

Sleepio

Instructions for Use



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Introduction

Indications for Use

Sleepio is a digital therapeutic intended for the improvement of poor sleep and the management of Insomnia Disorder in adults aged 18 years and older, as an adjunct to their usual medical care.

For adults diagnosed with Insomnia Disorder, Sleepio should be used under the supervision of a healthcare professional.

For otherwise healthy adults who have difficulty sleeping, Sleepio may be used as a non-prescription self-help tool to improve sleep health.

Benefits of Sleepio

Research has shown that individuals who use Sleepio experience reductions in symptoms of poor sleep, including nighttime (e.g., difficulty falling asleep or staying asleep) and daytime symptoms (e.g., fatigue, sleepiness) as well as improvements in work and social functioning, wellbeing, physical health, and mental health (e.g., anxiety and mood symptoms). Research also shows that the benefits of Sleepio are maintained during a 1-year period following Sleepio use.

Who Should and Shouldn't Use Sleepio

Who Should Use Sleepio?

Sleepio may be suitable for you if:

- You are 18 years or older

- You are experiencing sleep difficulties
- You have been diagnosed with Insomnia Disorder and are under the care of a doctor
- You have stable physical and mental health
- You are able to read, hear, and understand English
- You have regular access to a computer or mobile device
- You have periodic access to the internet

Who Should Not Use Sleepio?

One component of the Sleepio program is an intervention called 'sleep restriction'. Sleep restriction increases sleep efficiency by reducing time in bed to the amount of time spent asleep. Sleep restriction may exacerbate underlying pathophysiology and may increase risk in some individuals. Individuals with the following conditions, disorders, or symptoms should speak to their doctor before starting the Sleepio program and only use the program under the direct supervision of a doctor:

- Bipolar disorder, schizophrenia, or other psychotic spectrum disorders
- Epilepsy
- Individuals at high risk for falls
- Individuals who have other unstable or degenerative disorders that may be exacerbated by sleep restriction

Sleepio Program Sessions are delivered in a visual and auditory format. If you have vision or hearing impairment, you may need to arrange appropriate assistance to help you complete sessions.

Safety Information

Safety Information and Warnings

- **In accordance with FDA's Current Enforcement Discretion Policy for Digital Health Devices for Psychiatric Disorders, for patients aged 18 years and older, who are followed by and diagnosed with Insomnia Disorder by a medical provider, Sleepio is available as an adjunct to their usual medical care for Insomnia Disorder. Sleepio does not replace the care of a medical provider or the patient's medication. Sleepio has not been cleared by the U.S. Food and Drug Administration (FDA) for this indication.**
- If you have been previously diagnosed with Insomnia Disorder, please contact your doctor prior to using Sleepio.
- Sleepio is not a substitute for other medical or mental health treatment. The medical advice provided in Sleepio should not be solely or primarily relied upon to treat psychiatric conditions. Don't make any changes to your medications or treatment plan without consulting your doctor.
- If you notice a worsening of your insomnia symptoms, please consult your doctor.
- Increased sleepiness is common during the early stages of Sleepio. If sleepiness continues after several weeks, this may be a sign of another sleep disorder or medical condition. Please consult your doctor if you continue to experience excessive daytime sleepiness.

- Sleepio does not provide crisis support. If you are experiencing a crisis or medical emergency, including suicidal thoughts, call the National Suicide Lifeline at 988, call 911 or go to your nearest emergency room.
- Sleepio sessions are delivered in a visual and auditory format. If you have vision or hearing impairment, you may need to arrange appropriate assistance to help you complete techniques.

To reduce risk, modifications to the Sleepio program may be required for certain populations

Sleep restriction may result in temporarily increased daytime sleepiness. Individuals who experience excessive daytime sleepiness should speak to their doctor before starting the Sleepio program. Examples include individuals who have:

- Untreated sleep apnea
- Narcolepsy
- Parasomnias
- Shift work schedules

Sleepio has been evaluated in pregnant women and has been shown to be effective and safe. However, if you are pregnant you should not reduce your sleep window to below 6 hours.

Sleep restriction should not be used if daytime sleepiness imposes a risk to you or others. Individuals for whom sleep restriction may not be appropriate include:

- Truck or bus drivers
- Air traffic controllers
- Operators of heavy machinery
- Assembly line workers

If you are feeling sleepy while driving, operating heavy machinery, or other potentially dangerous situations, stop what you are doing immediately and take a nap until the sleepiness subsides.

To reduce risk, modifications to the Sleepio program may be required for certain populations

Another component of the Sleepio program is an intervention called the 'quarter of an hour rule'. The quarter of an hour rule encourages individuals to get out of bed if they are unable to fall asleep or return to sleep within approximately 15 minutes. Getting out of bed in the middle of the night may be challenging or may increase the risk of falls for some individuals. Speak to your doctor before using the quarter of an hour rule if you:

- Are over the age of 65
- Take sleep medications
- Are at high risk for falls
- Have physical limitations

Sleepio also includes progressive muscle relaxation, a technique that involves tensing and relaxing your muscles. If you experience pain while tensing your muscles, you can use an alternative exercise that does not involve muscle tensing.

Sleepio contains sensitive medical information. Please protect your privacy by password protecting your computer, tablet, or phone and ensure that nobody else can access the device.

Side Effects

No serious adverse events have been reported in relation to use of Sleepio. Participants using Sleepio have reported the following adverse events: fatigue and / or exhaustion (46.3%), difficulty with attention and concentration (33.2%), reduced motivation and / or energy (32.8%), extreme sleepiness (30.8%), irritability (28.2%), low mood (21.6%), difficulty remembering

things (19.2%), headaches and / or migraine (18.8%), agitation (18.1%), bodily pain (11.8%), changes in hunger and/or appetite (10.5%), dizziness (6.55%), blurred vision (4.59%), and euphoria and/or intense increase in mood (3.71%; Espie et al., 2019).

Additional Resources for Insomnia

Additional resources for the treatment of Insomnia Disorder can be found at:

The National Sleep Foundation

<https://www.sleepfoundation.org/sleep-topics/insomnia>

The American Academy of Sleep Medicine (AASM)

<https://www.sleepeducation.org/essentials-in-sleep/insomnia>

The American Psychological Association

<https://www.apa.org/topics/sleep-disorders>

Sleepio

What is Sleepio?

Sleepio is a fully automated digital sleep improvement program based on cognitive behavioral techniques for insomnia (CBT-I). While typically triggered by a stressful life event, insomnia is maintained by unhelpful behaviors and thoughts. Over the course of six sessions, your virtual sleep expert – The Prof – teaches you evidence-based cognitive and behavioral interventions, sleep hygiene education, and relaxation exercises to target these unhelpful behaviors and thoughts. Reducing these unhelpful behaviors and thoughts leads to a reduction in insomnia symptoms.

Common behaviors maintaining insomnia include spending an excessive amount of time awake in bed, sleeping in on the weekends, taking daytime naps, and drinking excessive caffeine. Sleep restriction (i.e., establishing a regular sleep window based on the actual amount of time spent asleep), stimulus control (i.e., reducing the amount of time awake in bed to reassociate the bed with sleep), and sleep hygiene (i.e., education about behaviors that interfere with sleep) are introduced in Sleepio to target unhelpful behaviors.

Common thoughts maintaining insomnia include excessive worries about sleep, dysfunctional beliefs about sleep, and bed-related tension and anxiety. Sleepio identifies, challenges, and addresses thoughts and worries that contribute to difficulty sleeping using cognitive therapy such as cognitive restructuring (i.e., identifying and challenging unhelpful thoughts) and paradoxical intention (i.e., instead of focusing on trying to sleep, focus on trying to stay awake). Relaxation techniques such as progressive muscle relaxation are also introduced to help reduce bed-related anxiety and tension.

Recommended Use

Sleepio consists of six, 15-20 minute sessions. After completion of a session, the next session is made available one week later. It is recommended that you complete one session per week. However, you can take as much time between sessions as needed.

During the Sleepio sessions, The Prof will teach you scientifically backed tools to reduce insomnia symptoms. It is recommended that you do your best to incorporate these tools into your routine as instructed. Research shows that putting in the work between sessions leads to better outcomes.

A core component of Sleepio is completion of the sleep diary. It is recommended that you complete the sleep diary every morning upon waking. The diary can be completed within the Sleepio program. If you prefer to have a paper copy of your diary, you can download and print the sleep diary and leave the paper copy near your bed as a reminder. It is recommended that you give Sleepio sessions your full attention and effort to ensure positive treatment results.

At times, the program will be challenging. Especially once sleep restriction is introduced. While sleep restriction is challenging, it is the most powerful tool of the program.

It is recommended that Sleepio be accessed on a password protected device to reduce the risk of unauthorized access. Visit info.sleepio.com/privacy to read our Privacy Policy.

Many Sleepio users start seeing improvements in their sleep by session 2 or 3, however, to get the full benefit of the program it is recommended that you complete all six sessions and practice the skills between sessions. If you have completed all six Sleepio sessions and are still struggling with your sleep, you may benefit from the help of a mental health professional. Please consult your doctor before requesting extended access if this is your experience.

User Instructions

Getting Started: Sign up and customize your program

Sign up for Sleepio through the link provided by your employer or health care provider. Select “Start Sleepio” on the website to start the sign up process. Answer each question, and create an account with your name, email, and password to access your Sleep Score. Then choose “Customize Sleepio” to start the Sleepio onboarding questionnaire. Answer all the required questions to set up your Sleepio Program.

Note: You may be asked to verify your benefit coverage by entering your employer identification or additional information.

You can logout of the Sleepio program at any time by selecting “Log out” from your browser or Sleepio app.

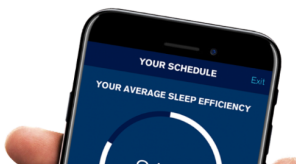


A science-based approach

Sleepio is a 6 week online program designed by sleep experts and based on cognitive and behavioral techniques.

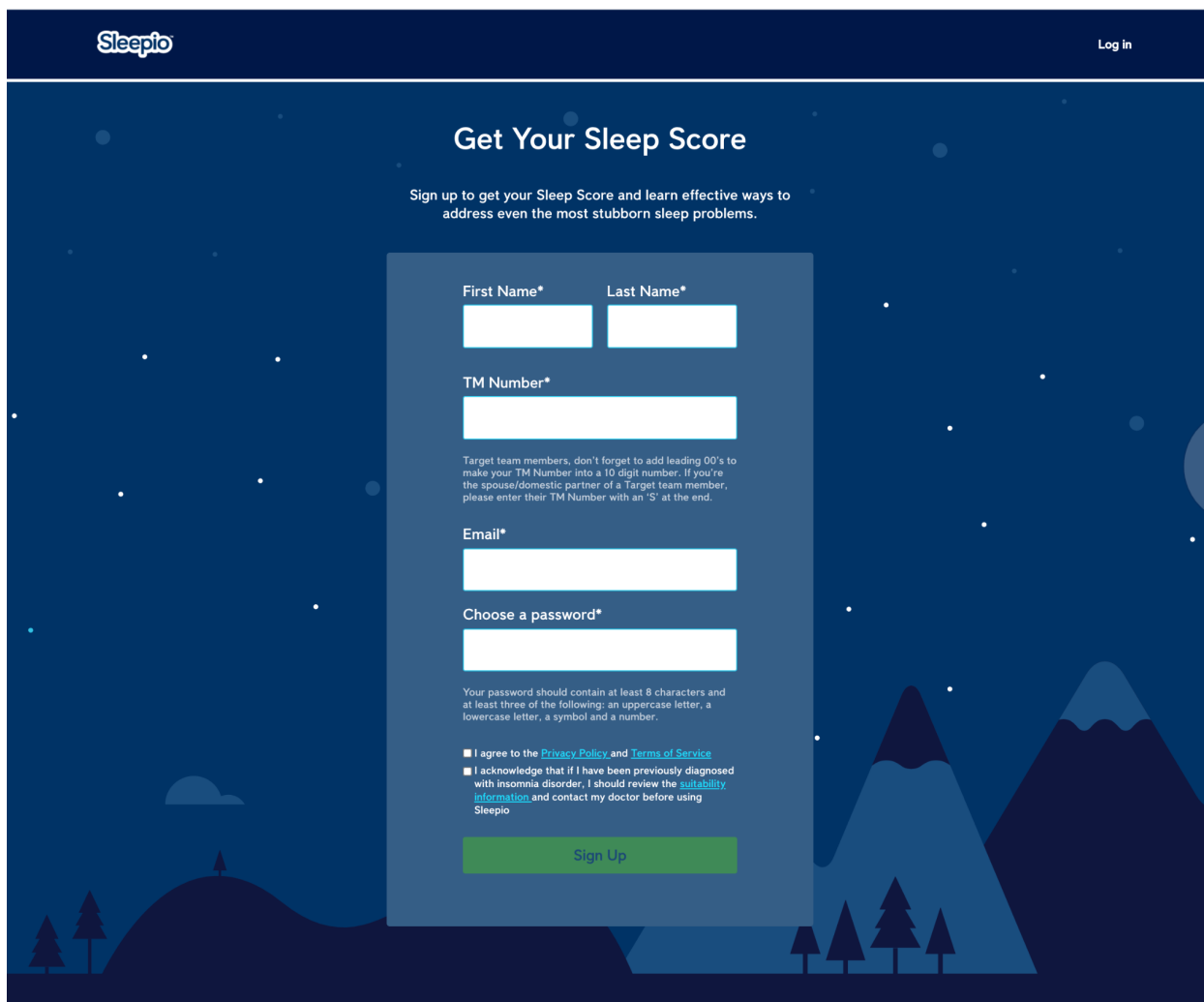


Sleep Restriction



Cognitive Tools

This is what you will see when you visit the link provided to you by your employer or healthcare provider.

The image shows the Sleepio website's sign-up page. The background is a dark blue night sky with stars and a mountain range silhouette. A central white form box contains the sign-up fields. At the top left is the Sleepio logo, and at the top right is a 'Log in' link. The main heading is 'Get Your Sleep Score'. Below it is a sub-heading: 'Sign up to get your Sleep Score and learn effective ways to address even the most stubborn sleep problems.' The form fields are: 'First Name*' and 'Last Name*' (two separate boxes), 'TM Number*' (one box), 'Email*' (one box), and 'Choose a password*' (one box). Below the password field is a note: 'Your password should contain at least 8 characters and at least three of the following: an uppercase letter, a lowercase letter, a symbol and a number.' There are two checkboxes: 'I agree to the [Privacy Policy](#) and [Terms of Service](#)' and 'I acknowledge that if I have been previously diagnosed with insomnia disorder, I should review the [safety](#) [information](#) and contact my doctor before using Sleepio'. At the bottom of the form is a green 'Sign Up' button.

Sleepio

Log in

Get Your Sleep Score

Sign up to get your Sleep Score and learn effective ways to address even the most stubborn sleep problems.

First Name* Last Name*

TM Number*

Target team members, don't forget to add leading 00's to make your TM Number into a 10 digit number. If you're the spouse/domestic partner of a Target team member, please enter their TM Number with an 'S' at the end.

Email*

Choose a password*

Your password should contain at least 8 characters and at least three of the following: an uppercase letter, a lowercase letter, a symbol and a number.

☐ I agree to the [Privacy Policy](#) and [Terms of Service](#)

☐ I acknowledge that if I have been previously diagnosed with insomnia disorder, I should review the [safety](#) [information](#) and contact my doctor before using Sleepio

Sign Up

After taking the Sleep Test you will be asked to sign up for an account.

You can secure your account by using the Multi-Factor Authentication (MFA) method following your first entry into Sleepio. To setup MFA, please navigate to Account > Settings from the Main Menu.

For more information on MFA and setup instructions, see the Multi-Factor Authentication Guide below.

Multi-Factor Authentication Guide

What is Multi-Factor Authentication (MFA)?

MFA is an authentication method that requires the user to provide two or more verification factors to gain access to a resource such as an application or an online account.

Why do I need MFA?

MFA protected services provide you with better security for your account by giving you more control over who can access it.

What options does Big Health support for MFA?

We support Authenticator apps such as Authy and Google Authenticator that pair with your account, then continually generate codes on a short timer which act as the needed verification key.

How do I enable MFA?

Before starting, be sure to download an authenticator app of your preference from the App Store or Google Play. Authy and Google Authenticator are popular choices.

1. Go to the “Account Settings” page in the Sleepio web or mobile application.
2. Turn on the “Multi-factor Authentication” toggle
3. Read the brief overview on the subsequent screen and then click “Continue”
4. Follow instructions on the next screen -
 - Open your Authenticator app
 - Add your Big Health account in the authenticator app
 - Pair your Big Health account with the authenticator app by:

- Option 1 (web and mobile apps): Copying and pasting the key provided by Sleepio into your authenticator app
 - Option 2 (web only): Scanning the QR code displayed on screen using your authenticator app
 - Click “Continue”
5. Once your Big Health account has been added to the authenticator app, copy the 6-digit verification code provided by the authenticator app to Sleepio.
 6. Click “Continue” to finish setting up MFA for your account.

What if I set up MFA and then happen to lose my phone or want to disable MFA?

Please email us for technical support at hello+mfa@bighealth.com.

Sleepio Program Sessions

Once you have completed the Sleepio onboarding questionnaire, you will be able to access Session 1 of the program. There are 6 sessions in the Sleepio program. Each session is available 7 days after the completion of the previous session. Please make sure you complete the whole session, or your next session may not unlock.

After completing each session, you will receive an email summary of that session. After completing Session 6, you may still access the Sleepio program and all the session content until account expiration.

Week 1 Identify the causes of your poor sleep and set goals for the program

Week 2 Learn to optimize your daytime for sleep

Week 3 Boost the connection between bed and sleep

Week 4 Learn a range of techniques that help clear the mind for sleep

Week 5 Grow your toolkit with final techniques tailored to what you need

Week 6 Assess your progress, revisit material, and pose any questions to our team of experts

You may replay sessions at any time. After completing Session 6, you can return any day to complete a check-in session where you can review your progress and adjust your sleep schedule until you achieve your optimal sleep window.

Accessing your session content

1. Accessing your session content

After completing your onboarding questionnaire, you will arrive at the landing page where you can tap the play button to begin watching Session 1. To access your sessions at any later point, visit app.sleepio.com and log in with your email and password. Once you are logged in, press on “Start Session” or choose to resume your session on the session tile.

You can also access Sleepio session content on a mobile device. Download Sleepio onto your mobile device, and login in with your email and password. From the main screen, select “Start Session” or “Resume Session” on the session tile to play your session content.

Once logged in, you can start an available session.

2. Pause and resume your session

You can pause your session at any time by pressing the “Pause” button or by exiting the Session. Resume the session by pressing the “Play” button or selecting “Start Session” or “Resume Session” from the session tile on the Sessions page.

3. Replay session content

You can replay previous session content by clicking on the session tiles.

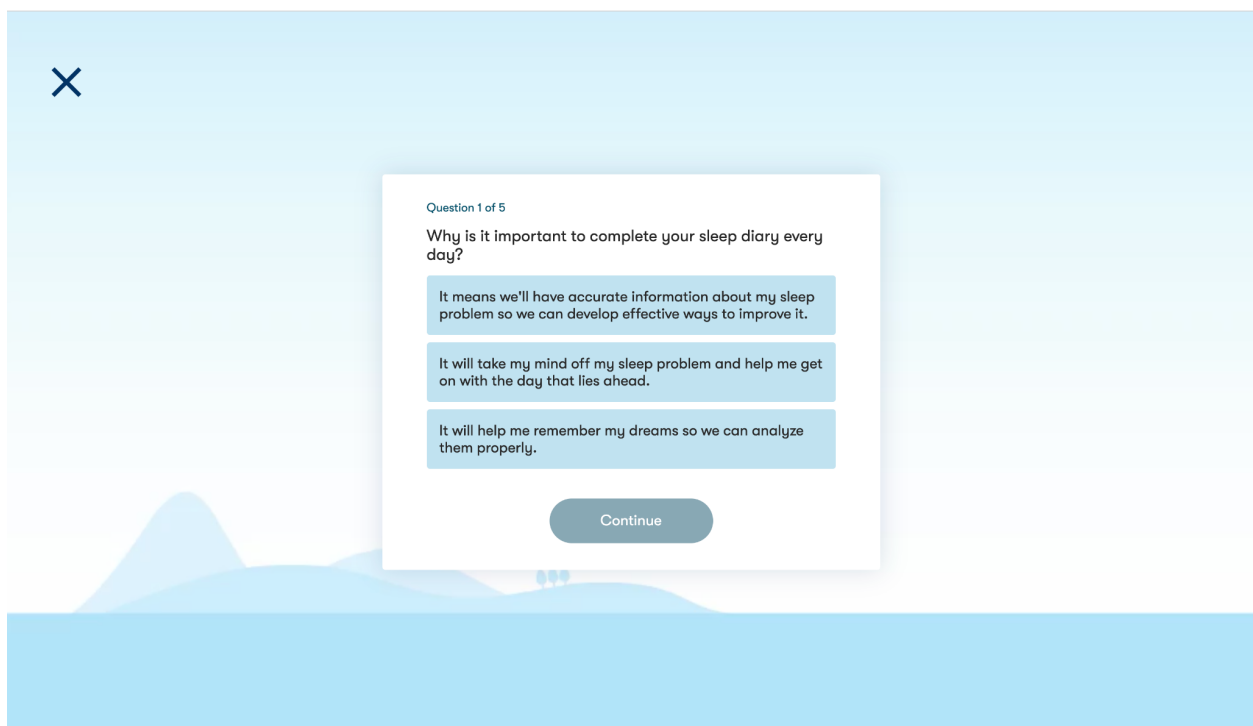
4. Structure of a Session

Each Sleepio session covers a number of topics and techniques for sleep improvement. The specific topics in each session are listed during the first few minutes of the session. At the end of the session there may be a quiz.

Throughout the session, you will be asked to engage with the content by answering questions and completing exercises. The more you engage with the content, the more you will get out of the program.

From Session 2, your session will begin with a summary of your progress, starting with how you slept based on your Sleep Diaries. Then, you will answer a few questions about your week to track your goals and overall progress. From Session 4, you will also receive feedback on how to adjust your sleep schedule.

As you complete each session, you will receive an email summary for that session and new content will be added to your Case File and to your Library.



Question 1 of 5

Why is it important to complete your sleep diary every day?

- It means we'll have accurate information about my sleep problem so we can develop effective ways to improve it.
- It will take my mind off my sleep problem and help me get on with the day that lies ahead.
- It will help me remember my dreams so we can analyze them properly.

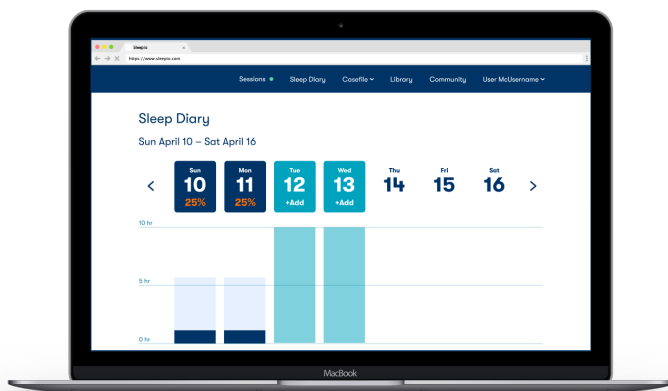
Continue

Sleep Diaries

You will be asked to keep a Sleep Diary throughout the duration of the program. They are used to track your progress, and determine your recommended sleep schedule in Session 3 and adjust your sleep schedule starting in Session 4.

Each Sleep Diary consists of 8 basic questions about your previous night's sleep, including when you went to bed, how long it took you to fall asleep, how many times you woke up, when you woke up, and how you rate your sleep quality.

You can log Sleep Diaries in Sleepio each day, or you can write them down using the provided print-out and add them at the beginning of each program. The Sleep Diary feature unlocks after you complete Session 1.

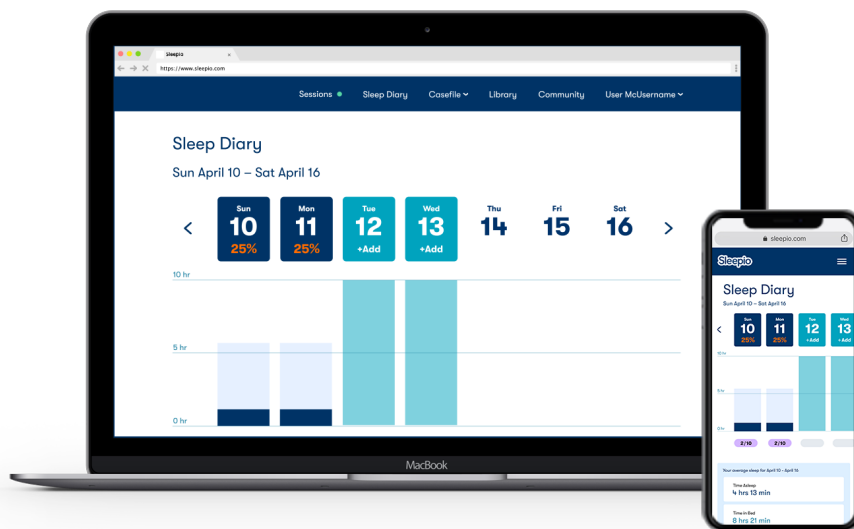


An important component of the program is the Sleep Diary, shown above.

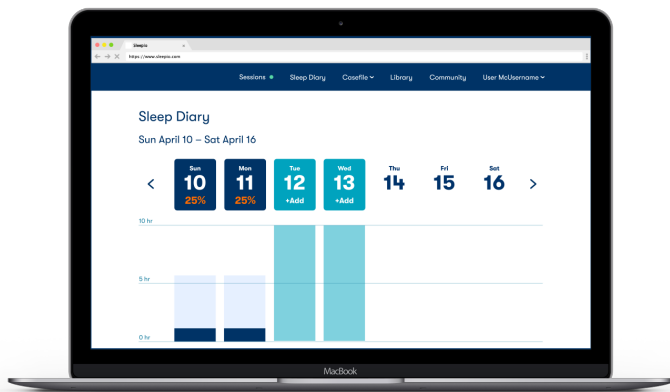
To add or edit a Sleep Diary on desktop, visit the Sleep Diary tab from the Sleepio program (<https://app.sleepio.com/sleepio/sleep-diary>). Choose the date you would like to add or edit. Answer all of the questions and press “Save”.

On mobile, open the Sleepio app and visit the Sleep Diary tab. Tap on the date you would like to add. Answer all of the questions and press “Save”. You can add or edit your diaries at any time.

If you have empty sleep diaries, you will have a chance to enter them when you start your next session. If you forget to keep diaries for that week, you will be asked to fill in missing entries or estimate your sleep diaries at the beginning of the session.



You can access your Sleep Diary on your desktop computer or mobile device.



You can add or edit your diary entries at any time.

Connecting devices to Sleep Diaries

If you regularly use a FitBit, you may also connect your Fitbit to Sleepio, this will help you automatically fill in sleep diaries on a daily basis. To connect your FitBit, go to the Accounts page in the Sleepio App, and select “Sync your Fitbit” to connect your Fitbit. Follow the steps as indicated by Fitbit. If you ever wish to disconnect your Fitbit, toggle the sync button.



Account settings

Account Status

Full course access expires on 28 July 2024.

Questions about your access? Ask us at hello@sleepio.com

Your Email

Janedoe@email.com

Want to disconnect your social login?
Let us know at hello@sleepio.com

Email Settings

Get updates on sessions, sleep diaries, and the community

☒

Sync your Fitbit

Import your sleep data into your Sleep Diary

☒

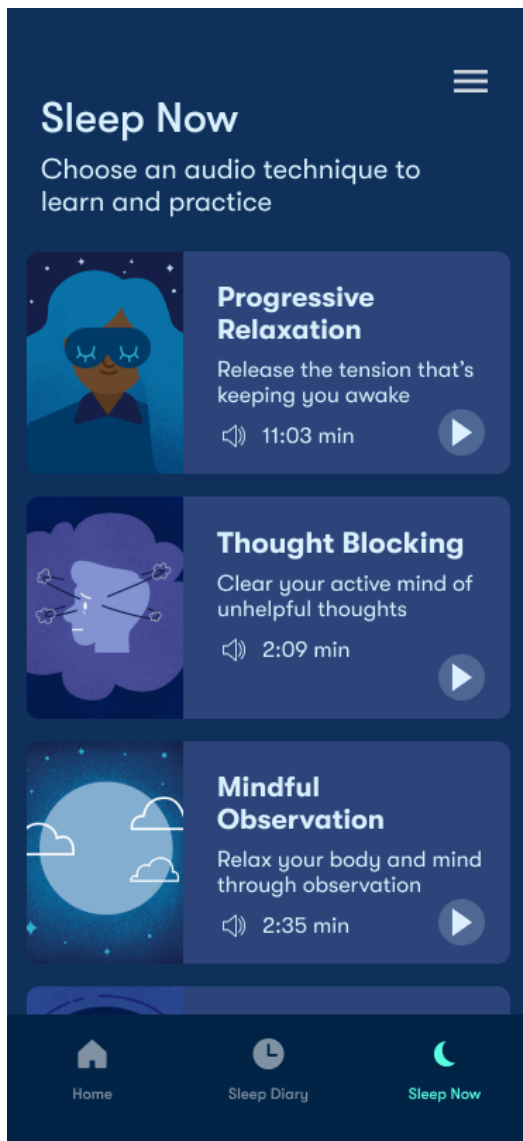
Multi-factor authentication

Add extra security to your account when you log in with multi-factor authentication.

☒

Sleep Now (iOS and Android devices Only)

On the mobile app, visit the Sleep Now tab to easily access an auditory guide for implementing cognitive techniques when you are experiencing difficulty sleeping in the moment. With this feature, you will be guided through implementation of the cognitive techniques learned in the Sleepio program.

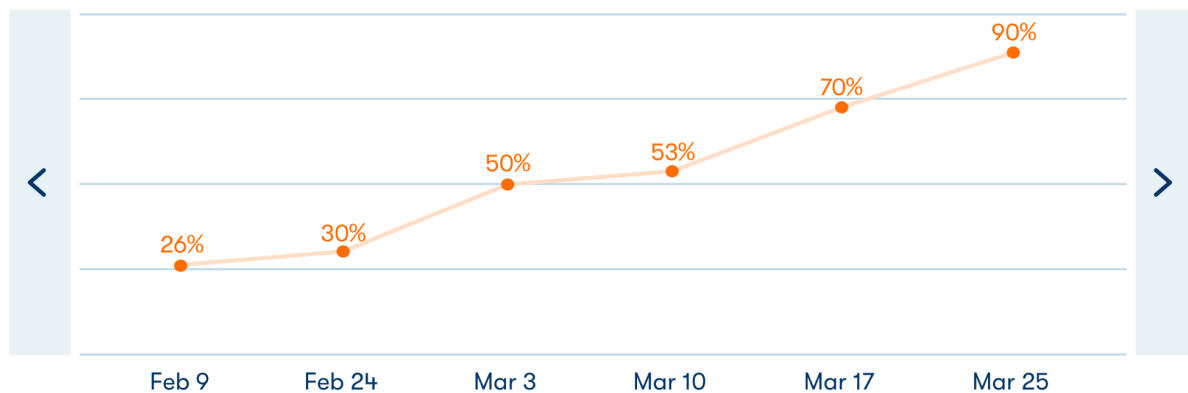


Case File & Library (Desktop Only)

Case File pages and the Library page contain tools and resources to support you during your program journey. When you start Sleepio, Case File pages will be quite sparse. As you complete Sleepio sessions, Case File pages will begin to populate based on your Sleepio program data. The Case File contains information about your progress, and various tools and techniques covered in the program. The Library lists a wide range of articles, resources, and additional reading organized by topic. Use the search box to find what you are looking for based on keywords.

Progress

Your Average Sleep Efficiency



Your Goal Progress Since Starting



Overall Goal

I want to have a more reliable sleep schedule



Daytime Goal

I want to improve my energy and ability to get through my work



Emotional Goal

I want to feel more relaxed and more confident

The Case File and Library pages contain tools and resources you can access as you progress through your journey

Library

Session 1

Session 2

Session 3

Session 4 & 5

Sleep basics

Technical help

Other Health Issues

Session 1

What causes poor sleep

Sleep's connection to mental and physical wellbeing

Stressful life events and sleep disturbance

The causes of persistent poor sleep: in depth

The Sleepio solution

Does CBT for poor sleep really work?

Putting Sleepio into action

The Sleepio solution: in depth

Setting goals

Why is it so important to set goals for the course?

Committing to the course

Sleepio Community (Desktop Only)

When you start Sleepio, you are asked to create a username to use for the program and for the Sleepio Community. To protect your anonymity and privacy, please do not use your real name or personal information in your Sleepio Community username.

Your participation in the Community is optional. You can access all Community discussion topics from the Community tab (<https://community.sleepio.com/>).

Using and Posting to the Community

Please review our Posting Policy (www.sleepio.com/postingpolicy/) before starting.

Search for relevant topics in the Community by typing keywords into the search bar.

To post to an existing discussion, navigate to the discussion forum, and select “Add a comment”.

To reply to a specific post, select “Reply” in the post you wish to reply to.



















To suggest a new discussion topic, from the Community home page (<https://community.sleepio.com/>), press “Start Thread.” Fill in the details for your proposed discussion topic. Your suggested topic will be reviewed by the Sleepio team and you will be notified once it has been reviewed.

Welcome to the Sleepio Community

[Start thread](#)

All My Posts New Unread Subscribed

Category

 Welcome to Sleepio! General Chat 87 replies	 AuntieHoho a month	☆ Disabled
 Sleepio First category 0 replies	 Peeps a month	☆ Disabled
 Sleep Efficiency - Time Spent in Bed Calculation First category 0 replies	 tablfe 2 months	☆ Disabled
 Painsomnia First category 0 replies	 SleepyJ31 2 months	☆ Disabled
 Using medication while doing the Sleepio course Sleep Aids 113 replies	 AuntieHoho 2 months	☆ Disabled
 What to do when you wake in the night General Chat 12 replies	 AuntieHoho 3 months	☆ Disabled
 Your experience at a sleep clinic General Chat 2 replies	 AuntieHoho 3 months	☆ Disabled
 Your thoughts on the Sleep Diary General Chat 72 replies	 Ellen 3 months	☆ Disabled
 ZEO sleep manager General Chat 14 replies	 Sleepio User 6 months	☆ Disabled

You can access all Community discussion topics from the Community tab

Getting Support to use Sleepio

If you have a question about how to use Sleepio, please email our support team at hello@sleepio.com. We are here to help!

Visit www.sleepio.com/faqs to read our frequently asked questions.

You can also access technical help articles from the Case File Library.

Compatible devices

You can access Sleepio through your web browser and on mobile & tablet devices that run iOS v13 or higher and Android versions v10 or higher. Supported web browsers include Chrome v115 or later, Safari v16 or later, and MS Edge v115 or later.

Sleepio supports import of sleep data through FitBit devices.

Sleepio mobile app has been tested on iPhone SE, iPhone 6s, iPhone 12 Pro Max, iPhone 12 mini, iPhone X, and on Android Samsung Galaxy S7, Motorola Moto G100, Samsung Galaxy S20 FE, Google pixel 6 PRO.

Supported Sleepio Versions

You can access Sleepio versions 2.18.0 or higher on listed compatible devices.

Clinical research

Sleepio Placebo-Controlled Pivotal Study

Study design

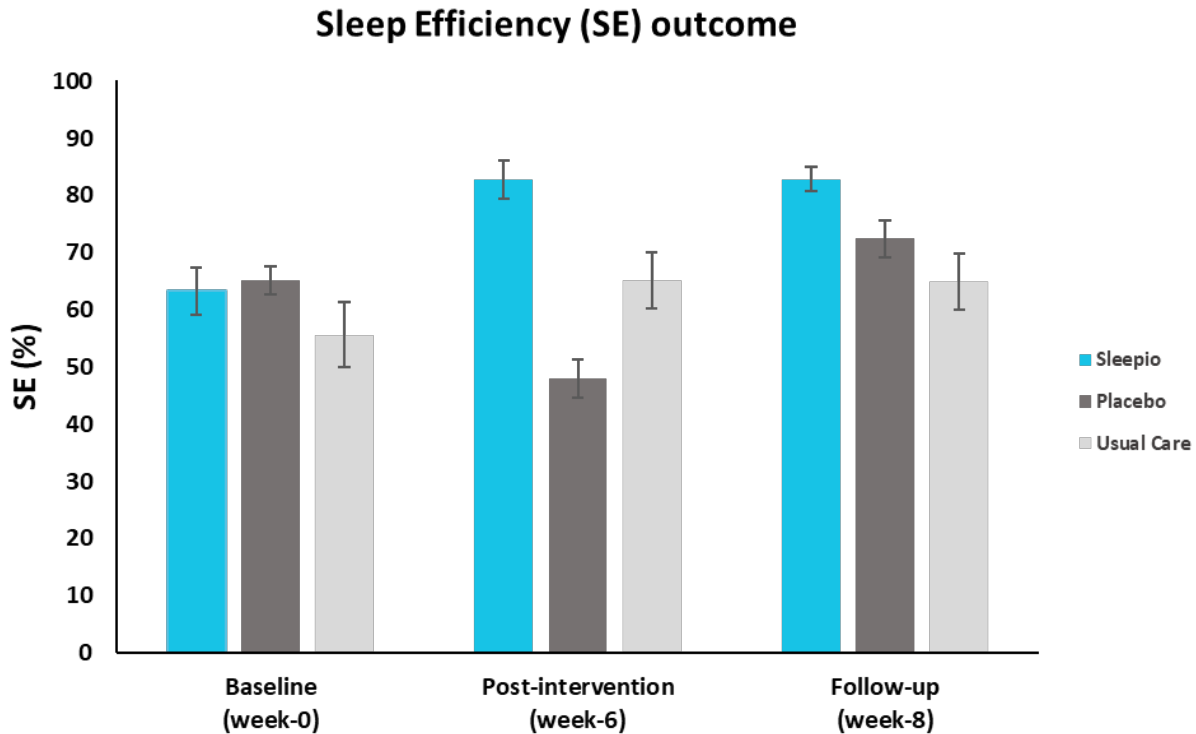
A randomized placebo-controlled trial comparing digital CBT (Sleepio) with placebo-control and usual care in 164 adults (18+) with DSM-5 insomnia disorder. Participants were randomized to receive Sleepio (n=55), placebo (n=55) or usual care (n=54).

Objectives

To examine change in sleep efficiency (the % of time spent in bed sleeping relative to the amount of time spent in bed; SE) from baseline (week-0) to post-intervention (Sleepio end; primary endpoint). This outcome was also assessed at follow-up (8-weeks after Sleepio end). Secondary outcomes included: sleep onset latency (SOL), wake after sleep onset (WASO), total wake time (TWT), total sleep time (TST), sleep quality, insomnia symptoms (Sleep Condition Indicator [SCI-8]) and mental health symptoms (Depression Anxiety Stress Scale [DASS-21]) and two questions assessing social functioning and daytime performance.

Results

At post-intervention, participants in the Sleepio group experienced a 19.5% increase in SE, compared to 5.7% for the placebo group and 6.4% for the usual care group. Sleepio was associated with significantly greater improvements in SE at post-intervention compared with placebo and usual care (CBT vs placebo: $d=1.06$; CBT vs usual care: $d=0.95$), which were maintained at follow-up (CBT vs placebo: $d=1.00$; CBT vs usual care: $d=0.69$). Significant reductions were observed in SOL ($p<0.001$) and WASO ($p<0.0001$) for Sleepio participants compared to placebo and usual care participants. Similarly, significant increases were observed in TWT ($p<0.0001$), TST ($p=0.026$) and sleep quality ($p=0.003$) for Sleepio, compared to placebo and usual care. Sleepio was associated with significant improvements in daytime and social functioning at post-intervention and follow-up compared to placebo ($d=-0.23$ to -0.37), and usual care ($d=-0.44$ to -0.85). Similarly, significant improvements in insomnia symptoms (SCI-8) were observed in participants receiving Sleepio compared to both placebo ($d=0.77$ to 0.95) and usual care ($d=1.11$ to 1.20) ($p<0.0001$). At post-intervention 76% of participants in the Sleepio group no longer had poor sleep (achieved SE $>80\%$)



which was significantly higher than both the placebo (29%) and usual care (18%) groups ($p < 0.001$). Sleepio demonstrated small improvements in mental health symptoms (DASS-21) compared to placebo ($d = -0.33$) at post-intervention and follow-up ($d = -0.28$).

Safety and Compliance

There were no adverse events reported by participants. Of those receiving Sleepio, 82% (43/55) completed the intervention, and 88% (47/55) completed ≥ 4 sessions.

Reference

Espie, C.A., Kyle, S.D, Williams, C., Ong, J.C., Douglas, N.J., Hames, P., Brown, J.S.L. (2012). A randomized, placebo-controlled, trial of online Cognitive Behavioral Therapy for chronic Insomnia Disorder delivered via an automated mediarch web application. *Sleep*, 35(6), 769-781.

DIALS-Sleepio Effectiveness Study

Study design

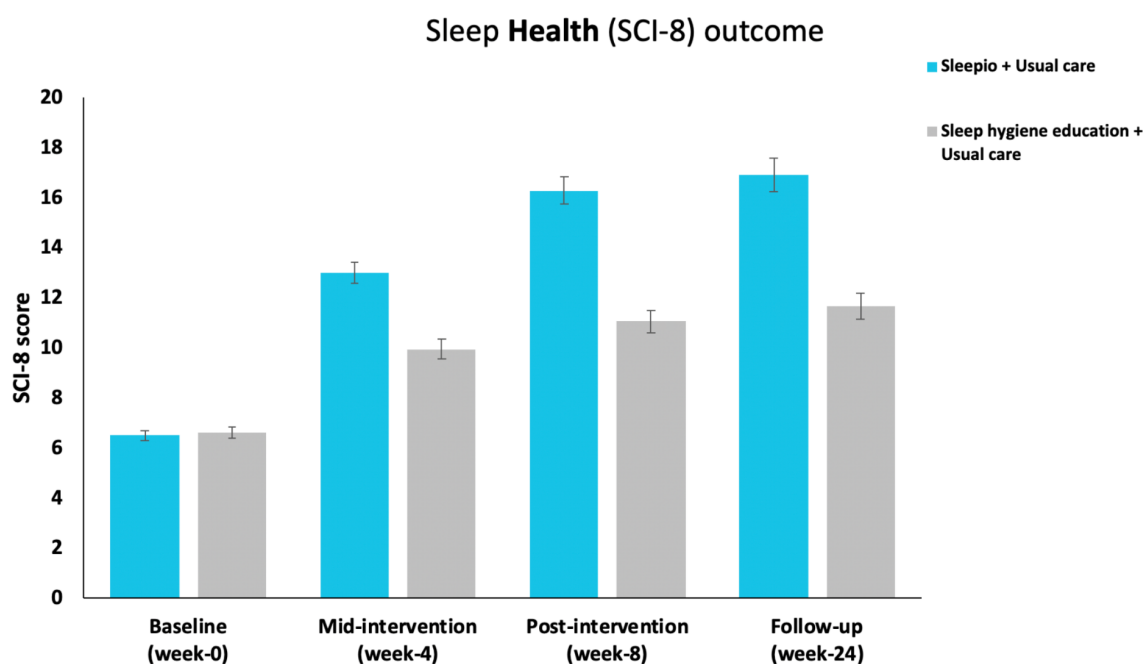
A randomized-controlled trial comparing digital CBT (Sleepio) with online sleep hygiene education in 1,711 adults (18+) with DSM-5 insomnia disorder. Participants were randomized to receive Sleepio (n=853) or sleep hygiene (n=858).

Objectives

To examine the effects of Sleepio on physical health (Patient Reported Outcomes Measurement Information System [PROMIS-10]), wellbeing (Warwick-Edinburgh Mental Wellbeing Scale [WEMWBS]) and sleep-related quality of life (Glasgow Sleep Impairment Index [GSII]) at post-intervention (week-12) (primary endpoints). Secondary outcomes were insomnia symptoms (SCI-8), depressive symptoms (9-item Patient Health Questionnaire [PHQ-9]), anxiety symptoms (7-item Generalized Anxiety Disorder scale [GAD-7]), fatigue (Flinders Fatigue Scale [FFS]), relationship satisfaction (RAS), cognitive functioning (Cognitive Failures Questionnaire [CFQ]), work performance and satisfaction (Work Productivity and Activity Impairment Index [WPAI] and 1 item on job satisfaction) and sleepiness (Epworth Sleepiness Scale [ESS]). A single item relating to life satisfaction was included as an exploratory measure. Analyses also examined whether improvements in insomnia symptoms explained improvements in primary outcomes.

Results

Compared to sleep hygiene, Sleepio significantly improved physical health (PROMIS-10) at post-intervention ($d=0.31$, $p<0.001$) and follow-up ($d=0.31$, $p<0.001$). Significant improvements were also observed in wellbeing (WEMWBS) for Sleepio compared to sleep hygiene at post-intervention ($d=0.35$, $p<0.001$) and follow-up ($d=0.38$, $p<0.001$). Sleepio led to significant reductions in the negative impact of sleep on quality of life (GSII) on participants' highest ranked complaint compared to sleep hygiene at post-intervention ($d=-1.38$, $p<0.001$) and follow-up ($d=-1.46$, $p<0.001$). Sleepio also significantly improved insomnia symptoms (SCI), depressive symptoms (PHQ-9), anxiety symptoms (GAD-7), sleepiness (ESS), fatigue (FFS), cognitive functioning (CFQ), life satisfaction and presenteeism compared to sleep hygiene at post-intervention and follow-up. There were no significant improvements in relationship functioning in the Sleepio group compared to sleep hygiene. Significant improvements in absenteeism and job satisfaction were observed at followup. Improvements in insomnia symptoms significantly explained improvements in primary outcomes.



Results from the DIALS-Sleepio Effectiveness Study

Safety and Compliance, Reference

Safety and Compliance

One serious adverse event was reported during the trial which was unrelated to Sleepio. Participants in the Sleepio group reported a significantly higher occurrence of unwanted symptoms than the sleep hygiene group including: headaches and/or migraine (18.8%), fatigue and/or exhaustion (46.3%), extreme sleepiness (30.8%), difficulty with attention and concentration (33.2%), reduced motivation and/or energy (32.8%) and irritability (28.2%).

Reference

Espie, C.A. Emsley, R., Kyle, S.D., Gordon, C., Drake, C.L., Siriwardena, A.N., Cape, J., Ong, J.C., Sheaves, B., Foster, R., Freeman, D., Costa-Font, J., Marsden, A., & Luik, A.I. (2019). Effect of Digital Cognitive Behavioral Therapy for Insomnia on Health, Psychological Well-being, and Sleep-Related Quality of Life: A Randomized Clinical Trial. *JAMA Psychiatry*, 76(1), 21-30.

Additional Studies

OASIS - Freeman et al., 2017

A randomized-controlled trial comparing digital CBT (Sleepio) with usual care in 3,755 young adults with insomnia. Participants were randomized to receive Sleepio (n=1,891) or usual care (n=1,864). Sleepio led to large and significant improvements in insomnia symptoms (SCI-8) at post-intervention (d=1.11, p<0.0001) and follow-up (d=1.12, p<0.0001). Improvements in insomnia symptoms at mid-intervention (week-3) explained 30% and 39% of Sleepio's effect on paranoia and hallucination at 10-weeks post-intervention respectively.

SPREAD - Cheng et al., 2018

A randomized-controlled trial comparing digital CBT (Sleepio) with sleep hygiene education in adults with insomnia disorder. Participants were randomized to receive Sleepio (n=358) or online sleep hygiene education (n=300). Sleepio led to significantly greater reductions in insomnia severity (ISI) at post-intervention than sleep hygiene education (p<0.001). At post-intervention, significantly more participants in the Sleepio group experienced a clinically significant intervention response (reduction in ISI score by ≥ 8) (65.1% vs 22.3%; p<0.0001) and remission (53.9% vs 14%) (ISI score ≤ 7) than the sleep education group (both p<0.0001).

DISCO - Kyle et al., 2019

A randomized-controlled trial comparing digital CBT (Sleepio) with waitlist control in 410 middle-aged adults who met DSM-5 criteria for insomnia disorder and had self-reported difficulties with concentration or memory. Participants were randomized to receive Sleepio (n=205) or waitlist control (n=205). Compared to control participants, Sleepio participants experienced large and significant improvements to insomnia severity (ISI) at post-intervention (d=-1.57) and follow-up (d=-1.6) (both p<0.0001); and sleep efficiency (PSQI) at post-intervention (d=0.91) and follow-up (d=0.72) (both p<0.0001).

Bostock et al., 2016

A randomized-controlled trial comparing digital CBT (Sleepio) with waitlist control in 270 adults who self-identified as poor sleepers. Participants were randomized to receive Sleepio (n=135) or waitlist control (n=135). Sleepio led to significant improvements in insomnia symptoms (SCI-8) compared to control (p<0.001) with a larger within-group effect for Sleepio (d=1.10) compared to control (d=0.34). Significant reductions were observed in daytime sleepiness (ESS) for Sleepio compared to control (p=0.43). Sleepio participants' sleep efficiency increased from 76% to 87% across the 6 weeks of Sleepio access.

SLEPT - McGrath et al., 2017

A randomized controlled trial comparing digital CBT (Sleepio) with usual care in 134 adults with self-reported sleep difficulties and a blood pressure of 130-160/<110mmHg. Participants were randomized to Sleepio (n=67) or usual care (n=67). Participants receiving Sleepio had significantly greater mean improvement in sleep quality (PSQI) ($p=0.04$); insomnia severity (ISI) ($p<0.001$), insomnia symptoms (SCI-8) ($p=0.01$), sleep efficiency (SE) ($p=0.02$) and WASO ($p=0.06$) at post-intervention than those receiving usual care. Improvements in sleep were greatest in those who completed 3 or more sessions of Sleepio ($p<0.001$). No significant differences were observed in TST or SOL between Sleepio and usual care.

Barnes et al., 2017

A randomized-controlled trial comparing digital CBT (Sleepio) with waitlist control in 223 adults who self-identified as poor sleepers. Participants were randomized to receive Sleepio (n=117) or to waitlist control (n=106). Sleepio significantly improved insomnia symptoms (SCI-8) compared to control ($p<0.001$). Participants using Sleepio experienced a 20% increase in total sleep time; a 38% reduction in wake after sleep onset; and a 26% improvement in sleep efficiency. Similar changes in sleep were also observed in the wait-list group after receiving Sleepio.

Pillai et al., 2015

A randomized controlled trial in adults with DSM-5 insomnia disorder. 22 adults with DSM-5 insomnia disorder were randomly assigned to Sleepio (n=13) or information control (n=9). Sleepio participants had a significantly greater decrease in insomnia severity (ISI) from baseline to post-intervention than the control group ($p<0.05$) with a large effect size ($d=0.9$). Similarly, significantly greater decreases were observed in SOL for Sleepio participants compared to control participants ($p<0.05$). No significant differences were observed in TST and sleepiness (ESS) between Sleepio and control.

REST - Felder et al., 2020

A randomized-controlled trial comparing digital CBT (Sleepio) with usual care in 208 pregnant women (up to 28 weeks gestation) who met DSM-5 criteria for insomnia disorder. Participants were randomized to receive Sleepio (n=105) or to usual care (n=103). Participants receiving Sleepio experienced significantly greater reductions in insomnia severity (ISI) from baseline to post-intervention than those in the usual care group ($p<0.001$) with a large effect ($d=-1.03$). Significantly more participants in the Sleepio group experienced insomnia remission ($ISI\leq 7$) at post-intervention (week-10) than in the usual care group ($p=0.002$). Sleepio participants had significantly greater improvements in SE ($d=-0.51$; $p=0.001$) and sleep quality ($d=1.04$; $p<0.001$) than usual care participants. Significant reductions in insomnia caseness were observed in the Sleepio group compared to usual care. Results were consistent at follow-up.

Kalmbach et al., 2020

A randomized-controlled trial comparing digital CBT (Sleepio) with sleep hygiene education in 91 pregnant women in their third trimester who had clinical insomnia (ISI). Participants were randomized to receive Sleepio (n=46) or to sleep hygiene education (n=45). Insomnia severity (ISI) significantly improved in the Sleepio group ($p<0.001$; $d=0.86$), but not the sleep hygiene education group. Significantly more participants in the Sleepio group experienced a treatment response on the ISI (≤ 6) than in the sleep hygiene education group (37.0% vs 13.3%, $p=0.01$). Insomnia remission was not significantly different between Sleepio and sleep hygiene education at post-intervention. Sleepio led to significantly lower sleep disturbance (PSQI) ($p=0.002$) than sleep hygiene education. Significantly more participants in the Sleepio group were classified as good sleepers at post-intervention (44.2%) than the sleep hygiene education group (15.0%; $p=0.007$). Sleepio led to a 32 minute increase in total sleep time from baseline to post-intervention ($p=0.008$), whereas no significant change was observed in the sleep hygiene education group. At post-intervention, those in the Sleepio group experienced significantly increased sleep duration by 55 minutes compared to controls ($p=0.01$). Six-weeks after birth, participants receiving Sleepio slept 40 minutes longer per night than participants in the sleep hygiene education group ($p=0.01$), however, for Sleepio participants, this was not significantly different to baseline. Sleep disturbance (PSQI) and insomnia severity did not differ between groups at 6-weeks after birth.




STOP - Denis et al., 2020

A randomized-controlled trial comparing digital CBT (Sleepio) with an attention puzzle-based control in 199 young adult women, not specifically selected for insomnia disorder. Individuals were randomized to receive Sleepio (n=99) or to problem solving control (n=100). Significant improvements were observed in insomnia symptoms (SCI-8) for Sleepio compared to control ($p=0.013$; $d=0.42$). A similar between-group effect was found when only including individuals that did not meet criteria for insomnia at baseline ($p=0.015$; $d=0.51$). A smaller between-group effect was found for those that did meet criteria for insomnia at baseline ($p=0.497$; $d=0.21$). There were no significant differences in change in insomnia symptoms for participants who met insomnia criteria at baseline and those who did not ($p=0.087$; $d=0.44$) in the Sleepio group. There was a significant reduction in the percentage of participants in the Sleepio group meeting criteria for insomnia at post-intervention (17%) compared to baseline (36%; $p=0.013$).

Anxiety and Mood Across Studies

The effects of Sleepio on mood and anxiety have been examined across 11 RCTs. Results demonstrate significant improvements in mood, with between-group effect sizes ranging from $d=0.38$ to 0.68 , and significant improvements in anxiety, with between-group effect sizes ranging from $d=0.25$ to 0.80 .

Symbols Glossary

	Caution, be aware of safety information to order to avoid undesirable consequences
	Read Instructions for Use
	Manufacturer

Big Health



Manufacturer

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