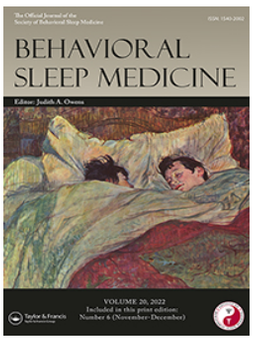

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Adapting Brief Behavioral Treatment for Insomnia for Former National Football League Players: A Pilot Study

Lindsey J. Wanberg[a], S. Justin Thomas[b], Michelle Reid[a], Rebecca Rottapel[a], Tayla von Ash[c], Nicole Jones[d], Laurie Brar[e], Rinad Beidas[f], Michael Rueschman[a], Robert R. Edwards[g], Daniel J. Buysse[e], Susan Redline[a,h,i], and Suzanne M. Bertisch[a,h,i]

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ABSTRACT

Objectives: Insomnia is highly prevalent among persons with chronic pain. Although cognitive behavioral therapy for insomnia is recommended as first-line treatment for insomnia, it is underutilized. We tested the feasibility of a potentially scalable alternative – Brief Behavioral Therapy for Insomnia (BBTI) for former National Football League (NFL) players, a group with a high prevalence of chronic pain. We assessed changes in sleep, pain, and psychological health.

Methods: Single-arm clinical trial of an adapted telephone-delivered BBTI intervention in 40 former NFL players with insomnia. We collected data on changes in sleep, pain, and psychological health outcomes.

Results: Among former players (30% racial/ethnic minorities), BBTI was both acceptable and feasible. BBTI was associated with improvements in sleep disturbance (primary exploratory sleep outcome, mean T-score change −6.2, 95% CI: −7.6, −4.8), sleep-related impairment (mean T-score change −5.7, 95% CI: −7.9, −3.5) and insomnia severity (mean change −5.3, 95% CI: −6.8, −3.5) post-intervention. Improvements were maintained at 2-months. BBTI was also associated with improvements in pain interference and intensity, but not psychological health.

Conclusion: An adapted telephone-delivered BBTI is acceptable and feasible among retired players with a range of insomnia symptoms and shows promise for improving sleep and pain. These data support the need for future trials assessing BBTI's effect on both sleep and pain outcomes.

Introduction

Robust evidence from numerous clinical trials demonstrates cognitive behavioral therapy for insomnia (CBT-I) improves sleep outcomes in patients with insomnia, including among patients with chronic pain (Qaseem et al., 2016; Jungquist et al., 2010; Martinez et al., 2014; McCrae et al., 2019; McCurry et al., 2021; Smith et al., 2015; Vitiello et al., 2009). Data also suggest that CBT-I may improve pain-related outcomes, such as pain intensity, across a range of pain conditions, including fibromyalgia, low back pain, and osteoarthritis (Jungquist et al., 2010; Martinez et al., 2014; McCrae et al., 2019; McCurry et al., 2021; Smith et al., 2015; Vitiello et al., 2009). CBT-I has also been shown to improve psychological health (Wu et al., 2015).

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Despite clinical guidelines and robust evidence supporting CBT-I's efficacy, CBT-I is underutilized and often unavailable in real-world settings. Barriers impeding the uptake and reach of insomnia treatments in clinical care include the relatively low number of trained clinicians, high time (4–8 total hours) demands, and protracted treatment duration (4–8 sessions over 2–3 months), and costs. As a result, substantial efforts have focused on expanding CBT-I's accessibility through briefer and potentially scalable approaches. One such treatment, brief behavioral treatment for insomnia (BBTI), was developed to deliver CBT-I's core behavioral components in 2–4 visits (total 1.5 hours) over one month by clinicians without specialty training in sleep (Buysse et al., 2011). However, few studies have examined delivery methods that may expand the reach and scalability of BBTI, such as using telephone-only delivery and recruiting across wide geographic areas, outside of the clinical setting, or examined BBTI's impact on pain outcomes. Thus, further work is needed to explore the impact of potentially more scalable behavioral treatments of insomnia (Edinger et al., 2021; Gunn et al., 2019) among patients with chronic pain.

American-style football players experience a high burden of sleep disturbance and physical and psychological comorbidity, including chronic pain, anxiety, depression, and reduced quality of life (Morris et al., 2019; Roberts et al., 2020; Zafonte et al., 2019). Thus, football players represent a suitable population to evaluate a briefer, potentially scalable, insomnia treatment on sleep, and sleep- and pain-related outcomes. Testing BBTI's acceptability in a specific group informs whether BBTI can be adapted to the needs of other populations, and if successful, BBTI could then be adapted to other specific groups within the general population, and thereby may be generalizable and scalable. In this context, we conducted a single-arm pilot study to test the acceptability and feasibility of telephone-delivered BBTI adapted for former National Football League (NFL) players residing in the community across wide geographic areas and secondarily to explore its effects on sleep, pain, and psychological health. The primary hypothesis was that telephone-delivered BBTI would be acceptable, feasible, and safe.

Methods

Harvard Football Players Health Study (FPHS)

The Harvard FPHS (https://footballplayershealth.harvard.edu) is a cohort of former NFL football players designed to develop and assess interventions to improve the health and well-being of former players (Zafonte et al., 2019). Players enrolled in FPHS between January 2015 and April 2020 and completed a standardized questionnaire (Q1) that collected information on demographics, physical, and mental health, cognitive function, and pain. In January 2019, all Q1 respondents were asked to complete a second survey (Q2) to evaluate changes in health.

Study overview

This project had two phases: (I) a qualitative phase to inform the intervention adaptation; (II) a single-arm clinical trial (pre-post intervention) of the adapted 4-week telephone-delivered BBTI in 40 former NFL players with insomnia symptoms. The Massachusetts General Brigham Committee on Human Subject Research approved the study, with Harvard University ceding review. The clinical trial was registered with ClinicalTrials.gov (NCT04159233).

Phase 1: BBTI Adaptation

We adapted the original BBTI manual for FPHS participants to enhance its relevance and acceptability while maintaining BBTI's core components that underlie BBTI's purported mechanism of action (Buysse et al., 2011; Germain et al., 2006; Troxel et al., 2012). Specifically, we retained BBTI's core components ("4 rules") and maintained additional content (i.e., health sleep education; discussion of the 2-process model), standardized delivery (1:1 delivery by trained practitioners) and intervention timing and duration (4 treatment sessions over four weeks). To

inform this adaptation, we conducted interviews with 15 FPHS participants using a theory-informed semi-structured guide (Michie et al., 2014). We elicited information on perceptions and values of healthy sleep, the impact of their football experience on sleep, barriers, and facilitators to achieving healthy sleep, and previous strategies employed for behavior change (Michie et al., 2014). A trained team member (RR) conducted the interviews, which were recorded and transcribed. Data were analyzed using a rapid analysis approach (Beebe, 2014; McNall & G, 2007). Using a modified thematic analysis approach, a qualitative researcher (TvA) generated a preliminary codebook (Braun & Clarke, 2008). The codebook was iteratively refined, and then the team identified codes and categorized them into themes. Table 1 details how the eight emergent themes informed the BBTI adaptation. Briefly, the manual was revised to include education on the relationship between sleep and pain, infused language used in sports (e.g., renamed BBTI to "Sleep Bootcamp"; used a "playbook"), and added brief player narratives. Additionally, we provided visual feedback on achieving weekly targets for these highly goal-directed individuals.

Phase 2: Single-arm telephone-delivered BBTI Pilot Trial

Figure 1 depicts the study flow. Upon enrollment, participants completed baseline surveys and one week of sleep diaries. The study visits included an intake session followed by four intervention visits. Participants then repeated the surveys and sleep diaries at the end of the intervention and 2 months post-treatment. All study visits were conducted remotely via telephone in the United States, similar to prior BBTI studies (Gunn et al., 2019).

Participants

The FPHS study team identified former players who responded on Q2 that they were bothered by "trouble falling or staying asleep or sleeping too much" at least "several days" in the last 2 weeks (Kroenke et al., 2009). Among the 53.9% of the cohort meeting this threshold, the staff emailed recruitment materials among a subset selected via purposive sampling to ensure racial diversity. Nearly 40% of individuals contacted identified as nonwhite. Interested participants then contacted study staff, and eligibility was determined via telephone.

Eligible participants had an Insomnia Severity Index [ISI] score >7 (Morin et al., 2011), reliable internet access, and were able to communicate in English. Exclusion criteria included self-reported history of untreated moderate-to-severe sleep apnea; excessive daytime sleepiness with a self-reported sleep duration >6 hours; habitual bedtime or waketime earlier than 8pm or later than 11am, respectively; working ≥1 nightshift/week; history of narcolepsy, severe psychiatric disease or current severe major depressive disorder (Kroenke et al., 2009); any severe medical condition that may require hospitalizations or surgery during the study period; use of seizure medication or any seizures within the past 10 years; active alcohol (Bush et al., 1998) or drug abuse (Tiet et al., 2017); or prior participation in behavioral therapy for insomnia (https://clinicaltrials.gov/ct2/show/NCT04159233). All participants provided informed consent electronically using the secure data capture tool, REDCap (Research Electronic Data Capture; Harris et al., 2009). Participants were then scheduled for a pre-intervention "intake" session to establish rapport, facilitate trust, and review study procedures and expectations.

Intervention

At the first session (Week 1, 30–60 min), the interventionist reviewed the adapted manual ("playbook") with the participant. This included a review of healthy sleep practices, the relationship between pain and sleep, the two-process model of sleep regulation, and BBTI's four rules focused on stimulus control and sleep restriction. The interventionist then prescribed an individualized "game plan" of sleep and wake times, informed by the participant's recent diary data (Buysse et al., 2011; Troxel et al., 2012). During the remaining three, 15-min weekly calls, the interventionist reviewed the participant's

Table 1. Interview themes and areas of adaption by COM-B TDF construct.

Qualitative Insight	Applicable Quote	Adaptation
COM-B/TDF Construct: Professional and social roles /reflective motivation		
Lack of trust and pervasive "tough guy" mentality may limit honesty and openness of participants	*"We're supposed to be bullet proof. We're not supposed to ever admit that we have any issues."* *"We're kind of ego-type guys. You don't want to say you're weak about something. So, a lot of guys don't want to communicate to say they have a problem."*	• Trained interventionists on the importance of establishing rapport and trust with participants. • Added intake session meant to support rapport-building
Competitive nature and goal-oriented	*"Something I value is constantly trying to make yourself a little bit better."*	• Gave participants feedback on goal-attainment each week through sleep diary reports • Emphasized the benefits of improving sleep • Emphasized that practice is essential to Sleep Bootcamp, and that set-backs do not mean that the program will not work
There is a high prevalence of sleep disturbance in the former NFL player population	*"Truthfully when you say the word sleep to me, I just think, 'oh my gosh'. It's just such a battle for me."*	• Included quotes in the manual the formative interviews so that the players could recognize that poor sleep was pervasive among former players, so that the players could relate and feel like they are not alone
COM-B/TDF Construct: Knowledge/ psychological capability		
Common report of memory and attentional limitations	*"I was starting to have memory issues. I would forget someone's name. Or a guy in a locker room would say 'hey did you get a chance to do what we talked about?' and then I would have to spend hours trying to figure out what he asked me to do. I would make a cheat sheet of all the players names and where their lockers were so I wouldn't forget someone's name when I went to the lockers room. I was even sometimes forgetting my own son's name. And he has the same name as me! So I decided to leave the job because I thought I would be able to slow down and get better. But I'm not better now. And I have no support now."*	• Added brief intake session to BBTI (split session 1: intake to review treatment logistics; avoid saturation)
Mental health was commonly mentioned as a cause of sleep disturbance.	*"There were some games during the year, the rivalries that we had, where I– well, especially if we lost to that team, for a week or two, I could almost be depressed, and it would just really get to me. So, I think there were a lot of emotional things going on during football that would have impacted my sleep."*	• Encouraged interventionists to gain trust and rapport with their participants, so the participant may feel comfortable discussing mental health concerns.
Most players experience daily pain, and it was noted as a common cause of sleep disturbance	*"Like a lot of guys, I've probably had 15 or 20 orthopedic surgeries . . . and I think all that contributes to me getting uncomfortable in bed."*	• Added page on the relationship between sleep and pain
Negative feelings about medication to improve sleep	*"I don't want to get hooked on pills. And I've had some surgeries. I just had surgery on my elbow twice months ago. And I've had surgery on my foot and on my shoulder, and a bunch of other things. And when I was coming off those surgeries, they give you the pain pills. And I was kind of paranoid because I've seen what can happen to some other former players that get hooked on opioids."*	• Leveraged preference for non-drug treatments in recruitment materials

(*Continued*)

Table 1. (Continued).

Qualitative Insight	Applicable Quote	Adaptation
COM-B/TDF Construct: Social Support		
Family and other player involvement	*"I'd say get the wives involved. Even if you interview a guy, have the wife there because he's going to lie. If he's lying in a coffin, you ask him, 'Are you dead?' 'No, I'm still alive. I'm still having a beer with you at 5 o'clock.'"*	• Encouraged participants to let their bed partner or people they live with know that they were going through Sleep Bootcamp, so that the players could ask for them for support and could also discuss how they might be affected by the participant's changing sleep schedule and new sleep habits

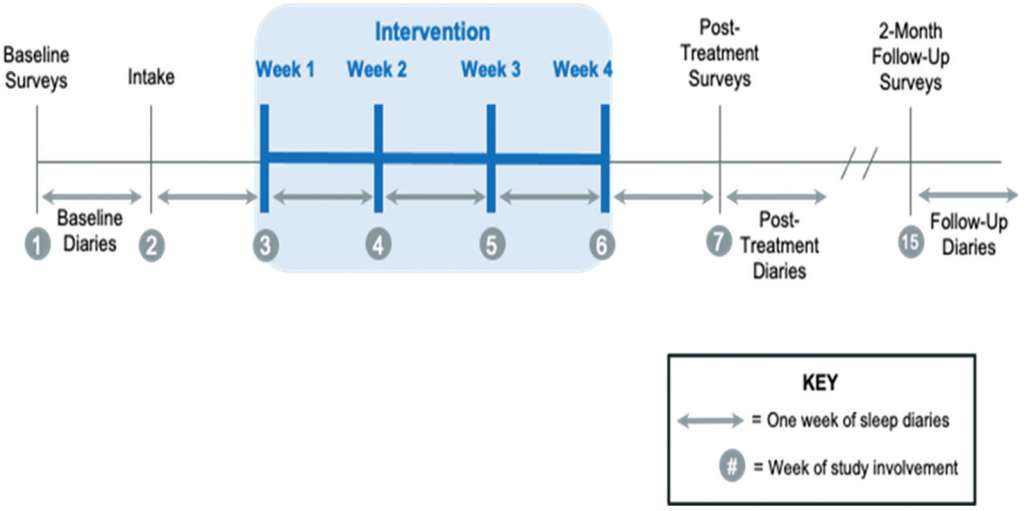

Figure 1. Study design.

weekly diary, addressed questions, troubleshot barriers, and adjusted the game plan based on sleep latency and efficiency (Buysse et al., 2011; Troxel et al., 2012). At the final session (Intervention Week 4), the interventionists collected information on adverse events.

Interventionist Training: To promote fidelity of treatment delivery, we selected qualified interventionists with clinical experience in sleep and/or mental health, provided standardized and ongoing training, and delivered the intervention using a protocol that included a treatment manual with a script. The five interventionists ("sleep coaches") varied in geographic location (AL, FL, MA, PA) and professional backgrounds (two clinical psychologists, one doctorate-level social worker, and two nurse practitioners). Interventionist training included two 30-min synchronous sessions and a separate prerecorded 45-min video that included a detailed review of the treatment manual. The interventionists also attended weekly team meetings with the study PI (SB) to discuss any questions about the protocol, intervention delivery, or any concerns.

Measures

Primary outcomes: feasibility and acceptability

We assessed the feasibility of the study conducted by measuring recruitment yields, the proportion of recruited participants that were eligible, the proportion of eligible individuals consented, and outcome assessment completion rates. Feasibility of the adapted telephone-delivered BBTI intervention was measured by visit attendance and engagement (i.e., time on calls), retention, and safety (i.e., unanticipated adverse events; Kane et al., 2017). We also assessed acceptability based on participant satisfaction with study procedures using a structured questionnaire.

Fidelity

Procedures for promoting and assessing fidelity were informed from guidelines and recommendations of the Treatment Fidelity Workgroup of the NIH Behavior Change Consortium (Bellg et al., 2004; Borrelli et al., 2005). We audio-recorded each treatment session, and we randomly selected one treatment and two check-in sessions from each interventionist (10.0% total sessions) for review. Fidelity was rated by an independent trained team member using a standardized checklist that

included whether the core aspects of BBTI (e.g., the two-process model of sleep regulation, four rules of BBTI, etc.) were delivered and whether additional treatments were avoided (e.g., relaxation and cognitive therapy techniques).

Timing of data collection

Data from questionnaires on sleep, pain, and psychological health, as well as 7-day sleep diaries, were assessed at baseline, post-treatment (1 week after the final visit), and at 2-month follow-up (2 months after final visit). All data were collected using REDCap.

Exploratory Sleep Outcomes

The primary exploratory sleep outcome was change in the Patient-Reported Outcomes Measurement Information System (PROMIS™) Sleep Disturbance Short Form, an eight-item questionnaire that assesses sleep quality during the previous week (Yu et al., 2012) from baseline to post-treatment. The PROMIS™ Sleep Disturbance Short Form scores range from 8 to 40, with higher scores indicating higher levels of sleep disturbance. Item responses are combined to yield a T-score with a population mean of 50 and standard deviation of 10.

Secondary exploratory sleep outcome measures included the PROMIS™ Sleep-Related Impairment Short Form (PROMIS™ SI SF; (Yu et al., 2012)), and the ISI (Morin et al., 2011). Though the ISI was a screening criterion, the ISI was additionally added as an outcome after the first six participants to capture remitter thresholds commonly used in the literature. Remission was defined as an ISI score <8 post-treatment (Morin et al., 2011). Each morning, participants completed the Core Consensus Sleep Diary (CSD; (Carney et al., 2012)) that collected daily information on the time the participant got into bed, time they started trying to fall asleep, sleep onset latency (SOL), wake after sleep onset (WASO), final wake-up time, and final time out-of-bed (rise time). From these data, total sleep time (TST) and sleep efficiency (SE) were derived.

Additional exploratory outcomes

Pain and psychological health

We explored multiple pain-related outcomes (i.e., PROMIS™ Pain Intensity [3a], Pain Interference [8a], and Pain Catastrophizing [13a], Widespread Pain Index [range 0–19]). Higher scores indicate greater pain symptomatology. We also assessed psychological health using the Perceived Stress Scale [PSS-10] (range 0–40, higher scores are considered higher perceived stress) and several PROMIS measures: PROMIS™ Anxiety [4a], PROMIS™ Depression [4a], PROMIS™ Anger [5a], and PROMIS™ Mental Health. Higher scores on the PROMIS anxiety, depression, and anger short forms indicate greater mood disturbance/anger, whereas higher mental scores indicate better mental health.

Data analyses

Participant characteristics using frequencies with percentages for categorical variables and means with standard deviations for continuous measures are presented. From the weekly diary, we computed weekly averages of SOL, WASO, TST, and SE. Mean change in outcomes from baseline to post-treatment and baseline to 2-month follow-up were calculated using paired *t*-tests or Wilcoxon ranked sum tests, based on distribution. Results with a two-sided p-value of less than 0.05 were considered statistically significant. All analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC).

Results

Study sample

Baseline characteristics are presented in Table 2. Ages ranged from 26 to 77 years; nearly half of the participants were between the ages of 55 to 64 years, and one-fourth were 65 years or older. Twenty-eight percent of participants identified as a race other than White, with 10 participants identifying as Black or African American and 1 participant identifying as more than one race. The majority were married (76.9%), and more than a quarter of participants were retired or not working, and 92.3% of participants completed a 4-year college degree. Participants commonly reported comorbidities, such as traumatic brain injury or concussion (43.6%), hypertension (35.9%), any obstructive sleep apnea (28.2%), anxiety (21.1%), and depression (20.5%). As anticipated, a high proportion of former NFL players experienced daily or near-daily pain (75.0%).

Primary outcomes: feasibility and acceptability

Recruitment yields and retention

Participant flow is shown in Figure 2. Starting in November 2019, recruitment e-mails were sent out to 450 potential participants, 76 (16.9%) expressed interest in the study, 66 were screened, and 47 were eligible. The most common reasons for ineligibility included ISI scores below the subclinical threshold, active alcohol abuse, and current use of seizure medication or experiencing a seizure in the past 10 years. Forty-two participants (89% of those eligible) consented, and 40 enrolled in the study. One participant who consented, but did not enroll, chose not to participate due to COVID-19 concerns. Another individual was lost to follow-up. All participants completed the intervention phase of the study.

Participation/engagement

From January through September 2020, 39 of the 40 participants completed all four sessions, and 100% completed at least 3 sessions. Only 4% of visits had to be rescheduled. Intake call duration was a median of 29 minutes (q1 23, q3 38 min), the first intervention call was a median of 49 minutes (q1 42, q3 50 min), and "check-in" calls averaged 19 minutes (q1 15, q3 25 min). No adverse events related to intervention were reported.

Acceptability

The majority of respondents were "very satisfied" with the study and intervention (Figure 3). 81.3% "strongly agreed" and 15.6% "agreed" that they would recommend the intervention to another retired player or athlete. Additionally, 97% of participants reported that they would recommend the intervention to another player.

Exploratory sleep outcomes

At post-treatment, we observed a significant decrease in mean change in PROMIS sleep disturbance (−6.2, 95% C.I., −7.6, −4.9; Table 3; Figure 4), PROMIS sleep-related impairment (−5.7, 95% C.I., −8.0, −3.5) and insomnia severity (−5.3, 95% C.I., −6.8, −3.5) that were maintained at 2-months. More than 75% achieved remission (ISI score <8) at post-treatment and 67.5% at 2-months follow-up.

We also observed an average reduction in diary-reported SOL of 12.4 (95% C.I., −17.2, −7.6) minutes, an 11.4-minute reduction in WASO (95% C.I.-21.7, −1.1 min), and an average increase of 6.2% in SE (95% C.I, 4.2, 8.3%) from baseline to post-treatment. Similar improvements were

Table 2. Participant characteristics at baseline.

	n (%)
Age	
18–34 years old	3 (7.5%)
35–54 years old	9 (22.5%)
55–64 years old	18 (45.0%)
≥ 65 years old	10 (25.0%)
Race	
Black or African American	10 (25.6%)
White	28 (71.8%)
More than one race	1 (2.6%)
Ethnicity	
Not Hispanic or Latino	38 (97.4%)
Unknown or not reported	1 (2.6%)
Marital Status	
Single (never married)	2 (5.1%)
Divorced/separated	4 (10.3%)
Married	30 (76.9%)
Widowed	1 (2.6%)
Living in a marriage-like relationship	2 (5.1%)
Highest degree completed	
Some college, 2-year degree, or technical school	3 (7.7%)
Graduate college (4-year college graduate)	24 (61.5%)
Completed graduate school	12 (30.8%)
Current daily activities	
Working full time	20 (50.0%)
Working part time	8 (20.0%)
Not working/retired	10 (25.0%)
Disabled	1 (2.5%)
NFL seasons	
<2	2
2 to 6	24
6 to 10	10
≥ 10	4
NFL Era	
≤ 1993	28
> 1993	12
Position	
Defensive back	8
Defensive line	1
Kicker/Punter	2
Linebacker	10
Offensive line	8
Quarterback	4
Running back	0
Tight end	2
Wide receiver	5
Body Mass Index, kg/m^2	
<25.0	4
25.0–30.0	21
>30.0	15
Met diagnostic criteria for insomnia (ISCD-3)	25 (62.5%)
Self-reported previous diagnosis	
Cancer (other than non-melanoma)	4 (10.3%)
Diabetes	5 (12.8%)
High Blood Pressure or hypertension	14 (35.9%)
Heart disease	5 (12.8%)
Sleep Apnea	11 (28.2%)
Restless legs syndrome	2 (5.1%)
Depression	8 (20.5%)
Anxiety or panic attacks	8 (21.1%)
Post-traumatic stress disorder (PTSD)	2 (5.1%)
Headache disorder	4 (10.3%)
Traumatic brain injury or concussion	17 (43.6%)
Mild cognitive impairment or dementia	3 (7.7%)
Osteoarthritis	6 (16.2%)

*missing n = 1 for race/ethnicity, marital status, education, employment status

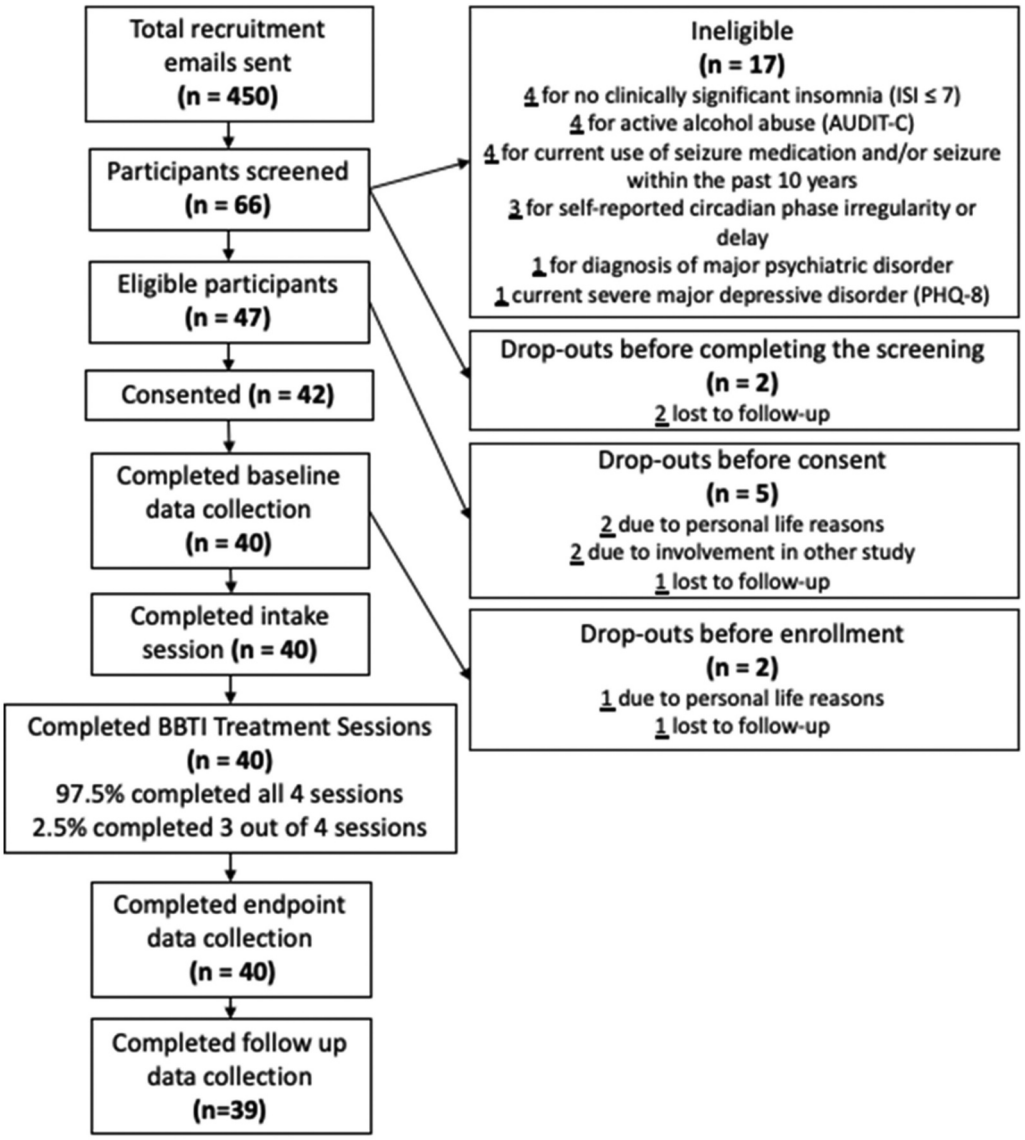

Figure 2. Study consort diagram.

maintained at 2-month follow-up. TST also increased by an average of 22.8 minutes (95% C.I., 5.4, 40.2) and 35.4 minutes (95% C.I., 19.2, 51.6) from baseline to post-treatment and 2-month follow-up, respectively.

Exploratory pain outcomes

PROMIS Pain intensity and Pain interference T-scores decreased from baseline to post-treatment (change scores: −3.6, 95% C.I., −5.9, −1.3; −2.6 95% C.I., −4.4, −0.9, respectively; Table 3). These change scores were maintained at 2-month follow-up (intensity −2.3 95% C.I., −4.10, −0.47; interference −2.6, 95% C.I., −4.6, −1.1). We also observed an average decrease from baseline to post-treatment in widespread pain of 0.35 (95% C.I., −0.8, 0.1 points) and in pain catastrophizing (range 0–52) of 0.20 points (95% C.I., −2.0, 1.6).

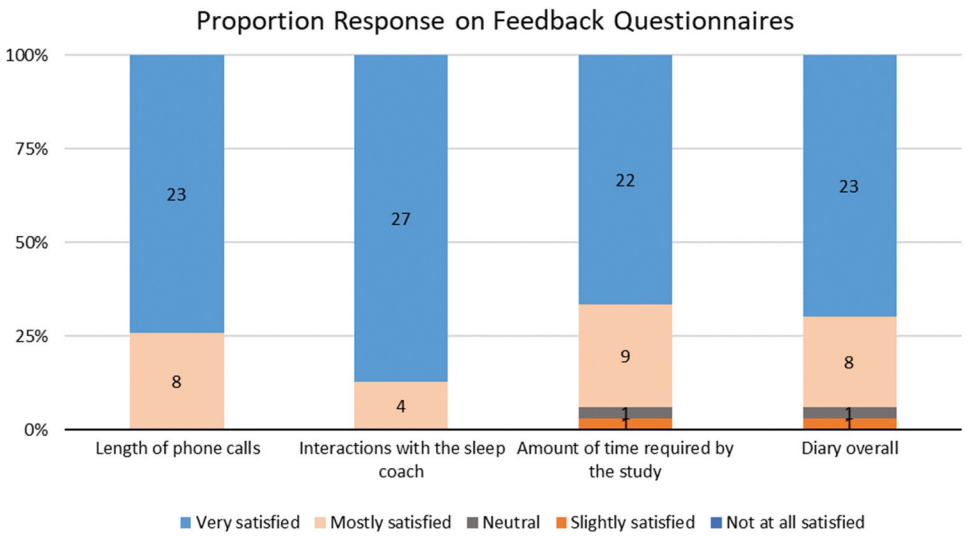

Figure 3. Proportion response on feedback questionnaires.

Exploratory psychological health outcomes

Overall, we observed modest changes in psychological health outcomes. On average, anxiety T-scores declined by −2.7 points (95% C.I., −4.9, −0.5) from baseline to post-treatment and −1.8 points (95% C.I., −3.9, 0.3) from baseline to 2-month follow-up. We also observed modest reductions in perceived stress, depression, anger, and global mental health that were not statistically significant.

Discussion

Our adaptation and delivery of a standardized telephone-delivered BBTI intervention were acceptable, feasible, and without reported adverse events for a sample of former NFL players with at least subclinical insomnia and a high prevalence of pain and other comorbidities. In exploratory analyses, we observed improvements in sleep disturbance, sleep-related impairment scores, and diary-reported SE and TST. More than three-quarters of the sample achieved remission post-treatment (Sateia et al., 2017). We also observed improvements in pain intensity, pain interference, and anxiety, despite no specific criteria for inclusion. The observed reductions in pain severity and interference are consistent with prior studies estimating the minimum clinically important difference (MCID) for these measures; MCIDs are generally in the range of 2–3 point changes in samples with substantial baseline pain (Chen et al., 2018). In addition, results appeared durable at 2-months follow-up. Thus, our pilot study results are promising, especially considering the all telephone-only delivery and the study's conduct amidst the stress and uncertainty of a global pandemic.

Feasibility and acceptability

Our telephone-delivered BBTI adaptation was feasible and highly acceptable to this multiracial/ethnic sample of former NFL players, as evidenced by high attendance rates, retention, data completion, and participant satisfaction. The intervention's high acceptability is largely consistent with studies assessing patient preference and satisfaction of psychological and behavioral treatments of insomnia that report patient preference for behavioral treatments (Cheung et al., 2018; McHugh et al., 2013) and suggest enhanced uptake of behavioral interventions when tailored for specific target users (Alcantara et al., 2021; Barrera et al., 2013; Hillier-Brown et al., 2014; Moredich & Kessler, 2014). Participants

Table 3. Adapted, tele-brief behavioral treatment for insomnia outcomes.

Outcomes	Baseline (n = 40) mean ± SD	Post-treatment (n = 40) mean ± SD	Change scores mean ± SE (CI)	*P*-value	*2-month follow-up (n = 40)* mean ± SD	*Change scores* mean ± SE (CI)	*P-value*
Sleep Questionnaires							
PROMIS Sleep Disturbance 8b - T-score	56.9 ± 3.7	50.6 ± 4.2 $^{\delta}$	−6.2 (0.7) (−7.6, −4.9)	<0.01	50.7 ± 4.1 $^{\delta}$	−6.3 (0.7) (−7.7, −4.9)	<0.01
PROMIS Sleep-Related Impairment 8a T-score	53.6 ± 6.9	47.9 ± 7.7	−5.7 (1.10) (−8.0, −3.5)	<0.01	47.2 ± 8.3 $^{\delta}$	−6.6 (1.3) (−9.2, −4.0)	<0.0001
Insomnia Severity Index (ISI)*	12.8 ± 5.0 $^{\alpha}$	7.9 ± 4.3	−5.2 (0.8) (−6.8, −3.5)	<0.01	6.7 ± 5.0 $^{\gamma}$	−7.2 (0.9) (−9.1, −5.3)	<0.01
Sleep Diary							
Sleep latency, min	30.4 ± 27.4	18.0 ± 18.9	−12.4 (2.4) (−17.2, −7.6)	<0.0001	18.7 ± 27.3	−11.7 (2.6) (−17.0, −6.4)	<0.0001
Wake after sleep onset, min	38.9 ± 33.9	28.4 ± 28.1	−11.4 (5.1) (−21.7, −1.1)	0.0031	19.8 ± 19.5	−19.6 (4.6) (−28.8, −10.3)	<0.0001
Sleep efficiency, %	85.1 ± 9.7	91.3 ± 6.8	6.2 (1.0) (4.2, 8.3)	<0.0001	92.2 ± 6.91	7.09 (1.3) (4.5, 9.7)	<0.0001
Total sleep time, hr	6.3 ± 0.9	6.7 ± 0.8	0.4 (0.1) (0.1, 0.7)	0.0121	6.91 ± 0.73	0.6 (0.1) (0.3, 0.9)	<0.0001
Pain Characteristics							
PROMIS Pain intensity, 3a, T- score	59.6 ± 6.8 $^{\gamma}$	55.8 ± 8.9	−3.62(1.1) (−5.9, −1.3)	0.003	57.9 ± 7.1 $^{\gamma}$	−2.3 (0.9) (−4.1, −0.5)	0.022
Widespread pain index (WPI)	4.4 ± 2.9	4.0 ± 2.8	−0.4 (0.2) (−0.8, 0.1)	0.19	4.2 ± 3.2 $^{\delta}$	−0.2 (0.3) (−0.9, 0.4)	0.48
PROMIS Pain interference, 8a, T-score	58.1 ± 7.4	55.5 ± 8.0	−2.6 (0.9) (−4.4, −0.9)	0.0006	55.8 ± 7.1 $^{\delta}$	−2.6 (0.7) (−4.6, −1.1)	0.0007
Pain catastrophizing, 13a	8.6 ± 8.7	8.4 ± 9.7	−0.2 (0.9) (−2.0, 1.6)	0.28	7.3 ± 8.6 $^{\delta}$	−1.5 (1.0) (−3.6, 0.6)	0.074
Psychological Health							
Perceived Stress Scale (PSS-10) score, mean ± SD	19.3 ± 2.7	18.1 ± 3.6	−1.2 (0.6) (−2.4, 0.1)	0.066	18.2 ± 3.5 $^{\delta}$	−1.2 (0.6) (−2.5, 0.1)	0.073
PROMIS anxiety, 4a, T-score	53.6 ± 7.5	50.9 ± 8.2	−2.7 (1.1) (−4.8, −0.5)	0.020	51.5 ± 9.0 $^{\delta}$	−1.8 (1.0) (−3.9, 0.3)	0.085
PROMIS depression, 4a, T-score	48.9 ± 9.5 $^{\delta}$	48.0 ± 8.9	−1.0 (0.8) (−2.5, 0.6)	0.22	48.9 ± 8.8 $^{\delta}$	−0.2 (0.8) (−1.9, 1.5)	0.94
PROMIS anger- 5a,T-score	52.4 ± 8.6	51.0 ± 9.1	−1.5 (1.0) (−3.7, 0.7)	0.19	51.5 ± 8.7 $^{\delta}$	−1.2 (1.1) (−3.4, 0.9)	0.25
Mental Health T -score	42.2 ± 4.8	40.8 ± 4.6 $^{\gamma}$	−1.2 (0.6) (−2.4, 0.0)	0.053	41.8 ± 4.7 $^{\beta}$	−0.3 (0.6) (−1.5, 0.9)	0.62

Key α: **n = 33**, β**: n = 37**, γ: **n = 38**, δ: **n = 39**

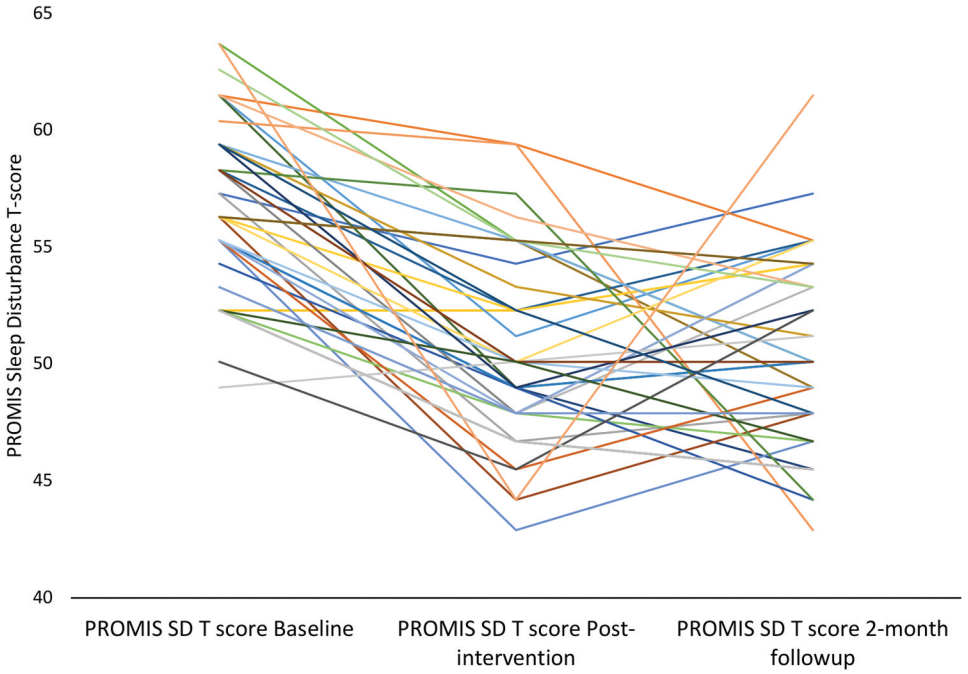

Figure 4. PROMIS sleep disturbance T-scores from baseline to post-treatment for each participant.

suggested that future iterations should include active involvement of spouses, bed partners, and family members, to enhance support and to coordinate sleep and wake times. Although a dyadic approach has been used in the treatment of obstructive sleep apnea (Ye et al., 2017), to our knowledge, only one current randomized control trial is evaluating partner-assisted CBT-I (Mellor et al., 2019). Given the high rate of satisfaction, future studies should consider targeting former and current athletes in behavioral sleep intervention studies and also consider participation by family members (McGraw et al., 2018) to further enhance acceptability.

Exploratory sleep outcomes

BBTI was associated with improvements in insomnia-related symptoms, a finding consistent with previous randomized controlled trials of BBTI (Buchanan et al., 2018; Germain et al., 2014; Gunn et al., 2019; Wang et al., 2016) and tele-delivered CBT-I, in which CBT-I and BBTI improved ISI scores by about 4 to 9 points (Bramoweth et al., 2020; McCurry et al., 2016, 2021). While the PROMIS sleep disturbance and sleep-related impairment measures have not been commonly used in BBTI research, a recent BBTI pilot study by Buchanan and colleagues reported that both sleep disturbance (as measured by the PSQI) and PROMIS sleep-related impairment decreased among participants living with HIV (Buchanan et al., 2018).

Additionally, we observed very high remission rates with 77.5% and 67.5% of participants in remission at post-treatment and 2-month follow-up, respectively. This finding varies from two previous BBTI studies reporting remission rates ranging from 28% to 53% (Buysse et al., 2011; McCrae et al., 2018). The substantially higher remission rates seen in our study are likely due to our inclusion of participants with subclinical insomnia (i.e., ISI score 8–14) rather than higher thresholds commonly used in behavioral insomnia treatment trials.

Although we did not observe clinically meaningful changes in SOL or WASO, we observed clinically meaningful improvements in SE and TST. The improvement in TST contrasts a recent meta-analysis of psychological and behavioral treatments of insomnia that did not observe improvements in TST with these treatments (Edinger et al., 2021).

Taken together, our results provide encouraging support as a proof-of-concept study for future work testing the efficacy and/or effectiveness of tailored, telephone-delivered BBTI on sleep outcomes for retired NFL players with significant comorbidities with at least subthreshold (mild) insomnia. Such studies should include comparisons to current standard of care and other behavioral treatments of insomnia. Though selecting for a population with lower insomnia symptoms severity reduces diagnostic specificity, it may extend the reach of our findings for real-world use, as our sample likely represented the broader range of insomnia present in the community setting. Additionally, though this cohort is comprised of participants with unique physical and psychologic attributes situated in an unusual life course as an elite athlete, this preliminary study supports additional investigation in which BBTI could be tailored for other groups within the general population, including those with a high burden of pain. However, it is important to note that this was a single-arm study and, therefore, findings could be due to placebo effects, regression to the mean, or the clinical variability of insomnia, and thus replication in a larger, controlled study is warranted.

Pain and psychological health outcomes

We observed improvements in pain intensity and interference that were maintained at 2-month follow-up. To our knowledge, this is the first study to examine the potential impact of telephone-delivered BBTI on pain outcomes. These findings are consistent with other studies that have examined the impact of CBT-I on pain (Jungquist et al., 2010; Martinez et al., 2014; McCrae et al., 2019; McCurry et al., 2021; Smith et al., 2015; Vitiello et al., 2009), including a recent randomized controlled trial by McCurry et al. reporting telephone-conducted CBT-I improved Brief Pain Inventory (BPI)-Severity and BPI-Interference pain measures at 2 months post-treatment in older adults with osteoarthritis pain and insomnia (McCurry et al., 2021). These findings provide a basis for testing a brief, convenient, potentially scalable treatment for patients with a range of insomnia symptoms and high prevalence of pain in a larger study.

The modest improvements in psychological health are consistent with recent clinical trials that did not find an effect of BBTI on depression (Buysse et al., 2020; McCrae et al., 2018) compared to control. On the other hand, earlier studies reported significant reductions in depression, but not anxiety, scores following BBTI (Buysse et al., 2011; Germain et al., 2006, 2014). While the literature on the effect of BBTI on anxiety and depression is mixed, it is important to note that in the present study, our sample had mild symptoms of anxiety and depression, but did have low global mental health scores. Any potential improvements in psychological health could have been offset by the stress, anxiety, and feelings of isolation inherent during the COVID-19 pandemic. Comparative effectiveness research designs may help determine differential effects for BBTI versus CBT-I on both sleep and non-sleep outcomes.

Study strengths and weaknesses

Our study had several strengths. Qualitative approaches were used to adapt a standard telephone-delivered BBTI protocol to the unique needs of the FPHS cohort. We assessed outcomes using validated measures that were relevant to this population. Our intervention was conducted entirely by telephone, which was particularly beneficial following the onset of the COVID-19 pandemic to extend the geographic reach of a behavioral intervention for sleep. Finally, the current study actively recruited Black and African American individuals, who have been underrepresented in behavioral sleep research. However, the study should be interpreted in the context of several limitations. Our study was a single-arm pilot study that did not include a control group. Therefore, the causal links between the intervention and differences in sleep and pain outcomes require further confirmation. In

addition, our study lacked objective measures of sleep and used self-reported questionnaires that could be subject to bias; however, self-reported outcomes are considered the gold-standard assessment of insomnia (as well as pain) and are typically used in intervention studies (Dworkin et al., 2005).

In conclusion, our results suggest that an adapted telephone-delivered BBTI intervention is both acceptable and feasible to a sample of former NFL players with at least mild insomnia symptoms. We also observed telephone-delivered BBTI was associated with better sleep and with lower pain intensity and pain interference at post-treatment and 2-month follow-up. The latter finding is particularly salient to populations where there is a high co-occurrence of sleep disturbances and pain. Given the relative ease of disseminating telephone-delivered BBTI for this target group, future larger trials should examine the efficacy and/or effectiveness of telephone-delivered BBTI on sleep and pain in this population. This work also lays the foundation for future randomized trials that tailor and test a potentially scalable delivery of BBTI for other populations that experience insomnia symptoms, including groups with a high burden of pain.

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