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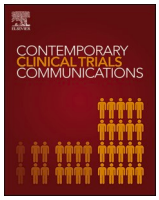

Protocol of Brief Behavioral Treatment for insomnia intervention for adult patients with cancer and their sleep-partner caregivers

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ABSTRACT

Background: Sleep disturbance is common and problematic among both patients with cancer and their sleep-partner caregivers. Although one's sleep affects the partner's sleep, existing psychobehavioral interventions have targeted patients' and caregivers' sleep problems independently.
Methods: We adapt the Brief Behavioral Treatment for Insomnia (BBTI) for both adult patients and their sleep-partner caregivers in the context of cancer. This protocol is to test the feasibility and acceptability as well as to provide preliminary efficacy of the BBTI for Couples with Cancer (BBTI-CC) intervention, which is to reduce sleep disturbance and improving sleep quality of both adults with cancer and their sleep-partner caregivers. The intervention will be delivered weekly for 4 weeks. Questionnaire and daily sleep logs will be collected at baseline (T1) and one-week after conclusion of the intervention (T2). Satisfaction with the intervention will be assessed weekly for 4 weeks.
Results: We estimate 18 dyads will be enrolled (18 patients and 18 caregivers). We expect >75 % of eligible and screened dyads will enroll within the enrollment period, >80 % of enrolled dyads will complete the intervention, and >80 % of participants will report satisfaction across all acceptability measures. We also expect BBTI-CC will reveal a small-to-medium effect on sleep efficiency (primary outcome), overall sleep disturbance, subjective sleep quality, and insomnia severity (secondary outcomes).
Conclusions: Results will inform the feasibility and acceptability of conducting a dyadic sleep behavioral intervention, and provide preliminary efficacy data to guide further refinement of intervention content and procedure for adult patients with cancer and their sleep-partner caregivers.

1. Introduction

Over 18.1 million people in the United States have a history of at least one cancer diagnosis in 2022, which is estimated to increase to 26 million by 2040 [1]. Sleep disturbances, including difficulties falling asleep and difficulties staying asleep due to frequent and prolonged nighttime awakenings that result in poor sleep quality [2–4], are prominent concerns of cancer survivors. In fact, 65 %–95 % of patients with cancer have reported sleep disturbance [5,6], which is notably higher than that of age-matched individuals who have not had cancer (14 %–30 % [5,7,8]: and the adult U.S. general population (35 %: 9). Sleep disturbance has been associated with impaired quality of life, disease progression, and poorer overall survival of patients with cancer [4,10,11].

Cognitive Behavioral Therapy for Insomnia (CBT-I) is the gold standard intervention endorsed by the American Academy of Sleep Medicine for treating sleep disturbance among the general population. Modified CBT-I has been primarily offered for adult patients with cancer [12–15]. Overall, evidence suggested that psychobehavioral sleep interventions improved sleep quality compared with standard care or treatment as usual as the control condition [16]. CBT-I typically includes sleep education, sleep hygiene, stimulus control, sleep restriction/-compression, and cognitive therapy to address anxiety-provoking beliefs about sleep. The clinical utility of CBT-I, however, has been limited due to the shortage of trained clinicians, the extensive duration of 6–10 h-long sessions over 6 to 20-week period, and focusing on patients with primary insomnia (excluding those with medical comorbidities).

Brief Behavioral Treatment for Insomnia (BBTI) has been developed as a briefer alternative to CBT-I and has demonstrated efficacy [17]. This treatment focuses on individuals' sleep restriction/compression and

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stimulus control, and is delivered over 2 to 4 weekly sessions by a range of clinicians who are familiar with health promotion but not necessarily trained in CBT, which enhances the value of the intervention by increasing access to care [17–19]. A recent meta-analysis documents the preliminary efficacy of BBTI in improving sleep quality for mid-to older adults with various health conditions [20].

Sleep disturbance is also common among family caregivers of patients with cancer: 63 %–90 % of cancer caregivers [21,22]. Such prevalence is higher than that reported by caregivers of individuals with chronic disease such as cardiovascular disease [23], Parkinson's disease [24], and dementia [25]. Sleep disturbance in caregivers has been attributed to their own and their patients' cancer-related stress [3,26], which is also associated with poor quality of life and adverse health outcomes of the caregivers [27,28].

Additionally, approximately 70 % of the general adult population sleep in the same bed with a significant other [9], as do adult patients with cancer and their spousal caregivers/intimate partners. One's sleep can affect the partner's sleep and both adult patients with cancer and their sleep-partner caregivers have greater sleep disturbance. However, existing sleep interventions including BBTI have targeted only patients [12,29] and caregivers [30] separately. Targeting both patients with cancer and their sleep partnered caregivers for mitigating their sleep disturbance would yield optimal outcomes of improved sleep health and general quality of life for both sleep partners [31,32]. Such approach may be a critical first step to advance understanding and treating sleep, a shared health behavior in these highly vulnerable populations touched by cancer. Yet, such interpersonal approach thus far has been applied only to healthy young-to-middle-aged adults [33–39], patients with insomnia [40,41], or parents with newborn babies [42,43], whose sources of sleep disturbance exclusively differ from those in cancer patient-caregiver dyads.

Specifically, patients with cancer who undergo cancer treatment may experience sleepiness or drowsiness from the treatment and the side effects. Thus, the sleep restriction therapy component may need to be relaxed to accommodate such medical conditions. In addition, an intervention delivered to two members of a dyad requires some discussion of negotiating different sleep schedules within the dyad. For example, one partner may need to go to bed later than the partner to reduce sleep onset latency, which can be a concern for couples who used to go to bed at the same time. As a major illness in the family, such as cancer, is a shared stressor, addressing its manifestation in disturbed sleep of both sleep partners is even more critical.

Thus, we will adapt the BBTI to target both adult patients with cancer and their sleep-partner caregivers. We chose BBTI for its brevity and deliverability by a range of clinicians who are familiar with health promotion but not necessarily trained in CBT [17–19]. The adapted BBTI protocol for patient-caregiver dyads is registered on ClinicalTrials.gov (NCT06571305) and approved by the University of Miami Institutional Review Board.

2. Methods

2.1. Study design

This study describes the development of the Brief Behavioral Treatment for Insomnia for Couples with Cancer (BBTI-CC) intervention, which is an adapted BBTI to improve sleep health of both adult patients with cancer and their sleep-partner caregivers. As a first step, the BBTI-CC will be tested in a single arm study design, delivered weekly for 4 weeks. This study aims to test the feasibility and acceptability of the BBTI-CC intervention for both adult patients with cancer and their sleep-partner caregivers. This study also aims to provide preliminary efficacy of the BBTI-CC intervention in reducing sleep disturbance and improving sleep quality for both adult patients with cancer and their sleep-partner caregivers.

2.2. Recruitment

Eighteen patient-caregiver dyads (36 persons) will be recruited using two methods. In the first method, patients are referred to the study team by treating clinicians at the Brevard Cancer Care Centers, FL. Treating clinicians provide study brochures to patients who are diagnosed with a solid tumor. Patients who are interested in getting more information contact the study team using the contact phone number provided on the brochure.

In the second method, patients are identified using the Sylvester Comprehensive Cancer Center (SCCC) Tumor Registry. The search criteria to screen potentially eligible patients are to reside in Brevard County, FL, have a visit to the SCCC in the past 3 years, be alive, and diagnosed with a solid tumor. Using the Dillman Method [44], all potential participants from the SCCC Tumor Registry received an introductory letter from the study team. After the letters are mailed, the study team calls the participants at least once a week, with a total of eight calls on weekdays and weekends and at different times of day for three weeks. For unreachable cases, a follow-up letter is mailed, followed by another set of eight recruitment calls. A partial HIPAA waiver is obtained to screen potentially eligible patients.

For either the first or second method, once a patient is determined to be eligible for the study, the patient is asked to nominate their sleep-partner caregiver, who is also screened by the study team. After both the patient and their caregiver meet the study eligibility criteria, they are scheduled the study sessions.

2.3. Eligibility

Eligibility, inclusion criteria for patients will be [1] having a diagnosis of stage I to IV of a solid tumor in the past 3 years at the time of enrollment and [2] having a consistent sleep partner who shares a bed with the patient most of the time ($\geq$4 out of 7 nights per week) when either partner is not traveling and who has lived together with the patient for at least one year. Eligibility criterion for caregivers will be being a sleep partner of the patient. Additional eligibility criteria for both patients and caregivers will be [1] having at least mild-to-moderate sleep disturbance Pittsburgh Sleep Quality Index: PSQI $\geq$5 [45] [2], willing to change sub-optimal sleep habits [3], 18 years or older [4], able to speak/read English at the 5th grade reading level, and [5] $>$ 4 weeks after surgery, if any, prior to enrollment because surgery affects sleep.

2.3.1. Exclusion criteria

Exclusion criteria for both patients and caregivers will be [1] having had a diagnosis of psychosis, major depressive disorder, or bipolar disorder that is not currently treated [2]; having had substance or alcohol dependency, or active suicidal attempt in the past year [3]; currently have narcolepsy or restless leg syndrome that is not treated [4]; both patients and caregivers have an extreme chronotype, or do shift work to have no overlap in sleep schedule between patients and caregivers [5]; plan trans-meridian travel during the period of data collection blocks; and [6] have hearing or visual impairment that is not adjusted with adequate aids, dementia, or cognitive dysfunction.

2.4. Informed consent

This study is approved by the University of Miami Institutional Review Boards. The protocol is registered with ClinicalTrials.gov (NCT06571305). The project coordinator will explain to each participant the purpose and procedures, the risks and benefits, the terms of confidentiality, and the compensation of the study. Participants will be given the opportunity to carefully review and ask questions regarding the written consent form, which is presented on a web-based and HIPAA-compliant Research Electronic Data Capture (REDCap) application. Signed consent, which is approved by the University of Miami

Institutional Review Boards, will be obtained from each participant. Participants will also be given the opportunity to keep a copy of their signed consent form.

2.5. Study procedure (Fig. 1)

Participants will complete the pre-intervention assessment (T1) that includes a questionnaire to be completed once on a web-based Qualtrics application and daily sleep measures for 7 days on REDCap application. This study will employ a single arm study design as a first step. The intervention will be delivered via a HIPAA-compliant Zoom video platform once a week to both patients and caregivers together for 4 weeks. Participants will complete an intervention satisfaction survey immediately after the end of each session on a web-based Qualtrics application. The project coordinator manages the intervention satisfaction survey, so that participants will be informed that the interventionist is blind to the survey data. The post-intervention assessment (T2) includes a questionnaire completed once on a web-based Qualtrics application and daily sleep measures for 7 days on REDCap application, which begins 7 days after final intervention session (see Fig. 2). In both T1 and T2 questionnaires, participants will be asked to list medical conditions [46] and medications taken to manage each condition. The interventionist will review the list of medications and note its potential effects on participants' sleep quality to incorporate the information into the intervention session. The interventionist also asks the type and date of cancer treatment received at each intervention session to incorporate it into the intervention content.

2.6. Intervention

The fundamental behavioral components of Brief Behavioral Treatment for Insomnia (BBTI), including sleep hygiene, sleep restriction/compression, and stimulus control, are included in the Brief Behavioral Treatment for Insomnia for Couples with Cancer (BBTI-CC) intervention. BBTI-CC will maintain the sleep restriction aspect to reduce the total time in bed to match the total time spent asleep plus 30 min. However, recognizing the sleepiness or drowsiness from cancer treatment and the side effects on and a couple of days after receipt of a treatment [47,48], BBTI-CC relaxes the sleep restriction therapy component of BBTI such that prescribed time in bed will not be less than 7 h, even if actual sleep time is less than 6.5 h. In addition to accommodating cancer-related sleep behaviors, the BBTI-CC is also adapted BBTI to target both sleep partners (patients with cancer and their family caregivers), given the dyadic nature of sleep and cancer.

The BBTI-CC intervention consists of four up to 1-h weekly sessions delivered by a master's level interventionist who has been trained in Clinical Psychology, Behavioral Medicine, Social Work, or related field, who are not necessarily trained in CBT yet promote access to sleep health care for those affected by cancer. The competency of the interventionist in the behavioral principles of sleep modification, cancer treatment and symptom management, and sleep in the close relationship context will be ensured through a minimum of three didactic training sessions and two full sets of intervention sessions with mock participants role playing. In addition, the intervention fidelity will be assessed by a research scientist who specializes in psycho-oncology and/or a licensed clinical psychologist for the first 9 dyads (50 %). Additional training will be performed with the interventionists if they do not meet ≥90 % of the protocol adherence checklist that is developed by the study team. The BBTI-CC is delivered via a HIPAA-compliant video platform to the patient and caregiver simultaneously.

Topics covered in the weekly sessions (see Fig. 2) will include psychoeducation on sleep processes and sleep hygiene (Session 1: Sleep hygiene behavior), psychoeducation on stimulus control and sleep compression (Session 2: Stimulus control and sleep compression), troubleshoot barriers to adherence to sleep hygiene and stimulus control guidelines (Session 3: Troubleshooting), and psychoeducation on addressing relapse prevention (Session 4: Relapse prevention). Before Session 1, seven days of sleep logs are individually completed by each participant and used to tailor the intervention sessions.

Session 1 introduces the intervention and provides psychoeducation about the two-process model of sleep [49,50] and sleep hygiene. Each partner's sleep hygiene habits from the 7 days of sleep logs are reviewed,

	Enrolment	Allocation	Pre-intervention Assessment	Intervention	Post-intervention Assessment
TIMEPOINT**	$-t_1$	0	t_1		t_2
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation (for 1-arm RCT)		X			
INTERVENTIONS:					
[DBBTI-C intervention]				⟷	
ASSESSMENTS:					
[Demographics]			X		
[Sleep behaviors]			X		
[Intervention session evaluation]				X	
[Sleep outcomes]			X		X

Fig. 1. Schedule of enrolment, interventions, and assessments.

Phases	Content	Timeline
Screening / Enrollment	❑ Initial contact / screening ❑ Enrollment	• Week 0, Day 0
Pre-Intervention Assessment	❑ Pre-intervention questionnaire ❑ 7 days of sleep logs	• Week 1, Day 1 • Week 1, Day 1 - Day7
Intervention Session 1: Introduction and Sleep Hygiene Behavior [60 minutes]	☐ BBTI-CC Introduction ☐ Individual Sleep Review ☐ Sleep Behavior Psychoeducation - Two process model of sleep - Sleep hygiene ☐ Setting Goals Regarding Sleep Hygiene Behavior Changes ☐ Home Practice (Homework) & Confirm Next Session Schedule - Checklist of sleep hygiene	• Week 2, Day 10
Intervention Session 2: Stimulus Control and Sleep Compression [60 minutes]	☐ Review Session 1 Homework - Address any problems with sleep hygiene ☐ Stimulus Control and Sleep Restriction Psychoeducation ☐ Setting Goals for Improving Stimulus Control and Sleep Restriction ☐ Home Practice (Homework) & Confirm Next Session Schedule - Checklist of sleep hygiene and stimulus control	• Week 3, Day 17
Intervention Session 3: Troubleshoot barriers to treatment adherence [60 minutes]	☐ Review Session 2 Homework - Address any problems with sleep hygiene and stimulus control ☐ Troubleshoot barriers to treatment adherence ☐ Home Practice (Homework) & Confirm Next Session Schedule - Checklist of sleep hygiene and stimulus control	• Week 4, Day 24
Intervention Session 4: Relapse Prevention [60 minutes]	☐ Review Session 3 Homework ☐ Address any problems with sleep hygiene / stimulus control Good Sleep Maintenance and Relapse Prevention ☐ Setting Goals Regarding Good Sleep Maintenance and Relapse Prevention ☐ Home Practice (Homework) & Confirm Post-Intervention Assessment Schedule	• Week 5, Day 31
Post-Intervention Assessment	☐ 7-day sleep logs that include sleep markers, sleep hygiene and stimulus control ☐ Post-intervention questionnaire	• Week 6, Day 38 – Day 44 • Week 6, Day 44

Fig. 2. BBTI-CC intervention content and timeline.

and goals for changing relevant sleep hygiene behaviors are collaboratively discussed and negotiated between participants and interventionist. During Session 2, progress with behavior changes for sleep hygiene is reviewed. Then, stimulus control and sleep compression principles are introduced. Session 2 is tailored according to each participant's reported sleep schedule and behaviors from the 7 days of sleep log (e.g., sleep onset latency, wake after sleep onset, non-sleep time in bed). If participants do not have any problems with sleep hygiene, stimulus control is introduced in Session 1. Similar to Session 1, goals for relevant stimulus control and sleep compression are collaboratively discussed and negotiated.

Session 3 reviews sleep hygiene, stimulus control, and sleep compression, as well as focuses on troubleshooting any barriers to adhering to guidelines and to making the progress toward the goals. If participants faced challenges during the past two weeks, the interventionist and each participant re-negotiated the most feasible and achievable behavioral goals, so that participants could practice these revised goals before the final session. If participants were able to adhere to treatment recommendations but continue to have sleep disturbance, behavioral goals would be adjusted. For example, if a participant continued to have more than 30 min of either wakefulness in the middle of the night or sleep latency, the interventionist would negotiate to further restrict bedtime window by 15 min (but no less than 6 h). In Session 4, the behavioral components of BBTI are reviewed again, if needed. Participants' progress and barriers experienced are also discussed. The focus of Session 4 is primarily on psychoeducation to support healthy behavior maintenance and relapse prevention. This will include instructions on how to self-titrate the total time in bed by increasing total time in bed by 15-min increments if total wakefulness is less than 30 min per night or decreasing total time in bed by 15-min increments if total wakefulness is greater than 30 min per night.

The order of the session content can be tailored for individual dyads based on the information obtained from pre-intervention questionnaire and daily sleep logs. For example, a dyad whose members reported no issues with sleep hygiene behaviors but greater issues with stimulus control related behaviors, stimulus control can be discussed in Sessions 1–4, while shortened psychoeducational information on sleep hygiene is presented in Session 1. On the other hand, a dyad whose members reported greater concerns relating to sleep hygiene but no or little concerns regarding stimulus control related behaviors, discussing their sleep hygiene behaviors in Sessions 1–3, while shortened psychoeducational information on stimulus control is presented in Session 3. Interventionist creates the tailored intervention planner reflecting each dyad's information collected from pre-intervention assessment prior to the first session and modifies the subsequent session planner, if necessary, after each intervention session ends.

2.7. Outcome measures

2.7.1. Feasibility measures

The enrollment rate will determine the feasibility of the BBTI-CC intervention. The feasibility criteria will be met if 75 % of eligible dyads enroll within the 12-month enrollment period, if 80 % of enrolled dyads complete the intervention (one week after the last intervention session and assessment), and no adverse events are reported.

2.7.2. Acceptability measures

Participants' evaluation of the intervention content and mode will determine the acceptability of the BBTI-CC intervention. Participants will evaluate the intervention content after each session by completing brief questions on a 5-point Likert scale (1: strongly disagree, 5: strongly agree). Acceptability questions are regarding the extent to which the session being engaging, easy to understand, comprehensive, useful, relevant, motivating sleep behavior changes, and helping to prepare for making sleep-related changes. The delivery mode of the intervention will be assessed at the post-intervention session as a part of the questionnaire packet for each participant. Specifically, participants will provide their opinions on the frequency (weekly), delivery mode (Zoom vs. in-person or telephone), and interaction mode with interventionist (live vs. non-interactive or animated interactions). The acceptability criteria will be met if 80 % of participants report satisfaction across all acceptability measures.

2.7.3. Sleep behavior measures

Participants will complete a sleep log each morning for 7 consecutive days using a modified consensus sleep diary [51]. The sleep log includes entries for bedtime, sleep onset, number and duration of awakenings, sleep offset, out-of-bed time, naps, physical activity, and caffeine or alcohol intake. The sleep log data collected during the pre-intervention block served to tailor the behavioral module of the dyadic sleep intervention.

2.7.4. Efficacy measures

Sleep efficiency. The sleep efficiency will be derived from daily sleep log (see 2.7.3). Sleep efficiency is calculated by the total time in bed asleep divided by the total time spent in bed including time spent asleep and awake per day. Average sleep efficiency scores across 7 days pre- and post-intervention blocks will serve as a primary outcome.

Global sleep disturbance and subjective sleep quality. The overall sleep disturbance and subjective sleep quality will be assessed using the 19-item Pittsburgh Sleep Quality Index (PSQI) at baseline and post-intervention [45]. Higher scores of overall sleep disturbance and subjective sleep quality indicate greater sleep disturbance and poorer sleep quality. The global sleep disturbance score will serve as an eligibility criterion. Both the global sleep disturbance and subjective sleep quality scores will serve as secondary outcomes.

Insomnia severity. The severity of insomnia symptoms will be assessed using the Insomnia Severity Index ISI [52] at pre- and post-intervention. ISI total scores 0–7 indicate absence of insomnia, 8–14 indicate sub-threshold levels of insomnia, 15–21 indicate moderate levels of clinical insomnia, and 22–28 indicate severe levels of clinical insomnia. The insomnia severity score will serve as a secondary outcome.

2.8. Statistical considerations

2.8.1. Statistical analysis

Demographic characteristics of the sample, means and standard deviations or percentages of study variables will be reported. Differences in demographics and study variables between patients and caregivers at pre- and post-intervention will be tested using paired t-tests. Feasibility will be supported when enrollment rate is $\geq$ 75 % and retention rate at intervention completion is $\geq$ 80 %. Acceptability will be supported when ratings on the 8 satisfaction domains are $\geq$4.0 (out of 5: $\geq$80 % satisfaction). Preliminary efficacy will be tested with changes in study variables from pre-intervention (T1) to post-intervention (T2) using paired t-tests. Cohen's d will also be reported for information regarding the effect size [50]. Statistical significance will be set at a 2-tailed p-value $<$.05. Supplemental analyses will explore changes in the subdomains of the PSQI, and sleep onset latency, wake after sleep onset, and sleep duration derived from sleep logs.

2.8.2. Sample size and power

To detect a large effect of the BBTI-CC intervention based on the meta-analysis of BBTI ($d = .8$) [20], on 4 sleep indices (sleep efficiency, overall sleep disturbance, subjective sleep quality, and insomnia severity) that are correlated at .5 with each other, with 80 % power, and two-tailed alpha at .05, we will need 15 dyads (30 persons: 83 % of 18 dyads enrolled) at the completion of the study (T2).

2.9. Data and safety monitoring considerations

The informed consent, all assessment measures, and intervention

modules have been reviewed and approved by the University of Miami Institutional Review Boards. In addition, the study will be closely monitored by the Sylvester Comprehensive Cancer Center Data and Safety Monitoring Committee (DSMC) in accordance with the Cancer Center's Data and Safety Monitoring Plan (DSMP). In its oversight capacity, the DSMC bears responsibility for suspending or terminating this study. DSMC oversight of the conduct of this trial includes ongoing review of adverse event data, and periodic review of the study's aims. In addition, the DSMC will review reports from all audits, site visits, or study reviews pertaining to this study and take appropriate action.

2.10. Study timeline

All information provided regarding the research, as well as all information collected and documented during the study will be regarded as confidential. The financial disclosure information has been completed prior to study participation from the principal investigator and co-investigators who are involved in the research study. Participant recruitment and data collection have begun August 2024 and estimated to complete June 2025. Results will be published per agreements with the funding agency and per institutional guidelines. Once accepted for publication, we will make the data available on Open Science Forum.

3. Discussion

This study is designed to investigate the feasibility, acceptability, and preliminary efficacy of the 4-week Brief Behavioral Treatment for Insomnia for Couples with Cancer (BBTI-CC) intervention for both adult patients with cancer and their sleep-partner caregivers simultaneously. It will also provide data on the effects of this intervention on modifying sleep hygiene and stimulus control behaviors, reducing sleep disturbance and improving sleep quality in sleep-partners.

We learned several lessons while developing the protocol. Recruitment to the BBTI-CC intervention will involve potential participants' active contact with the study team, as the regional oncology clinics do not allow non-nationwide clinical trials through their network and there were no other oncology clinics in the target region within a 100-mile radius. The alternate approach of identifying potential participants through a tumor registry of a National Cancer Institute designated cancer center in the region (e.g., SCCC) will help increase the potential pool of participants. Recruiting patients who are already willing to participate in research may facilitate recruitment and assist investigators in meeting their recruitment goals. However, it may also limit the sample to those who are motivated to engage in an intervention and/or study that assesses the efficacy of the interventions. In addition, those identified through SCCC Tumor registry are likely to visit SCCC, one of the two National Cancer Institute designated comprehensive cancers within 200-mile radius of the target region, for seeking a second opinion. Their records are often outdated or they are unreachable and less motivated to participate in a research study initiated by an institution or hospital that is not where they receive medical care, which may result in a lower enrollment rate. Furthermore, attrition that is common in any clinical trials and insomnia treatment needs to be considered in estimating the target enrollment number. Thus, aiming for enrolling a larger number of participants more than that derived from power calculation is recommended.

Additionally, employing an inclusion criterion of any types of solid tumor will help increasing enrollment, yet it will also impose challenges as various cancer types and treatments are likely to be attributable to the sleep disturbance of the patients [53–55]. Individualizing the intervention content thus will require additional medical knowledge on various types of cancer and treatment side effects. On the other hand, narrowing to a specific type of cancer or treatment will limit generalizability of the findings, although individualizing the intervention content can be efficient. Furthermore, as the majority of adult cancer occurs in individuals older than 55 years of age [56], common morbid conditions associated with aging, such as arthritic or back pain, enlarged prostate or bladder, fatigue due in part to generally elevated inflammation, as well as retirement and lack of daily routine in meal and sleep time, which are also closely related to sleep disturbance and poor sleep quality, also need to be addressed. Assessing certain cancer- or cancer-treatment-related symptoms that affect the patients' sleep is a must at the pre-intervention assessment to be incorporated throughout the intervention sessions. The interventionist should be cognizant of cancer- and treatment-related symptom management strategies. For example, cancer-related fatigue, a physical and emotional feeling of tiredness or exhaustion, does not typically get better with rest and sleep [57,58]. For managing cancer-related fatigue, behavioral therapy, such as physical activity and healthy diet, are recommended to reduce fatigue and improve sleep health [59,60].

Study participants will highly favor flexibility in scheduling the pre- and post-assessment sessions as well as intervention sessions in the evening and weekends, because many adult patients with cancer and their family caregivers/partners wish to continue carrying out their existing social roles (e.g., maintaining their employment, caring for children or grandchildren, taking care of an aging parent). However, it may also require additional study personnel cost. Clear communication about the study expectations and allowing flexible working hours and days for study staff will be necessary.

Some participants may achieve their sleep hygiene and stimulus control behavior goals by Session 2. For those, Sessions 3 and 4 can be shortened to evaluate if they maintain the changed behavioral patterns. Additionally, the interventionist may have to make efforts to maintain the engagement of the intervention for any member in a dyad who has fewer sleep problems or achieves the desired sleep health sooner than the other member. The interventionist also needs to be cognizant of different sleep drives between the two members of a dyad yet the common relationship expectation of having the same or similar sleep schedule (e.g., going to bed together) to provide effective recommendations for optimizing individuals' sleep while maintaining and promoting relationship closeness of the dyad.

The results of this study will inform the feasibility and acceptability of conducting a dyadic sleep intervention adapted from the BBTI intervention for adult patients with cancer and their sleep-partner caregivers. Results will also guide further refinement of the BBTI-CC intervention content and procedure, which efficacy will be tested in randomized control trials.

CRediT authorship contribution statement

Youngmee Kim: Writing – review & editing, Writing – original draft, Visualization, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization. **Thomas C. Tsai:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Investigation, Conceptualization. **Wendy M. Troxel:** Writing – review & editing, Writing – original draft, Investigation, Conceptualization.

Data availability

The study protocol for data collection will be registered and the data will be available on Open Science Forum.

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Declaration of competing interest

The authors declare that they have no known competing financial

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References

[1] E. Tonorezos, T. Devasia, A.B. Mariotto, M.A. Mollica, L. Gallicchio, P. Green, et al., Prevalence of cancer survivors in the United States, J Natl Cancer Inst (2024).
[2] G.E. Dean, N.S. Redeker, Y.J. Wang, A.E. Rogers, S.S. Dickerson, L.M. Steinbrenner, et al., Sleep, mood, and quality of life in patients receiving treatment for lung cancer, Oncol. Nurs. Forum 40 (5) (2013) 441–451.
[3] G. Kotronoulas, Y. Wengstrom, N. Kearney, Sleep patterns and sleep-impairing factors of persons providing informal care for people with cancer A critical review of the literature, Cancer Nurs. 36 (1) (2013) E1–E15.
[4] O. Palesh, A. Aldridge-Gerry, J.M. Zeitzer, C. Koopman, E. Neri, J. Giese-Davis, et al., Actigraphy-measured sleep disruption as a predictor of survival among women with advanced breast cancer, Sleep 37 (5) (2014) 837–842.
[5] N.S. Gooneratne, G.E. Dean, A.E. Rogers, J.E. Nkwuo, J.C. Coyne, L.R. Kaiser, Sleep and quality of life in long-term lung cancer survivors, Lung Cancer 58 (3) (2007) 403–410.
[6] J.L. Otte, J.S. Carpenter, S. Manchanda, K.L. Rand, T.C. Skaar, M. Weaver, et al., Systematic review of sleep disorders in cancer patients: can the prevalence of sleep disorders be ascertained? Cancer Med-Us 4 (2) (2015) 183–200.
[7] K.O. Anderson, C.J. Getto, T.R. Mendoza, S.N. Palmer, X.S. Wang, C.C. Reyes-Gibby, et al., Fatigue and sleep disturbance in patients with cancer, patients with clinical depression, and community-dwelling adults, J. Pain Symptom Manag. 25 (4) (2003) 307–318.
[8] O.G. Palesh, J.A. Roscoe, K.M. Mustian, T. Roth, J. Savard, S. Ancoli-Israel, et al., Prevalence, demographics, and psychological associations of sleep disruption in patients with cancer: university of rochester cancer center-community clinical oncology program, J. Clin. Oncol. 28 (2) (2010) 292–298.
[9] National Sleep Foundation, 2012 Bedroom Poll (2012).
[10] S. Ancoli-Israel, L. Liu, M. Rissling, L. Natarajan, A.B. Neikrug, B.W. Palmer, et al., Sleep, fatigue, depression, and circadian activity rhythms in women with breast cancer before and after treatment: a 1-year longitudinal study, Support. Care Cancer 22 (9) (2014) 2535–2545.
[11] J.L. Steel, L. Terhorst, K.P. Collins, D.A. Geller, Y. Vodovotz, J. Kim, et al., Prospective analyses of cytokine mediation of sleep and survival in the context of advanced cancer, Psychosom. Med. 80 (5) (2018) 483–491.
[12] J.A. Johnson, J.A. Rash, T.S. Campbell, J. Savard, P.R. Gehrman, M. Perlis, et al., A systematic review and meta-analysis of randomized controlled trials of cognitive behavior therapy for insomnia (CBT-I) in cancer survivors, Sleep Med. Rev. 27 (2016) 20–28.
[13] J. Savard, H. Ivers, M.H. Savard, C.M. Morin, A. Caplette-Gingras, S. Bouchard, et al., Efficacy of a stepped care approach to deliver cognitive-behavioral therapy for insomnia in cancer patients: a noninferiority randomized controlled trial, Sleep 44 (11) (2021).
[14] O. Palesh, L. Peppone, P.F. Innominato, M. Janelsins, M. Jeong, L. Sprod, et al., Prevalence, putative mechanisms, and current management of sleep problems during chemotherapy for cancer, Nat. Sci. Sleep 4 (2012) 151–162.
[15] O. Palesh, N. Solomon, E. Hofmeister, B. Jo, H. Shen, E. Cassidy-Eagle, et al., A novel approach to management of sleep-associated problems in patients with breast cancer (MOSAIC) during chemotherapy : a pilot study, Sleep 43 (10) (2020).
[16] C.J. Cooper, P.J. Owen, M. Sprajcer, M.E. Crowther, E.A. Craige, S.A. Ferguson, et al., Interventions to improve sleep in caregivers: a systematic review and meta-analysis, Sleep Med. Rev. 64 (2022) 101658.
[17] D.J. Buysse, A. Germain, D.E. Moul, P.L. Franzen, L.K. Brar, M.E. Fletcher, et al., Efficacy of brief behavioral treatment for chronic insomnia in older adults, Arch. Intern. Med. 171 (10) (2011) 887–895.
[18] A. Germain, D.E. Moul, P.L. Franzen, J.M. Miewald, C.F. Reynolds, T.H. Monk, et al., Effects of a brief behavioral treatment for late-life insomnia: preliminary findings, J. Clin. Sleep Med. 2 (4) (2006) 407–408.
[19] W.M. Troxel, A. Germain, D.J. Buysse, Clinical management of insomnia with brief behavioral treatment (BBTI), Behav. Sleep Med. 10 (4) (2012) 266–279.
[20] M. Kwon, J. Wang, G. Wilding, S.S. Dickerson, G.E. Dean, Brief behavioral treatment for insomnia: a meta-analysis, Behav. Sleep Med. 20 (6) (2022) 674–694.
[21] J. Gibbins, R. McCoubrie, A.H. Kendrick, G. Senior-Smith, A.N. Davies, G. W. Hanks, Sleep-wake disturbances in patients with advanced cancer and their family carers, J Pain Symptom Manage 38 (6) (2009) 860–870.
[22] B.A. Morris, F.P. Thorndike, L.M. Ritterband, N. Glozier, J. Dunn, S.K. Chambers, Sleep disturbance in cancer patients and caregivers who contact telephone-based help services, Support. Care Cancer 23 (4) (2015) 1113–1120.
[23] S.M. McCurry, R.G. Logsdon, L. Teri, M.V. Vitiello, Sleep disturbances in caregivers of persons with dementia: contributing factors and treatment implications, Sleep Med. Rev. 11 (2) (2007) 143–153.
[24] S. Happe, K. Berger, F.S. Investigators, The association between caregiver burden and sleep disturbances in partners of patients with Parkinson's disease, Age Ageing 31 (5) (2002) 349–354.
[25] H.L. Peng, Y.P. Chang, Sleep disturbance in family caregivers of individuals with dementia: a review of the literature, Perspect Psychiatr Care 49 (2) (2013) 135–146.
[26] M. Rittman, M.S. Hinojosa, K. Findley, Subjective sleep, burden, depression, and general health among caregivers of veterans poststroke, J. Neurosci. Nurs. 41 (1) (2009) 39–52.
[27] P.A. Carter, A brief behavioral sleep intervention for family caregivers of persons with cancer, Cancer Nurs. 29 (2) (2006) 95–103.
[28] A. Dhruva, K. Lee, S.M. Paul, C. West, L. Dunn, M. Dodd, et al., Sleep-wake circadian activity rhythms and fatigue in family caregivers of oncology patients, Cancer Nurs. 35 (1) (2012) 70–81.
[29] E.S. Zhou, A.H. Partridge, K.L. Syrjala, A.L. Michaud, C.J. Recklitis, Evaluation and treatment of insomnia in adult cancer survivorship programs, J Cancer Surviv 11 (1) (2017) 74–79.
[30] K.M. Shaffer, S.N. Garland, J.J. Mao, A.J. Applebaum, Insomnia among cancer caregivers: a proposal for tailored cognitive behavioral therapy, J. Psychother. Integrat. 28 (3) (2018) 275–291.
[31] Q. Chen, L. Terhorst, D.A. Geller, W. Marsh, M. Antoni, M.A. Dew, et al., Trajectories and predictors of stress and depressive symptoms in spousal and intimate partner cancer caregivers, J. Psychosoc. Oncol. (2020).
[32] H.E. Gunn, D.J. Buysse, B.P. Hasler, A. Begley, W.M. Troxel, Sleep concordance in couples is associated with relationship characteristics, Sleep 38 (6) (2015) 933–939.
[33] B.P. Hasler, W.M. Troxel, Couples' nighttime sleep efficiency and concordance: evidence for bidirectional associations with daytime relationship functioning, Psychosom. Med. 72 (8) (2010) 794–801.
[34] W.M. Troxel, T.F. Robles, M. Hall, D.J. Buysse, Marital quality and the marital bed: examining the covariation between relationship quality and sleep, Sleep Med. Rev. 11 (5) (2007) 389–404.
[35] H.S. Kane, R.B. Slatcher, B.M. Reynolds, R.L. Repetti, T.F. Robles, Daily self-disclosure and sleep in couples, Health Psychol. 33 (8) (2014) 813–822.
[36] C. Segrin, T.J. Burke, Loneliness and sleep quality: dyadic effects and stress effects, Behav. Sleep Med. 13 (3) (2015) 241–254.
[37] H.E. Gunn, S. Lee, K.R. Eberhardt, O.M. Buxton, W.M. Troxel, Nightly sleep-wake concordance and daily marital interactions, Sleep Health 7 (2) (2021) 266–272.
[38] H.E. Gunn, D.J. Buysse, K.A. Matthews, C.E. Kline, M.R. Cribbet, W.M. Troxel, Sleep-wake concordance in couples is inversely associated with cardiovascular disease risk markers, Sleep 40 (1) (2017).
[39] E.M. Walters, A.J.K. Phillips, J.M. Boardman, P.J. Norton, S.P.A. Drummond, Vulnerability and resistance to sleep disruption by a partner: a study of bed-sharing couples, Sleep Health 6 (4) (2020) 506–512.
[40] E.M. Walters, A.J.K. Phillips, A. Mellor, K. Hamill, M.M. Jenkins, P.J. Norton, et al., Sleep and wake are shared and transmitted between individuals with insomnia and their bed-sharing partners, Sleep 43 (1) (2020).
[41] A. Mellor, K. Hamill, M.M. Jenkins, D.H. Baucom, P.J. Norton, S.P.A. Drummond, Partner-assisted cognitive behavioural therapy for insomnia versus cognitive behavioural therapy for insomnia: a randomised controlled trial, Trials 20 (2019).
[42] M.E. Feinberg, D.E. Jones, M.L. Hostetler, M.E. Roettger, I.M. Paul, D.B. Ehrenthal, Couple-focused prevention at the transition to parenthood, a randomized trial: effects on coparenting, parenting, family violence, and parent and child adjustment, Prev. Sci. 17 (6) (2016) 751–764.
[43] A. Sadeh, J.A. Mindell, J. Owens, Why care about sleep of infants and their parents? Sleep Med. Rev. 15 (5) (2011) 335–337.
[44] D.A. Dillman, Mail and Telephone Surveys: the Total Design Method, John Wiley & Sons, New York, 1978.
[45] D.J. Buysse, C.F. Reynolds, T.H. Monk, S.R. Berman, D.J. Kupfer, The Pittsburgh Sleep quality Index - a new instrument for psychiatric practice and research, Psychiatry Res. 28 (2) (1989) 193–213.
[46] Y. Kim, C.S. Carver, R.S. Cannady, K.M. Shaffer, Self-reported medical morbidity among informal caregivers of chronic illness: the case of cancer, Qual. Life Res. 22 (6) (2013) 1265–1272.
[47] K.F. Maltby, C.R. Sanderson, E.A. Lobb, J.L. Phillips, Sleep disturbances in caregivers of patients with advanced cancer: a systematic review, Palliat. Support Care 15 (1) (2017) 125–140.
[48] Q. Chen, L. Terhorst, A. Lowery-Allison, H. Cheng, A. Tsung, M. Layshock, et al., Sleep problems in advanced cancer patients and their caregivers: who is disturbing whom? J. Behav. Med. 43 (4) (2020) 614–622.
[49] A.A. Borbely, A two process model of sleep regulation, Hum. Neurobiol. 1 (3) (1982) 195–204.
[50] NIoM. Health, Arousal and Regulatory Systems: Workshop Proceedings (2013).
[51] C.E. Carney, D.J. Buysse, S. Ancoli-Israel, J.D. Edinger, A.D. Krystal, K.L. Lichstein, et al., The consensus sleep diary: standardizing prospective sleep self-monitoring, Sleep 35 (2) (2012) 287–302.
[52] C.M. Morin, G. Belleville, L. Belanger, H. Ivers, The insomnia severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response, Sleep 34 (5) (2011) 601–608.
[53] A.R. Costa, F. Fontes, S. Pereira, M. Goncalves, A. Azevedo, N. Lunet, Impact of breast cancer treatments on sleep disturbances - a systematic review, Breast 23 (6) (2014) 697–709.
[54] A. Divani, M.E. Heidari, N. Ghavampour, A. Parouhan, S. Ahmadi, O.N. Charan, et al., Effect of cancer treatment on sleep quality in cancer patients: a systematic review and meta-analysis of Pittsburgh Sleep Quality Index, Support. Care Cancer 30 (6) (2022) 4687–4697.
[55] S. Ancoli-Israel, Recognition and treatment of sleep disturbances in cancer, J. Clin. Oncol. 27 (35) (2009) 5864–5866.

[56] N.C. Institute, Incidence rates by age at diagnosis, all cancer types. Source: SEER 21 2013–2017, all races, both sexes (2021).
[57] A.M. Berger, A.P. Abernethy, A. Atkinson, A.M. Barsevick, W.S. Breitbart, D. Cella, et al., NCCN clinical practice guidelines cancer-related fatigue, J. Natl. Compr. Cancer Netw. 8 (8) (2010) 904–931.
[58] J.E. Bower, Cancer-related fatigue–mechanisms, risk factors, and treatments, Nat. Rev. Clin. Oncol. 11 (10) (2014) 597–609.
[59] A. Fabi, R. Bhargava, S. Fatigoni, M. Guglielmo, M. Horneber, F. Roila, et al., Cancer-related fatigue: ESMO clinical practice guidelines for diagnosis and treatment, Ann. Oncol. 31 (6) (2020) 713–723.
[60] M.F. Luctkar-Flude, D.L. Groll, J.E. Tranmer, K. Woodend, Fatigue and physical activity in older adults with cancer: a systematic review of the literature, Cancer Nurs. 30 (5) (2007) E35–E45.