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Protocol

Efficacy of synchronous, virtual cognitive behavioral therapy for insomnia across phases of cancer survivorship: a study protocol

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ABSTRACT

Background: Chronic insomnia affects up to 50% of cancer survivors, contributing to emotional distress, fatigue, and reduced quality of life. Cognitive behavioral therapy for insomnia (CBT-I) is the recommended first-line treatment, yet access remains limited, particularly for cancer survivors across different phases of survivorship. This study evaluates the efficacy of a synchronous, virtual CBT-I intervention targeted for cancer survivors survivorship sleep program (SSP) across curvivors, those in active treatment, and metavivors.
Methods: This randomized controlled efficacy trial will enroll 198 cancer survivors with clinically significant insomnia and will randomize participants 1:1 to the SSP (n=99) or enhanced usual care (EUC; n=99). SSP consists of four weekly 45-minute sessions and one booster session at week 6. The primary outcome is change in insomnia severity (ISI) from baseline (T0) to week 10 (T2). Secondary outcomes include subjective (sleep diary) and objective (Fitbit) sleep metrics, emotional distress, fatigue, sleep medication use, perceived cognitive functioning, work presenteeism/absenteeism, and health behaviors, assessed acutely (week 6; T1) and 3-months post-SSP (week 18; T0-T3). Exploratory outcomes include acceptability metrics and treatment effects by survivorship phase.
Conclusions: This trial addresses major gaps in the CBT-I literature by evaluating key subjective and objective sleep outcomes for cancer survivors across various phases of treatment. Findings will inform the scalable delivery of CBT-I in oncology, advancing access to evidence-based insomnia care.
Trial registration: NCT06181643.

Keywords: Insomnia, Cancer, Survivorship, Randomized controlled trial, Cognitive behavioral therapy, Sleep

INTRODUCTION

30-50% of cancer survivors, a population expected to grow to 26 million in the US by 2040, report clinically significant symptoms of insomnia.[1-3] Chronic insomnia is associated with poor quality of life in patients with cancer, including mood disruptions, fatigue, impaired daytime functioning, diminished immune functioning, and reduced survival.[2,4-6]

CBT-I is the first-line treatment recommended by the American college of physicians and the national

comprehensive cancer network.[7,8] Meta-analyses by our team and others have found that existing CBT-I programs tested with cancer survivors provide significant, medium-sized improvements in insomnia severity, sleep efficiency, sleep onset latency, and wake after sleep onset.[9,10] Patients receiving CBT-I may also report improvements in mood, fatigue, and pain, though these findings are modest and mixed.[11,12] Despite these observed benefits, tailored CBT-I is not widely available in oncology care.[13] Moreover, ongoing challenges with retention and adherence to CBT-I skills in patients with cancer suggest that the content and delivery of CBT-I may be further optimized to improve its acceptability.[10,14,15]

In response, our team developed the survivorship sleep program (SSP), a synchronous, virtual CBT-I intervention consisting of four weekly individual sessions, tailored to the unique needs of cancer survivors.[16] Data from our pilot trial of the SSP (N=40) demonstrated high enrollment (56%), session attendance (100%), and retention (90%) across longitudinal assessments, with statistically significant, large, and clinically meaningful reductions in insomnia severity.[16] These promising, yet preliminary findings, support the need for a fully powered randomized controlled trial (RCT) to evaluate the efficacy of the SSP across all phases of cancer survivorship.

Moreover, despite the repeated calls to address sleep health disparities in oncology, most CBT-I trials exclude cancer survivors currently receiving treatment and metavivors (i.e., cancer survivors who are living with metastatic cancer but not in active treatment).[15,17,18] Instead, most trials restrict enrollment to curvivors, or those who have already completed primary cancer treatment.[15,19] Cancer survivors receiving active treatment and metavivors may be at an even greater risk for developing insomnia, yet few studies have examined the efficacy of CBT-I in these subpopulations.[1] While emerging research that suggests that CBT-I may be beneficial for these survivors, extant studies have not utilized synchronous, virtual delivery via video-conferencing in their study designs, which may increase the accessibility of CBT-I for those with greater symptom burden while also allowing for personalization and accountability.[20-24] Lastly, no trial to date has compared the efficacy of CBT-I across these three survivorship groups (i.e., curvivors, those in active treatment, and metavivors). It is critical that we understand the efficacy of CBT-I across all survivorship phases in order to increase the intervention's scalability in real-world oncology settings.

There remain other opportunities for improving the content and delivery of CBT-I for cancer survivors. First, previous trials of CBT-I among cancer survivors have not yet examined how the intervention impacts patients' use of sleep medications; these medications are known to produce more severe side effects in cancer survivors and can lead to adverse events such as falls, fractures, and motor vehicle accidents.[25,26] Additionally, few CBT-I trials of cancer survivors assess both subjective and objective sleep metrics simultaneously. Notably, CBT-I may differentially impact self-reported and objective measures of sleep, underscoring the need to compare both metrics to fully understand the intervention's efficacy.[15,27,28] Finally, the sample composition of prior CBT-I trials has been notably limited by the underrepresentation of racial and ethnic minorities, who may face additional barriers to accessing this evidence-based treatment.[29] By purposefully sampling racial and ethnic minorities and including outcomes relevant to cancer survivors (e.g., use of sleep medications), we may continue to optimize CBT-I to meet the needs of this rapidly expanding population.

To address these gaps in the literature, we designed a RCT (n=198; 1:1) that evaluates the efficacy of the SSP (n=99) vs. EUC (n=99) among cancer survivors with insomnia across all phases of the survivorship continuum. The primary outcome of this fully powered RCT is to evaluate change in insomnia severity from baseline (T0) to follow-up (T2). Our secondary aim is to examine changes (T0-T3) in other key outcomes commonly associated with cancer-related insomnia, including established sleep metrics (measured using sleep diaries and wrist-worn actigraphy), emotional distress, fatigue, sleep medication use, perceived cognitive functioning, work presenteeism/absenteeism, and other health behaviors. We hypothesize that the SSP will yield greater improvements in insomnia severity and secondary outcomes compared to EUC. Lastly, we will explore differences in SSP treatment effects and feasibility/acceptability across three cancer survivorship phases (i.e., curvivors, those in active treatment, and metavivors) to inform future program refinements by survivorship phase.

METHODS

Study design

This is a preregistered (NCT06181643) RCT (n=198). Participants will be randomized 1:1 to either the SSP, (n=99) or the EUC (n=99) control condition. The consolidated standards of reporting trials (CONSORT) flow diagram is shown in Figure 1. This study is approved by the Dana-Farber/Harvard cancer center (DF/HCC) institutional review board (Protocol #24-594, first approved 02/26/2025).

Participant selection

Participants must be age 18 or older and meet DSM-5 criteria for chronic insomnia.[30] Eligible individuals will be cancer survivors, defined as: (A) history of nonmetastatic, localized or regional, solid or blood malignancy(ies) and completion of primary cancer treatment (i.e., radiation, surgery, and/or chemotherapy). Use of hormonal, maintenance, oral, and immunotherapies is permitted; or (B) history of

nonmetastatic, localized or regional, solid or blood malignancy(ies) and current primary cancer treatment (i.e., radiation, surgery, and/or chemotherapy); Use of hormonal, maintenance, oral, and immunotherapies is permitted; or (C) history of metastatic solid or blood malignancy(ies) taking hormonal, maintenance, oral, or immunotherapies to prevent further disease progression. Patients will be excluded when they endorse: an inability to speak and write in English, undertreated non-insomnia sleep disorders (e.g., untreated sleep apnea), undertreated epilepsy, undertreated serious mental illness, a psychiatric hospitalization within the past year or active suicidality, and/or being unwilling or unable to discontinue night shift work (Table 1).

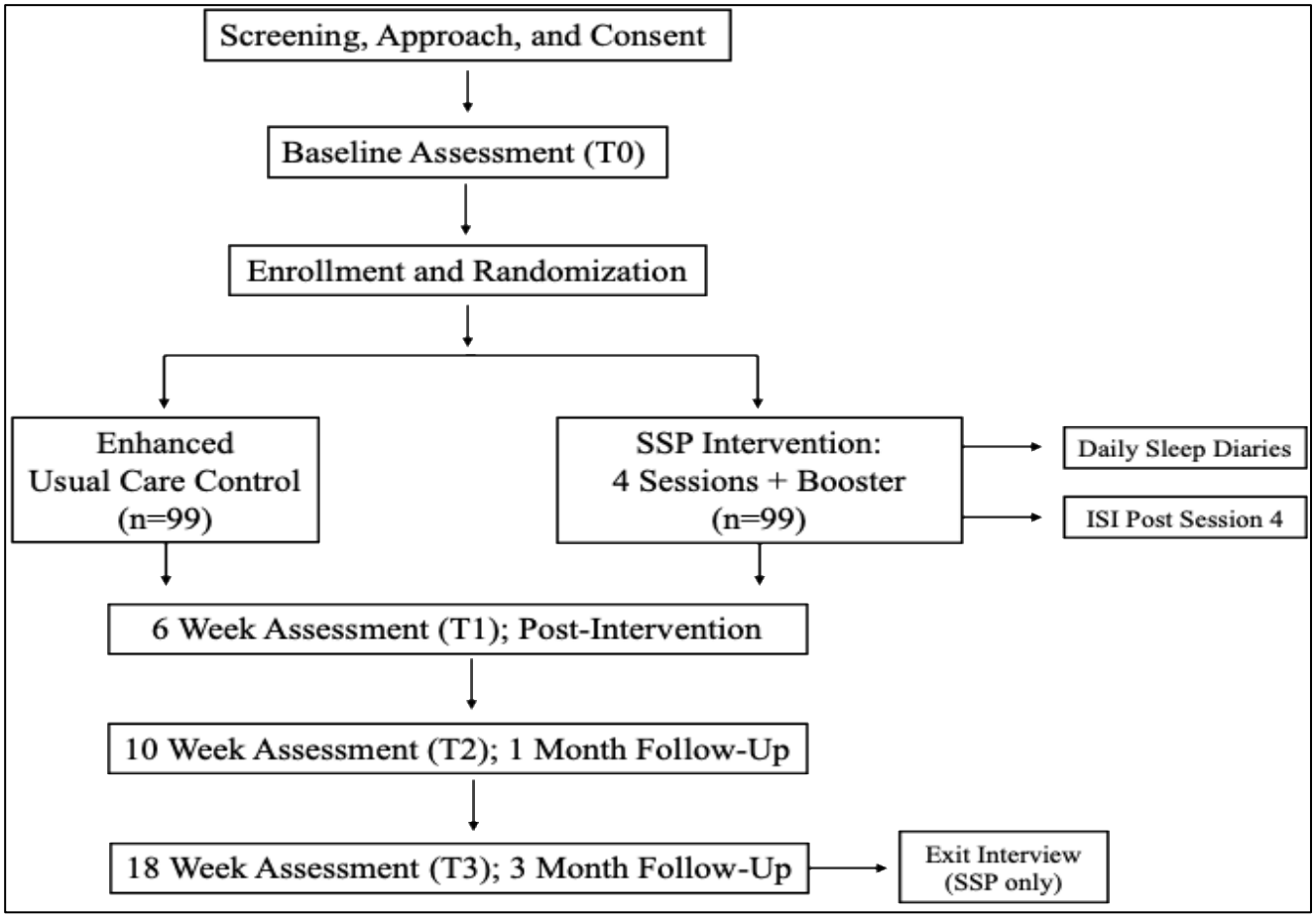

Figure 1: SSP RCT study schema.

Participant recruitment

We will employ a multi-modal recruitment strategy to enroll 198 cancer survivors. First, study staff will proactively screen electronic health records (EHRs) for clinical and demographic eligibility criteria. Once a patient is identified as eligible, study staff will request permission from their oncology clinician to approach them at their next scheduled clinic visit or via telephone. We received a partial HIPAA waiver approved by the IRB for this recruitment method. Second, we will rely on centralized data warehouses and recruitment portals within our hospital that gather clinical information based on user-generated criteria. Identified patients will be sent opt-out letters prior to any outreach. Third, we will post IRB-approved study flyers in high-traffic areas throughout the MGH cancer center. Next, providers from the MGH cancer center, the department of psychiatric oncology, and the behavioral sleep medicine clinic may directly refer patients to the SSP. Finally, in order to recruit >25% racial and ethnic minority participants, we will extend our flyer distribution to local community partners.

Enrollment and randomization

The total number of subjects to be enrolled is 198 (n=99/arm across 2 arms). Enrollment will be stratified by three levels of cancer survivorship phase: curvivors, in treatment, and metavivors (n=66/survivorship phase, balanced between study arms). Those who meet eligibility criteria will be enrolled and randomized after providing informed consent and completing the baseline assessment. The study biostatistician will randomly assign 198 participants (1:1) to the SSP intervention or EUC control arm in stratified blocks (3 strata of cancer survivorship phases; block size n=4) using a computer-derived random number generator to randomly. The PI and outcome assessors will be blind to allocation.

The SSP intervention

The SSP is a virtual, synchronous CBT-I intervention delivered individually across four weekly 45-minute sessions, with one 45-minute booster session two weeks after session 4. SSP sessions were modeled after an evidence-based CBT-I protocol and adapted with refined content and delivery plans based on a review of the literature and findings from our qualitative study and pilot RCT.[16,31] An overview is provided in Table 2.

SSP interventionists and fidelity

SSP interventionists will be supervised clinicians (e.g., clinical psychology trainees) who complete training in CBT-I. The PI and a licensed clinical psychologist will train the interventionists on the SSP protocol and will provide weekly supervision. Sessions will be recorded, and interventionists will record information about session length, content covered, and attendance after each session to ensure fidelity. Additionally, the PI will randomly select one session from each participant to review for fidelity using a blinded, computer-generated randomized list created by study biostatistician.

Control arm

Participants randomized to the control group will receive EUC, which includes a sleep hygiene handout and referral information for accessing CBT-I locally. The sleep hygiene handout mirrors what is provided in the SSP intervention (Session 2).

Assessments

Data will be collected electronically via REDCap, on paper, or by phone as needed.[32] Surveys will be administered at baseline (T0), six weeks (T1), 10 weeks (T2), and 18 weeks (T3). For those randomly assigned to SSP, these timepoints correspond to pre-intervention, immediate post-intervention (4 sessions and booster), one-month follow-up, and three-month follow-up, respectively. Each assessment battery will take approximately 20 minutes to complete. Those assigned to the SSP will additionally complete insomnia severity index immediately following session 4 to allow for examination of interim effects of our primary outcome (Table 3).[30]

Additionally, participants will be asked to complete a sleep diary and wear a Fitbit to assess their sleep for 7 days at each timepoint and daily during SSP Sessions 1-4. Fitbits will be mailed to participants along with detailed instructions about when and how to wear the devices. Study participants will mail back the devices to the study team upon completion of data collection. Lastly, a member of the study team will randomly selected subset of participants (n=30; n=10 per survivorship phase) to complete a 30-minute exit interview at 18 weeks (T3) to assess intervention acceptability. All participants assigned to the SSP will complete a 5-item acceptability questionnaire during the T3 assessment. Accordingly, those in the EUC arm will not complete these acceptability measures. Participants will be compensated $20 per survey (4 total surveys) and $20 for completing the exit interview.

Table 1: Eligibility criteria.

Inclusion criteria	Exclusion criteria
Adults (≥18 years)	Self-reported inability to speak or write in English
Chronic insomnia (DSM-5 criteria)	Undertreated non-insomnia sleep disorder (for e. g., sleep apnea)
Cancer survivor, defined: History of nonmetastatic, localized or regional, solid or blood malignancy(ies) and completion of primary cancer treatment (i.e., radiation, surgery, and/or chemotherapy). Use of hormonal, maintenance, oral, and immunotherapies is permitted History of nonmetastatic, localized or regional, solid or blood malignancy(ies) and current primary cancer treatment (i.e., radiation, surgery, and/or chemotherapy): Use of hormonal, maintenance, oral, and immunotherapies is permitted History of metastatic solid or blood malignancy(ies) taking hormonal, maintenance, oral, or immunotherapies to prevent further disease progression.	Undertreated epilepsy, undertreated serious mental illness, undertreated suicidality, and/or psychiatric hospitalization in the past year
	Unwilling or unable to discontinue night shift work

Table 2: SSP intervention content.

Week	Session	Content
1	1	Welcome: Building rapport, confidentiality Assessment: Review sleep history and cancer-related factors affecting sleep Education: Sleep diary, sleep drive and circadian rhythm, 4 Factor Model Skill: Stimulus control (adapted) Skill: Efficient sleep (adapted) Develop sleep prescription Identify and problem-solve potential barriers to adherence
2	2	Identify and problem-solve barriers to adherence Review sleep diary and titrate sleep prescription Skill: Sleep hygiene (adapted) Skill: Relaxation (adapted)
3	3	Identify and problem-solve barriers to adherence Review sleep diary and titrate sleep prescription Skill: Cognitive techniques (adapted): Reframing thoughts and worry time
4	4	Identify and problem-solve barriers to adherence Review sleep diary and titrate sleep prescription Education: Insomnia relapse prevention
6	Booster	Identify and problem-solve barriers to adherence Review sleep and titrate sleep prescription Review Insomnia relapse prevention plan Discuss next steps in the study

Table 3: Study instruments and assessment time points.

Outcome	Study instrument	Baseline (T0)	During SSP	Post session 4	6 weeks (T1)	10 weeks (T2)	18 weeks (T3)
Sociodemographic and medical history	Patient self-report	X					
Insomnia severity	Insomnia severity index (ISI)	X		X	X	X	X
Subjective sleep	Consensus sleep diary	X	X		X	X	X
Objective sleep	Wrist-worn actigraphy via fitbit inspire 3	X	X		X	X	X
Anxiety	PROMIS anxiety short form	X	X		X	X	X
Depression	PROMIS depression short form	X	X		X	X	X
Fear of cancer recurrence	Fear of cancer recurrence inventory (FCRI)	X	X		X	X	X
Fatigue	PROMIS fatigue short form	X	X		X	X	X
Use of sleep aid meditations	Self-report and electronic health record	X			X	X	X
Perceived cognitive impairment	Functional assessment of cancer therapy-cognitive function (FACT-Cog)	X			X	X	X
Smoking	Investigator-generated items	X			X	X	X
Physical activity	International physical activity questionnaire (IPAQ)	X			X	X	X
Perceived wt change	Investigator-generated items	X			X	X	X
Work functioning	Work productivity and activity impairment questionnaire-general health	X			X	X	
Use of mind-body practices	Mind-body practice questionnaire	X			X	X	X
SSP acceptability	Brief exit interview#						X
	Investigator-generated items#						X

[a]PROMIS refers to patient-reported outcomes measurement information system; [b]these measures are administered to participants randomized to the intervention arm.

Demographic and medical history

During eligibility screening, the following information will be collected via self-report: date of birth, race, ethnicity, cancer diagnosis, date of cancer diagnosis, treatment received, and date of treatment completion (if applicable). During the baseline assessment, the following information will be collected via self-report: education, relationship status, employment status, health insurance, and annual household income.

Primary outcome measure

The primary outcome for this study is change in insomnia severity from T0-T2 (10 weeks), as measured by the ISI.[30] The ISI has been validated in cancer survivors and reductions of >8 points are considered clinically meaningful.[30,33]

Secondary outcome measures

Secondary endpoints will examine acute (T0-T1; 6 weeks) and 3-month (T0-T3; 18 weeks) changes in the following outcomes:

Sleep diaries

Participants will track their sleep using the consensus sleep diary, a validated and standardized self-report tool used to assess subjective sleep patterns on a daily basis.[34] Participants complete 9 items about their sleep each morning. Derived metrics include total sleep time, total time in bed, sleep efficiency, sleep onset latency, and wake after sleep onset.

Wrist-worn actigraphy

To measure sleep objectively, we will use the Fitbit Inspire 3 device, a wrist-worn actigraphy tool utilized in our previous SSP trials.[16] Fitbit data will be collected during SSP Sessions 1-4 and for 7 days at each assessment (T0-T3) to derive sleep onset time, sleep wake-up (offset) time, sleep midpoint (difference between onset and offset), sleep duration, sleep efficiency, sleep onset latency, and wake after sleep onset. Discrepancy scores between subjective (e.g., sleep diary) and objective sleep metrics (e.g., Fitbit) will also be examined.

Anxiety

We will measure anxiety using PROMIS anxiety short form, 4-item self-report questionnaire.[35] Response options range from 1 (Never characteristic of me) to 5 (Always). Items include "In past seven days, I felt fearful."

Depression

We will measure depression using the PROMIS depression short form, a 4-item self-report questionnaire.[35] Response options range from 1 (Never characteristic of me) to 5 (Always). Items include "In the past seven days, I felt worthless."

Fear of cancer recurrence (FCR)

We will measure FCR using the fear of cancer recurrence inventory-severity subscale.[36] Items such as "I am afraid of cancer recurrence" are rated on a five-point Likert scale, from 0 (Not at all) to 4 (A great deal).

Fatigue

We will measure fatigue using the PROMIS fatigue short form, a 7-item self-report questionnaire.[35] Response options range from 1 (Never characteristic of me) to 5 (Always). Items include "In the past seven days, how often did you feel tired?"

Use of sleep aid meditations

Use of sleep aid medications (frequency, dose) will be evaluated via self-report surveys and the EHR when possible.

Perceived cognitive impairment

We will measure perceived cognitive using the perceived cognitive impairment subscale of the functional assessment of cancer therapy-cognitive function (FACT-Cog), a 20-item self-report questionnaire.[37] Responses range from 0 (Never) to 4 (Several times a day). Participants are asked to rate items such as "My thinking has been slow" over the past 7 days.

Work presenteeism/absenteeism

To assess work functioning, we will use the 6-item work productivity and activity impairment-general health questionnaire.[38] Items use a variety of Likert-style and open-ended questions to measure the effect of health problems on one's ability to work over the past week.

Smoking

To assess cigarette smoking status, we will use a 2-item self-report questionnaire that assesses current and prior cigarette smoking use: "Do you now smoke cigarettes every day, some days, or not at all?" and "About how long has it been since you last smoked a cigarette, even a puff?"

Physical activity

To measure physical activity in the past 7 days, we will use the international physical activity questionnaire, a 4-item self-report questionnaire. Items include, "on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling?"

Perceived weight change

To measure perceived weight changes, we will use a 2-item self-report questionnaire assessing both accidental weight changes as a result of cancer treatment and intentional weight changes.

Integrative healthcare use

Integrative modality use was assessed by asking participants to report whether or not (yes/no) they used 16 different integrative modalities since being diagnosed with cancer, including: acupuncture, biofeedback, chiropractor, crystals/magnets, diet, herbal remedies, homeopathic remedies, hypnosis, massage, meditation, mind-body exercise, naturopathic, spirituality, supplements, therapeutic touch, and vitamins.

Exploratory measures

We will explore feasibility and acceptability of the SSP across survivorship phase using both qualitative and quantitative measures.

Exit interview

SSP participants will complete a brief individual exit interview via videoconferencing. Interviews will be led by a trained study coordinator using a semi-structured interview guide with open-ended responses to characterize intervention preferences and future delivery considerations.

Acceptability questionnaire

SSP participants will complete a five-item Likert questionnaire (very low=1 to very high=5; benchmark=median scores of 4) that asks about intervention enjoyableness, convenience, helpfulness, odds of future use, and overall satisfaction.

Feasibility. The primary benchmark for feasibility is study enrollment (≥56% enrolled/eligible). Additional metrics include retention per timepoint and attendance in sessions.

Statistical analyses

Sample justification

Using a one-sided Wilcoxon Rank-Sum test with significance level (alpha) of 0.05 and power of 80%, the effect size for differences between the SSP and EUC on the primary outcome (ISI change from T0-T2) for n=30, n=60 and n=90 in each arm is 0.67, 0.47 and 0.38, respectively. Therefore, an overall sample size of 198 (and assuming at most 10% dropout) should yield between n=90-99 per arm, which is sufficient for targeting a much more conservative effect size by 1-month. Because enrollment is stratified by survivorship phase (3 phases, n=66 per phase), there will be n=33 (or n=30 with 10% dropout) survivors in each phase per arm, affording sufficient power to detect differences in study arms by survivorship phase.

Primary aim

We hypothesis that those randomly assigned to the SSP will yield greater improvements in insomnia severity (ISI) from T0-T2 compared to those assigned to the EUC control condition. All randomized participants will be analyzed using Intention-to-Treat in adjusted and unadjusted general linear mixed effects models across four repeated measures on ISI: T0, T1, T2, and T3. Fixed effects will be specified for time and condition, and random effects will account for nesting (within-subjects) across timepoints. Within linear mixed models, missing data are handled using the maximum likelihood, which incorporates information from all randomized participants using all available timepoints and minimizes the risk of producing biased estimates inherent in other methods (e.g., pairwise or listwise deletion).

As the primary analysis, in Model 1 we will examine the effect of the intervention condition on the change in ISI scores from T0-T2 (primary outcome), a random intercept model will be conducted with T0 as the timepoint reference and EUC as the treatment group reference to produce contrasts at T2 by study arm. Time, treatment condition, and time×treatment condition will be included as fixed effects, with magnitudes calculated as partial r-squared values. A Cohen's d value of between-group effects will be calculated using estimated marginal means from T0 and T2. Time will be treated as a 4-level categorical variable (T0-T3) to obtain estimated marginal means and standard errors by condition at each timepoint. In exploratory analyses, we will examine potential acute effects (T0-T1) and sustained effects (T0-T3) on ISI scores from T0. Sensitivity analyses will also analyze ISI as a categorical variable (i.e., below/above clinical cutoff=15).

Secondary aims

We also anticipate greater acute (T0-T1) and 3-month (T0-T3) improvements in secondary outcomes among participants assigned to the SSP compared to those in the EUC control condition. Secondary outcomes will be analyzed in linear mixed effects models to model changes from baseline through 3-month follow-up (T0-T3). Secondary outcome models will be modeled separately in models structured after Model 1 (above). Use of sleep aids will be examined as an exploratory outcome of group x time effects from T0-T3 (hypothesis: SSP vs UC reduces use of sleep aids) and separately as an exploratory effect moderator (hypothesis: participants who use sleep aids at study entry will have similar benefits as participants who do not use sleep aids at study entry).

Exploratory aims

Lastly, we will explore differences across the three survivorship phases in terms of treatment effects (T0-T3), feasibility, and acceptability. Both primary and secondary outcomes will be characterized within survivorship phases using descriptive statistics (Mean, median, range) and data visualization (scatterplots with trend lines). In addition, we will conduct pair-wise comparisons between any two survivorship phases using a two-sample permutation test. Specifically, we will resample the empirical data without replacement 1000 times and calculate the difference in medians between the groups for each sampled data. The p value will be calculated as the fraction of times the resampled difference exceed the observed difference, multiplied by 2 (for a two-sided test). To adjust for comparisons multiplicity, a p=0.015 will be considered as significant.

Feasibility of the intervention across survivorship phase will be determined using established benchmarks and calculated using proportions. The primary benchmark for feasibility is study enrollment (≥56%), which is the proportion of participants enrolled of those eligible. Additional metrics include data retention per timepoint and proportion of SSP sessions attended.

Acceptability of the intervention for survivors across phases will be analyzed using quantitative and qualitative methods. Quantitatively, ratings will be summarized by medians, means, and response ranges. The primary benchmark for acceptability is 80% or more of satisfaction responses rated 4 or higher (indicating high acceptability). Qualitatively, recorded and transcribed exit interviews will undergo directed content analysis by two independent coders to identify the most and least acceptable aspects of the intervention for each of the 5 acceptability items. Preferences, challenges, and future intervention delivery considerations will be explored by coding exit interviews for emergent themes, for the entire sample and stratified by race and ethnicity. A hybrid deductive and inductive coding structure will allow for emergent themes by two independent coders. For all qualitative analyses, discrepancies will be reconciled by the PI until acceptable reliability (Kappa index ≥0.80) is achieved.

Data sharing and monitoring

The study is registered on ClinicalTrials.gov (NCT06181643). Results of the study will be posted to the ClinicalTrials.gov database at the conclusion of the study. Self-report assessments will be monitored regularly by the study team. Participants will give voluntary responses to interview questions and may decline to answer any questions they choose. If patient expresses suicidal ideation in a session or responds “often” or “always” to the PROMIS depression item that assesses passive suicidal ideation, the PI will be notified and will initiate any necessary actions to ensure participant safety.

DISCUSSION

Chronic insomnia is a prevalent yet treatable issue in cancer survivors. CBT-I is an evidence-based intervention that improves both insomnia severity and emotional distress, yet further investigations are warranted to fully elucidate this intervention’s impact in oncology and acceptability across the cancer care continuum. Our synchronous, virtual CBT-I program demonstrated preliminary efficacy in reducing insomnia severity while increasing accessibility in our pilot trial.[16] Building off these results, the current trial now seeks to test the efficacy of the SSP compared to EUC. The results from this fully powered trial will characterize the efficacy of the SSP in terms of insomnia severity (primary outcome), subjective and objective sleep metrics, emotional distress, fatigue, sleep medication use, perceived cognitive functioning, and other health behaviors. The results will also begin to characterize how the SSP functions across three phases of cancer survivorship. Collectively, these findings will offer a critical evidence base to guide implementation of scalable, equitable sleep interventions for all cancer survivors, a long-standing gap in supportive oncology care.

CONCLUSION

This trial addresses major gap in the CBT-I literature by evaluating key subjective and objective sleep outcomes for cancer survivors across various phases of treatment. Findings will inform the scalable delivery of CBT-I in oncology, advancing access to evidence-based insomnia care.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee Dana-Farber/Harvard Cancer Center (DF/HCC).

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