



**A Randomized Controlled Trial of  
Three Internet-delivered  
Treatments for Insomnia  
Conducted in the BWHS**



**BLACK WOMEN'S  
HEALTH STUDY**

# BACKGROUND

**Sleep problems.** Black women report worse sleep quality than women of other racial/ethnic groups. Insomnia disorder — trouble falling asleep and staying asleep — can increase risk of psychiatric illnesses, heart disease, accidents, and other poor health outcomes. The *Insomnia Severity Index* is a 7-question survey about sleep problems. Based on answers to this survey which was included on the 2015 BWHS health questionnaire, 15% of BWHS participants have symptoms of insomnia disorder.

**Sleep treatments.** People with sleep problems may be treated with prescription or over-the-counter drugs. Drugs can have adverse reactions and lose their effect after long use. Patient education about sleep is often used: a health care practitioner provides educational material that describes good *sleep hygiene*, such as eliminating naps or limiting screen time before bedtime. *Cognitive behavioral therapy for insomnia* (CBT-I) is the gold standard treatment. CBT-I seeks to change beliefs and behaviors that result in chronic insomnia. Few health professionals are trained in CBT-I, but an online CBT-I treatment program for insomnia called SHUTi (**S**leep **H**ealthy **U**sing the **I**nternet) has worked well in lessening insomnia in randomized clinical trials. Based on the small number of Black participants in those trials, Black women were less likely to complete SHUTi than White participants. We thought a SHUTi program modified to appeal to Black women might result in more Black women completing it.

**SHUTi modifications for Black women.** SHUTi consists of 6 “modules”, each 45 to 60 minutes, which an individual works through on the internet. We created a modified program, SHUTi-BWHS, guided by a Leadership Team that included a BWHS participant, a Black woman from the local community who had struggled with sleep problems, and a Black female patient advocate. After working through SHUTi, the Team recommended that the stories in the modules be about Black families and their sleep problems (e.g., multigenerational households), and that Black physicians be filmed giving sleep advice. The SHUTi modules were then rewritten and re-filmed with Black actors and Black sleep physicians.

**The randomized controlled trial.** A randomized controlled trial is the best way to determine which of two or more treatments works best. We conducted a randomized controlled trial of patient education, SHUTi, and SHUTi-BWHS to determine which worked best in lessening insomnia symptoms. We also assessed whether SHUTi-BWHS was more engaging than SHUTi, as indicated by a higher completion rate for SHUTi-BWHS.

## CONTACT INFORMATION



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# PARTICIPANTS AND TREATMENTS

**Potential participants.** BWHS participants who had a score of 15 or more on the *Insomnia Severity Index* on the 2015 BWHS questionnaire were invited to be in the randomized trial. Of 3,071 women contacted, 1,010 completed eligibility questionnaires. Some potential participants were excluded and others decided not to participate. Reasons for exclusion included working night shifts and not having reliable internet access. A total of 333 of the potential participants took part in the trial.

**Treatment assignment.** In randomized trials, people are assigned by a random method to their treatment, rather than selecting it themselves. The purpose of randomization is to make all the treatment groups similar — for example, similar in the severity of their sleep problems. For each of the 333 women in the trial, a random number generator in a computer program generated one of three numbers at random — 1, 2, or 3. If 1 came up, the woman was assigned to patient education; if 2 came up, she was assigned to SHUTi; if 3 came up she was assigned to SHUTi-BWHS. The women were not told the name of their treatments — just to log in to a particular website.

**The treatment websites.** People who go to a physician seeking help with their insomnia usually get “standard care”, which is educational material about how to deal with sleep problems. Women assigned to **patient education** logged in to a website that contained information on sleep problems and good sleep practices. It discussed insomnia symptoms, causes of insomnia, stress and sleep, good sleep environments, reading habits and sleep, lifestyle factors that affect sleep, and when to see a sleep physician. The women could access this website as often as they liked.

Women assigned to **SHUTi** or **SHUTi-BWHS** viewed the six modules on their assigned websites, which had stories, filmed vignettes, advice from experts, and relaxation techniques. They filled out sleep diaries daily, reporting on the times they got into bed, fell asleep, woke up during the night, and got out of bed in the morning. Depending on the woman’s sleep habits, the program recommended changes, such as getting into bed later. The participants had access to all the information provided on the patient education website, plus techniques such as “sleep restriction”, which was used to limit how much time was spent in bed, or relaxation techniques, such as meditation.

# TIMELINE OF THE TRIAL

**Time 1.** After treatment assignment at Time 1, participants filled out questionnaires and sleep diaries. They were given 9 weeks to access their treatment websites as often as they wished.

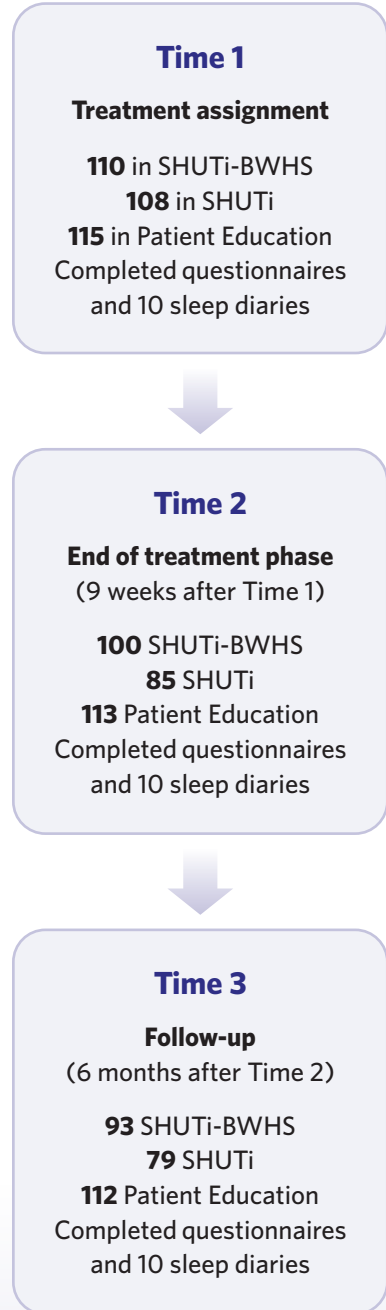
**Time 2.** Nine weeks after treatment assignment at Time 1. At Time 2, participants completed questionnaires and sleep diaries.

**Time 3.** Six months after Time 2. At Time 3, participants once again completed questionnaires and sleep diaries.

As shown in **Figure 1**, 110 women were assigned at random to SHUTi-BWHS, 108 women to SHUTi, and 115 women to patient education at Time 1. At the end of the trial, Time 3, which was six months after Time 2, 93 SHUTi-BWHS participants, 79 SHUTi participants, and 112 patient education participants completed questionnaires and sleep diaries.

**Note:** *At the end of Time 3, participants were allowed access to the other treatment websites, but this did not count as part of the research.*

**Figure 1**



# RESULTS OF THE TRIAL

**The Insomnia Severity Index.** Higher scores indicate worse sleep. A score of 15 or greater is an indicator of insomnia disorder. **Figure 2** shows that the average *Insomnia Severity Index* scores in the three treatment groups were similar at Time 1: 18.7 for SHUTi-BWHS, 18.3 for SHUTi, and 19.2 for patient education. At Time 3, the end of the trial, the scores of SHUTi-BWHS and SHUTi had decreased to 9.4 and 8.4, respectively, but the scores of patient education participants had decreased to only 15.6. Thus, the *Insomnia Severity Index* scores of the women assigned to either SHUTi-BWHS or SHUTi had decreased considerably more than those of women in patient education.

**The Pittsburgh Sleep Quality Index.** The *Pittsburgh Sleep Quality Index* is an important marker of sleep quality. Lower scores indicate better sleep quality.

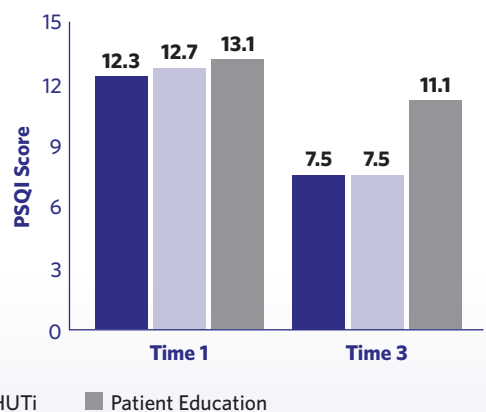
Scores at Time 1 were similar in the three treatment groups: 12.3 for women in SHUTi-BWHS, 12.7 for SHUTi, and 13.1 for patient education (**Figure 3**). At Time 3, the scores had improved to 7.5, 7.5, and 11.1, respectively. Thus, the improvement in sleep quality in the two SHUTi groups was greater than that in the patient education group.

**Completion of the program.** A higher percentage of women assigned to SHUTi-BWHS, 78.2%, than of women assigned to SHUTi, 64.8%, completed all six modules of their program. Women who completed all six modules had better sleep outcomes than women who completed fewer modules.

**Figure 2**  
**Average Insomnia Severity Index Scores at Time 1 and Time 3**



**Figure 3**  
**Average Pittsburgh Sleep Quality Index Scores at Time 1 and Time 3**



# CONCLUSIONS

The SHUTi-BWHS and SHUTi programs were much more successful in reducing symptoms of insomnia than patient education. In addition, the percentage of women who completed all six modules of SHUTi-BWHS was greater than the percentage of women who completed all six modules of SHUTi, suggesting that SHUTi-BWHS was more engrossing. Women who completed all six modules had greater improvement in their sleep than women who completed fewer modules.

More details about the study and its results can be found in a scientific article about the trial published in JAMA Psychiatry. (Zhou ES, Ritterband LM, Bethea TN, Robles YP, Heeren TC, Rosenberg L. Effect of Culturally Tailored, Internet-Delivered Cognitive Behavioral Therapy for Insomnia in Black Women: A Randomized Clinical Trial. JAMA Psychiatry, published online April 20, 2022. doi:10.1001/jamapsychiatry.2022.0653)

**Can BWHS participants get access to SHUTi-BWHS or SHUTi?** This is not possible at the present time. In order for a treatment like this to be available to the public, it must be approved by the Food and Drug Administration. SHUTi is available only in clinical trials. A company called Pears Therapeutics owns the commercial rights to SHUTi and obtained approval from the Food and Drug Administration for a version of SHUTi called Somryst®. (You can find the website on the internet — just key in Somryst®). To find out if this program is available to you, ask your physician or health care provider if Somryst® can be prescribed for you, and how much of the cost is covered by your health plan. We are currently exploring how to make SHUTi-BWHS available through the same company. We will keep you posted.

## THANK YOU TO BWHS PARTICIPANTS!

The BWHS trial of sleep treatments was a huge success. Participation rates were greater than in most clinical trials of insomnia, a tribute to the dedication of BWHS participants to contributing to improved sleep health. We will do what we can to pursue avenues that could result in SHUTi-BWHS becoming widely available.

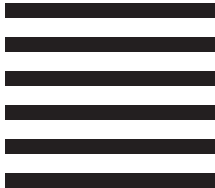


# FUNDING & CONTRIBUTORS TO THE STUDY

This study was funded by grant AD-2017C1-6314 from the Patient-Centered Outcomes Research Institute. The BWHS is supported by U01 CA164974 from the National Cancer Institute. The Principal Investigators of the study were Dr. Lynn Rosenberg (Slone Epidemiology Center at Boston University) and Dr. Eric S. Zhou (Harvard Medical School and Dana-Farber Cancer Institute). Patricia Simmons was the study coordinator; she was assisted by Lauren Delp. The SHUTi program and infrastructure were run at the University of Virginia, under the supervision of Dr. Lee M. Ritterband. Dr. Timothy C. Heeren, biostatistician, provided expertise on the statistical analyses. Yvonne P. Robles, MPH, carried out the computer runs and statistical analyses. The Leadership Team consisted of Lynette Griffeth Fields, Catherine Joseph, Josephine Nash, Dr. Sanford Auerbach, Dr. Tracy Trevorow, Dr. Lynn Rosenberg, and Dr. Eric S. Zhou. Additional advice was provided by Dr. Traci Bethea. Dr. Zhou and Dr. Ritterband wrote the scripts for SHUTi-BWHS and directed the filming of the vignettes. Dr. Chantale Branson and Dr. Kyra Clark are sleep physicians who provided expert advice on sleep in the SHUTi-BWHS modules.



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