Development and Pilot Testing of Sleeping Healthy/Living Healthy, a Comprehensive Sleep Intervention for Adolescents in Urban SBHCs
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1. Study Purpose and Rationale

Study Purpose

We propose to develop a novel intervention that combines sleep hygiene with mind-body integrative health (MBIH) approaches to improve sleep quality among predominantly Black and Hispanic adolescents with poor sleep quality served in urban school-based health centers (SBHCs).

Our team's prior research serves as the key support for the proposed study, including our **preliminary needs assessment studies** with urban, minority adolescents, which documented: (1) improved sleep as a top health goal; (2) significant interest in MBIH services; and (3) compromised sleep quality in urban Hispanic and Black adolescents willing to participate in an intervention to improve their sleep. The intervention format and content will be determined based on our collective clinical experiences, our expertise in developing sleep and other evidence-based health interventions,[1-11] and through an **iterative community-based participatory research approach**[12-15] with adolescents, sleep medicine experts, and SBHC medical and mental health providers, health educators, and staff. Drawing on our prior sleep and MBIH interventions, the *Sleeping Healthy/Living Healthy* intervention will be grounded in social-cognitive theory[16,17] and use motivational interviewing[9,18-21] to support MBIH and sleep hygiene strategies. We anticipate the intervention will consist of two group and two one-on-one sessions held once a once a week. Results will inform a future, large-scale randomized controlled trial (RCT) with sufficient power to test the efficacy of the intervention in urban SBHCs.

Specific Aims:
Aim 1. To develop *Sleeping Healthy/Living Healthy*, a SBHC-based intervention combining MBIH and sleep hygiene strategies to improve sleep quality in urban adolescent patients with poor sleep quality;
Aim 2. To evaluate the feasibility and acceptability of intervention procedures; and
Aim 3. To assess preliminary intervention effects over 2.5 months on sleep quality in urban adolescents.

Hypotheses:
Hyp 1: The intervention will be feasible and acceptable as evidenced by high rates of recruitment, adolescents' high adherence to the treatment protocol, and their high satisfaction ratings of the intervention.
Hyp 2: Over 2.5 months post-treatment, relative to controls, adolescents randomized to our innovative sleep intervention will have improvement on two **primary sleep quality outcomes** – (a) sleep duration and (b) sleep fragmentation (i.e., sleep efficiency and disruptions) – measured objectively (actigraphs) and subjectively (*Core Consensus Sleep Diary* [CSD][22] and the *Pittsburgh Sleep Quality Index* [PSQI] [23,24]).

To accomplish these aims, this study includes two phases.

Phase 1: Development Phase. We will develop the intervention using a participatory design with input from adolescents, sleep experts, and SBHC providers and staff;

Phase 2: Pilot Individually Randomized Group Treatment Trial (IRGT). We will enroll 60 adolescents from two high SBHCs in New York City whose typical sleep duration is below what is recommended for this age group. Adolescents within each SBHC will be randomized to one of two study arms: (1) the *Sleeping Healthy/Living Healthy* intervention or (2) an attention control consisting of health education including sleep hygiene in adolescents. We will follow adolescents for 2.5 months post-intervention.

Background/ Rationale

Poor sleep quality – characterized by insufficient sleep duration, disrupted sleep, and difficulty falling asleep – in urban adolescents is a growing public health concern.[25-31] Sleep is critical for healthy development. While adolescents have a greater need for sleep than pre-pubertal children, poor sleep hygiene, shorter sleep duration, and poor sleep quality, including sleep disruptions, are particularly prevalent among adolescents in general[25-36]– and more specifically urban adolescents.[37-39] Poor sleep is associated with increased risk-taking, poor academic performance, and impaired psychological and physical health.[31,40-57]

Racial and ethnic disparities in sleep quality are prevalent in adolescents. White youth have better sleep hygiene, longer sleep duration (average 20 minutes more per night),[58,59] and better sleep quality than minority youth.[35,39,60] Observed disparities in sleep reflect urban contextual factors and stressors,[30,36,39,61-65] which include noise, shared sleep space, safety, household crowding, neighborhood stress, housing, and parental variable work schedules.[66-74] This highlights the need for culturally tailored interventions.

Adolescent sleep hygiene interventions are lacking. Sleep hygiene interventions have been shown to improve sleep behaviors and quality in younger children and college students.[11,75-77] However, none focus on high school students, a group with unique developmental needs,[78] including biological (pubertal) and social changes associated with reduced sleep duration and irregular sleep timing,[79] that present both challenges and opportunities for self-care.[65]

Mind-body integrative health (MBIH) approaches improve sleep quality and duration in adults.[80-88] Such approaches, which include meditation, mindfulness, self-hypnosis, Emotional Freedom Technique (EFT) tapping, acupressure, and aromatherapy, have rarely been applied to adolescent sleep, and when they do, Blacks, Hispanics, or males are not included.[89-92] MBIH improves sleep in adults, in part by reducing stress.[89,93-95] This is important for an adolescent sleep intervention because school-based MBIH interventions targeting adolescents have been shown to reduce stress.[90,96-98] This highlights the capacity of MBIH to improve sleep in adolescents.

Interventions to promote sleep quality by combining *both* sleep hygiene and MBIH approaches in this vulnerable population are needed. Integrating MBIH with sleep hygiene strategies has the potential for a synergistic effect on improving sleep quality. MBIH and sleep hygiene each have the potential to independently improve sleep quality, and MBIH may improve the effectiveness of sleep hygiene behaviors by reducing stress. To date, no interventions simultaneously utilize MBIH and sleep hygiene strategies to improve sleep disparities in urban adolescents, representing a major gap in intervention research.

SBHCs are an effective, but overlooked, intervention setting to improve adolescents' well-being. SBHC access is associated with adolescents engaging in greater number of health-promoting behaviors and positive health outcomes,[99-102] and with a reduction in health disparities.[99-103] There were 2,584 SBHCs serving 6.3

million children and adolescents in the US in 2016–2017, a number that has doubled in the last two decades.[104] A third of the SBHCs are located in high schools.[105] Additionally, SBHCs often have multi-disciplinary teams of medical, mental health, and health education trained providers.[103,104] Therefore, SBHCs offer an opportunity to reach underserved youth and are an ideal setting to deliver a multi-disciplinary integrated sleep intervention like the one we are proposing.

Sleep intervention research can be improved. Use of rigorous measurement of sleep quality outcomes is needed.[57,82] Also, evidence-based interventions may be difficult to sustain,[106-108] in part because factors associated with implementation are overlooked.[108,109] To close this gap between research and practice, formative assessments with the target audience and program providers should be conducted prior to full-scale testing of interventions and the features to enhance a program's reach should be evaluated.[109-111] Yet, formative process evaluations are often lacking in health intervention studies, including those for urban youth.

Impact. This study will increase potential access to a sleep intervention for racial/ethnic minority adolescents, an especially vulnerable group for poor sleep. The impact of utilizing traditional sleep hygiene and MBIH modalities simultaneously could be dramatic, particularly for a high-risk group that may be over-burdened with multiple stressors.

Strengths and Weaknesses in the Rigor of Prior Research. Although prior intervention studies have addressed sleep hygiene in children and college students and have used MBIH approaches in adults, these successes have not been transferred to adolescents, and none are culturally tailored for racial/ethnic minority adolescents. No intervention has integrated sleep hygiene and MBIH approaches. Prior research has also failed to utilize formative process evaluations during the development of health interventions with urban youth.

In sum, the proposed study has high significance because it builds on the strengths of prior research while addressing weaknesses by: (1) targeting a highly vulnerable population which is greatly impacted by poor sleep quality – racial/ethnic minority urban adolescents – and has been largely ignored in the intervention literature to date; (2) serving as the first intervention to simultaneously leverage MBIH and sleep hygiene, which has the potential to amplify intervention effects; (3) utilizing existing effective resources within SBHCs which allows for an expanded reach and scalability given the breadth of their coverage; and (4) utilizing rigorous sleep quality measures and including a formative process evaluation to provide essential information regarding the implementation of our intervention, bridging the gap between research and practice, and aiding in the design of a successful full-scale individually randomized group treatment trial (IRGT).[112]

2. Study Design and Statistical Procedures

PHASE 1 – Development Phase

Phase 1 of this study is a participatory design development phase, which will include 4 steps, outlined below. Participatory design considers adolescents to be the experts in terms of what an effective and relevant intervention would include. The majority of the information collected from the participants in Phase 1 will be qualitative information on potentially effective messages and activities. Adolescents will participate in the focus group sessions led by Drs. Garbers and Bruzzese, with support from the study staff. Trained study staff, under supervision of the Principal Investigators (PIs) and Dr. Gold, the SBHC Medical Director and study Co-Investigator, will collect qualitative data using semi-structured interviews with SBHC providers, health educators, and staff about the feasibility and acceptability of intervention elements.

The SBHCs will be conducting most care, during this academic year, using telehealth. Therefore, Phase 1 activities will be conducted remotely. If restrictions are lifted, and the SBHC (and CUIMC) move to an all in-person model, we will modify data collection procedures to add in-person procedures. Phase 1 interviews and focus groups will be conducted using the CUIMC Zoom platform, which is HIPAA compliant. Per the Zoom website (https://zoom.us/docs/doc/Zoom-hipaa.pdf), Zoom "do[es] not have access to identifiable PHI and [protects] and encrypt all audio, video, and screen sharing data."

Statistical Procedures. We will content-code the focus groups and interviews with the adolescents and SBHC providers, health educators, and staff. Working from recordings of the focus groups and interviews, we will transcribe the qualitative data and enter it into *nVivo*, a qualitative software program that meets CUIMC guidelines for data safety. Qualitative data analysis will focus on goals for intervention development. Comments will be tabulated and coded for response patterns to prioritize recommendations for improving *Sleeping Healthy/Living Healthy*. Dr. Garbers will work with the trained study staff to code the qualitative data from these sessions, using thematic analysis.

PHASE 2 – Pilot Individually Randomized Group Treatment Trial (IRGT) Phase

Phase 2 of this study is the individually randomized group treatment trial phase that will allow estimation of parameters crucial for a larger randomized controlled trial including final content specification, participant recruitment rates, and potential intervention effect sizes. Adolescents from two SBHCs in NYC will be individually randomized to the treatment (*Sleeping Healthy/Living Healthy*) or control (*Sleep for Teens*) group. The treatment intervention will consist of five group and two individual sessions, delivered over the course of seven weeks. Sessions will be led by SBHC staff and will cover MBIH and sleep hygiene practices. Adolescent participants in both the treatment and control arms will be asked to wear actigraph watches (see attached "Actigraph Watch Manual") and complete daily sleep diaries.

The control intervention, *Sleep for Teens*, will meet the requirements for a comparison treatment for testing behavioral interventions[130] – equivalent in contact time, credible and interesting, and exert limited treatment effects. In the same number and type of sessions as our integrated MBIH–sleep hygiene intervention, adolescents will receive information about sleep hygiene, as well as other health topics relevant to adolescents (e.g., nutrition, stress, time managements). Similar to the daily sleep diaries used as an intervention tool, control participants will also learn to monitor their health by using diaries to record behaviors, such as what they eat, and/or exercise activities (see attached "Sleep for Teens Daily Checklist").

Measures. As detailed in Table 1 on the next page (and in "Inventory of Assessments" document attached), sleep quality indicators are primary outcomes; we will examine treatment mediators on outcomes. All outcomes are assessed at each time point. We will utilize objective and subjective measures because the latter capture aspects of sleep more salient to patients.[131,132]
(1) Wrist actigraphy, a valid, objective method of estimating sleep-wake parameters.[133,134] [will be assessed for two weeks at each time point. Actigraph data will be used to assess total sleep time and fragmentations.]
(2) The Consensus Sleep Diary (CSD)[22] is a 9-item diary developed through expert and patient collaboration. Diaries, reliable ways to assess sleep,[22,135,136] will be electronically accessed using any electronic device via Qualtrics, a secure online research data collection platform; to increase adherence, participants will receive daily text reminders with the link to the diary via REDCap.
(3) Additional validated measures are as detailed in Table 1 (and in attached "Inventory of Assessments" document). We will also collect process evaluation data (see attached "Group Implementation Checklist" and "Individual Implementation Checklist").

Statistical Analysis. Statistical analysis in the context of an R21 must balance two primary agendas: (1)

effect size estimation and (2) tests of statistical significance. Our primary goal is to examine design feasibility, which will allow us to be poised for a subsequent full-scale IRGT. We plan to use information about potential design problems to guide modifications of design elements for a larger scale follow-up study, if warranted. Descriptive data analysis will proceed with formal hypothesis testing and model building in order to understand the distribution of the data and to check for outliers. We will examine patterns of missing data, paying special attention to the balance of missing data in study arms, and will impute missing data using multiple imputation approach.[137] We will examine univariate and joint distributions of potential confounders outcome variables; discrepancies will be corrected. Psychometric properties of outcome variables will be examined. We will transform continuous outcome variables if needed. Analyses will use the Intent-to-Treat (ITT) principle,[138] which requires subjects' data to be analyzed as randomized.

Table 1. Summary of Measures Assessing Outcomes

Baseline	Sleep actigraphy (2 weeks)	During intervention (7 weeks)	Post-Intervention	Sleep actigraphy (2 weeks)	Follow-Up (2.5 months post intervention)	Sleep actigraphy (2 weeks)	Measure	Construct	# of items	During...	Time duration	Notes
X							*Participant demographics*	Age, gender, grade, school, race, ethnicity	6	N/A	5 mins	
X							*General Sleep Inventory (GSI)*	Sleep location	10	Current	<5min	*In baseline survey*
	X		X		X		*Actigraphy*	Sleep duration, sleep onset latency, sleep efficiency				*Participants wear actigraph for 2 weeks, return actigraph for data download and charging*
	X			X		X	*Core Consensus Sleep Diary (CSD)*	Sleep duration; sleep fragmentation; subjective sleep quality	9	Daily	2-5 mins	
		X					*National Youth Physical Activity Survey (NYPANS)*	Daily physical activity (total Q8; vigorous Q10) in previous day	2	Daily	1 min	*Control group only*
X			X		X		*Pittsburgh Sleep Quality Index (PSQI)*	Sleep duration; sleep fragmentation	18	Last month	~5-15min	*Omitted Q10*
X			X		X		*Adolescent Sleep Hygiene Scale (ASHS)*	Sleep hygiene	33	Last month	~5min	
X			X		X		*Perceived Stress Scale (PSS-14)*	Stress	14	Last month	<5min	
X			X		X		*PROMIS Ped Psychological Stress Experiences 8a*	Stress	8	Last 7 days	<5min	
X			X		X		*PROMIS Ped Anxiety 8a*	Anxiety	8	Last 7 days	<5min	
X			X		X		*PROMIS Ped Sleep 8a*	Sleep-related impairment	8	Last 7 days	<5min	
X			X		X		*MAAS-A*	Mindfulness	14	Last 7 days	<5min	
			X				*Participant Experience Survey – Part 1*	Contamination, satisfaction, self efficacy				
			X		X		*Participant Experience Survey – Part 2*	Use of skills in last week				*Treatment group only*

3. Study Procedures

PHASE 1 – Development Phase

To develop *Sleeping Healthy/Living Healthy*, the PIs will use a 4-step iterative process.

Step 1: Identify Salient Intervention Components. We will initially identify salient intervention components four ways.

(1) The investigative team will update our literature review and review published sleep hygiene interventions to ensure we have the most relevant potential intervention components.

(2) We will review our existing sleep interventions and MBIH interventions. We will then review these findings, together with those from #1, to ascertain based on our collective experiences which components are most relevant for urban racial and ethnic minority adolescents from a developmental and cultural perspective. Expertise among the professionals is represented in: adolescent, behavioral, and sleep medicine; developing and rigorously evaluating behavioral interventions; MBIH modalities; and behavioral sleep assessments. The Teen Advisors contribute an adolescent racial and ethnic minority perspective.

(3) The PIs will conduct **focus groups, with a trained study staff member assisting, with up to 12 adolescents from the SBHCs (up to 6 adolescents/SBHC), to ascertain what they would like to see included in the intervention** (see attached "Step 1 Focus Group Discussion Guide")**;** adolescents will also evaluate the relevance of the intervention components retained from our existing interventions and published interventions. We will use CUIMC-hosted Zoom to conduct and to record the focus groups. Participants will be asked to fill out a brief demographic survey (included in documents) at the beginning of the group. The survey will be deployed through REDCap, which is HIPAA-compliant (https://projectredcap.org/about/faq/). To protect confidentiality, surveys will not include participant names. Rather, a unique but non-identifying study ID will be used.

(4) Study staff will synthesize the findings from these groups, and will then share this information (without any patient identifiers) with the SBHC medical and mental health providers and health educators to learn what is feasible to deliver in a SBHC setting.

Step 2: Write Session Manuals. Drs. Bruzzese and Gold, working closely with the Teen Advisors and with Dr. Bertisch, will write each intervention module. Visualizations (e.g., infographics) are useful for health communication, for engaging patients, and for increasing patient adherence to health instructions,[113,114] especially when used with written or oral instructions,[115,116] and when used with those with low health literacy.[113] Therefore, the team will work closely with Dr. Arcia, an expert in visualization research,[114,117,118] and Mr. Diaz, the graphic artist, to develop visualizations used in the intervention that are culturally relevant for ethnic/racial minority adolescents and that reflect best practices in design.

Step 3: Expert Review – Adolescents. Up to 28 adolescents who meet inclusion/exclusion criteria similar to that used in the Phase 2 pilot trial (individually-randomized group trial, or IRGT) will participate in focus groups where they review the intervention details and materials and provide feedback on its appropriateness and utility (see attached "Step 3 Expert Review Focus Group Discussion Guide"). We will conduct 6 focus groups with 4-5 adolescents per group. Participants will be asked to fill out a brief demographic survey before the group. The survey will be deployed through CUIMC-hosted REDCap, which is HIPAA-compliant. To protect confidentiality,

surveys will not include participant names. Rather, a unique but non-identifying study ID will be used. The PIs will conduct the focus groups collecting quantitative data using brief surveys where the curricula are rated and qualitative data using open-ended questions to obtain feedback regarding the intervention, including the visualizations. Quantitative surveys will be deployed using the polling function in Zoom. Polls will be anonymous and live results will not be shared with participants. In the quantitative surveys, participants will rate curriculum elements, revise and prioritize sleep hygiene behavior messaging, and critique messages using quantitative ratings. The qualitative discussion guide will be drawn from our prior focus group interviews and will emphasize a review of the content, barriers, and facilitators of intervention implementation, as well as suggestions for improvement. Both positive and potentially negative outcomes will be elicited. Utilizing methods used in our prior work,[119-125] focus groups will be audio recorded and transcribed, and a study staff member will take field notes. Qualitative data analysis will focus on goals for intervention development.

Step 4: Expert Review – Professionals. Using a semi-structured interview guide (see attached "Step 4 SBHC Interview Guide"), trained study staff will interview up to 12 SBHC medical and mental health providers, health educators, and staff (4-6 per SBHC), who will review the intervention to ensure the active intervention ingredients are properly operationalized.[126] We will revise the intervention based on obtained feedback in Steps 3 and 4 and continue this process until the experts agree on each module.

PHASE 2 – IRGT Phase

Randomization. We will enroll 60 adolescents from two SBHCs in NYC (n=30 per SBHC). Within each school, we will randomize participants in equal numbers to the treatment (n=30) or control (n=30) group using urn randomization techniques[139-141]. Participants will be randomized within each SBHC (2 arms x 2 SBHCs x 2 cohorts) in equal numbers to receive either the intervention or an attention control condition. Randomization of each participant will occur when the participant completes the baseline assessments. The urn randomization algorithm will be implemented using SAS 9.3 (SAS institute, 2002) by our biostatistician. This procedure conceals allocation to treatment or control from participants and study staff until just before the intervention begins. Sex and sleep duration at baseline will factor into the urn randomization procedure, making it more likely that groups will be balanced on these variables.

We will minimize contamination [using procedures used in our prior trials]: (1) train half the providers in each SBHC to deliver the intervention, allowing control participants to be seen by the other providers; (2) encourage control providers to not address sleep above and beyond what they would normally do when seeing non-intervention patients; [(3) ask treatment providers to not share the intervention content or materials with colleagues]; and (4) emphasize to the adolescents the importance of minimizing discussion of intervention content beyond the intervention setting.

Intervention Training and Fidelity. Providers at each SBHC will deliver the *Sleeping Healthy/Living Healthy* because we are creating a dissemination model leveraging existing resources. Drs. Bruzzese and Gold have each trained providers to deliver interventions.[142-146] To ensure consistency in training across SBHCs, we will use identical training procedures for each SBHC using a structured training curriculum [adapted from our prior research]. We will employ established procedures to minimize interventionist effect. Drs. Bruzzese and Gold will provide training and lead bi-weekly supervision meetings. Group intervention and control sessions will be audio recorded; a trained study staff member will review each tape and complete a Fidelity Checklist based on Borrelli's framework.[126] Because recording the individual sessions has the potential to interfere with provider-participant rapport, to assess fidelity of these sessions, immediately after each individual session, each provider will complete a Fidelity Checklist. For all Fidelity Checklists, a fidelity score is generated by dividing the number of covered elements by the total number of session elements; fidelity scores below 85% will trigger discussion in supervision meetings. [Fidelity Checklists will be examined for contamination, retraining providers as needed.]

Data Collection. Blinded trained study staff will interview adolescents three times: (1) baseline; (2) immediate post-intervention; and (3) 2.5-month follow-up. Interviews will take place at school or via telephone/Zoom during the school day; telephone interviews and/or online surveys will be utilized as needed to capture chronically absent students. Adolescents will wear the actigraphs for two weeks prior to each interview with actigraphy data being downloaded during the interview. The formative process evaluation includes immediate post-intervention interviews with the adolescents and SBHC providers and staff to obtain feedback regarding intervention procedures.

Implementation. *Sleeping Healthy/Living Healthy* (treatment) and *Sleep for Teens* (control) will run concurrently in two waves: one wave during the fall semester and a second wave in the spring semester. Both *Sleeping Healthy/Living Healthy* and *Sleep for Teens* will consist of five group sessions and two individual sessions delivered once a week over the course of seven weeks (see Table 2 below and "Sample Sleeping Healthy/Living Healthy Group Manual" attached). Sessions will be delivered in person at the SBHC or school, or remotely via Zoom. Each group will consist of 7-8 adolescent participants. *Sleeping Healthy/Living Healthy* will be implemented by two SBHC staff per group, with the same staff conducting individual sessions to build facilitator-participant rapport. *Sleep for Teens* will be run by non-SBHC staff. All group and individual sessions will be audio recorded using a secure Zoom account or a password-protected device to monitor fidelity. Recordings will be transmitted to authorized study personnel via encrypted message, and will be destroyed once fidelity checklists are completed.

Table 2. Treatment and Control Pilot Implementation

					FALL		FALL		SPRING		SPRING	
			Wave>		**Wave 1A**		**Wave 1B**		**Wave 2A**		**Wave 2B**	
			School>		GW	GW	IS 52	IS 52	GW	GW	IS 52	IS 52
			Implementer>		SBHC staff	Non-SBHC staff	SBHC staff	Non-SBHC staff	SBHC staff	Non-SBHC staff	TBD	Non-SBHC staff
			Arm>		Treatment	Control	Treatment	Control	Treatment	Control	Treatment	Control
Week		**Duration**	**Intervention Topics**	**Control Topics**								
1	Group 1	40m	Sleep basics, mindful breathing	Importance of sleep for health	1 group	1 group	1 group	1 group	1 group	1 group	1 group	1 group
2	Group 2	40m	Good sleep practices, acupressure	Stress management	1 group	1 group	1 group	1 group	1 group	1 group	1 group	1 group
3	1:1	20m	Review of sleep data & use of techniques, problem solve	Review of stress management techniques	7-8 meetings	7-8 meetings	7-8 meetings	7-8 meetings	7-8 meetings	7-8 meetings	7-8 meetings	7-8 meetings
4	Group 3	40m	Sleep routines, tapping	Nutrition & physical activity	1 group	1 group	1 group	1 group	1 group	1 group	1 group	1 group
5	1:1	20m	Review/problem solve, teach body awareness	Review of nutrition and physical activity	7-8 meetings	7-8 meetings	7-8 meetings	7-8 meetings	7-8 meetings	7-8 meetings	7-8 meetings	7-8 meetings
6	Group 4	40m	Sleep environment & mindful attention	Time management	1 group	1 group	1 group	1 group	1 group	1 group	1 group	1 group
7	Group 5	40m	Wrap up & celebration	Wrap up & celebration	1 group	1 group	1 group	1 group	1 group	1 group	1 group	1 group

Notes: 8 x 7.5 participants = N of 60
Control topics: didactic content on importance of healthy sleep, stress management, nutrition, exercise, time management
Control sessions will be held at SBHC locations but will not be conducted by SBHC staff or providers

Compensation.
All adolescent and adult participants will receive compensation for their time and effort in the form of an Amazon electronic gift card, purchased through the Mailman School of Public Health.

Phase 1 compensation is as follows:

Teen Advisors will receive, as compensation for their time and effort, a total of $250 in incentives over the first year of the project (and $150 in the second year of the project, Phase 2). The payment schedule will be: $100 following the first study team meeting with the Advisors, with $50 at the end of each subsequent quarter in Phase 1. The card will be mailed or emailed to the address provided to the study staff at the time of enrollment.

Identifying Salient Components (Step 1 Focus Group, Adolescent Participants) will receive, as compensation for their time and effort, an Amazon gift card valued at $30. The card will be mailed or emailed to the address provided to the study staff at the time of enrollment.

Expert Review – Adolescents (Step 3 Focus Group Participants) will receive, as compensation for their time and effort, an Amazon gift card valued at $30. The card will be mailed or emailed to the address provided to the study staff at the time of enrollment.

Expert Review - Professionals (Step 4 Interview Participants) will receive, as compensation for their time and effort, an Amazon gift card valued at $30. The card will be mailed or emailed to the address provided to the study staff at the time of enrollment.

Phase 2 compensation is as follows:

Incentive schedules are planned to be meted out across assessment periods, providing incentives for each data submission and distinguishing between survey and actigraphy data submission. To incentivize return of both types of data, all intervention and control participants will receive $25 for submission of actigraphy data and $20 for completion of assessments at three time points (baseline, immediate post-intervention, and follow-up), totaling $135 per participant.

4. Study Subjects

Subject Population Justification:
Children (specifically, adolescents) are the target of our intervention, and the primary study participants. Adults, including SBHC staff and providers, will be enrolled in Phase 1 of the study. There is no maximum age limit for these adults. This study will develop and pilot test an intervention to improve sleep quality in adolescents who are between the ages of 13 and 17.9 years; adolescents will participate in the focus groups conducted in Study Year 1 to inform the development of the intervention and in the randomized pilot study in Year 2. The specific age range of the students was selected because adolescents are a group at especially high risk for poor sleep quality due to poor sleep hygiene. We are limiting our enrollment to high school students because our intervention is designed for this age group and is based in SBHCs. We have used the enrollment and retention strategies proposed in this application in our past research.

PHASE 1 – Development Phase

Adolescent Participants. We will enroll up to 40 adolescents (age 13.0 – 17.9) who are SBHC patients to participate in three different aspects of the study: (1) two adolescents will serve as Teen Advisors working closely with the study team on all aspects of the intervention development; (2) up to 12 adolescents will participate in Step 1 (Identifying Salient Intervention Components) focus groups; and up to 28 adolescents will participate in the Step 3 (Expert Review – Adolescents) focus groups (6 focus groups with 4-5 participants per group).

Based on clinical administrative data from the SBHC sites, we estimate that 50% of eligible adolescents will be female, 68% Hispanic or Latino, 28% African American or Black, 42% White, 20% more than one race, and 10% Asian (race and ethnicity not mutually exclusive).

Any adolescent participant who turns 18 during the course of their active participation in the study will be re-consented using an adult consent form.

Teen Advisors. Two adolescents will serve as Teen Advisors throughout all steps of the study. Inclusion criteria include being between the ages of 13 and 17.9, patients enrolled in one of the SBHCs, and in grades 9 – 12. Here we include 12th graders they may have valuable insight into what would make the intervention relevant and engaging for their younger peers. If an Advisor is in 12th grade in Year 1, they will be replaced by another Advisor in Year 2. Exclusion criteria include report of prior diagnosis of a sleep disorder (e.g., sleep disordered breathing, restless leg syndrome); significant developmental delay and/or severe psychiatric or medical conditions that preclude completion of study procedures or confound analyses; or not being able to communicate in English.

Step 1 (Identifying Salient Intervention Components).

Focus Group Participants. Up to 12 adolescents will participate in focus groups in Step 1. Inclusion criteria include being between the ages of 13 and 17.9, patients enrolled in one of the SBHCs, and in grades 9 – 11. Exclusion criteria include report of prior diagnosis of a sleep disorder (e.g., sleep disordered breathing, restless leg syndrome); significant developmental delay and/or severe psychiatric or medical conditions that preclude completion of study procedures or confound analyses; or not being able to communicate in English.

Step 3 (Expert Review – Adolescents).

Focus Group Participants. Up to 28 adolescents will participate in focus groups in Step 3. Inclusion criteria include being between the ages of 13–17.9, in grades 9–12, and patients enrolled in one of the SBHCs. Exclusion criteria include report of prior diagnosis of a sleep disorder (e.g., sleep disordered breathing, restless leg syndrome); significant developmental delay and/or severe psychiatric or medical conditions that preclude completion of study procedures or confound analyses; or not being able to communicate in English.

Step 4 (Expert Review – Professionals).

Adult Participants (SBHC Providers, Health Educators, and Staff). We will enroll up to 12 SBHC medical or mental health providers, health educators, and staff, ensuring that at least one individual in each job function (medical provider, mental health provider, health educator, staff) is enrolled. The only inclusion requirement is that they are employed at one of the SBHCs with whom we are collaborating; there are no exclusion criteria.

PHASE 2 – IRGT Phase

Adolescent Participants. We will enroll 60 adolescents in grades 9 – 11 with poor sleep from two SBHCs in NYC (n=30 per SBHC). Based on SBHC data [and our prior trials], we anticipate 50% will be female, and 86% will be racial/ethnic minorities (68% Hispanic; 28% Black, not mutually exclusive). Inclusion criteria include being between the ages of 13 and 17.9, patients enrolled in one of the SBHCs, in grades 9 – 11, and reporting sleep duration <8 hours (below the recommended number of hours of sleep for this age group[127, 128]) using the following questions: What time do you: (a) usually fall asleep on weekdays and (b) usually wake up on weekdays? Exclusion criteria: Report of prior diagnosis of a sleep disorder (e.g., sleep disordered breathing, restless leg syndrome); significant developmental delay and/or severe psychiatric or medical conditions that preclude completion of study procedures or confound analyses; or not be able to communicate in English.

5. Recruitment

PHASE 1 – Development Phase

Recruitment of adolescent participants: Teen Advisors (n=2);
Adolescent participants will be recruited through the SBHC communication channels while school is in hybrid/remote format. Flyers will be provided to SBHC providers and staff to share with patients in person, through their telehealth visits with patients, or via secure message sent by the treating physician through EPIC, the SBHCs' electronic health record system. In the secure message, the treating physician will ask the patient for permission to be contacted by the Research Coordinator, and will also provide the Research Coordinator's contact information if the patient wants to learn more about the study, A separate recruitment flyer will be developed for each Phase 1 study component. Flyers will be posted in the SBHCs and throughout the school. All recruitment materials will specify that the study is only open to registered SBHC patients. Adolescents who are interested in participating in serving as an advisor, or as a focus group participant, will be provided with the CUIMC email address and cell phone number for the study staff (Research Coordinator) to learn more about the project, and to conduct initial eligibility screening. We are seeking a waiver of written informed consent for Phase 1 procedures (included in documents), as the participants are not being seen in-person so having to print, sign, and send written consent forms increases the risk of a breach of confidentiality. The study staff will use an Information Sheet script to describe the study components and the features of participation (included in documents) and solicit informed consent, which will be documented by study staff.

> **Eligibility Screening – Teen Advisors.** Trained study staff will initially screen potential Teen Advisors for eligibility by asking 1) if they would like to determine their eligibility to participate in a study; 2) if so, their age; 3) grade; 4) whether they are enrolled in the SBHC. For the Teen Advisor candidates only, the PIs will interview potential Teen Advisor candidates to confirm their interest in, availability, and ability to complete study tasks.

Adolescent Focus Group Participants:
Step 1 Focus Group Participants (n=12) and Step 3 Expert Review Focus Group Participants (n=28)
Participants will be recruited through both virtual, verbal, and posted SBHC communication channels while school is in hybrid/remote format. Flyers will be provided to SBHC providers and staff to share with patients in person, through their telehealth visits with patients, or via secure message sent by the treating physician through EPIC. In the secure message, the treating physician will ask the patient for permission to be contacted by the Research Coordinator, and will also provide the Research Coordinator's contact information if the patient wants to learn more about the study, To reach patients who are in the school in person, flyers will be posted in the SBHCs and throughout the school, specifying studies are open to SBHC patients only.

Participants will also be reached through word-of-mouth recruitment by the Teen Advisors, and through SBHC providers and staff during telehealth visits. These materials will inform potential participants about the purpose of the project, and offer the opportunity to participate in focus group sessions. Interested adolescents can learn more about the study by directly contacting the trained study staff at their CUIMC contact information (email, phone, texting) provided on the recruitment materials. Staff will then screen the adolescents for eligibility.

> **Adolescent Focus Group Eligibility Screening – Step 1 Focus Group Participants and Step 3 Expert Review Focus Group Participants.** Trained study staff will screen adolescents for eligibility for the focus groups detailed above in Section 4 for Step 1 (Identify Salient Components) and Step 3 (Expert Review – Adolescents). To screen participants, trained study staff will ask adolescents: 1) if they would like to determine their eligibility to participate in a study; 2) if so, their age; 3) grade; 4) and whether they are enrolled in the SBHC.

For all eligible adolescent participants, trained staff will orally read through the approved, detailed Study Information sheet (included in documents) which will explicitly convey who is conducting the study, the purpose of the study, the procedures (e.g., time needed for the focus groups or interviews, the number of surveys and assessments and sessions, study risks and benefits, a discussion of compensation, and a statement that participation is voluntary and will not affect their care at the SBHCs. Oral informed consent or assent will be solicited and documented. All informed consent processes for Zoom-based sessions will be conducted privately in a 1:1 Zoom room appointment or telephone consultation prior to the date of the focus group, or in a breakout room with the trained study staff, without recording, before the focus group. Recording will start only after all participants have been consented. Participants will be asked for an email address to send a copy of the Information Sheet.

Adult Participants (SBHC Providers, Health Educators, and Staff - Step 4 Interviews). Potential SBHC providers, health educators, and staff participants will be recruited to participate in the Development Phase in-depth interviews. Dr. Gold, Medical Director of the SBHCs, will inform SBHC providers and staff of the opportunity to participate at staff meeting announcements, at team huddles, and via email, emphasizing the voluntary nature of their participation.

> **Eligibility Screening- SBHC Staff.** As mentioned in Section 4, the only inclusion requirement is that they are employed at one of the SBHCs with whom we are collaborating and there are no exclusion criteria. Eligibility will be confirmed prior to the interview.

PHASE 2 – IRGT Phase

Adolescent Control and Intervention Participants (n=60). As in Phase 1, participants will be recruited through the SBHC communication channels and through the Teen Advisors. Flyers will be provided to SBHC providers and staff to share with patients in person, through their telehealth visits with patients, or via secure message sent by the treating physician through EPIC, the SBHCs' electronic health record system. In the secure message, the treating physician will ask the patient for permission to be contacted by the Research Coordinator, and will also provide the Research Coordinator's contact information if the patient wants to learn more about the study. Study team members will be onsite at the SBHCs to distribute flyers to patients, describe the study, and ask interested patients for their permission to be contacted by the Research Coordinator about the study. Flyers will also be posted in the SBHCs and throughout the school where permitted. All recruitment materials will specify that the study is only open to registered SBHC patients.

Adolescents who are interested in participating in the program will be provided with the CUIMC email address and cell phone number for the study staff (Research Coordinator) to learn more about the project, and to conduct initial eligibility screening. Given the current COVID-19 situation, we are seeking a waiver of written informed consent for Phase 2 procedures as we did in Phase 1 to allow for the possibility that NYC schools move to remote learning. In this case, participants may not be seen in-person so having to print, sign, and send written consent forms increases the risk of a breach of confidentiality. The study staff will use an Information Sheet script to describe the study components and the features of participation (included in documents) and solicit informed consent, which will be documented by study staff.

> **Eligibility Screening - Adolescent Control and Intervention Participants –** Trained study staff will screen adolescents for eligibility for the program detailed above in Section 4. To screen participants, trained study staff will ask adolescents: 1) if they would like to determine their eligibility to participate in a study; 2) if so, their age; 3) grade; 4) whether they are enrolled in the SBHC; and 5) what time they: (a) usually fall asleep on weekdays and (b) usually wake up on weekdays.

6. Informed Consent Process

All Informed Consent procedures will start with a concise presentation, in lay language, of the key information about the research study. Sufficient information about the study purpose, procedures, risks, and benefits will be provided to all potential subjects. All potential subjects will have an opportunity to discuss the information provided.

Adolescent Participants. All adolescent participants are expected to be able to provide assent to participate, as they are currently enrolled students in high school and English speaking. Trained study staff will use structured oral scripts (information sheet) to describe the study to eligible patients, review the elements of informed consent to obtain assent, and describe the process for contacting the parent/guardian for parental consent. The materials will explain that the SBHC is conducting a study to improve adolescents' sleep, and will include contact information for the study team so that parents/guardians will be given the opportunity to call the investigators to have any questions answered or concerns addressed. The informed consent (for adults)/assent (for the SBHC patients age <18) forms provided will explain, in plain language written at no higher than 8th grade reading level, who is conducting the study, the purpose of the study, the procedures (including the length of focus groups and program sessions and the number of assessments and surveys), study risks and benefits, a discussion of compensation, and a statement that participation is voluntary and their participation will not affect their care at the SBHC. Because a written signature would serve as a source of identification that introduces risk, following reading of the informed consent information sheet, the trained study staff will obtain verbal consent from the participant prior to the date of the focus group for Step 1 and Step 3, first meeting for Teen Advisors, and baseline assessment for Phase 2 participants. All oral explanations and verbal consent forms will be IRB and HIPAA compliant. Informed consent forms for the Phase 2 trial will include mention that the study is registered with the ClinicalTrials.gov website.

Adult Participants (SBHC Providers, Health Educators, and Staff). Trained study staff will conduct the informed consent process with adult SBHC providers, health educators, and staff who express interest in participating in the in-depth interviews during the Development Phase. The trained study staff will read the entire informed consent aloud (using an information sheet), and the informed consent will review points that uphold the principles in the Belmont Report: that participation is voluntary, that the participant can choose to not answer any question, and that their choice to participate or not participate in the interview will not affect their employment at the SBHC. Specific steps that will be taken to protect confidentiality will also be reviewed

during this process. All data collection, including the informed consent process, will take place in a private Zoom room. Because a written signature would serve as a source of identification that introduces risk, following reading of the informed consent information sheet, the trained study staff will obtain verbal consent from the participant before conducting the interview. All informed consent materials (information sheets) will be IRB and HIPAA compliant, and will include mention that the study will be registered with the ClinicalTrials.gov website.

7. Study Instruments

PHASE 1 – Development Phase

Step 1 (Identifying Salient Intervention Components) Focus Groups. In our focus groups with up to 12 adolescent SBHC patients, we will ascertain what they would like to see included in the intervention. Please see attached *Step 1 Focus Groups* for an overview of the questions we will ask.

Step 3 (Expert Review Focus Groups – 28 Adolescents). After reviewing the intervention, including its visualizations (e.g., infographics), adolescents will provide quantitative and qualitative feedback on intervention appropriateness, relevance, and utility. We will collect quantitative data using brief surveys and qualitative data using open-ended questions. Please see attached *Step 3 Expert Review Adolescents* for the focus group guide.

Step 4 (Expert Review – 12 SBHC Providers & Staff). Using a semi-structured interview guide, trained study staff will interview SBHC professionals to ensure that intervention components are properly operationalized.[113] Please see attached *Step 4 Expert Review Professionals* for the semi-structured interview guide.

PHASE 2 – IRGT Phase

We will collect objective and subjective data from treatment and control participants at three time points: baseline, immediate post-intervention, and follow-up. Please see attached "Inventory of Assessments" document for a full list of data collection instruments. We will also collect process evaluation data - see attached "Group Implementation Checklist" and "Individual Implementation Checklist."

THE FOLLOWING SECTIONS APPLY TO BOTH PHASE 1 AND PHASE 2 unless otherwise specified

8. Confidentiality of Study Data

Data collection and storage protocols will minimize the use of identifying information. All research participants will be identified on all research forms and logs (other than the study ID linkage forms) by unique but non-identifying codes. Code linkage files relating ID codes to names will be maintained on RedCap, a password-protected site, accessed only by the lead study staff (Garbers, Bruzzese, and Maier). Access to medical records will be limited to recruitment by the treating provider.

Phase 1: Focus groups and interviews will be recorded only using CUIMC-hosted Zoom accounts, with a password required for entry into the room. Recordings of the focus groups will only be recorded onto encrypted, password-protected endpoint computer temporarily. This electronic data will be maintained on the encrypted, password-protected computer files on encrypted devices with limited access to data by staff –

different levels of access will depend on the person's specific level on the staff, and server security safeguards that in the aggregate provide a high degree of protection from unauthorized users. Focus groups and interviews will be transcribed as quickly as possible; once transcribed and checked for accuracy, the recordings will be deleted.

Phase 2: Group and individual sessions will be recorded using secure Zoom accounts or password-protected devices. Recordings of the sessions will only be recorded onto an encrypted, password-protected endpoint computer temporarily. This electronic data will be maintained on the encrypted, password-protected computer files on encrypted devices with limited access to data by staff – different levels of access will depend on the person's specific level on the staff, and server security safeguards that in the aggregate provide a high degree of protection from unauthorized users. Recordings will be destroyed as soon as fidelity checklists are completed.

All qualitative and quantitative information will be coded by identification number, so that no full names or other personally identifying information (PII) are associated with any of the data. Identity of participants – including deductive disclosure -- will not be revealed in the presentation or publication of any results from the project. All personnel working on the project will be regularly trained and re-trained about the importance of strictly respecting participants' rights to confidentiality and specific approaches to ensure such protections. The only data for which PII cannot be inextricably separated from the data is a voice print. Special steps will be taken to protect this data.

Confidentiality and privacy for audio/video recording of human subjects
The project will ensure the following steps are followed, and will include these steps in the consent forms for participants:

PHASE 1 – Development Phase
1. Participants will be informed that the focus groups and interviews will be recorded. Their voices will be recorded, but no other likenesses will be recorded. Names and likenesses (pictures or live video) will not be recorded. The focus group moderator will instruct participants to change their screen name on Zoom and to turn their cameras off.
3. The recording will not start until all participants have turned off their video cameras and changed their screen name to a first name or other name they would like to use.
4. The video recording will be recorded and viewed by only two individuals: the Research Coordinator and one of the Principal Investigators, who will be on the focus group. The recording will be downloaded to extract the transcription of the audio feed. No identifiers will be included in the transcriptions. The Research Coordinator will review the transcript for accuracy, consulting the original audio as needed. As soon as the accuracy of the transcription is confirmed, the recordings will be destroyed from all locations.
5. The video recordings (before destruction) and the transcriptions (without identifiers) will be stored temporarily on an encrypted and password protected computer.
6. There will be no future use of the recordings, once the recordings are transcribed.

PHASE 2 – IRGT Phase
1. Participants will be informed that the group and individual sessions will be audio recorded. For in-person sessions, their voices will be recorded, but no other likenesses will be recorded. Names and likenesses (pictures or live video) will not be recorded. For sessions delivered via Zoom, both audio and video will be

recorded due to Zoom's recording settings. However, the video file will be immediately destroyed, and only the audio file will be used for fidelity monitoring purposes.
2. The audio recordings will be stored temporarily on an encrypted and password protected computer.
3. The audio recordings will be used by only two individuals: the facilitator and a trained study staff member, both of whom will be responsible for completing the fidelity checklists. As soon as the fidelity checklists are completed, the audio recordings will be destroyed.
4. There will be no future use of the recordings once the fidelity checklists are completed.

Participants will be consented individually in a private Zoom appointment or phone call prior to the focus group or program start date, and all of these points will be reviewed.

9. Privacy Protections

We will ensure confidentiality is protected by taking several steps. Per CUIMC Institutional Review Board (IRB) guidelines, all members of the study staff must complete trainings in human subjects protection and HIPAA requirements, as well as ongoing training by the PIs and the Co-Investigators in all aspects of human subjects protection. The platforms we will use for data collection, Zoom and REDCap, will use only the CUIMC-hosted versions, which are HIPAA compliant. For purposes of the research database, each participant will be assigned a unique identifier that bears no systematic relation to the family, or school, or SBHC records. Information to be excluded from the research data base includes names of study participants, addresses, telephone numbers, school, clinician, and other information that has the potential to identify individuals. All outcome data will be de-identified by HIPAA standards using the "safe-harbor" method (i.e., all 18 PII elements will be stripped) prior to being stored on a password-protected, encrypted server.

Explicit instructions at the start of the focus group sessions and group education sessions will remind participants: (1) all participants are to respect each other's right to privacy; (2) to use only first names (or, if desired, pseudonyms) during the session, and (3) to not share the details of the group discussions with others.

10. Potential Risks

Participation in this research involves minimal risk, defined in the Federal guidelines as "the probability and magnitude of harm anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."[129] Insufficient sleep is associated with impaired physical and mental health. Our proposed intervention, however, is educational and behavioral, and does not include any changes in drug therapy by the study staff. Therefore, the study carries little to no risk with the following minor exceptions.

(1) Adolescents and adults who review the curriculum as part of the focus groups, and adolescents participating in Phase 2, learn about signs and ramifications of poor sleep quality, which may cause them to worry about their health.
(2) Because the focus groups and interviews assessing the preliminary efficacy of the intervention and the IRGT assessments utilize self-reported data, loss of confidentiality of study data is a potential risk. While the data obtained from the focus groups are confidential, the focus group interviews by definition are not anonymous. Similarly, nor are the group-based education sessions for the intervention participants, given their group nature. It is impossible for investigators to assure total confidentiality given we cannot monitor disclosure of group participants after the discussions end. Limits to confidentiality will be reviewed during the informed consent process.

(3) It is also possible that the adolescent and/or adult participants will experience some inconvenience, embarrassment, or distress while participating in the focus groups or completing surveys in the randomized pilot.

Adolescent participants reporting distress to the study team will be referred to onsite mental health providers that are always available at the SBHCs. Adolescent participants in both phases have access to primary care through the SBHCs, if parental permission is on file for them to receive primary care. If adolescents present with significant sleep-related risk, they will be referred to the Pediatric Sleep Disorders Center at Columbia University.

Since the risks to individual study participants are minimal, the study appears to be readily justifiable.

11. Data and Safety Monitoring

This is a minimal risk study. The PIs (Garbers and Bruzzese) will be responsible for all data safety and monitoring. They will have responsibility for ensuring that the policies outlined above to minimize risk – including staff training, storing identifiers separately from survey, interview, and focus group data, and storing all data on encrypted, password-protected servers – are followed. The PIs will conduct regular checks of data storage procedures, ensuring, for instance, that: any recordings have been destroyed following transcription; access to electronic data is limited to trained study staff, and the research database does not include any personally identifying information.

In their weekly team meetings, Drs. Garbers and Bruzzese will review with the study staff weekly data reports regarding all study-related activities. This will include the sample size and proportion of approached contacts, eligibility rates (and reasons), consent/refusals, and surveys, focus groups, and interviews completed.

All study personnel will report any study-related adverse events and/or unanticipated problems involving risks to participants to Drs. Garbers, Bruzzese, and Gold. In the case of any adverse event or unanticipated problem, Drs. Garbers and Bruzzese will notify Dr. Gold (given her role as Medical Director of the SBHCs) and the CUIMC IRB. Dr. Garbers will, if appropriate, inform the NIH Project Officer in writing of any actions taken by the IRBs as a result of such adverse events.

12. Potential Benefits

There are few interventions that have been shown to improve sleep quality for urban adolescents, let alone Black and Hispanic urban adolescents. We are developing a novel, tailored intervention specifically for urban youth that integrates traditional sleep hygiene approaches with mind-body integrative approaches. With proper training, such as that proposed in our intervention, sleep hygiene and mind-body integrative approaches can be used by adolescents on their own; if effective, future studies may be replicable to other urban settings. There are more than 2,500 SBHCs in the United States, serving 6.3 million children and adolescents, where a similar intervention could be carried out and tested with a larger patient population.

13. Alternatives

Currently, there are no alternative interventions that focus on improving sleep for Black and Latino urban-dwelling adolescents through MBIH. Participants have the alternative to not participate in this research.

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