Reducing Health Disparities for Black Women in the Treatment of Insomnia

H-37156

ClinicalTrials.gov number: **NCT03613519**

Protocol Version Number: 1.0
Protocol Version Date: November 15, 2019
Funding Mechanism: PCORI AD-2017C1-6314

Principal Investigator: **Lynn Rosenberg, PhD**
Phone: (617) 734-6006
E-mail: lrosenbe@bu.edu

Statistical Analysis Plan- *Section 12, page 13*

CONFIDENTIAL

TABLE OF CONTENTS

1 List of Abbreviations

Abbreviation	Abbreviation definition
BWHS	Black Women's Health Study
GLMM	General Linear Mixed Model
CBT-I	Cognitive-behavioral therapy for insomnia
ISI	Insomnia Severity Index
SOL	Sleep Onset Latency, i.e., time awake before first falling asleep
SHUTi	Sleep Healthy Using the Internet
SHUTi-BW	modified SHUTi six-module program tailored for Black women
WASO	Wake After Sleep Onset, i.e., amount of time awake after first falling asleep

2 Protocol Summary

Title:	Reducing Health Disparities for Black Women in the Treatment of Insomnia
Population:	Participants in the Black Women's Health Study (BWHS) who reported symptoms of insomnia on the 2015 follow-up questionnaire ages 45-85 who have internet access via a computer or laptop and provide informed consent for participation.
Intervention:	For drugs: name, dose, route of administration, regimen; for other interventions: name, method, timing.
Objectives:	The goal of this study is to conduct a comparative effectiveness trial of three internet-based intervention approaches to insomnia treatment to assess which of these insomnia interventions are most effective for Black women: 1) patient education (PE) which is usual care (website providing sleep hygiene information) 2) standard SHUTi six-module program 3) modified SHUTi six-module program tailored for Black women, i.e., SHUTi-BW
Design/Methodology:	A single-blind (participants), parallel randomized clinical trial among eligible Black women with insomnia, using an equal allocation ratio. Participants will be randomized to 1 of 3 groups: patient education (PE) (sleep hygiene information), Sleep Healthy Using the Internet (SHUTi - a cognitive behavioral therapy for insomnia (CBT-I) program), or SHUTi modified for Black women. Participants will be randomized to patient education (also called sleep hygiene or sleep information) will use a website that discusses ways to improve behaviors and environments that can affect sleep.
Total Study Duration:	Total study duration is expected to be about 24 months.
Subject Participation Duration:	Individual participant duration is approximately 9 months.

3 Background/Rationale & Purpose

3.1 Background Information

Black women are at a higher risk of developing insomnia and insomnia has profound adverse physical and psychological health consequences, including cardiovascular disease, diabetes, and anxiety. There is a non-pharmacological internet-based self-administered treatment for insomnia called SHUTi (Sleep Healthy Using the Internet) that has been shown to be effective in multiple randomized trials among populations that were predominantly white. There were few Black participants and there is little evidence of the effectiveness of this treatment among Black women; specifically, the few Black women in the trials were less likely to finish the treatment program than other participants, though those that finished had improvement similar to that of other participants who finished.

This study aims to provide the much-needed evidence to assess how three different internet-based insomnia interventions affect insomnia symptoms in Black women which will help Black women make informed decisions regarding treatment for their insomnia. The three interventions are:
1) patient education or usual care (website providing sleep hygiene information)
2) standard SHUTi six-module program
3) modified SHUTi six-module program tailored for Black women, i.e., SHUTi-BW

This study will be conducted in compliance with the protocol, applicable regulatory requirements, and BMC/BU Medical Campus Human Research Protection policies and procedures.

3.2 Rationale and Purpose

This study aims to fill a gap in treating insomnia by providing evidence-based interventions to help Black women make informed decisions regarding treatment for their insomnia.

4 Objectives

4.1 Study Objectives

The goal of this study is to conduct a comparative effectiveness randomized trial of three internet-based intervention approaches to insomnia treatment to assess which of these insomnia interventions are most effective:

1) patient education (usual care) (website providing sleep hygiene information)
2) standard SHUTi six-module program
3) modified SHUTi six-module program tailored for Black women, i.e., SHUTi-BW

We will develop the modified SHUTi program, SHUTi-BWHS with the aid of a stakeholder group that includes Black women, a sleep physician who treats patients with sleep problems at a hospital that serves large numbers of minority patients, sleep experts, and leaders of the randomized trial. Each member of the group will work through the SHUTi cores and be interviewed after each core for suggestions on how to make the program more relevant to Black women. Based on the consensus of the stakeholder group, SHUTi will be modified to with specific sleep problems of Black women in mind.

4.2 Study Outcome Measures

4.2.1 Primary Outcome Measures

The primary study outcome measure will be insomnia severity, assessed with the Insomnia Severity Index (ISI). The ISI is a 7-item questionnaire well-validated in insomnia research in multiple patient populations, including in Black women. Total scores range from 0 to 28, with those scoring <8 considered to not have clinically significant insomnia symptoms; a score of 15 or greater is compatible with having insomnia disorder. An ISI score reduction of >7 points is considered a clinically significant improvement in insomnia symptoms

4.2.2 Secondary Outcome Measures

Secondary sleep outcomes will include:

- time taken to fall asleep (sleep onset latency)
- time awake after falling asleep (wake after sleep onset)
- total sleep duration
- total time in bed, and
- sleep efficiency (total sleep duration divided by total time in bed, multiplied by 100)
- for participants in SHUTi or SHUTi-BWHS, engagement with the program, measured by %completing all 6 Cores.

These data will be collected via online sleep diaries.

Another secondary outcome measure will be overall sleep quality which will be assessed by the Pittsburgh Sleep Quality Index (PSQI), a 19-item survey that has been validated extensively, including among Black women.

5 Study Design

We will implement a single-blind (participants), parallel randomized clinical trial among eligible Black women with insomnia, using an equal allocation ratio. Participants will be randomized to 1 of 3 groups: patient education (usual care -sleep hygiene information), Sleep Healthy Using the Internet (SHUTi - a cognitive behavioral therapy for insomnia (CBT-I) program), or SHUTi modified for Black women SHUTi-BWHS. Participants randomized to patient education (also called sleep hygiene or sleep information) will use a website that discusses ways to improve behaviors and environments that can affect sleep.

6 Potential Risks and Benefits

6.1 Risks

We will minimize the potential risks to participants by:

We will train staff to maintain a sensitive and responsive approach to speaking with participants.

Confidentiality concerns: In order to minimize any risks of loss of confidentiality, participants will be identified by coded study number. The file linking this coded study number to patient identifiers will be stored in a password protected database available only to relevant members of the study team involved

in direct contact with participants. The data collected via the Internet will be obtained through secured means and stored on secure servers at the University of Virginia. All data on the servers are password protected and limited to authorized research personnel. The University of Virginia study team has previously worked out a system with their prior Internet intervention studies in which two servers have been set up with one private server configured behind the HIPAA compliant firewall where secured data resides and only individuals who have onsite or VPN access are able to connect to this server. A second server maintains the front-end web system so that individuals (the participants) offsite can access the program. Data submitted by these users are captured and transferred to the secure server. Analyses will be conducted without identifiers.

Concerns about using an internet program: participants will be instructed to contact study staff if they have any concerns or questions about the on-line program. They are invited to contact study staff through either email or phone calls.

Concerns about answering personal questions: BWHS participants have provided personal data for 24 years in the BWHS. If they have concerns, they can call the project coordinator who will explain the safeguards for the data.

Initial tiredness: Participants who follow recommendations to restrict sleep could initially feel more tired. To minimize the risk associated with sleep restriction, the SHUTi system does not recommend that participants restrict sleep beyond the total amount of sleep the participant is already getting (based on diary data). We will instruct participants that they may contact us if they have significant concerns. As needed, we will instruct participants to contact their primary care provider or seek professional help at a sleep clinic.

6.2 Potential Benefits

There are two major potential benefits. Women taking part in the study may well improve their sleep, which in turn can improve their emotional and physical health. Those randomized to a program they do not like will be able to take the program, at no cost, that they think they will prefer after completing their assigned treatment.

The second benefit is to Black women in general who have insomnia. The effectiveness of SHUTi has not been established in Black women. This study will establish whether SHUTi, or SHUTi-BWHS (which are cognitive behavioral treatments for insomnia (CBTi), or both, are better at treating insomnia in Black women than usual care, which is giving the person sleep information. Since there are very few trained practitioners in CBTi, very few individuals get this most effective treatment for insomnia. Demonstration that online SHUTi or SHUTi-BWHS are effective will provide an impetus to make an online CBTi sleep treatment program accessible to Black women.

6.3 Analysis of Risks in Relation to Benefits

The risk/benefit ratio is highly favorable. Confidentiality is protected by the use of numbers to identify data; the protection of computer files by firewalls and limiting access to study personnel; the storage of consents in locked files; the statistical analysis of de-identified data; and the presentation of results of aggregate data. The benefit to scientific knowledge is large and far outweighs any risk.

7 Study Subject Selection

7.1 Subject Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

- Participants in the Black Women's Health Study (H-31535)
- BWHS participants with clinically elevated symptoms of insomnia previously reported on the 2015 BWHS questionnaire
- Internet access
- Access to computer or tablet

7.2 Subject Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

- Self-reported unstable or acute medical condition, or condition requiring surgery in the next two months
- Self-reported untreated, current, and/or severe psychiatric condition
- Self-reported night shift work or alternating shift work employment
- Employed in a position where sleep restriction may endanger others' lives
- Self-reported 1 or more sleep disorders other than insomnia, such as sleep apnea, that are not being managed by a medically prescribed method.
- Intention to change use pattern of prescribed or over-the-counter sleep aid
- Consume 14 or more alcoholic drinks/week

8 Study Intervention

The study interventions will be determined by the treatment arm e to which the participant is randomized and are summarized below.

1) Patient education (website providing sleep hygiene information) In this active control arm randomized participants will receive 'usual care' which will include internet-delivered patient education materials about sleep. The PE website focuses on symptoms of insomnia, the impact, prevalence, and causes of insomnia, considerations on when to see a doctor, and basic lifestyle, environmental, and behavioral strategies to improve sleep.
2) Standard SHUTi six-module program- SHUTi. This is an automated intervention that will be delivered over six sessions/modules, each lasting approximately 45-60 minutes. SHUTi tailors content based upon each participant's reported baseline sleep function, treatment adherence, and sleep progress. It incorporates all core elements of cognitive-behavioral therapy for insomnia (CBT-I).
3) SHUTi-BWHS (modified SHUTi six-module program tailored for Black women) We will develop this tailored version of SHUTi over a course of one year. The development will include an iterative process between the study investigators and key stakeholders such as Black women with a history of insomnia, a BWHS participant, a sleep physician from a medical center which serves a diverse patient population, and sleep researchers.

9 Study Procedures

Eligible subjects will be BWHS participants who completed a 7-question questionnaire about sleep, called the Insomnia Severity Index (ISI), which was included in the 2015 BWHS biennial follow-up questionnaire. The ISI was scored, with a score of 15 or more indicating symptoms of clinical insomnia disorder. Women with scores of 15 or more will be sent a brochure and email that will inform them of the opportunity to participate in a free program designed to test which of three insomnia treatments works best in Black women. Women will be selected at random since there are many more potentially eligible women (4000+) than women who can participate in the trial (n ~303). We will start with a group of 300 women selected at random from the potentially eligible subjects. The women will be directed to a special BWHS insomnia study website that contains the information in the brochure as well as an online screening questionnaire. Up to 6 reminders will be sent to the women to encourage participation. Once this group has been contacted and received a reminder, we will proceed to select a second group of 300 women at random. This procedure will be followed until the final group of 303 participants has been entered into the study.

After a woman submits her screening questionnaire (attached to this IRB application as "Eligibility Questionnaire"), an assessment will be made by the project coordinator to determine if she is eligible (e.g., does not have untreated sleep apnea). Those determined to be ineligible will be sent a thank you email and informed that they were not eligible for this trial. Those who meet the qualifications for the study will be contacted by the project coordinator to set up a telephone call to discuss the study and the informed consent. The coordinator will then call the woman; during the call the coordinator will review each section of the consent form. The consent form will contain a description of the study and describe all aspects of the study. Subjects will have ample time to consider whether or not they want to participate in the study. A verbal acknowledgement of consent, or non-consent, will be recorded in the study and a copy of the consent sent to the participant. A waiver of documentation of consent will be obtained from the IRB.

At this point, the BWHS Project Coordinator will enroll participants by entering their email and study ID into the SHUTi Administrative site. The BWHS Project Coordinator will be responsible for SHUTi program administration during the clinical trial. The SHUTi program will maintain contact with the woman through regular emails until the end of the woman's participation, as described below. Participants needing help will contact BWHS via email (bwhs@bu.edu) or the BWHS toll free number (800-786-0814) posted on the SHUTi website. At the end of each woman's participation, the data she has supplied (ISI scores, etc.) will be transferred from the SHUTi database to BWHS. None of the data collected will have identifiers such as names and addresses.

Once a participant is enrolled, she will be sent a Welcome email with instructions for setting her password. Enrolled participants will login and complete an online Questionnaire (attached to this IRB application as "Pre-Assignment Questionnaire") asking about her health, sleep habits, and daily life activities (approximately 30-45 minutes). Participants will receive reminder emails to complete the Questionnaire.

After completing the Pre-Assignment questionnaire, participants will advance to the Sleep Diary phase. Participants will record their sleep online by entering Sleep Diaries (2 minutes to complete each) during the next two weeks. Participants must complete at least 10 diaries in those two weeks to complete this

phase with success. Participants will receive daily email reminders to complete the Sleep Diaries. A sample Sleep Diary is attached to this IRB application as "SHUTi Sleep Diary".

After a participant has completed both the Pre-Assignment Questionnaire and 10 Sleep Diaries in a two-week time period, the program automatically advances the participant to the treatment phase. Via email, participants will be directed to 1 of the 3 study programs to which they have been randomly assigned. For the next nine (9) weeks, each participant will use her assigned study website.

Sleep Education/Sleep Hygiene

One program, patient education, will be a commonly used treatment for insomnia, called sleep information or sleep hygiene. Participants assigned to this treatment program will use a website that discusses ways to improve behaviors and environments that can affect sleep. This material is also included in the other 2 treatments but is presented in a different way. Participants may log in as often as they like and there are no time requirements. An example of this program is attached to this IRB application as "Draft - Sleep Education Website".

SHUTi (Sleep Healthy Using the Internet)

The other 2 treatment programs, Sleep Healthy Using the Internet (SHUTi), and a modification of SHUTi designed for Black women called SHUTi-BWHS, will involve participation in online treatment programs that have six modules called Cores. Each participant will log in to the six modules of her assigned treatment program over a 6 to 8-week period. Participants will use a website program designed to provide tailored instructions about how to improve their sleep. Cores are completed one at a time in order. Each Core is expected to take 45 to 60 minutes to complete. Each Core contains information and exercises designed to help change behaviors and thoughts that can contribute to sleep problems. Participants will receive automated emails encouraging them to complete tasks. Participants will be asked to complete weekly to dos and enter daily Sleep Diaries to track their sleep. After each module, participants will need to complete 5 sleep diaries to proceed to the next module (2 minutes to complete each).

Nine weeks after she completes the initial (Pre-Assignment) questionnaire, regardless of which treatment program she is assigned to, the participant will be asked to complete a Post-Assignment questionnaire about her sleep and health (45 minutes) and she will be asked again to complete 10 sleep diaries. The Post-Assignment Questionnaire will include the same questions asked at the beginning and additional evaluation questions. Six months later, participants will be asked again to complete a questionnaire, including evaluation questions, (45 minutes) and 10 sleep diaries. These three questionnaires are attached to this IRB application as Pre-Assignment Questionnaire, Post-Assignment Questionnaire and 6 Month Follow-up Questionnaire.

Participants can continue to use their assigned website between the two post treatment questionnaires.

After participants have finished their assigned program for the research, they may choose to take one of the other insomnia treatment programs. It will be offered free of charge but it will not be counted as part of this research.

The SHUTi program has 6 cores that include behavioral, educational, and cognitive components. Most cores contain "vignettes" or stories about the sleep problems of specific (fictional) individuals, that may be presented in videos or written material with the names and faces of a variety of (fictional) men and women, of whom one is a Black woman. Some of the cores contain advice from sleep experts (mostly actors playing those roles). This will be revised to make SHUTi-BWHS with the advice of the stakeholder team.

Core 1 provides an overview and rationale for the treatment.

Cores 2 and 3 are behavioral cores that provide rules for sleep restriction and stimulus control. Rules are provided to regulate the sleep-wake schedule and strengthen the connection between the bedroom and sleep. Stimulus control means going to bed only when sleepy, getting out of bed when unable to sleep and returning to bed when sleepy, and curtailing other activities in the bedroom (e.g., reading, television). Sleep restriction means limiting the time spent in bed to increase sleep efficiency (amount of time in bed spent sleeping).

Core 4 focuses on improving sleep hygiene practices (e.g., avoiding alcohol before bedtime).

Core 5, the cognitive core, addresses unhelpful beliefs about sleep (e.g., the belief that a certain number of hours of sleep are required).

Core 6, the last core, integrates the various elements and presents strategies to prevent relapse.

SHUTi-BWHS will have the same structure and elements as SHUTi. The vignettes will be changed, so that Black women will be the characters of interest. The vignettes will also contain material that was not covered in SHUTi, such as sleep problems resulting from housing that is not quiet or that may require room sharing. The "experts" will be Black physicians. . The changes will be made with the advice of a stakeholder team that includes Black women from the community who have sleep problems, a Black community advocate, a sleep expert, a physician who treats individuals with sleep problems, and the co-PIs of this study.

This table summarizes by study week what will happen in this randomized trial.

Step	Week	Study Phase	What happens during this phase	Time required
1	1-2	Pre assignment	Complete Pre- Assignment Questionnaire Enter 10 sleep diaries in 14 days	30 minutes 2 minutes each
2	3-12	Treatment 9 weeks	Use assigned website	
3	12	Post treatment	Complete Post-Assignment Questionnaire Enter 10 sleep diaries in 14 days	45 minutes 2 minutes each

4	38	6 months after post treatment	Complete 6 Month Follow-up Questionnaire Enter 10 sleep diaries in 14 days	45 minutes 2 minutes each

10 Assessment of Safety and Data Safety Monitoring Plan (DSMP)

10.1 Definitions

The following definitions will be used in the assessment of safety:

Adverse Event (AE) is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious Adverse Event (SAE) is any adverse event that

(1) results in death;
(2) is life-threatening;
(3) results in inpatient hospitalization or prolongation of existing hospitalization;
(4) results in a persistent or significant disability/incapacity;
(5) results in a congenital anomaly/birth defect; or
(6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Life-threatening means that the event places the subject at immediate risk of death from the event as it occurred.

Unanticipated Problem is defined as an event, experience or outcome that meets **all three** of the following criteria:

- is unexpected; AND
- is related or possibly related to participation in the research; AND
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research

Unexpected means the nature, severity, or frequency of the event is not consistent with either:

- the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol–related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or

- the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

10.2 Reporting Plans

The Principal Investigator at BU Medical Campus will report Unanticipated Problems, safety monitors' reports, and Adverse Events to the BMC/BU Medical Center IRB in accordance with IRB policies:

- Unanticipated Problems occurring at BMC/BU Medical Campus involving a fatal or life-threatening event will be reported to the IRB within 2 days of the investigator learning of the event.
- Unanticipated Problems occurring at BMC/BU Medical Campus not involving a fatal or life-threatening event will be reported to the IRB within 7 days of the investigator learning of the event.
- Reports from safety monitors with recommended changes will be reported to the IRB within 7 days of the investigator receiving the report.
- Adverse Events (including Serious Adverse Events) will be reported in summary at the time of continuing review, along with a statement that the pattern of adverse events, in total, does not suggest that the research places subjects or others at a greater risk of harm than was previously known.
- Reports from safety monitors with no recommended changes will be reported to the IRB at the time of continuing review.

10.3 Stopping Rules

The study has no stopping rules.

11 Data Handling and Record Keeping

11.1 Confidentiality

Study data/results, documents, CRFs, and other documents/files will be identified with a unique study ID #. The study ID # will be linked to a master-code list that contains all study ID #s and direct subject identifiers (i.e. name, address, DOB, MRN, etc.). The master-code list will be maintained separately from study files and access limited to the researchers.

Study data, documents, CRFs, and other documents/files for subjects who have been assigned a study ID # will NOT contain any subject identifiers that by themselves or when combined with others identifiers, could result in identifying a subject.

The only identifiable data stored in the SHUTi program will be the participant's email. The assignment into the treatment group in this randomized trial will be done by the BU study coordinator. The email address will be entered into the program by the BU study coordinator. The email will be used to send reminders to the participant of the various phases of the trial; messages will be sent by the SHUTi program at the University of Virginia in an automated fashion. The only identifying information stored in the SHUTi application is the email address. No other identifiable data will be shared or input into the SHUTi program. No identifiable data will be shared with the analyst.

11.2 Study Records Retention

Study records will be maintained until seven years post completion of this insomnia treatment study. University of Virginia will destroy emails at the end of the trial.

12 Statistical Plan

12.1 Sample Size Determination

Power calculations will be based on the data collected from a prior SHUTi trial which included a subset of Black women. The study will be powered at 80% to detect pre-post differences between groups with α=.01, a recruitment sample size of 303 (n=101 for each randomization group) was targeted. We conservatively estimated 28% study attrition based on prior SHUTi trials, for an anticipated final analytic sample of n=72 for each of the two randomization groups.

12.2 Statistical Methods

The chief outcome of interest will be improvement in the ISI score. An ISI score reduction of 8 is considered to be a clinically significant improvement in insomnia symptoms. Other outcomes of interest will be WASO (wake after sleep onset, i.e., amount of time awake after first falling asleep) and SOL (sleep onset latency, i.e., time awake before first falling asleep).

We will analyze the data on an intention to treat basis.
For the primary outcome, ISI, a factorial 2 (groups) x 3 (times) mixed model analysis will compare improvement in the treatment groups to the usual care group, and to one another. Using a General Linear Mixed Model (GLMM) analysis will allow us to include dropouts in the analysis and to model the appropriate temporal dependencies in the dataset.
Analyses for WASO and SOL will be similar.

Finally, an important variable will be the proportion of women who complete SHUTi or SHUTi-BWHS.

13 Ethics/Protection of Human Subjects

This study is to be conducted according to applicable US federal regulations and institutional policies (which are based in federal regulations, guidance, and ICH Good Clinical Practice guidelines).

This protocol and any amendments will be submitted to the Boston Medical Center and Boston University Medical Campus IRB, for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. The consent form will be submitted with the protocol for review and approval by the IRB. The consent of a subject, using the IRB-approved consent form, must be obtained before that subject is submitted to any study procedure. Consent will be documented as required by the IRB.

14 Literature References

Adenekan B, Pandey A, McKenzie S, Zizi F, Casimir GJ, Jean-Louis G. Sleep in America: role of racial/ethnic differences. Sleep Med Rev. 2013;17(4):255-262.

Bastien CH, Vallieres A, Morin CM. Validation of the Insomnia Severity Index as an outcome measure for insomnia research. Sleep Med. 2001;2(4):297-307.

Bethea TN, Zhou ES, Schernhammer ES, Castro-Webb N, Cozier YC, Rosenberg L. Perceived racial discrimination and risk of insomnia among middle-aged and elderly Black women. Sleep. 2020;43(1): zsz208.

Christensen H, Batterham PJ, Gosling JA, et al. Effectiveness of an online insomnia program (SHUTi) for prevention of depressive episodes (the GoodNight Study): a randomised controlled trial. Lancet Psychiat. 2016;3(4):333-341.

Durrence HH, Lichstein KL. The sleep of African Americans: a comparative review. Behav Sleep Med. 2006;4(1):29-44.

Javaheri S, Redline S. Insomnia and risk of cardiovascular disease. Chest. 2017;152(2):435-444.

Lauderdale DS, Knutson KL, Yan LL, et al. Objectively measured sleep characteristics among early-middle-aged adults: the CARDIA study. Am J Epidemiol. 2006;164(1):5-16.

Morin CM, Belleville G, Belanger L, Ivers H. The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response. Sleep. 2011;34(5):601-608.

Morin CM. Cognitive-behavioral therapy of insomnia. Sleep Medicine Clinics. 2006;1(3):375-386.

Profant J, Ancoli-Israel S, Dimsdale JE. Are there ethnic differences in sleep architecture? Am J Hum Biol. 2002;14(3):321-326.

Qaseem A, Kansagara D, Forciea MA, Cooke M, Denberg TD. Management of chronic insomnia disorder in adults: A clinical practice guideline from the American College of Physicians. Ann Intern Med. 2016;165(2):125-133.

Rao U, Poland RE, Lutchmansingh P, Ott GE, McCracken JT, Lin K-M. Relationship between ethnicity and sleep patterns in normal controls: implications for psychopathology and treatment.J Psychiatric Res. 1999;33(5):419-426.

Ritterband LM, Bailey ET, Thorndike FP, Lord HR, Farrell-Carnahan L, Baum LD. Initial evaluation of an Internet intervention to improve the sleep of cancer survivors with insomnia. Psychooncology. 2012;21(7):695-705.

Ritterband LM, Thorndike FP, Gonder-Frederick LA, et al. Efficacy of an Internet-based behavioral intervention for adults with insomnia. Arch Gen Psychiatry. 2009;66(7):692-698.

Ritterband LM, Thorndike FP, Ingersoll KS, et al. Effect of a web-based cognitive behavior therapy for insomnia intervention with 1-year follow-up: A randomized clinical trial. JAMA Psychiatry. 2017;74(1):68-75.

Rosenberg L, Adams-Campbell L, Palmer JR. The Black Women's Health Study: a follow-up study for causes and preventions of illness. J Am Med Womens Assoc (1972). 1995;50(2):56-58.

Rottapel RE, Zhou ES, Spadola CE, et al. Adapting sleep hygiene for community interventions: a qualitative investigation of sleep hygiene behaviors among racially/ethnically diverse, low-income adults. Sleep health. 2020;6(2):205-213.

Ruiter ME, Decoster J, Jacobs L, Lichstein KL. Normal sleep in African-Americans and Caucasian-Americans: A meta-analysis. Sleep medicine. 2011;12(3):209-214.

Thorndike FP, Ritterband LM, Saylor DK, Magee JC, Gonder-Frederick LA, Morin CM. Validation of the Insomnia Severity Index as a web-based measure. Behav Sleep Med. 2011;9(4):216-223.

Thorndike FP, Saylor DK, Bailey ET, Gonder-Frederick L, Morin CM, Ritterband LM. Development and perceived utility and impact of an internet intervention for insomnia. E J Appl Psychol. 2008;4(2):32-42.

Trauer JM, Qian MY, Doyle JS, Rajaratnam SM, Cunnington D. Cognitive behavioral therapy for chronic insomnia: A systematic review and meta-analysis. Ann Intern Med. 2015;163(3):191-204.

Williams NJ, Grandner MA, Wallace DM, et al. Social and behavioral predictors of insufficient sleep among African Americans and Caucasians. Sleep medicine. 2015.