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Pilot randomized trial of brief behavioral treatment for insomnia in patients with heart failure

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ABSTRACT

Background: Insomnia is prevalent among patients with heart failure (HF) and is associated with reduced physical and mental functioning, including possible exacerbation of cognitive deficits.
Objectives: This study evaluated the effects of Brief Behavioral Treatment for Insomnia (BBTI) on insomnia and related factors among HF patients.
Methods: Twenty-three HF patients with insomnia (70% women; 65% white; M_{age} = 55.7 ± 11.3 years; NYHA Class II = 70%) were randomized to a behavioral intervention (BI; n = 12) or sleep monitoring (SM; n = 11) group. Sleep, cognitive functioning, quality of life, distress, self-care, and functional status were assessed pre- and post-intervention.
Results: BI participants experienced reduced insomnia and increased sleep quality and efficiency, with 58% demonstrating clinically meaningful improvements in insomnia and 25% achieving remission of insomnia symptoms. Depression and anxiety also improved in BI participants.
Conclusions: BBTI was tolerated well within this symptom-limited patient population and was associated with reduced symptoms of insomnia and distress.

Introduction

Among patients with heart failure (HF) the prevalence of insomnia is significantly greater than in the general population, with approximately half of all HF patients reporting difficulty initiating or maintaining sleep, or waking prematurely.[1] Risk for comorbid insomnia is greatest in HF patients older than age 65 and in those with more severe disease.[2,3] Insomnia in HF patients is associated with decreased health-related quality of life, as well as with increased depression, daytime fatigue, excessive daytime sleepiness, and worse functional performance, independent of the presence of sleep-disordered breathing.[1,4]

The full impact of insomnia in HF is unknown, but insomnia also may exert negative effects on self-care and cognitive functioning in patients with HF. Excessive daytime sleepiness is associated with insomnia and is related to poor self-care, including reduced medication adherence.[5] Deficits in self-care appear to be compounded when patients experience both excessive daytime sleepiness and mild cognitive decline.[5] Cognitive deficits in attention, executive functioning, memory, and motor functioning are common in HF, and are associated with increased risk for mortality.[6,7] Cognitive impairments are exacerbated in HF patients with sleep disturbance, as poorer sleep quality is associated with worse performance on tests of attention and executive function[8,9] and the presence of comorbid insomnia is associated with lower global cognitive function.[10] No prior studies have specifically examined whether decreases in insomnia symptoms are associated with improvements in self-care and cognitive function.

Cognitive behavioral therapy for insomnia (CBT-I) is recommended as a first-line treatment for insomnia[11] because it produces sustained improvements in insomnia, increased sleep continuity, and reduced daytime symptoms, and patients may prefer CBT-I over pharmacological treatments due to negative side effects of the standard medications.[12] CBT-I implementation, however, is often stifled by the two-month treatment duration and limited availability of qualified providers trained in behavioral sleep medicine. Brief Behavioral Treatment for Insomnia (BBTI)[13] was developed as an alternative to CBT-I to address these barriers and increase the feasibility of training clinicians with no prior formal training in behavioral sleep medicine to administer a behavioral treatment for insomnia in clinical settings.[14,15] Both CBT-I and BBTI emphasize stimulus control and sleep restriction techniques, educating patients about healthy sleep practices and behaviors that adversely affect sleep quality. However, BBTI does not include a cognitive restructuring component and the treatment duration is half that of typical CBT-I, requiring only two shorter in-person visits and two phone calls.[14]

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BBTI completion is associated with improvements in self-report and actigraphy-measured outcomes, including later bedtimes, improved sleep quality, shorter onset latency, less wakefulness after sleep onset, greater sleep efficiency, and decreased nocturia, with most participants reporting sustained improvements six months after completing treatment.[13,16,17] Individuals with greater psychological distress (anxiety and depression) and those with longer sleep latency (amount of time to transition from wakefulness to sleep) are most likely to respond to BBTI.[18] Conversely, short sleepers, i.e., those who sleep less than 6 h per night at baseline, are less likely to experience symptom improvements following BBTI.[18] The efficacy of BBTI has been established in clinical and community samples of older adults with insomnia, many with comorbid chronic health conditions, and a recent single-arm study demonstrated the feasibility of BBTI in persons living with HIV.[19] No randomized clinical trial of BBTI in a disease-specific population, such as HF, has been published.

In HF patients, only one prior trial has examined a behavioral intervention for insomnia. Group-delivered CBT-I was compared to an attention control condition in patients with stable NYHA Class I to III HF.[20] CBT-I completers experienced clinically meaningful reductions in insomnia and daytime fatigue that were significantly greater than outcomes in control patients. However, the group format of treatment delivery introduced scheduling challenges that resulted in many participants completing make-up sessions via telephone.

Although findings from this initial trial of CBT-I in patients with HF are promising, it is important to determine whether a brief, clinically feasible intervention, such as BBTI, is effective for treating insomnia in patients with HF. This pilot randomized controlled trial was conducted to evaluate the effects of BBTI on insomnia in HF. As a secondary aim, the study evaluated effects of the intervention on factors related to insomnia in HF, including cognitive function, self-care, psychological distress, quality of life, and functional status. It was hypothesized that BBTI participants would report decreased insomnia symptoms and increased sleep quality and sleep efficiency, as well as reduced distress and improvements in the other related factors.

Method

This study was approved by the IRB at The Ohio State University and all participants provided written consent. The trial was registered on clinicaltrials.gov (NCT03636880).

Participants

Symptomatic HF patients with comorbid insomnia were recruited from outpatient cardiology clinics and cardiac rehabilitation programs at The Ohio State University Wexner Medical Center (OSUWMC) and from Research Match, a NIH-funded internet site designed to help researchers identify potentially eligible subjects. Eligible participants had a diagnosis of HF and NYHA Class I-III symptoms, were at least 18 years old, fluent in English, and reported at least mild chronic insomnia (Insomnia Severity Index score $\geq$ 8).[21]

Exclusion criteria included restless legs syndrome, narcolepsy, and performing night or rotating shift work. Individuals with seizure disorders, excessive sleepiness (Epworth Sleepiness Scale score $\geq$ 19),[22] or a current or past diagnosis of Bipolar disorder or a psychotic disorder also were excluded as these conditions are contraindicated with sleep restriction in BBTI. Patients with significant cognitive impairment (Mini-Mental Status Exam-2 score $<$ 24)[23] that could impact their ability to complete assessments or participate in treatment also were excluded.

Obstructive sleep apnea (OSA) and insomnia are often comorbid in HF, yet OSA is not necessarily associated with the presence or severity of insomnia in HF.[1] Individuals with OSA who were adherent to continuous positive airway pressure (CPAP) treatment (use $\geq$ 6 h per night, $\geq$ 6 nights per week) were eligible for enrollment. Further, individuals with mild OSA (apnea-hypopnea index $<$ 15) were eligible to enroll, regardless of CPAP use, given limited evidence for the effectiveness of CPAP in this group. Patients with moderate to severe OSA or unknown OSA severity who were not adherent to CPAP treatment were excluded from participation. Individuals without a prior OSA diagnosis were evaluated with the STOP-BANG Questionnaire and those who were at high risk for OSA (score $\geq$ 5)[24] also were excluded.

Procedures

Potentially eligible participants were identified by medical chart review in outpatient settings or through Research Match and were then contacted to determine interest. All interested patients completed informed consent, followed by a brief assessment to ensure eligibility. If eligible, a baseline visit was scheduled approximately two weeks later and participants were given two-week sleep diaries to complete in the interim. At the baseline visit, participants submitted the sleep diaries and completed self-report questionnaires, cognitive functioning assessments, and functional status assessment. After completing the baseline assessments, participants were randomized to a behavioral intervention (BI) group or a sleep monitoring (SM) control group using stratified randomization based on sex, age ($<$ 65 vs. $\geq$ 65 years), and OSA diagnosis (prior negative sleep study or low-risk based on the STOP-BANG questionnaire vs. OSA diagnosis). Approximately four weeks after baseline, all participants were contacted and instructed to complete a second two-week sleep diary. Following diary completion, participants attended a final in-person assessment. Baseline assessments were conducted by the two clinicians who administered the BI. Final assessments were conducted by two research assistants who received $\geq$ 15 h of supervised training and were blinded to participant randomization.

Study interventions

Sleep monitoring (SM) control group

Participants randomized to this active control condition were told they were tracking their sleep patterns prior to each assessment. There was no contact with SM participants between assessments, except for a reminder call to initiate the final two-week sleep diary and schedule the final assessment.

Behavioral intervention (BI) group

The manualized intervention utilized Buysse and colleagues' 'Brief Behavioral Treatment for Insomnia (BBTI).' Patients are provided with sleep education and individualized 'sleep prescriptions' based on the main rules of BBTI: (1) reduce time in bed; (2) get up at the same time every day, regardless of sleep duration; (3) do not go to bed unless sleepy; and (4) do not stay in bed unless asleep.[15] The treatment was delivered over the four-week period between assessments (see Table 1) by two graduate students with Master's degrees in Clinical Psychology and no formal training in behavioral sleep medicine. Due to the frequent symptom exacerbations experienced by patients with HF, some participants were not able to complete all BI sessions within the prescribed four-week period. Missed sessions were rescheduled as soon as possible, whenever the patient was able to continue treatment.

Treatment fidelity

BBTI was delivered to the BI group using a standardized manual[15] and a checklist was used during each session to verify delivery of essential treatment components. In-person BI sessions (Sessions 1 and 3) were audio recorded, and a random sample of 20% of each session was reviewed by two independent raters to assess the degree to

Table 1
Behavioral intervention (BI) timeline and session content.

Week	Delivery method	Approximate length	Behavioral intervention (BI) session content
1	In-person	45–60 min	Education on the function of sleep, the two-process model of sleep, insomnia, and habits that help and hurt sleep. The four rules of treatment are introduced with accompanying rationale and an individualized sleep prescription is formulated based on the patient's prior two-week sleep diary.
2	Telephone	20 min	Review of treatment progress, including sleep pattern, daytime functioning, and adherence to the sleep prescription during the prior week. Difficulties with treatment are addressed.
3	In-person	30 min	Review of treatment progress using the prior two-week sleep diary. Difficulties with treatment are addressed and adherence to treatment recommendations is reinforced. Instructions for increasing sleep time are provided.
4	Telephone	20 min	Review of treatment progress. Instructions for increasing sleep time are reviewed and relapse prevention strategies are discussed.

which the essential components were delivered. Each content area was rated on a scale of 1 (no adherence; section skipped entirely) to 10 (perfect adherence; all material presented as specified).

Measures

Participants completed two-week sleep diaries[13] logging their daily bed and wake times, the number of hours of sleep each night, and nightly sleep quality (0 = poor to 10 = excellent). Sleep efficiency (SE) was calculated as the percentage of sleep time divided by time spent in bed with SE > 85% indicative of "good sleep." NYHA classification was derived from participant medical records at the time of enrollment.

The following self-report questionnaires were completed by participants at the baseline visit and at the final visit, unless otherwise noted.

Demographics and health status (baseline only)

Information regarding age, sex, marital status, race, highest education level, and employment status was collected. The Charlson Comorbidity Index (CCI)[25] was used to determine the type and total number of comorbid disorders, yielding a total score of 0 to 37, with higher scores indicating greater comorbidity.

Sleep

The Insomnia Severity Index (ISI)[21] is a 7-item measure that assesses the severity of sleep-onset and maintenance difficulties, sleep satisfaction, and daytime dysfunction and distress. Total scores range from 0 to 28, with higher scores reflective of greater insomnia severity. Internal consistency reliability in the current sample was adequate ($\propto$ = 0.76) and comparable to prior studies.[20]

The Pittsburgh Sleep Quality Index (PSQI)[26] is a 19-item questionnaire that measures sleep quality over the past month in clinical populations. Total scores range from 0 to 21, with scores > 5 associated with poor sleep quality.[18] Internal consistency reliability in this sample was lower than prior validation samples[26] but acceptable with $\propto$ = 0.66.

The ISI, PSQI, and sleep diary SE were evaluated as the primary study outcomes.

Distress, quality of life, and self-care

The Hospital Anxiety and Depression Scale (HADS)[27] is a 14-item measure of anxiety and depression symptoms in patients with physical illness. Scores for anxiety and depression subscales range from 0 to 21, with scores ≥ 8 indicating clinically-relevant symptoms. Internal consistency reliability in this sample was consistent with previously reported values,[28] with $\propto$ = 0.84 for anxiety and $\propto$ = 0.86 for depression.

The Kansas City Cardiomyopathy Questionnaire (KCCQ)[29] is a 23-item HF-specific measure used to quantify physical limitations, symptoms, and HF-related quality of life in stable and decompensated HF patients. Overall summary scores range from 0 to 100, with higher scores indicating better functioning and fewer symptoms, and scores < 75 considered clinically significant. Internal consistency reliability in the current sample was $\propto$ = 0.95.

The Self-Care of Heart Failure Index (SCHFI)[30] is a 15-item self-report questionnaire measuring self-care maintenance, management, and confidence in HF patients with sufficient reliability and validity for use in clinical research. The maximum score for each subscale is 100, with higher scores representing better self-care and scores ≥ 70 considered adequate. Internal consistency reliability in this sample varied across subscales ($\propto$ range = 0.52 to 0.87).

The following measures of cognitive function and functional status were conducted at each assessment.

Attention and psychomotor speed

Coding[31] is a subtest in the Wechsler Adult Intelligence Scale - Fourth Edition (WAIS-IV) that assesses sustained attention and psychomotor performance, including response speed and visuomotor coordination. The task has demonstrated high test-retest reliability and is not generally affected by practice effects.[31] Age-based norms from the WAIS-IV were used to evaluate performance.

Executive function

The Trail Making Test (TMT)[32] is comprised of two parts, A and B. TMT A measures visual search, attention, and motor functioning, while TMT B measures higher-order executive functioning. Alternate forms, with comparable difficulty and high test-retest reliability, were used in the final assessment to reduce the risk of practice effects from repeated administrations.

Memory

Verbal Paired Associates I and II (VPAI and VPAII)[33] are subtests in the Wechsler Memory Scale – Fourth Edition (WMS-IV) neuropsychological battery. VPAI assesses immediate recall of verbally-presented associated word pairs while VPAII measures delayed, long-term memory. Both VPAI and VPAII have demonstrated good reliability and validity, and WMS-IV age-based norms were used to evaluate performance.

Functional status

The Sixty-Foot Walk Test (60ftWT)[34] is a brief, clinically feasible ambulatory measure of functional status that has been validated among symptomatic HF patients. Participants walk four laps on a 15-foot course as rapidly as possible and total completion time is recorded in seconds. The measure has good test-retest reliability (r = 0.79).

Statistical analyses

An intention-to-treat approach was utilized for all analyses. Pearson correlations and analyses of variance (ANOVAs) were conducted to examine the relationship of outcomes to demographics (age, sex, race, and education). Demographics associated with outcomes were statistically controlled in analyses evaluating that outcome. Chi-

square tests and independent samples t-tests were used to evaluate characteristics across the two study conditions. Correlations were conducted of length of treatment (in days) with primary and secondary outcomes.

The primary mode of data analysis was repeated measures multivariate analysis of variance (MANOVA), with time (baseline and program completion) as a within-subjects variable and group (BI versus SM) as a between-subjects variable. Clusters of related variables were analyzed together (*sleep:* ISI score, PSQI score, SE; *executive function:* TMT A and B completion times; *memory:* VPAI and VPAII scores; *distress:* HADS anxiety and depression scores; *self-care:* SCHFI maintenance, management, and confidence scores) followed by evaluation of univariate effects in the presence of significant multivariate effects. Analysis of variance (ANOVA) was utilized for domains with a single outcome variable (*attention and psychomotor performance:* Coding score; *HF-related quality of life:* KCCQ score; *functional status:* 60ftWT time). Effect size was calculated using partial eta squared (η_p^2) and Hedges' *g*. IBM SPSS Statistics for Mac v.24 (IBM Corp., Armonk, N.Y., USA) was used for all analyses.

Previously established criteria[13] were used to evaluate the clinical efficacy of BBTI in HF and to classify participants as in remission from insomnia, treatment responders, partial responders, or non-responders based on PSQI scores and SE. Clinically meaningful change in insomnia also was determined by ISI total score reductions of $\geq$ 6 points between assessments.[35]

Results

Sample characteristics

The sample consisted of 23 enrolled participants randomized to the BI (n = 12) or SM (n = 11) groups (see Fig. 1). Of the enrolled participants, one was recruited from Research Match, while all others were recruited from OSUWMC outpatient programs. One SM participant

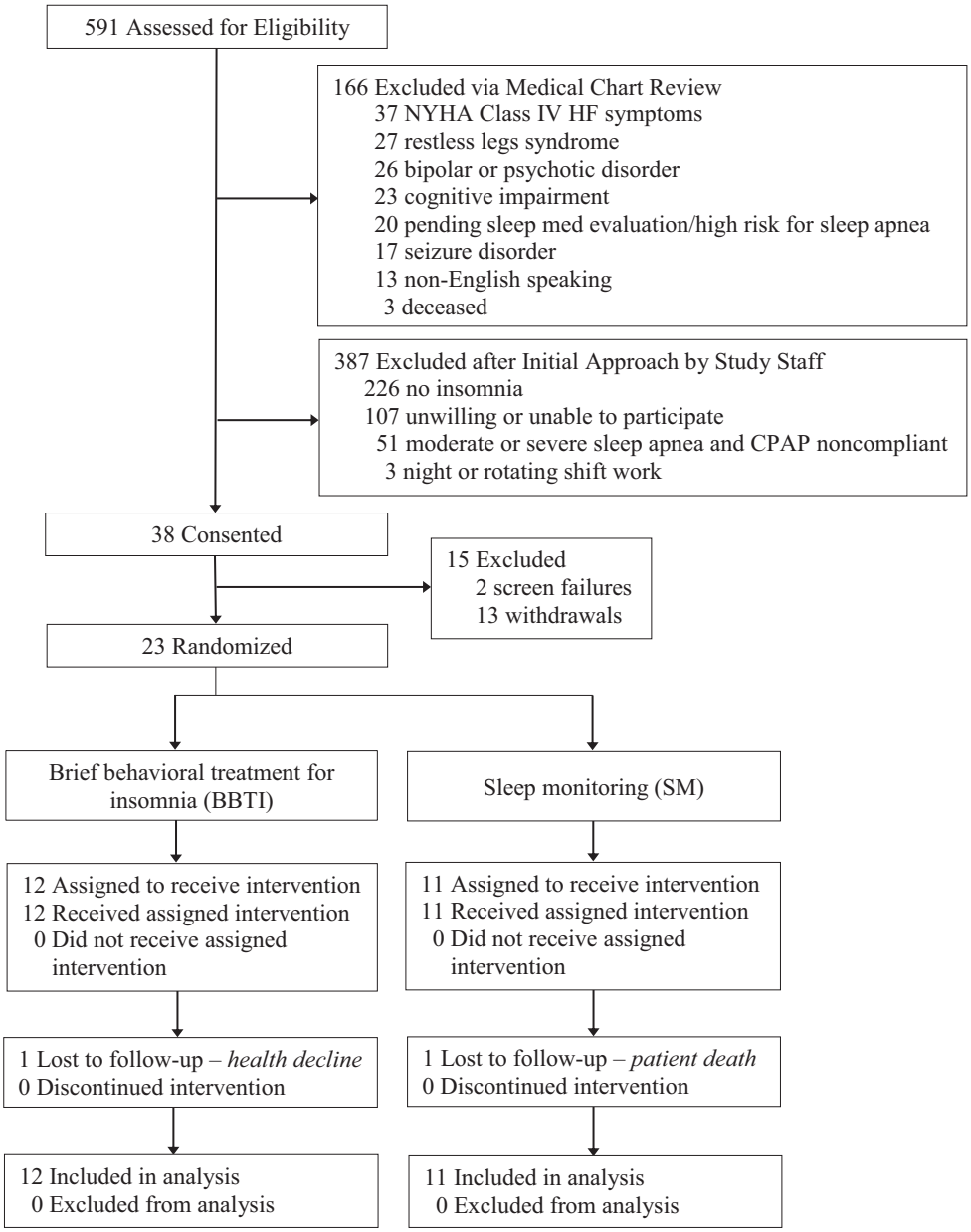

Fig. 1. CONSORT diagram.

died prior to the final assessment and one BI participant completed all four intervention sessions but withdrew prior to the final assessment due to a significant decline in health status.

The sample was primarily female (70%) and white (65%), with mild HF symptoms (NYHA Class II = 70%; see Table 2). The average number and severity of comorbid conditions was higher than in other samples of HF patients with comorbid insomnia.[20] As shown in Table 3, participants reported, on average, moderate severity insomnia, poor sleep quality, and low sleep efficiency at baseline. Participants scored above clinical cutoffs for anxiety and depressive symptoms. They demonstrated adequate self-care maintenance, but less than adequate self-care management and confidence. Also, HF-related quality of life (KCCQ) was below clinical cutoffs, indicating that participants were experiencing clinically significant HF symptoms at a level associated with poorer prognosis. However, ambulatory functional status (60ftWT) was higher than in other samples of symptomatic HF patients.[34]

Patients with significant global cognitive impairment were excluded, yet several participants obtained baseline scores indicative of impairments in specific domains. Extremely low scores ($\leq$ 16th percentile) were obtained by 30.3% ($n = 7$) of participants in sustained attention and psychomotor performance (Coding), 27.1% ($n = 5$) in immediate verbal memory (VPAI), and 17.2% ($n = 4$) in delayed long-term memory (VPAII). Similarly, 26.1% ($n = 5$) of participants scored below average in visual search, attention, and motor functioning (TMT A) and 39.1% ($n = 9$) were below average in executive functioning (TMT B).[36]

Table 2
Demographic and medical characteristics in full sample and within conditions.

Variables	Total Sample ($n = 23$)	SM ($n = 11$)	BI ($n = 12$)
Age, mean (SD)	55.7 (11.3)	55.6 (10.8)	55.7 (12.2)
Sex, n (%)			
Male	7 (30.4)	3 (27.3)	4 (33.3)
Female	16 (69.6)	8 (72.7)	8 (66.7)
Race/Ethnicity, n (%)			
American Indian	1 (4.3)	0 (0.0)	1 (8.3)
Black	6 (26.1)	4 (36.4)	2 (16.6)
Hispanic	1 (4.3)	1 (9.1)	0 (0.0)
White	15 (65.2)	6 (54.5)	9 (75.0)
Marital Status, n (%)			
Single, never married	6 (26.1)	4 (36.4)	2 (16.7)
Married	11 (47.8)	4 (36.4)	7 (58.3)
Divorced/separated/widowed	6 (26.1)	3 (27.3)	3 (25.0)
Living Arrangements, n (%)			
Alone	5 (21.7)	4 (36.4)	1 (8.3)
With others	18 (78.3)	7 (63.6)	11 (91.7)
Work Status, n (%)			
Employed, full or part-time	5 (21.7)	3 (27.3)	2 (16.6)
Retired	3 (13.0)	1 (9.1)	2 (16.6)
On Disability	13 (56.5)	5 (45.5)	8 (66.7)
Unemployed	2 (8.7)	2 (18.2)	0 (0.0)
Education, years, mean (SD)	15.5 (2.6)	15.8 (2.5)	15.3 (2.9)
NYHA Class, n (%)			
I	2 (8.7)	0 (0.0)	2 (16.6)
II	16 (69.6)	9 (81.8)	7 (58.3)
III	5 (21.7)	2 (18.2)	3 (25.0)
Charlson Comorbidity Index, mean (SD)	4.7 (2.7)	4.7 (2.7)	4.7 (2.7)
Ejection Fraction, n (%)			
Reduced, <50%	14 (60.9)	8 (72.7)	6 (50.0)
Preserved, ≥50%	9 (39.1)	3 (27.3)	6 (50.0)
Cardiac-Related Comorbidities, n (%)			
Myocardial Infarction	7 (30.4)	4 (36.4)	3 (25.0)
High Cholesterol	12 (52.2)	6 (54.5)	6 (50.0)
Hypertension	17 (73.9)	8 (72.7)	9 (75.0)
Heart Valve Disease	7 (30.4)	3 (27.3)	4 (33.3)
Non-Cardiac Comorbidities, n (%)			
COPD	8 (34.8)	3 (27.3)	5 (41.7)
Diabetes Mellitus	8 (34.8)	4 (36.4)	4 (33.3)
Kidney Disease	7 (30.4)	3 (27.3)	4 (33.3)
Liver Disease	3 (13.0)	3 (27.3)	0 (0.0)
Sleep Apnea	9 (39.1)	3 (27.3)	6 (50.0)

SM = Sleep Monitoring group; BI = Behavioral Intervention group; NYHA = New York Heart Association; COPD = Chronic Obstructive Pulmonary Disease.

Preliminary analyses

Participants randomized to the two conditions did not differ in age, education, race/ethnicity, or sex (see Table 2). Thus, demographics were not controlled in analyses examining treatment effects across groups.

Treatment fidelity and adherence to intervention

Intervention adherence for specific components of the BBTI ranged from 8 to 10 (10 = perfect adherence) for Session 1 and 9 to 10 for Session 3, with a modal score of 10 for each session. Total adherence (average of all component ratings across rated sessions) was 9.50 (SD = 0.74) and 9.75 (SD = 0.44) for Sessions 1 and 3, respectively.

Mean length of treatment for BI participants was 27 days (SD = 7 days; range = 21 to 40 days). Length of treatment was not associated with the change in sleep outcomes from baseline to final assessment. Among secondary outcomes, treatment length was correlated with change in 60ftWT completion time between assessments ($r = 0.77$, $p = .006$), with a longer treatment period associated with greater decline in functional status from baseline to final assessment.

Insomnia symptoms

There was a significant time by condition interaction ($F(3,15) = 6.27$, $p = .006$, $\eta_p^2 = 0.56$) for the primary sleep variables. Four participants did not complete baseline sleep diaries, creating a sample size discrepancy ($n = 23$ for ISI and PSQI and $n = 19$ for SE). The model remained significant with SE removed and consistent with the hypothesis that BI participants would experience greater improvements in sleep compared with SM participants ($F(2,20) = 4.46$, $p = .03$, $\eta_p^2 = 0.31$). Univariate analyses revealed significant group by time interactions for ISI ($F(1,21) = 5.50$, $p = .03$, $\eta_p^2 = 0.21$), PSQI ($F(1,21) = 9.36$, $p = .006$, $\eta_p^2 = 0.31$), and SE ($F(1,17) = 8.70$, $p = .009$, $\eta_p^2 = 0.34$). BI participants experienced significant improvements on all primary outcomes, but SM participants did not change (see Table 3). For BI participants, final ISI ($t(11) = -3.71$, $p = .003$, Hedges' $g = 1.07$) and PSQI scores ($t(11) = -3.53$, $p = .005$, Hedges' $g = 0.99$) were lower compared to baseline, while SE was higher ($t(9) = 3.45$, $p = .007$, Hedges' $g = 0.72$).

Eight participants (34.8% of total sample; $n = 7$ in BI group) achieved clinically meaningful reductions in insomnia symptoms (reduction of $\geq$ 6 points on ISI) from baseline to final assessment. Using the BBTI clinical efficacy criteria based on PSQI scores and SE,[13] 27.3% ($n = 3$) of BI participants completing the final assessment achieved remission of insomnia symptoms, 45.5% ($n = 5$) met treatment response criteria, and 27.3% ($n = 3$) were treatment non-responders. One SM participant met treatment response and one met partial response, while all others ($n = 8$; 72.7% of participants in group) were treatment non-responders (see Fig. 2).

Distress, quality of life, and self-care

There was a significant time by condition interaction for HADS anxiety and depression scores ($F(2,20) = 10.05$, $p = .001$, $\eta_p^2 = 0.50$). Univariate analyses revealed significant interactions for anxiety ($F(1,21) = 12.05$, $p = .002$, $\eta_p^2 = 0.37$) and depression ($F(1,21) = 15.16$, $p = .001$, $\eta_p^2 = 0.42$). BI participants experienced significant reductions in anxiety ($t(11) = -4.45$, $p = .001$, Hedges' $g = 0.97$) and depression

Table 3
Mean values for outcome variables at baseline and final assessments across groups.

Variables	Total Sample ($n = 23$)	Sleep Monitoring (SM) Control ($n = 11$)		Behavioral Intervention (BI) ($n = 12$)	
	Baseline Mean (SD)	Baseline Mean (SD)	Final Mean (SD)	Baseline Mean (SD)	Final Mean (SD)
1. ISI	17.1 (5.3)	16.6 (4.9)	14.8 (4.7)	17.6 (5.8)	10.0 (8.2)*
2. PSQI	10.4 (3.5)	9.0 (3.5)	10.0 (3.8)	11.8 (3.1)	7.7 (4.9)*
3. SE	74.4 (19.1)	84.5 (7.9)	84.3 (8.5)	65.3 (21.9)	81.7 (23.9)*
4. HADSA	9.2 (5.4)	7.1 (5.1)	7.0 (4.9)	11.2 (5.1)	6.4 (4.7)*
5. HADSD	7.4 (4.5)	5.1 (3.4)	5.4 (3.0)	9.5 (4.3)	6.0 (4.0)**
6. KCCQ	55.3 (24.9)	57.6 (24.5)	61.0 (23.3)	53.2 (26.1)	65.6 (29.9)
7. SCHFMN	72.3 (12.0)	70.9 (9.9)	71.8 (12.4)	73.6 (14.0)	76.9 (16.0)
8. SCHFMG	62.5 (28.4)	66.4 (16.3)	64.3 (13.4)	66.0 (29.8)	67.5 (20.7)
9. SCHFCO	66.2 (21.5)	68.2 (18.4)	70.3 (13.0)	64.4 (24.7)	74.1 (29.4)
10. VPAI	10.7 (3.9)	11.1 (3.6)	11.3 (3.7)	10.3 (4.3)	11.4 (3.6)
11. VPAII	10.5 (3.4)	10.9 (3.3)	10.6 (3.2)	10.2 (3.6)	10.7 (2.9)
12. Coding	8.7 (2.8)	8.8 (1.7)	8.3 (2.5)	8.6 (3.7)	8.8 (3.5)
13. TMTA	34.7 (9.7)	38.3 (10.1)	35.2 (3.8)	31.3 (8.3)	34.0 (8.5)
14. TMTB	93.2 (30.4)	104.7 (36.9)	81.3 (31.5)	82.6 (18.9)	85.7 (29.4)
15. 60ftWT	24.7 (10.6)	23.1 (7.9)	23.6 (11.2)	26.4 (13.2)	27.0 (19.4)

ISI = Insomnia Severity Index total score; PSQI = Pittsburgh Sleep Quality Index global score; SE = Sleep Efficiency; HADSA = Hospital Anxiety and Depression Scale anxiety score; HADSD = Hospital Anxiety and Depression Scale depression score; KCCQ = Kansas City Cardiomyopathy Questionnaire overall summary score; SCHFMN = Self-Care of HF Index Maintenance Score; SCHFMG = Self-Care of HF Index Management Score; SCHFCO = Self-Care of HF Index Confidence Score; VPAI = Verbal Paired Associates I; VPAII = Verbal Paired Associates II; TMTA = Trail Making A; TMTB = Trail Making B; 60ftWT = 60 ft Walk Test completion time.
* $p < .01$;
** $p < .001$;

($t(11) = -4.50$, $p < .001$, Hedges' $g = 0.84$) but SM participants did not change. There was no change in HF-related quality of life (KCCQ overall summary scores) or self-care (SCHFI subscales).

Cognitive functioning and functional status

There were no significant time by condition interactions for any of the cognitive outcomes (TMT A and B, VPAI, VPAII, and Coding). Two participants were confined to wheelchairs and did not complete the 60ftWT at either assessment. All other participants completed the assessment, but repeated measures ANOVA revealed no effect.

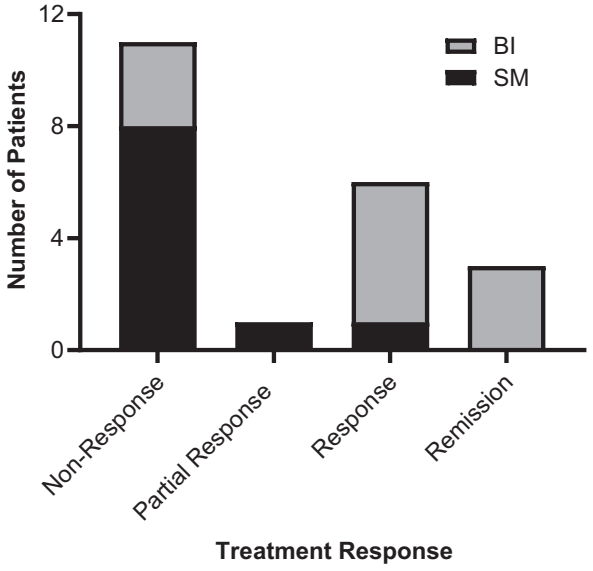

Fig. 2. Treatment response in sleep monitoring versus behavioral intervention participants. BI = Behavioral intervention group; SM = Sleep monitoring group. Remission of insomnia = post-intervention Pittsburgh Sleep Quality Index (PSQI) score < 5 and Sleep diary sleep efficiency (SE) > 85%; Treatment response = pre- to post-intervention change in PSQI global score ≥ 3 points or in SE of ≥ 10%; Partial response = improvement in PSQI global score or SE as defined in 'Treatment response', but a worsening on the other measure; Non-response = change in PSQI score of < 3 and an increase in SE < 10%.

Discussion

This study represents the first application of BBTI to a cardiovascular patient population. Participants who completed the manualized 4-session BBTI intervention experienced significant improvements in insomnia, sleep quality, and sleep efficiency compared to SM control participants. Treatment response rates in this study were similar to prior BBTI studies,[13,16,18] with two-thirds of participants demonstrating treatment response or a remission of insomnia symptoms. Unlike the one prior trial of group-delivered CBT-I in HF,[20] the full treatment course was completed by all participants assigned to it, including patients who demonstrated deficits in one or more cognitive domains. The brief, individualized format of delivery facilitated accommodation of participants needing to cancel sessions due to HF symptom exacerbations, and delays in delivering intervention sessions did not adversely affect treatment response.

Treatment fidelity ratings were highly concordant and showed a high level of adherence to the treatment protocol by the two clinicians, despite the clinicians having no formal training in behavioral sleep medicine. The BBTI manual was originally written for an older adult population, yet only minor wording changes to the clinician script were required to make the content applicable to HF patients of any adult age.

As observed in a prior BBTI study,[18] post-hoc analyses revealed that BI participants reporting < 6 h of nightly sleep at baseline ($n = 5$) were less likely than others to experience treatment response or remission ($x^2(2) = 6.16$, $p = .046$). Unlike prior BBTI trials, neither baseline psychological distress nor sleep onset latency predicted treatment response. In a subset of participants ($n = 10$) who completed a third assessment at 6-month follow-up, improvements in insomnia, sleep quality, sleep efficiency, anxiety, and depression were maintained in BI participants ($n = 5$) from baseline (all $p < .05$), and SM participants ($n = 5$) remained unchanged.

Although nocturia was not directly assessed in the present study, the PSQI includes a rating of the weekly frequency of sleep being disrupted by using the restroom. Post-hoc analyses revealed no differences in treatment response among participants with no disrupted sleep in the past month due to having to use the restroom, and those with one or more occasions of disrupted sleep in the past month due to having to use the restroom. This suggests that HF patients can derive the benefits of BBTI despite continued nocturia. Indeed, a prior

study found that BBTI was effective in reducing nocturia by consolidating sleep and reducing time in bed.[17]

Considerable evidence suggests that insomnia decreases quality of life and increases distress. This study demonstrated that BBTI was associated with reduced depression and anxiety. The majority of BI participants reported clinically significant anxiety (75.0%, $n = 9$) and clinically significant depression (75.0%, $n = 9$) at baseline. At the final assessment, only 30% ($n = 3$) of BI participants continued to experience anxiety, while 33.3% ($n = 4$) experienced depression. As increasing evidence emerges about the positive relationship between distress and mortality in HF,[37] it is important that effective treatments are made available to this symptom-limited population. Findings from this study suggest that BBTI may be a useful option for patients whose distress includes insomnia.

There were no significant changes in cognitive functioning, self-care, or ambulatory functional status. Prior studies suggesting a link between sleep and HF self-care used excessive daytime sleepiness as an indicator of poor sleep.[5] While insomnia may produce excessive daytime sleepiness, sleepiness does not necessarily reflect sleep disturbance,[38] and in HF may be more attributable to HF-related symptoms. Results from this study suggest that the presence of insomnia alone is not associated with HF self-care. Also, the 6-week time frame between study assessments may not have been long enough for significant cognitive changes to emerge. Future studies are warranted to examine the longitudinal relationship between insomnia and cognitive functioning and to determine the degree to which improvements in cognition are possible in HF.

This study had several limitations. Many interested participants were not eligible due to exclusion criteria and men may have been disproportionately excluded due to higher rates of sleep apnea. This may have resulted in a sample that was not fully representative of HF patients and thus may limit generalizability of the findings. Variations were observed in participant adherence to treatment recommendations, especially regarding sleep diaries. Feedback about this measure was not obtained, but daily tracking may have been overly burdensome or too complicated for participants with cognitive difficulty. This study measured sleep exclusively via self-report which may not accurately reflect actual behavior. Although key demographics were distributed across conditions, BI participants started the study with lower sleep efficiency ($p = .02$) and greater depression ($p = .01$) than SM participants, and there were no group differences in these values post-intervention. It is possible that the improvements in BI participants may reflect regression to the mean rather than clinically important change. Larger replication studies are needed to examine this further.

This study involved the application of an intervention with established efficacy to a subpopulation of patients for whom the efficacy and specificity of behavioral treatment of insomnia could be substantially improved. Eliminating in-person visits could potentially extend the reach of this treatment to patients who are especially limited by their symptoms or other obligations. Thus, further research could evaluate an exclusively telephone-based intervention. Future studies of BBTI also may benefit from including a standardized adherence measure to determine if adherence to specific treatment components affects outcomes.

Physical symptoms represent only one aspect of the disease experience for HF patients. Disease burden is often increased by psychological concerns, including distress, cognitive deficits, and sleep disturbance. Results from this study suggest that BBTI is a suitable option for managing insomnia and distress that is tolerated well by symptom-limited patients, with minimal risks, and low patient and provider burden. This pilot efficacy study represents an important first step in applying BBTI to HF patients with comorbid insomnia. The positive outcomes should be used to spur investigation of this treatment in larger studies of patients with HF, including in HF patients with greater disease severity and more diverse comorbidities.

Declaration of Competing Interest

None.

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