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A randomized controlled trial of a digital cognitive behavioral therapy for insomnia for older adults

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Older adults with insomnia face considerable challenges accessing treatment given limited availability to first-line therapy (Cognitive-Behavioral Therapy for Insomnia, CBT-I). This study evaluated the efficacy of Sleep Healthy Using the Internet for Older Adults Suffering with Insomnia and Sleeplessness (SHUTi OASIS), a tailored CBT-I internet intervention for older adults with insomnia, in a 3-arm randomized controlled trial (SHUTi OASIS alone, SHUTi OASIS + stepped support, online patient education [PE]). 311 participants (ages 55–95) were randomized to receive SHUTi OASIS (alone $n = 105$; with stepped support $n = 102$), with both conditions reporting significant improvements across post, 6-month, and 12-month follow-ups in insomnia severity compared to those receiving PE ($n = 104$). Clinically meaningful indices of insomnia response and remission were also higher among those receiving SHUTi OASIS. Those who received SHUTi OASIS also significantly outperformed those receiving PE on secondary outcomes, including sleep onset latency, wake after sleep onset, sleep efficiency, number of awakenings, sleep quality, and fatigue, across most timepoints. Results indicate that digital CBT-I provides important benefits for older adults, offering strong potential to expand access to insomnia treatment for this underserved population.

Insomnia affects older adults more than any other age group, with prevalence rates of 20%–30%[1,2]. Although diagnostic criteria for insomnia indicate symptoms must be present for at least three months[3,4], the course of chronic insomnia is typically measured in years or even decades[5]. The clinical and health care burden of chronic insomnia is significant. Compared to age-matched controls, older adults with insomnia exhibit more cognitive impairments[6,7]. They are also more likely to experience co-occurring psychiatric symptoms, including depression[8,9]. In addition, sleep problems in older adults are associated with other health issues, such as increased risk for falls, even after controlling for medication use[10]. Direct and indirect costs of chronic insomnia include higher health care resource utilization, higher mortality, and health care costs[11], resulting in healthcare expenses as high as $100 billion annually[12].

Cognitive-Behavioral Therapy for Insomnia (CBT-I) is a guideline-endorsed, first-line treatment for individuals with insomnia[13]. CBT-I is strongly recommended by the American Academy of Sleep Medicine (AASM)[14] and is the insomnia treatment of choice for those with comorbid medical and psychological conditions[13,14]. Meta-analyses support CBT-I as efficacious and safe, with long-lasting effects in older adults[13]. As a behavioral rather than pharmacological approach to treatment, it is preferred for older adults, as sedative-hypnotic medications in older patients have limited benefits and higher rates of adverse events[15]. In fact, guidelines caution against sleep medication use in older adults[16]. Unfortunately, a small number of appropriate specialists[17,18] and restrictions in reimbursement[19] limit the accessibility of CBT-I.

Digital therapeutics may fill the gap between treatment need and accessibility. Internet-delivered interventions take advantage of technology and are typically based on effective, behaviorally based in-person treatments that are operationalized and transformed for digital delivery[20]. They have been shown to be feasible and effective in a range of conditions for older adults[21,22]; however, to our knowledge, this is the first trial of an internet-delivered intervention for older adults with insomnia.

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To address the unmet need for an accessible, first-line treatment for insomnia for older adults, this study investigated whether older adults could benefit from a digital therapeutic for chronic insomnia. Specifically, we hypothesize that the internet intervention for insomnia called SHUTi OASIS (Sleep Healthy Using the Internet—Older Adults Suffering with Insomnia and Sleeplessness), both with and without a stepped support (SS) protocol, will be more effective than online Patient Education (PE) in reducing overall insomnia severity. We expect similar findings with the sleep diary metrics of wake after sleep onset (WASO) and sleep onset latency (SOL), as well as other sleep, medication, and usage outcomes.

Results

Participants were recruited from May 2018 to April 2019, with 1487 individuals completing the online interest form. Of these, 311 were randomized (see Fig. 1 for CONSORT chart). Participants came from 38 different states across the US and the District of Columbia.

Of the total sample, the average age was approximately 66 (range: 55–95), with 31% ($n = 95$) over the age of 70 (see Table 1 for baseline characteristics). Most participants were female (68.5%), white (91.0%), and had obtained at least a college degree (74.9%). On average, participants reported experiencing chronic insomnia (duration median = 10 years), with difficulties falling asleep and staying asleep occurring most nights (median = 3 and 6 nights/week, respectively). Additionally, most (82.0%) reported feeling "very comfortable" using the Internet.

Primary outcome

Participants in both SHUTi OASIS conditions showed significant, large improvements in ISI from baseline to each follow-up time point (ds = −1.04, −1.24, −1.29 for SHUTi OASIS only at post, 6-months, and 12-months, respectively; −1.35, −1.43, −1.41 for SHUTi OASIS + SS, respectively; see Fig. 2). Comparatively, PE participants showed small to medium improvements in ISI from baseline to each follow-up time point (ds = −0.28, −0.50, −0.67, respectively). The overall 3-group by 4-time interaction for ISI was significant ($F_{6,773} = 15.70$, $p < 0.001$). Post-hoc analyses examining the fixed effects for interactions showed that those who received SHUTi OASIS (with and without stepped support) had significantly lower ISI scores than those who received PE at each time point (ps < 0.001), confirming the primary study hypothesis.

Meaningful group differences on treatment response (defined by an ISI reduction of >7 points from baseline[23]) and insomnia remission (ISI score of <8[23]) were also found. Participants in both SHUTi OASIS conditions had multiple-fold higher response and remission rates at all time points compared to PE (see Table 2).

Secondary outcomes

The overall group by time interactions of the collapsed SHUTi OASIS and PE conditions were significant for several of the secondary outcomes as well, specifically: SOL ($F_{3,774} = 6.15$, $p < 0.001$), WASO ($F_{3,778} = 11.13$, $p < 0.001$), sleep efficiency ($F_{3,775} = 11.52$, $p < 0.001$), number of awakenings ($F_{3,770} = 4.83$, $p = 0.002$), sleep quality ($F_{3,778} = 10.87$, $p < 0.001$), and fatigue ($F_{3,776} = 12.26$, $p < 0.001$), with those receiving SHUTi OASIS experiencing significantly improved sleep outcomes compared to those receiving PE. In post-hoc analyses examining the fixed effects for interactions at each time point (see Table 3), those receiving SHUTi OASIS significantly outperformed those receiving PE in all comparisons (ps < .001) for WASO, sleep efficiency, number of awakenings, sleep quality, and fatigue. For SOL, SHUTi OASIS outperformed PE at post and 6-months (ps < 0.001), but not at 12-months ($p = 0.01$). Effect sizes were similar to those of the primary variables. While there was an overall main effect of time for increased total sleep time ($F_{3,772} = 18.95$, $p < 0.001$), there was no significant interaction effect for the difference between conditions across time ($F_{3,772} = 0.82$, $p = 0.48$). There was no significant interaction effect for the difference between conditions across time for attention and concentration ($F_{3,767} = 0.70$, $p = 0.55$).

Sleep medication use

A significant group by time interaction was found for the percentage of nights participants reported using any pharmacologic sleep aid ($F_{3766} = 4.08$, $p = 0.01$). SHUTi OASIS participants reported a greater decline in percentage of medicated nights across time points relative to PE. A similar pattern emerged when evaluating the proportion of participants who reported taking a sleep aid at least one night during the 10-day sleep diary assessment window. See Fig. 3 for detailed data.

Utilization and adherence

During the 9-week intervention period, SHUTi OASIS participants logged in between 0 and 111 times (median = 48) and submitted between 0 and 63 sleep diaries (median = 52). During that same time period, 63% ($n = 131$) completed all six SHUTi Cores (see Fig. 1 CONSORT table for details on intervention-period Core completion). Notably, an additional 41 individuals completed through Core 6 after the 9-week intervention period, resulting in a total of 83% of participants ($n = 172$) who ultimately finished the entire SHUTi OASIS program.

PE participants logged in between 0 and 21 (median = 1) times during the same 9-week intervention period. Regarding program completion, 88% ($n = 91$) completed PE, 10% ($n = 10$) initiated but did not complete PE, and 3% ($n = 3$) never initiated the program.

For participants who received SHUTi OASIS and completed at least four of the six Cores within the 9-week intervention period (82%, $n = 169$), which included the fundamental instruction on sleep restriction, stimulus control, and cognitive therapy components of CBT-I and considered a sufficient dose of the intervention based on previous data[24], the estimated marginal mean (EMM) ISI score at post was 9.62 (95% confidence interval [CI] = 8.83–10.40) compared to 12.48 (95% CI = 10.44–14.50) for those who completed fewer than four Cores (group difference $p = 0.01$). However, over the follow-up period, the difference in ISI EMM scores diminished: At 6-month and 12-month follow-ups, those who completed at least four Cores had ISI EMMs of 8.90 (95% CI = 8.09–9.72) and 8.81 (95% CI = 7.98–9.64), respectively, while those who completed fewer than four Cores had an ISI EMM of 10.20 (95% CI = 7.94–12.48) and 9.94 (95% CI = 7.59–12.60), respectively (group difference ps > .29).

Discussion

This is the first trial to demonstrate the efficacy and usability of a fully automated, Internet-delivered CBT-I intervention for older adults. These findings are consistent with a systematic review conducted by the AASM task force, which endorses CBT-I as the first-line treatment for chronic insomnia[14,25], as well as meta-analyses reviewing CBT-I studies exclusively with older adults[26] and meta-analyses of digital CBT-I[27,28].

Consistent with the primary study hypothesis, participants in both SHUTi OASIS conditions experienced significantly greater reductions in insomnia severity compared to those receiving online PE. At 12-month follow up, ~2–3 times more older adults exhibited a meaningful treatment response and insomnia remission when they were randomized to SHUTi OASIS versus PE. The differences between the treatment groups' 1-year response and remission rates, compared to the PE group, well exceed the 10 percentage-point threshold establishing clinically meaningful differences[25]. These 1-year follow-up data fill a notable gap in the existing CBT-I intervention literature about the long-term benefits of CBT-I for older adults.

SHUTi OASIS participants from both treatment groups also showed greater improvements than PE participants on most of the secondary outcomes (SOL, WASO, sleep efficiency, number of awakenings, sleep quality, and fatigue). For total sleep time (TST), however, participants across conditions reported significantly more TST from baseline to each follow-up time point, gaining about 24–46 min on average. Increasing TST is not necessarily a goal of CBT-I; rather, improved sleep that is more restful, of higher quality, and better consolidated is the target. These elements are all meaningfully addressed by SHUTi OASIS with the significant improvements observed in number of awakenings, sleep quality, and sleep efficiency. Still, the finding that both SHUTi OASIS and PE improved TST is

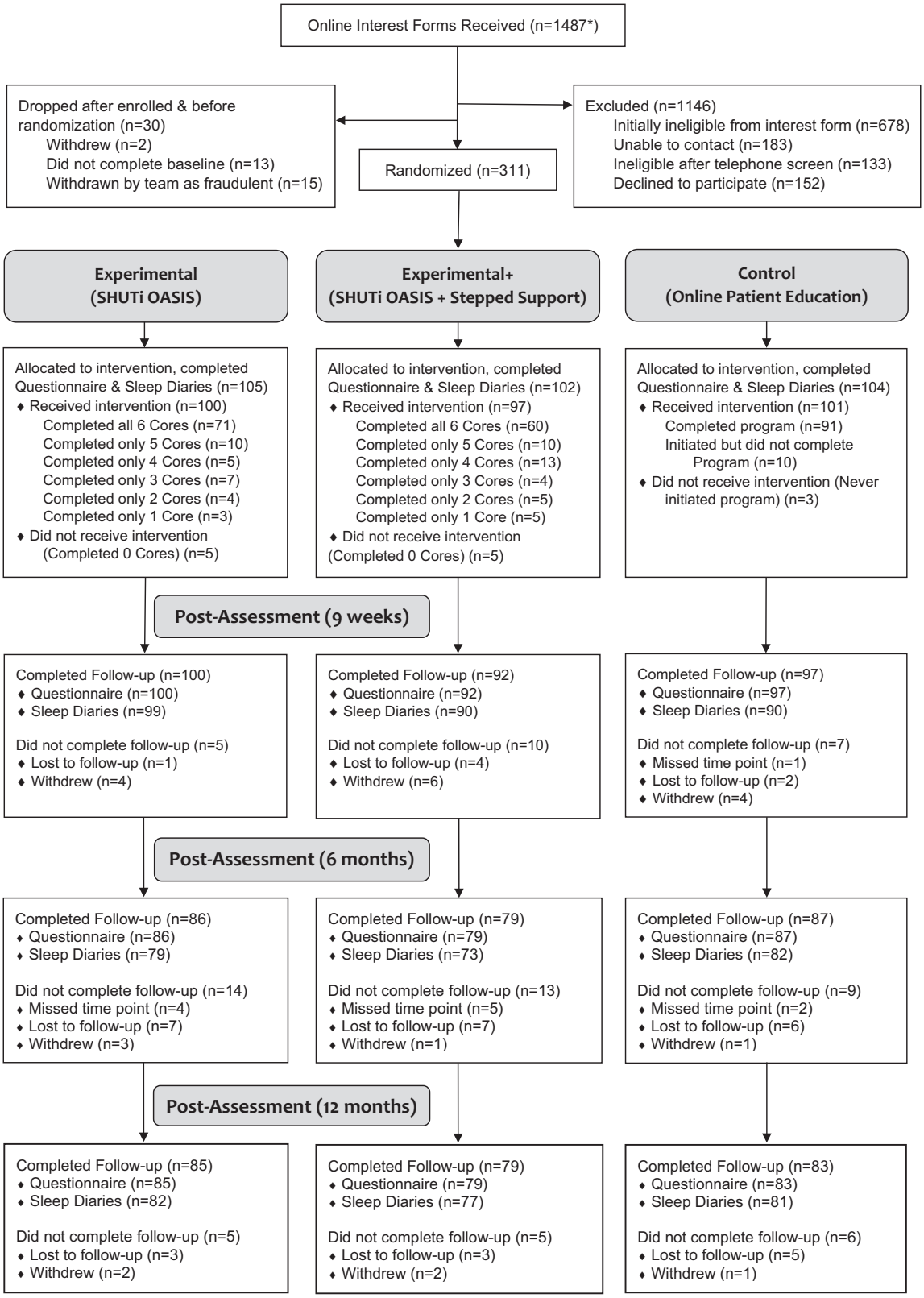

Fig. 1 | SHUTi OASIS Trial CONSORT Chart. *Note: Number of interest forms received (1487) does not include 281 forms received after recruitment was closed, which were included in Glazer et al. (2020).

noteworthy given that studies of CBT-I typically show little change on TST in older adults and only a small to medium effect for younger adults[29].

In addition to TST, the PE group did experience improvements in other sleep metrics. Given similar findings from other CBT-I trials[30–32], this was not surprising. Sleep education has been shown to be nominally helpful to individuals with insomnia[33]. For this trial, a PE control condition, however, was considered a useful comparison as it provided content that could readily be found with simple searches online, something that is likely already

Table 1 | Baseline characteristics

Participant characteristics	SHUTi OASIS only (*n* =105)	SHUTi OASIS+SS (*n* =102)	Patient education (*n* = 104)	Total (*n* = 311)
Age, years, mean (SD)	66.5 (7.7)	66.3 (7.9)	66.2 (5.9)	66.3 (7.2)
Female, # (%)	74 (70.5%)	61 (59.8%)	78 (75.0%)	213 (68.5%)
Race, # (%)				
White	93 (88.6%)	96 (94.1%)	94 (90.4%)	283 (91.0%)
Black	9 (8.6%)	1 (1.0%)	4 (3.8%)	14 (4.5%)
Asian	2 (1.9%)	4 (3.9%)	3 (2.9%)	9 (2.9%)
Other	1 (1.0%)	1 (1.0%)	3 (2.9%)	5 (1.6%)
Hispanic, # (%)	2 (1.9%)	0 (0%)	3 (2.9%)	5 (1.6%)
College degree or higher, # (%)[a]	82 (78.1%)	70 (68.6%)	81 (77.9%)	233 (74.9%)
Employed, # (%)	51 (48.6%)	46 (45.1%)	49 (47.1%)	146 (46.9%)
Married/partnered, # (%)	72 (68.6%)	70 (68.6%)	70 (67.3%)	212 (68.2%)
Years of sleep problems, median (IQR)	10 (5–20)	10 (5–19.5)	9.5 (3.75–20)	10 (5–20)
Nights per week with difficulty falling asleep, median (IQR)	3 (1–7)	3 (1–6)	3.5 (1–6)	3 (1–6)
Nights per week with difficulty staying asleep, median (IQR)	6 (3–7)	6 (4–7)	6 (4–7)	6 (4–7)
Very comfortable with internet, # (%)	86 (81.9%)	86 (81.9%)	83 (79.8%)	255 (82.0%)

[a]One participant in the Patient Education condition and one participant in the SHUTi OASIS+SS condition did not report.

being done by those interested in participating in an insomnia trial. A PE website, as a control condition, provides a typical approach to what an individual might consume when seeking treatment information, and while it might have some limited impact, it falls far short of what can be obtained from a CBT-I intervention.

Older adults who used SHUTi OASIS also experienced a significant reduction in nights using sleep medication compared to those in the PE group. Although the literature on the impact of CBT-I on medication usage is limited, existing literature supports a small reduction in medicated nights or dosage, observed in both face-to-face and digital CBT-I trials[34,35]. Knowing the concerns with pharmacotherapy in older adults with insomnia, this is a valuable intervention benefit. This finding is also notable given that SHUTi does not include medication tapering instructions. Future trials may investigate whether adding a tapering program to digital CBT-I results in even greater medication reduction than CBT-I alone.

The completion rates of SHUTi OASIS were similar to those in previous studies of SHUTi[30–32,36]. Engagement with SHUTi OASIS was of particular interest in this study, given existing doubts about older adults' ability to use and benefit from digital health interventions[37]. This finding provides a strong argument for older adults being able to independently use and complete fully-automated digital health interventions and obtain clinically significant and meaningful gains in doing so. The notion that older adults require human support to effectively use digital health programs is not substantiated by the findings of this study.

The study boasts several notable strengths, particularly the long-term follow-up period with older adults, a third of whom were over the age of 70. However, limitations stem from the study's lack of diversity in terms of ethnicity, race, and education, which diminishes generalizability. Parallel efforts have and continue to be made to address this limitation. For example, in a study with the Black Women's Health Study cohort[31], Black women were found to benefit similarly from the standard SHUTi program and a version of SHUTi modified specifically for Black women (SHUTi BW); however, they demonstrated higher engagement in the culturally tailored version[31]. Further work on how to address intersectionality in modified digital health programs–for example, how to effectively merge program modifications from SHUTi BW and SHUTi OASIS to address the unique needs of older Black women—is needed. Regarding generalizability, it is important to keep in mind that the sample in this study was from the general population and not specifically a clinical patient population.

It is worth noting that there were no adverse events reported by participants in this trial. While this may be an accurate result, reporting of adverse events are often limited in CBT-I trials for a variety of methodological and conceptual reasons, such as lack of awareness of the potential of AEs, assumption of safety with psychological interventions, AEs being poorly defined by the researchers, failure of participants to recognize or report negative effects, and limited follow-up. Fortunately, it appears that attention to AEs is improving, resulting in better and more accurate reporting[38–40].

The findings of this study offer compelling evidence for the efficacy of tailored, digital CBT-I to treat chronic insomnia among older adults. Nearly half of participants who received the fully automated SHUTi OASIS intervention no longer experienced insomnia at the 1-year follow-up. Moreover, 63% of adults who received the program completed it within the 9-week intervention period, and 83% finished the program overall. These results not only underscore the specific clinical benefits of the SHUTi OASIS intervention, but contrary to prevailing assumptions, this study emphasizes that older adults should not be overlooked or dismissed as a group who can benefit from a fully automated internet intervention approach. As the global population ages, there is an urgency to address not only sleep-related issues but the wider behavioral and mental health challenges of the expanding demographic of older adults. The development and rigorous testing of digital health interventions specifically tailored to older adults must be prioritized to meet the pressing need for evidence-based treatments that address the unique needs of older adults.

Methods

Design

This single-blind, randomized controlled trial (RCT) included 311 participants aged 55 and older randomized with equal odds into three conditions: Internet-delivered CBT-I alone (SHUTi OASIS alone), Internet-delivered CBT-I with stepped support (SHUTi OASIS + SS), and online patient education (PE). Randomization was stratified by age (younger than 70 years old and those 70 and over), with two separate randomization schedules used to assign participants across the three groups. The random allocation sequence, generated by FPT with an online randomization tool, was

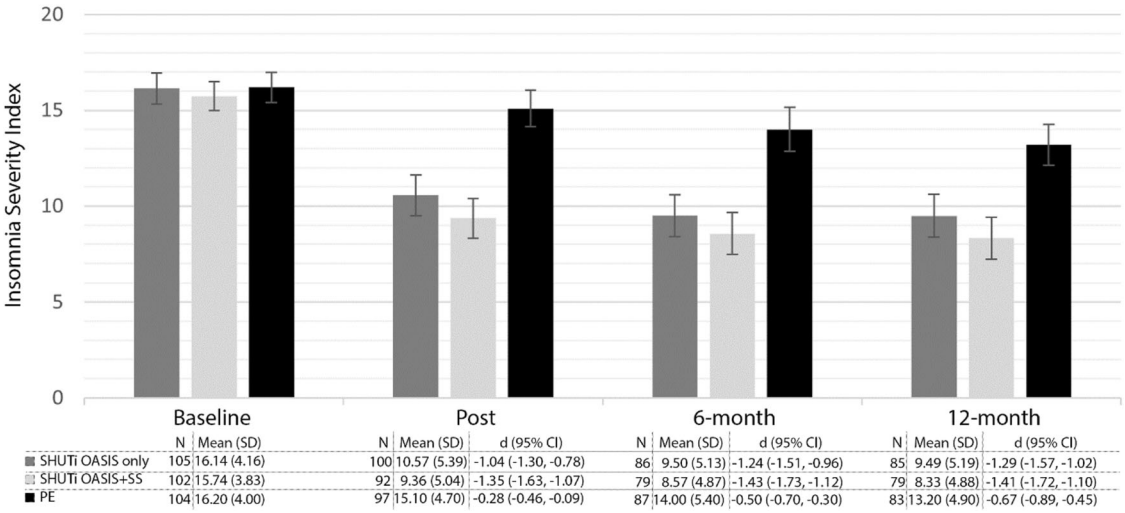

Fig. 2 | Primary sleep outcomes. *Note: Total participants and raw means (SDs) are shown beneath each time point, followed by within-group effects for each time point from baseline to each postassessment and follow-up.

Table 2 | ISI responders and remitters[a]

	Responders			Remitters		
	Post	6 Mo	12 Mo	Post	6 Mo	12 Mo
SHUTi OASIS only	38/100 (38%)	34/86 (40%)	34/85 (40%)	30/100 (30%)	34/86 (40%)	34/85 (40%)
SHUTi OASIS + SS	39/92 (42%)	37/79 (47%)	39/79 (49%)	39/92 (42%)	40/79 (51%)	40/79 (51%)
PE	5/97 (5%)	14/87 (16%)	15/83 (18%)	2/97 (2%)	14/87 (16%)	13/83 (16%)

[a]Responder is a decrease of >7 points on the ISI; Remitter is an ISI total score of <8 which aligns with the disease severity category of "no clinically significant insomnia".

concealed in a spreadsheet on a secure server accessible to study staff enrolling and allocating participants. At the time of a participant's enrollment, the next condition assignment was revealed and assigned by the study coordinator. Participants and the study statistician were blind to group allocation.

This study was approved by the University of Virginia's Institutional Review Board for Social and Behavioral Sciences and registered at ClinicalTrials.gov (Identifier NCT03213132; https://clinicaltrials.gov/study/NCT03213132; first registered July 6, 2017).

Participants

Inclusion criteria were age ≥55 years; met chronic insomnia criteria based on Diagnostic and Statistical Manual of Mental Disorders (DSM)-5[41] and estimated sleep ≤6.5 h per night[42]. Participants must have had the ability to use the internet and email at least twice per week, and were US residents who could read and speak English. Exclusion criteria included night shift work or irregular sleep schedules that would prevent adoption of intervention strategies (i.e., work schedule resulting in usual bedtime outside of 8 p.m. to 2 a.m. or arising time outside of 4 a.m. to 10 a.m.), current psychological treatment for insomnia, initiation of insomnia treatment within the previous three months, mental or medical health conditions that could interfere with the trial or put the individual at undue risk, other untreated sleep disorders, severe cognitive impairment as measured by the Telephone-Assessed Mental State (TAMS) scale[43], or use of medications known to interfere with sleep or changes in sleep medication use within the previous three months.

Procedure

Participants were recruited from across the US through a combination of traditional methods, online platforms, and social media channels. The study was promoted nationwide through advertisements placed in 126 senior facilities, community centers, medical offices, and businesses. Individuals also learned about the study from media coverage of SHUTi, healthcare providers, and word of mouth. Craigslist and Meta (Facebook and Instagram) advertisements were the primary sites for online recruitment. Geographic areas and interest groups with higher proportions of older adults and racial-ethnic minority populations were targeted. Additional details regarding recruitment have been previously published[44].

Individuals interested in the trial were directed to the study website, where they could access further information and complete an online interest form that included basic demographic information and study eligibility criteria. A telephone interview was scheduled with those who appeared to be qualified to confirm eligibility. Eligible and interested individuals provided informed consent after reviewing an electronic consent form with study staff. Following consent, participants completed a baseline assessment that included the study questionnaires and 10 days of sleep diaries. Once these were completed, they received access to their assigned web program (i.e., SHUTi OASIS or PE) for 9 weeks. Participants could request technical support, but no clinical guidance was offered. After this intervention period, participants completed the post-assessment of questionnaires and another 10 sleep diaries. This assessment was repeated at 6-months and 12-months. Participants received online gift cards for completing the post-assessment and 6-month follow-up ($50 each) and the 12-month follow-up ($100). Participants were directed to contact study staff in the event of adverse events; none were reported.

Interventions

- The SHUTi OASIS program: SHUTi is a tailored, interactive, fully automated web-based program grounded on the principles of face-to-face CBT-I (sleep restriction, stimulus control, cognitive restructuring, sleep hygiene, and relapse prevention)[45]. The intervention is delivered through six treatment Cores. Users gain access to a new Core based on a time (i.e., 1 week after prior Core completed) and event-based schedule (i.e., completing sleep

Table 3 | Secondary outcomes

Sleep variable	SHUTi OASIS [a]			Patient education		
	n	Mean (SD)	d (95% CI)	*n*	Mean (SD)	d (95% CI)
SOL						
Baseline	207	40.29 (36.92)		104	43.88 (41.49)	
Post	189	20.98 (17.16)	−0.60 (−0.75, −0.45)	90	37.45 (41.67)	−0.24 (−0.39, −0.08)
6-month	156	19.70 (15.02)	−0.64 (−0.81, −0.48)	82	34.60 (34.23)	−0.18 (−0.37, 0)
12-month	159	19.49 (14.68)	−0.62 (−0.80, −0.44)	82	30.76 (26.24)	−0.35 (−0.56, −0.14)
WASO						
Baseline	207	89.40 (47.70)		104	92.57 (57.44)	
Post	189	44.16 (27.77)	−1.08 (−1.26, −0.90)	90	77.20 (45.43)	−0.37 (−0.55, −0.19)
6-month	156	45.05 (33.81)	−1.02 (−1.22, −0.83)	82	67.84 (40.78)	−0.51 (−0.73, −0.30)
12-month	159	47.65 (37.15)	−0.91 (−1.10, −0.71)	82	70.80 (48.02)	−0.44 (−0.67, −0.21)
Sleep efficiency						
Baseline	207	72.96 (10.94)		104	71.64 (14.10)	
Post	189	85.08 (7.48)	1.19 (1.00, 1.38)	90	76.77 (12.01)	0.55 (0.38, 0.72)
6-month	156	85.53 (8.93)	1.17 (0.96, 1.38)	82	79.20 (10.62)	0.64 (0.43, 0.84)
12-month	159	85.28 (9.28)	1.13 (0.92, 1.34)	82	79.14 (11.94)	0.60 (0.38, 0.82)
# Awakenings						
Baseline	207	2.19 (1.36)		104	2.06 (1.12)	
Post	189	1.60 (1.23)	−0.60 (−0.72, −0.48)	90	1.85 (1.10)	−0.25 (−0.41, −0.10)
6-month	156	1.62 (1.09)	−0.55 (−0.70, −0.40)	82	1.82 (1.09)	−0.24 (−0.45, −0.04)
12-month	159	1.60 (1.16)	−0.50 (−0.66, −0.34)	82	1.83 (1.26)	−0.20 (−0.41, 0.01)
Sleep quality						
Baseline	207	2.87 (0.53)		104	2.88 (0.55)	
Post	189	3.33 (0.58)	0.74 (0.56, 0.91)	90	3.03 (0.62)	0.32 (0.15, 0.49)
6-month	156	3.36 (0.61)	0.74 (0.54, 0.94)	82	3.16 (0.58)	0.43 (0.22, 0.64)
12-month	159	3.46 (0.57)	0.85 (0.63, 1.06)	82	3.10 (0.66)	0.31 (0.10, 0.51)
Total sleep time (min)						
Baseline	207	347.53 (62.64)		104	344.97 (75.83)	
Post	189	374.83 (59.19)	0.51 (0.37, 0.65)	90	373.70 (67.29)	0.57 (0.40, 0.73)
6-month	156	385.19 (59.06)	0.68 (0.52, 0.85)	82	387.14 (60.30)	0.65 (0.45, 0.86)
12-month	159	390.06 (61.93)	0.70 (0.53, 0.88)	82	380.85 (69.41)	0.48 (0.26, 0.69)
Attention and concentration (MASQ)						
Baseline	207	2.02 (0.50)		104	2.10 (0.51)	
Post	192	1.99 (0.49)	−0.09 (−0.19, 0.01)	96	2.16 (0.53)	0.05 (−0.11, 0.20)
6-month	164	2.04 (0.50)	0.06 (−0.05, 0.17)	86	2.16 (0.53)	0.08 (−0.07, 0.24)
12-month	163	2.03 (0.49)	0 (−0.12, 0.12)	83	2.12 (0.49)	0 (−0.18, 0.18)
Fatigue (FSI)						
Baseline	207	4.03 (1.58)		104	4.20 (1.68)	
Post	192	3.35 (1.64)	−0.43 (−0.58, −0.29)	96	4.50 (1.65)	0.19 (0.02, 0.36)
6-month	164	3.37 (1.62)	−0.48 (−0.63, −0.34)	86	4.36 (1.85)	0.11 (−0.05, 0.27)
12-month	164	3.13 (1.52)	−0.67 (−0.81, −0.52)	83	4.22 (1.92)	0.01 (−0.18, 0.21)

Raw means (SD) are presented. Cohen's *d* effect sizes (with 95% Confidence Intervals [CI]) represent within-group change between baseline and follow-up time point.
MASQ Multiple Ability Self-Report Questionnaire, *FSI* Fatigue Symptom Inventory.
[a]This group collapses the two SHUTi intervention groups (SHUTi OASIS alone and SHUTi OASIS+SS).

diaries as needed), consistent with traditional CBT-I delivery[46] and the AASM's recommendation of six to eight sessions for "adequate treatment exposure"[25]. The program relies on user-centered online sleep diaries to track progress and to tailor intervention recommendations, such as for sleep restriction. SHUTi OASIS was modified from the SHUTi program specifically for older adults based on numerous interviews, focus groups, and expert input. It includes all of the standard SHUTi content, as well as: (1) strategies for the older adult population (e.g., allowance of brief naps, modified stimulus control procedures if mobility is limited at night, age-appropriate sleep norms, increased information on the effect of health conditions and medications on sleep, strategies for coping with nocturia); (2) additional stories and testimonials featuring older adults to increase peer relevance; and (3) application interface changes to improve usability and readability (e.g., sans serif typeface, increased font size, altered

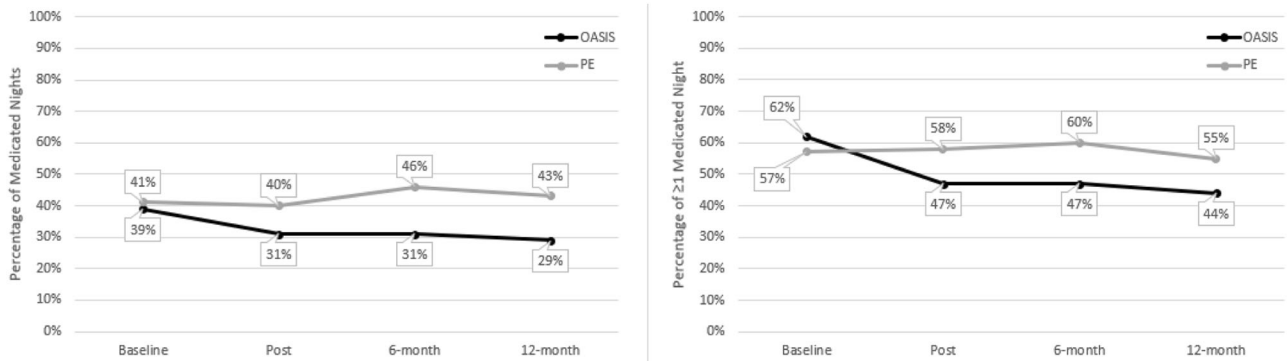

Fig. 3 | Changes in sleep medication. The first panel is the percentage of medicated nights. The second panel is the percentage of equal to or greater than one medicated night.

background and colors to increase differentiation, clear navigation, fewer distractions on the screen, shortened videos, and removal of pull down menus).

- Online Patient Education: Participants assigned to PE received access to a static website with general insomnia educational material, including basic CBT-I principles. The content is similar to what might be found if searching online for information about insomnia; however, this content was vetted, and accuracy was ensured. Unlike the SHUTi OASIS program, the content was not interactive or tailored. Additionally, PE content was not distributed gradually over time, but was presented all at once. A detailed description of the PE program has been published[30].

Measures

The primary outcome measure was the Insomnia Severity Index (ISI), a seven-item self-report questionnaire measuring severity of insomnia symptoms, including nighttime sleep and daytime impairment. ISI scores range from 0 to 28 with the following clinical cutoffs: 0–7 (absence of insomnia), 8–14 (sub-threshold insomnia), 15–21 (moderate insomnia), and 22–28 (severe insomnia). The ISI is the gold-standard measure for assessing insomnia severity, with strong validity, reliability, and sensitivity to changes in insomnia treatment[23,47].

A digital sleep diary based on the Consensus Sleep Diary[48,49] captured sleep-wake times that allowed calculation of secondary sleep outcome measures[50], including sleep onset latency (SOL), wake after sleep onset (WASO, inclusive of early morning awakening), number of awakenings, sleep quality (1 = very poor to 5 = very good), sleep efficiency, and total sleep time. Participants were also instructed to list the name, amount, and time of any over-the-counter or prescription medicine they took to help with sleep.

Additional secondary patient-reported outcomes included the Multiple Ability Self-Report Questionnaire (MASQ)—Attention Concentration Subscale[51] measuring attention and concentration, as well as the Fatigue Symptom Inventory[52] measuring daytime fatigue. Measures of depression and anxiety were also included and have been published previously[53]. Program use and adherence metrics, including number of logins, diaries submitted, and Cores completed, were captured automatically by the program.

Statistical analysis

Sample size was determined to adequately power tests of differences across conditions at post, controlling for baseline scores, on the primary outcome of ISI as well as SOL and WASO. G*Power 3 software[54] was used to calculate the minimum number of participants needed for attaining 80% power at $p < 0.01$ to detect effect sizes derived from older adult participants from the previous large efficacy trial of SHUTi (ISI $f = 0.459$; SOL $f = 0.287$; WASO $f = 0.306$)[30]. A conservative $\alpha = 0.01$ was selected given that the multi-method approach to measuring insomnia necessitates multiple variables. Accounting for an estimated 29% attrition based on past trial data, a sample size of $N = 309$ ($n = 103$ per group) was targeted to allow for detectable results for these three key outcomes.

Analyses were conducted using R[55]. For each outcome, a linear mixed effects model was computed (using the lmer function from the lme4 package in R[56]) with default estimation options, including restricted maximum likelihood estimation. Specifically, the hypothesis that the SHUTi OASIS groups would outperform PE on outcomes across time was examined by testing the group by time interaction and post-hoc fixed effects. Models included a random intercept for each subject for more conservative inference. An intent-to-treat approach was used, with all enrolled participants included in all analyses. Linear mixed-effects models are estimated using all available data and provide unbiased estimates for parameters where data are missing at random. Statistical significance was set at $\alpha = 0.01$. Within-group differences (Cohen's d) were calculated based on established methods for independent groups with pretest-posttest designs[57].

For secondary outcomes, the SHUTi OASIS alone and SHUTi OASIS + SS conditions were collapsed into a single group (SHUTi OASIS), given that the experience of almost all the participants in the SHUTi OASIS + SS was identical to those in the SHUTi OASIS only group. The only study protocol difference between these conditions was that the SHUTi OASIS + SS group would receive added prompts from study staff to complete the first two Cores of the intervention if they were not completed in a predetermined time frame[58]. Because only a few participants ($n = 14$) received any of these prompts, the experience for the two treatment groups was practically identical. In addition, no significant differences were found between the two treatment groups on any engagement metric or sleep outcome[58]. Collapsing these groups not only greatly improves the clarity and interpretability of the findings, it reduces the number of statistical tests (27 fewer statistical comparisons), appreciably reducing Type 1 error. Therefore, the final distribution of participants for the secondary analyses was 2:1, with 207 participants in the SHUTi OASIS group and 104 participants in the PE group.

Data availability

De-identified row-level data are available via data use agreement with the University of Virginia per institutional requirement; contact corresponding author to initiate the contracting process.

Code availability

Analyses were conducted using R. R script for computing sleep diary outcomes is available open-access at: https://github.com/BHT/SHUTiForResearchers. R script for manuscript analyses is available upon reasonable request to the corresponding author.

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Author contributions

L.M.R., F.P.T., L.G.-F., K.S.I., W.F.C., M.S.Q., M.B. and C.M.M. designed the study. C.F., K.M. and J.V.G. conducted the study. All authors provided input during the implementation of the study. K.M.S. provided statistical support on data analysis. C.F. and M.M.H. provided intervention development support. L.M.R., K.M.S., F.P.T., P.I.C., K.S.I., M.S.Q. and C.M.M. contributed to the writing of the manuscript. All authors approved the final manuscript.

Competing interests

K.M.S., P.I.C., K.S.I., W.F.C., C.F., K.M., J.V.G., M.K.M., M.M.H., M.S.Q. and M.B. have no financial conflicts of interest to report. L.M.R., F.P.T., L.G.-F. and C.M.M. report having equity ownership in BeHealth Solutions, L.L.C., the company that was originally established to make available digital health products, including Sleep Healthy Using the Internet, now licensed by Nox Health. F.P.T. is an employee of Nox Health, which owns the IP of Somryst, a commercial PDT for insomnia based on the SHUTi program. L.M.R. and C.M.M. are paid consultants of Nox Health. C.M.M. has also served on advisory boards for Eisai, Merck, and Phillips; served as consultant for Eisai, Merck, Sunovion, and Weight Watchers; received research support from Eisai, Idorsia, Canopy Health, and Lallemand Health. These companies had no role in the preparation of this manuscript. The terms of these arrangements have been reviewed and approved by the University of Virginia in accordance with its policies.

Additional information

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