguliyasana	Active	Raising the arms above the head with interwoven fingers	X
7) Utkatasana	Active	Standing with bent knees and hips, chest lifted (a.k.a. chair pose)	X
8) Utthita hasta padasana	Active	Standing with legs wide apart	
9) Virabhadrasana II	Active	Legs wide with one knee bent 90° (a.k.a. Warrior II)	X
10) Bharadvajasana	Transition to relaxation	Seated twist (on blankets or a chair)	
11) Setu bandha sarvangasana	Transition to relaxation	Supine with chest and hip supported, legs bent or straight (a.k.a. support bridge pose)	
12) Viparita karani	Transition to relaxation	Supine with legs up the wall	
13) Viloma II	Deep relaxation (Pranayama)	Supine with blanket supporting upper body, practicing breath control (two-part inhale, full exhale)	X
14) Savasana	Deep relaxation	Supine in a relaxed position (a.k.a. corpse pose)	X

was calculated by taking the average of the duration from bedtime to wake-up time over the last seven days of sleep diary. The Sleep Hygiene Index, a 13-item self-report questionnaire, was used to assess sleep hygiene behaviors (e.g., “I use alcohol, tobacco, or caffeine within 4 h of going to bed or after going to bed”) [35]. Total scores range from 0 to 52, with a higher score representing poorer sleep hygiene.

2.5.2. Psychosocial characteristics

The Perceived Stress Scale (PSS-10) was used to measure perceived stress over the past month [23]. The PSS scale has good reliability and validity and has been used in many settings [24,25]. Depression was assessed using the Patient Health Questionnaire (PHQ-8), an 8-item depression diagnostic and severity measure that has demonstrated validity in clinical and general populations [26].

2.5.3. Acceptability of CALYPSO intervention

To assist the research team with future intervention refinement, participants were administered a post-intervention questionnaire to assess the utility of specific components of the interventions on a five-point scale (strongly disagree – strongly agree, including neutral/no opinion). To obtain more granular feedback and assess acceptability of the intervention (i.e., utility of the sleep hygiene education and yoga components of the intervention, recruitment and retention, and assessment comprehension), we conducted three focus groups post-intervention. Focus groups were moderated by an experienced qualitative researcher (CS), who utilized a semi-structured interview guide. Participants were asked to describe their thoughts about the overall intervention, their thoughts about specific intervention components, what they liked, and what could be improved. Focus groups were audio-recorded and transcribed verbatim.

2.6. Analysis

Quantitative data were analyzed using Stata version 14 [27]. We used descriptive statistics to summarize demographic information and quantitative intervention feedback. We performed paired t-tests to compare sleep and psychosocial measures between baseline and post-intervention. Qualitative data were analyzed using a qualitative content analysis approach that facilitates contextual meaning of the text through categorization of participant responses and extraction of significant statements to develop emerging themes [28].

3. Results

3.1. Participants

Table 3 lists the sample characteristics. Participants were predominantly female (88.2%) with an average age of 43.6 years (SD = 19.3). The sample was racially/ethnically diverse with 56.3% African-American, 18.8% Hispanic/Latino and 6.3% non-Hispanic white. Half of the sample attended some college and 25% had a four-year college degree. Average self-reported sleep duration at baseline was 5.3 h/night and self-reported sleep onset latency was 65.9 min.

Fig. 2 depicts attendance and retention data. We consented 23 eligible participants. All participants completed the sleep hygiene group session and almost 70% took part in the sleep hygiene coaching phone call. Over half attended at least two of the four scheduled yoga classes. The average reported home yoga practice was three times/week. Seventeen participants completed both pre- and post-intervention assessments, which comprises our analytic sample. Fourteen participated in post-intervention focus groups. Reasons for loss to follow-up included competing demands, primarily family obligations and illness (Tables 5 & 6).

Table 3
Participant demographics (n = 17).

	Completed follow up visit	Did not complete follow up visit N = 6	Did not participate in ≥ 2 yoga classes N = 2
Female, N (%)	15 (88.2%)	5 (83.3%)	1 (50.0%)
Age, mean \pm SD	43.6 \pm 19.3	36.0 \pm 9.8	Values: 18.0, 48.0
Race/Ethnicity (n = 16)			
African-American	9 (56.3%)	5 (83.3%)	1 (50.0%)
White	1 (6.3%)	0 (0.0%)	0 (0.0%)
Hispanic/Latino	3 (18.98%)	0 (0.0%)	0 (0.0%)
Other	3 (18.8%)	1 (16.7%)	1 (50.0%)
Education, N (%) (n = 16)			
Some high school, but did not graduate	1 (6.3%)	1 (16.7%)	1 (50.0%)
High school or GED	3 (18.8%)	3 (50.0%)	1 (50.0%)
Some college or 2 year degree	8 (50.0%)	2 (33.3%)	0 (0.0%)
4-year college graduate or more	4 (25.0%)	0 (0.0%)	0 (0.0%)
Hours of sleep per night, workdays mean \pm SD	5.3 \pm 0.9	4.8 \pm 0.9	Values: 4.0, 6.0
Minutes to fall asleep, typical night's sleep	65.9 \pm 58.7	35.9 \pm 50.3	Values: 4.5, 120.0

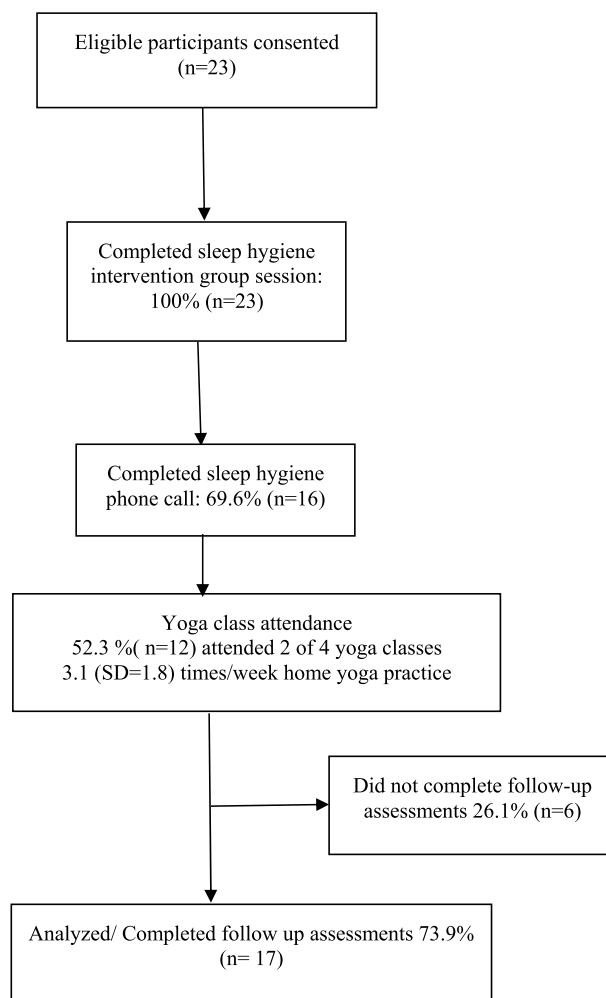


Fig. 2. Attendance & retention.

3.2. Primary outcomes

Pre- and post-intervention assessments (Table 4) revealed significant improvements in self-reported sleep duration, from 5.4 h ± 1.2 h/night at baseline compared to 6.9 ± 1.7 h/night post-intervention (p = 0.001). Sleep-related impairment scores (56.6 ± 11.3 to 48.5 ± 11.1), sleep disturbance scores (58.2 ± 7.0 to 52.3 ± 7.7), and sleep hygiene behaviors (SHI: 34.0 ± 8.0 to 28.5 ± 6.0) significantly improved from baseline to post intervention (p < 0.01). There were no significant changes in perceived stress or depressive symptoms.

3.3. Intervention acceptability

3.3.1. Sleep hygiene intervention

The majority of participants (73.7%) rated the in-person sleep education session as helpful or very helpful. Focus group data corroborated the utility of the sleep hygiene group session: “We live, we don’t think, we don’t reflect on us ... And he gives us this ... lecture and we start to see what we do wrong ... And now, when I go to sleep, maybe it’s wrong, maybe I should not do like this.” Another participant stated: “We always need that extra input from someone that actually knows and says, ‘what are we doing.’” Another participant described how she eliminated evening use of caffeine: “And it’s been almost three weeks and I feel like my sleep has improved; my energy levels are up.” Overall, focus group participants indicated they enjoyed the socialization aspects that were inherent in the group sessions, including hearing about fellow participants’ sleep challenges and solutions.

Sixty-four percent of participants rated the sleep diary as helpful/very helpful. Focus group data further elucidated that the sleep diary was beneficial in bringing awareness to sleep habits: “How can we identify [how to sleep better] without seeing what we need to work on?” Another participant commented on the usefulness of documenting your sleep: “I liked the most where it made you pay attention to your sleep ... it’s a constant reminder.” A participant summarized: “... documenting kinda helped you be more consistent in a sense.” However, some participants reported that the sleep diary was “a pain” to complete and that it had “a lot of questions.”

Table 4
Primary Outcomes - Pre and Post intervention^a.

Assessment	Baseline score	Post-Intervention Score	Change	n	p-value
	Mean (SD)	Mean (SD)	Mean (95% CI)		
Sleep duration ^b	5.44 (1.19)	6.85 (1.70)	1.41 (0.68–2.13)	15	p = 0.001 ^a
PROMIS Sleep-Related Impairment instrument (t-score) (range 30.0–80.0)	56.61 (11.25)	48.46 (11.06)	-8.15 (-13.97 to -2.32)	17	p = 0.009 ^a
PROMIS Sleep Disturbance instrument (t-score)(range 28.9–76.5)	58.24 (7.01)	52.29 (7.70)	-5.95 (-10.37 to -1.52)	17	p = 0.001 ^a
Sleep hygiene index	34.00 (7.97)	28.5 (6.00)	-5.50 (-9.32 to -1.68)	16	p = 0.008 ^a
Perceived Stress Scale	15.31 (6.09)	17.08 (6.06)	1.77 (4.94 to -1.41)	13	p = 0.249
Physician Health Questionnaire-8	10.00 (4.91)	9.07 (4.58)	-0.93 (-3.44 to 1.59)	14	p = 0.440

^a All participants for whom we have follow up data completed at least 2 yoga classes.

^b Assessed via different methodology at pre-intervention vs. post-intervention.

Sixty percent of participants rated the sleep health infographic (Fig. 1) as helpful/very helpful. Focus group data revealed that one participant stated the infographic was helpful “especially identifying when it is okay and when it’s not okay” (e.g., ingestion of caffeine in the morning, but not in late afternoon/evening). However, several indicated that they never referred to the infographic during the study, mainly because the presentation covered everything: “We went over it in depth. And I think folks understood the pros and the cons.”

3.3.2. Yoga intervention

The yoga component of the intervention was deemed favorable among our participants. Over 80% of participants agreed or strongly agreed that the yoga intervention improved their sleep, and that the in-person yoga classes and nightly home yoga routine left them feeling relaxed and less stressed. The focus group data corroborated the acceptability of the yoga intervention: “What I liked least [about the program was] when the class ended, because it was so good!” Of note, at least two participants recommended the option of adding more advanced, challenging poses.

When specifically probed for critical feedback of the intervention, responses included: “making sure that the ambiance is as relaxing as possible.” Participants suggested “adding music,” and being more cognizant of “temperature of the room, temperature of the floor, and lighting.”

3.3.3. Recruitment and retention

Timing of classes can play an important role in recruitment and retention. When participants were asked about their perceived reasons why yoga classes did not have full attendance on participant responded: “Because it’s dinner time and they have their kids and they gotta cook.” Recommendations to increase retention include “serve food.” Another participant added “that’s why I’m here now.” Of note, focus group participants were provided with dinner as an incentive for focus group participation.

When asked about ways to recruit more men into a sleep and yoga study, some participants stated that there is “no way” the men they know would participate. Some suggested employing male recruiters and ensuring that there were enough men in the yoga classes to promote retention. As a male participant stated: “And I’m thinking to myself, maybe I shouldn’t go. And it’s a feminine thing ... the first week, I didn’t see a dude ... so I feel if you had more male participation [it would help].”

Participants described the grocery store gift card incentives as helpful: “You need some bread and some milk. And you don’t have any cash and you know if you go to this study ... it’s a win-win.” However, one participant added: “I feel like if a person’s really serious about the class too, the incentive is nice, but at the same time, if they are really serious they’ll go.” Classes were conducted in the community room of the housing community and location was also deemed to be an important factor for recruitment and retention: “It’s right across the street. I don’t have to take the bus.”

3.3.4. Questionnaire acceptability

Our data collection team received numerous questions surrounding comprehension of pre- and post-intervention assessments. As such, the focus group facilitator specifically inquired about participants’ experiences completing the assessments. Participants perceived the assessments to be repetitive: “same questions over and over,” which made them feel that “[the assessment was] trying to catch us.” Three participants described how the assessments can be perceived as tricky because “the way it’s worded.” One participant commented: “You kinda just want to skip over the questions.” Another participant commented: “Cuz you aren’t understanding, and you just check off [responses].” When specifically probed, participants stated that it would be useful to have a research staff member administer the assessments.

Table 5
Lessons learned from pilot study data & changes for Randomized Controlled Trial (RCT).

Area of intervention	Information source	Lesson learned	Planned changes for RCT ^a
Recruitment & retention	Community partner input	Community partners suggested holding information sessions about the study. Face to face encounters are more likely to elicit trust and promote recruitment.	Hold recruitment informational sessions in the target community.
	Focus group data	To address the underrepresentation of males in the study sample, focus group participants suggested that recruitment materials should promote the program to men specifically, and males from the program should help with recruitment	The male yoga instructor will attend the recruitment informational sessions when possible. Recruitment flyers will specify that men and women are welcome.
	Investigator observations	Highest attrition occurred among mothers of young children.	Offer babysitting and dinner for children during yoga/sleep hygiene sessions.
	Focus group data & investigator observations	Despite enthusiasm of many participants, attending sessions was difficult for participants facing life challenges (i.e., health, family issues)	To reduce the likelihood of attrition over a 12-week period, we will compensate participants with \$10 gift cards for all the study sessions they attend.
	Focus group data	Participants reportedly liked receiving texts reminding them to attend classes and practice yoga and sleep hygiene at home	Continue.
Sleep hygiene intervention	Focus group data	Social support was important. Participants enjoyed hearing the challenges and solutions of other participants	For feasibility and to increase social interaction, the sleep hygiene session will be changed to two in-person sessions, versus one in-person session and an individual phone call.
	Focus group data	Participants felt that the diary was an important self-monitoring tool, and suggested shortening it	We will ask participants to complete the diary for the entirety of the RCT and will be simplified.
Yoga intervention	Focus group data, investigator observations	Participants respond to a mix of active poses and relaxation poses	Maintain yoga class structure: introduction, active poses, relaxation poses, breathing exercises
	Focus group data	Participants requested more support for home practice (e.g., audio recording)	In addition to the home manual, develop and provide downloadable audio recording and YouTube video to support home practice
Assessments	Investigator observations & focus group data	Many participants appeared to have comprehension difficulties and did not understand certain questions and wording in validated assessments	Investigators will make minor adjustments to simplify wording on questions that many participants struggled to understand. Trained staff will administer all assessments to participants.
	Focus group data & investigator observations	Participants felt that questionnaires were at times too long, repetitive, and burdensome.	Assessments will only occur at baseline and follow-up assessments. Investigators will be judicious about selecting instruments in terms of necessity and brevity.
Community partnership/engagement	Investigator observations	Investigators credited positive and productive community engagement to the following practices: -Conducting face-to-face meetings; -"Asking not telling", asking for input on study design, materials and respecting opinions as experts in their context; -Providing community members with important materials, to enhance sense of control and ownership; -Expressing gratitude throughout the collaboration (thank you cards, etc.); -Offering to share study results in the form of manuscripts or presentations; and -Volunteering for other community activities to show support and good will	Continuation of best practices for community engagement and partnership

^a Randomized controlled trial.

4. Process for intervention refinement

We proceeded to refine our intervention protocol for a future RCT using two concurrent refinement processes: compiling lessons learned and mapping the intervention to the behavioral change wheel theoretical model.

4.1. Compilation of lessons learned

Our first step to refine the intervention for future studies was to compile information or "lessons learned" from our study data (i.e., quantitative assessments and focus groups), community partners, and investigator observations. The investigator team, along with content experts on an advisory panel, reviewed the data and discussed modifications to refine the intervention to improve retention, acceptability, and efficacy for a future trial. Table 5 details the source of information, the lessons learned, and the planned changes for the next iteration of our intervention. Key areas for refinement included improved methods for recruitment and retention (e.g., targeted recruitment practices to recruit more males; offer concurrent babysitting services and meals for participants' children for classes that occur during mealtimes) and acceptability (e.g., include a second group session in lieu of the check-in phone

call). Planned changes are also detailed in Table 5, including research team-administered interviews to improve participant comprehension of the assessments and validity of the results.

4.2. Mapping the intervention to the behavioral change wheel theoretical model

Next, our transdisciplinary team, including experts in sleep medicine, yoga, public health, and social work, systematically mapped the intervention using the Behavioral Change Wheel (BCW) framework. Central to this framework is the "COM-B system" of behavior change that explicitly identifies three essential conditions for behavior change to occur: capability, opportunity, and motivation [29]. Capability, opportunity, and motivation interact to influence behavior change. For example, knowledge of sleep hygiene and yoga (capability) and possession of a yoga mat (opportunity), may increase motivation to perform a yoga bedtime routine. As part of intervention development, targeted behavioral changes can then be mapped to intervention functions (e.g., education, persuasion, enablement, and modeling) that are then linked to appropriate behavior change techniques (BCTs) [30], BCTs are defined as observable, replicable, and irreducible components of an intervention that aim to change behavior [29]. Following

Table 6
Applying intervention to COM-B³ theoretical model.

COM-B ³ Component	BCT ^b	BCT applied to <u>existing</u> intervention	Changes for <u>future</u> intervention
Capability (psychological)	Information about health consequences	Provision of written, verbal, and visual consequences of poor sleep in the sleep hygiene education session and sleep hygiene infographic.	Continue.
	Information about emotional consequences	In sleep hygiene education session, briefly comment how inadequate sleep can be associated with mood disorders, suicide.	Continue.
	Credible source	Information presented by “sleep hygiene expert” and well-trained, certified yoga instructor.	Continue.
	Habit formation	Encouragement of nightly, home-yoga practice to promote nightly relaxation habit and promote healthy sleep	Throughout entire study, ask participants to document if sleep hygiene goals and yoga goals were met via daily sleep diary.
Opportunity (physical)	Prompts/cues	Encouragement of continuous practice of “sleep hygiene” Send text messages (opt in option) about class attendance, home practice, sleep diary completion. Encourage sleep hygiene behavior prompts, as appropriate (e.g., setting a TV off-timer to avoid TV at bedtime). Encourage prompts for regular yoga practice, as appropriate (e.g., leaving yoga mat out)	Continue. Continue. Continue.
	Self-monitoring of behavior	Provide sleep and yoga diary for self-monitoring of sleep hygiene behaviors and yoga home practice (sleep and yoga diary; individual SH call, in-class yoga practice)	To motivate self-monitoring via sleep and yoga diary, simplify the diary and improve aesthetics.
	Self-monitoring of outcome(s) of behavior	Not addressed.	In sleep and yoga diary, ask participants about mood to assist them in self-monitoring of links between sleep, yoga practice, and mood
	Restructure the physical environment	In SH in-person session and phone call, discuss the physical environment and overcoming barriers to implementing sleep health and yoga goals (e.g., ambient light, not enough physical space to practice yoga). Provide participants with yoga props (mat, blankets, video/ audio) for home yoga practice Advise on use of white noise, ear plugs, temperature control of bedroom (if needed, lighting of bedroom). Advise participants as appropriate on individual physical environmental changes (i.e., removing TV from bedroom to avoid watching TV before bedtime and restricting a room to make it conducive to yoga practice).	In sleep hygiene group session, allow opportunities for participants to discuss any barriers present in the physical environment to implementing sleep hygiene and yoga practice goals; group facilitator and fellow participants offer each other ideas for trouble shooting. Continue.
Opportunity (social)	Restructure the social environment	Employ warm, welcoming intervention and research staff and yoga instructor with “desirable” characteristics as documented in qualitative formative research.	.Continue. Continue.
		Serve healthy refreshments post SH/yoga class to promote within group socialization, enhancing group dynamics, identity, and promote positive social influences.	Because of RCT design, this is not possible. However, closed cohort format will allow participants to gain familiarity with each other
		Yoga instructor gives “teaser” yoga practice at SH intervention to reduce anxiety associated with yoga and begins to establish comradery with participants.	Continue.
		Allow for social support by asking participants to share their experiences with sleep and yoga in sleep education sessions and yoga classes.	Replace sleep hygiene check in call with second group session. Second group session is a more open discussion for participants to hear from peers about successes and challenges enacting sleep hygiene goals.
Motivation (reflective)	Verbal persuasion about capability	Provide on-site childcare to alleviate barriers to participation.	
		Provide one on one sleep hygiene check in phone call with participants.	
		Provide continuous positive reinforcement to participants.	Continue.
		Use the second sleep hygiene group discussion session to provide positive reinforcement; even for participants who feel they were not “successful” in meeting their goal, provide positive reinforcement for the successes they did have (no matter how small).	
Motivation (reflective)	Identification of self as role-model	Inform participants that by promoting their own sleep health behaviors, and practicing sleep hygiene, other household members might follow suit (i.e., children).	Specifically highlight that sleeping well can help with mood, and may lead to greater role functioning.
		Discussion about emotional and physical consequences of inadequate sleep	Continue.
		Ask participants to set a sleep hygiene goal(s) at the sleep health education session.	Have participants set new sleep hygiene goals <u>each week</u> , by indicating in sleep and yoga diary.
		Goals are incentivized through imparting knowledge about the benefits of sleep, socialization at sleep hygiene sessions and yoga classes, and earning a gift card for every yoga class attended.	Continue. Attendance to yoga sessions will be incentivized through a “yoga attendance poster.” For each session that participants attend, they mark their attendance with a sticker.
Motivation (reflective)	Information about health consequences	Goals are incentivized through imparting knowledge about the benefits of sleep, socialization at sleep hygiene sessions and yoga classes, and earning a gift card for every yoga class attended.	Sleep hygiene goals will instead be reviewed during second group session, so participants can hear their peers’ goals, challenges, and successes.
		Ask participants to set a sleep hygiene goal(s) at the sleep health education session.	Participants can visually track yoga attendance through “yoga attendance poster” displayed at every yoga class.
		Goals are incentivized through imparting knowledge about the benefits of sleep, socialization at sleep hygiene sessions and yoga classes, and earning a gift card for every yoga class attended.	Continue.
		Provide financial incentives for attendance to sleep hygiene sessions, in-person yoga classes, data capture visits.	
Motivation (reflective)	Goal setting (behavior)	Goals are incentivized through imparting knowledge about the benefits of sleep, socialization at sleep hygiene sessions and yoga classes, and earning a gift card for every yoga class attended.	
		Ask participants to set a sleep hygiene goal(s) at the sleep health education session.	
		Goals are incentivized through imparting knowledge about the benefits of sleep, socialization at sleep hygiene sessions and yoga classes, and earning a gift card for every yoga class attended.	
		Provide financial incentives for attendance to sleep hygiene sessions, in-person yoga classes, data capture visits.	
Motivation (reflective)	Review behavior goal (s)	Sleep hygiene goals are reviewed during individual SH call.	
		Yoga practice goals are reviewed during yoga class “check in.”	
		Provide financial incentives for attendance to sleep hygiene sessions, in-person yoga classes, data capture visits.	
		Provide financial incentives for attendance to sleep hygiene sessions, in-person yoga classes, data capture visits.	

(continued on next page)

Table 6 (continued)

COM-B ^a Component	BCT ^b	BCT applied to <u>existing</u> intervention	Changes for <u>future</u> intervention
	Material incentive (behavior)	Provide positive reinforcement for attendance, trying to implement sleep hygiene goals, trying to implement a home yoga practice, etc.	Continue.
	Social reward	Provide food during/after in-person visits to allow for socialization and to establish camaraderie with fellow participants.	Continue.

^a COM-B theoretical framework: Capability, opportunity, motivation are essential intervention components to influence behavior change.

^b BCT: Behavior change technique.

identification of our key behavior targets, we mapped our intervention functions to appropriate BCTs to direct further refinement of the CALYPSO intervention for our future intervention study.

Table 6 details the mapping of the existing intervention to the BCW, the COM-B model constructs that were addressed by our existing intervention, and planned changes to the intervention. Through this process, we also identified additional key areas for refinement, including supporting habit formation and self-monitoring, and identified additional barriers to physical opportunity, as well as ways to enhance motivation (Table 6). For example, in the future iteration, we will consider the following changes: (1) further explicate how obtaining adequate sleep can improve mood and role functioning (motivation), (2) allow for continuous documentation/self-monitoring of sleep hygiene and yoga goals (capability), and (3) allow for more social opportunities by adding a second group sleep health education session.

5. Discussion

To the best of our knowledge, this represents the first published investigation assessing a sleep hygiene and yoga intervention that directly targets individuals residing in affordable housing communities. This article details our dual process for intervention refinement in which we utilized: (1) feedback from community partners and investigator observations, and (2) a theoretical behavior change model of intervention development. To date, this detailed process of describing intervention refinement and mapping intervention components to behavioral change techniques has been missing from the sleep health literature, with only one known publication [31].

Our pilot data suggest that a sleep health and yoga intervention may extend self-reported sleep duration and improve sleep disturbance, sleep-related impairment, and sleep hygiene behaviors among racially/ethnically diverse adults residing in affordable housing communities. While it is difficult to contextualize our findings within the extant literature due to the uniqueness of our study and our target population, the improvements in sleep disturbance and sleep related impairment are clinically significant. The magnitude of changes we observed in sleep disturbance and sleep-related impairment (assessed using the PROMIS questionnaires) is similar to a study reporting effects of positive airway pressure (PAP) therapy in a cohort of adults with obstructive sleep apnea [32]. Thus, our preliminary findings are promising, especially considering the short length of the intervention and our small sample size.

Our qualitative formative work, which included input from our target population and community stakeholders [12,13], was important in designing this pilot study. While our intervention was deemed to be acceptable among our target population, we encountered obstacles with retention and with recruiting men. However, these barriers have also been reported in other yoga intervention studies [34] and attrition appeared to be the result of competing demands (e.g., caretaking responsibilities), rather than low acceptability. In terms of recruiting men, the housing communities were predominantly female which likely made it even more difficult to recruit male participants.

To date, there are few published accounts of effective ways to deliver a sleep hygiene intervention in community settings. As such, we employed both quantitative and qualitative data collection

methodologies to assess the acceptability of our sleep hygiene intervention approach and to inform future delivery. Quantitative and qualitative data revealed that the in-person sleep education session was the most helpful component of the sleep hygiene intervention, followed by the sleep diary. We were surprised at the popularity of the daily sleep diary; participant feedback obtained via focus groups was integral in informing our decision to employ (simplified) sleep diaries for the entire duration of our future 12-week RCT (Tables 5 & 6).

Focus group data revealed participants' frustrations surrounding data collection. Literacy and cultural appropriateness of data collection instruments are often not adequately addressed in the published literature. This can have far reaching implications (e.g., study participation, engagement, and retention) and studies that target individuals who might have low-literacy levels (often associated with lower-socioeconomic groups), as well as individuals who speak English as a second language (ESL), need to consider comprehension/acceptability challenges. This is a particular challenge in sleep research, as there is a paucity of self-reported sleep assessments that have been validated using lower-literacy populations or ESL individuals. At the very least, it seems until there are validated sleep health assessments for low-literacy and/or ESL populations, assessments should be interviewer administered to further clarify questions and to gauge participant comprehension for validity purposes. Future work is needed to assess the utility of sleep assessments using cognitive interviews with persons of lower health literacy and who speak English as a second language.

Our study had a number of strengths, including the successful delivery of a sleep health and yoga intervention in two affordable housing communities, quantitative and qualitative assessment of intervention acceptability, and our multi-modal process for intervention refinement. Moreover, our main findings are both logical and promising in that we saw improvements in sleep health behaviors (Sleep Hygiene Index) and all aspects of sleep that were measured (duration, disturbance, and sleep-related impairment). However, the results of the study need to be interpreted within the context of study limitations. Specifically, our primary outcomes were assessed via self-report and some participants reported difficulty comprehending the assessments; the research team did their best to assist participants who seemed to be having difficulty with assessment completion. As this was a single-arm pilot study, we were not able to control for several factors, such as attention, time, regression to the mean, and placebo effects.

6. Conclusion

This pilot study suggests that our sleep hygiene and yoga intervention conducted in affordable housing communities holds promise in improving sleep hygiene behaviors, self-reported sleep duration, sleep-related impairment, and sleep disturbance. Assessing intervention acceptability through both quantitative and qualitative data, engaging key stakeholders, and using a behavioral change theoretical model are useful modalities to further refine the intervention to optimize acceptability for a future study. Larger trials that utilize objective assessments of sleep as well as a control group are needed to more definitively assess the impact of a sleep hygiene and yoga intervention.

Declaration of competing interest

None.

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Appendix**Description of Yoga Intervention**

Essential Properties of Yoga Element	Included in protocol
1) Acceptance/compassion	X
2) Breath work	X
3) Physicality	X
4) Active Postures (Asanas)	X
5) Restorative Postures	X
6) Body Locks (Bandhas; engaging muscles at various regions)	
7) Body Awareness	X
8) Mental & Emotional Awareness/Release	X
9) Health Benefits	X
10) Individual Attention	X
11) Social Aspects	X
12) Spirituality	X
13) Meditation & Mindfulness	X
15) Yoga Philosophy	

Conflicts of interest and disclosure of funding

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