

A pilot trial of brief group cognitive-behavioral treatment for insomnia in an adult cancer survivorship program

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Abstract

Background: Cognitive-behavioral therapy for insomnia (CBT-Insomnia) is effective, yet rarely available for cancer survivors. This is unfortunate because survivors are at elevated risk for insomnia, which is associated with significant health consequences in this already at-risk population. Barriers to delivering CBT-Insomnia in oncology settings include a lack of trained providers, distance to cancer centers, and treatment duration.

Purpose: To address insomnia treatment barriers, we adapted standard CBT-Insomnia treatment and evaluated a pilot group-based approach for feasibility and efficacy in an adult cancer survivorship program.

Methods: Thirty-eight cancer survivors (mean age = 52.2 years) enrolled in our three-session program delivered over 1 month. They were primarily diagnosed with breast cancer (58.6%) and were an average of 6.0 years post-diagnosis and 3.6 years post-treatment. Participants completed sleep logs throughout the study and measures of sleep at baseline and week 4.

Results: Participants reported experiencing insomnia symptoms an average of 2.4 years, with 89.7% indicating that the cancer experience had caused/exacerbated symptoms. Significant pre/post-intervention group improvements in sleep efficiency (77.3% to 88.5%), sleep quality, and insomnia symptoms were reported (all $ps < .01$). Less than 1 in 3 had discussed insomnia symptoms with their oncology providers in the prior year.

Conclusions: Pilot data indicate that a brief, group-based CBT-Insomnia intervention in a survivorship setting is both feasible and efficacious. There is a need to increase awareness about insomnia and its treatment among both cancer survivors and oncology providers. If validated in future studies, this novel approach can improve cancer survivors' access to much needed insomnia treatment.

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Received: 13 August 2015

Revised: 17 December 2015

Accepted: 18 January 2016

Introduction

The majority of patients diagnosed with cancer will survive [1], although the intensive treatments that cure also place patients at risk for wide range of late effects [2]. Insomnia is one of the most common and distressing consequences of cancer treatment, with some cancer survivors describing their poor sleep as 'more overwhelming than the effects of cancer treatment' [3]. Despite evidence that more 38% of patients will experience clinically diagnosable insomnia disorder during the first 1.5 years of cancer treatment [4], and that this insomnia will often become an enduring condition [5–7], it remains frequently overlooked by both patients and providers who see it as only a transient reaction to the cancer diagnosis or treatment [5]. If left untreated, chronic insomnia is associated with many negative physical and psychosocial health outcomes including cardiovascular disease, diabetes, anxiety and depressive disorders, and mortality [8–11], in a population already at increased risk for poor health. Given the significant health implications of insomnia for survivors,

the National Cancer Institute emphasizes the importance of addressing sleep as part of survivorship care [12], yet research consistently shows insomnia remains 'under-recognized and undertreated' [13] in cancer populations.

Cognitive-behavioral therapy for insomnia (CBT-Insomnia) is considered front-line insomnia treatment [14] and is designed to address cognitive and behavioral factors, which contribute to persistent insomnia symptoms [15]. Treatment is multi-faceted and focuses on sleep restriction, stimulus control, sleep hygiene, and cognitive restructuring of maladaptive sleep-related beliefs [16]. There is consistent evidence indicating that it is effective at improving insomnia symptoms in both the short and long-term [17,18], including in oncology populations [19]. Unfortunately, access has been extremely limited for cancer survivors [20] as a result of several important obstacles. First, there is a considerable shortage of trained CBT-Insomnia providers available for survivors seeking community-based treatment [21]. If a survivor were to seek insomnia treatment at their cancer center instead, many would face a significant commute: 54.8% of Americans must travel at least

an hour to reach the nearest National Cancer Institute designated cancer center and 30.6% to the nearest academic medical center providing cancer care [22]. This travel burden presents a practical hardship for many survivors and may be experienced as a barrier to treatment [23]. Next, even if a survivor were able to identify a trained provider close to their home, treatment duration may be discouraging. Standard CBT-Insomnia is delivered in 5–8 individual treatment sessions over the course of several months, which can create financial and time burdens for the survivor. Because of these barriers, there is an ‘imperative to develop alternatives’ for insomnia treatment in cancer populations [20].

There have been efforts to improve overall CBT-Insomnia accessibility and to maximize the reach of the limited number of trained providers. There is evidence suggesting that Internet-delivered [24] and group-based interventions may be helpful for patients suffering from insomnia [25,26]. However, computerized CBT interventions can be limited by lower patient uptake and higher dropout rates [27,28] and may be better suited as the entry level in a stepped care model [29] for insomnia patients who present with fewer co-morbidities or complications than cancer survivors. Further, although there is encouraging preliminary evidence, group-based approaches in oncology populations [19] have either omitted key CBT-Insomnia components such as sleep restriction [30,31] or lasted the standard 5–8 treatment sessions [32–36]. To address the continuing problem of providing accessible and briefer insomnia treatment, we piloted a consolidated CBT-Insomnia program delivered in three 60-minute group sessions over the course of 1 month. We hypothesized that an adapted CBT-Insomnia intervention would be feasible and effective at improving sleep efficiency, self-reported insomnia severity, and overall sleep quality in an adult cancer survivorship program.

Methods

Participants

Adult cancer survivors at least 18-years-of-age, who had completed cancer treatment, and were experiencing insomnia disorder were invited to a group program at our cancer center, located in a large metropolitan city. Participants were recruited through flyers distributed around the cancer center and through direct oncologist referrals. Potential participants were excluded from the current study if they reported current shift work, active substance abuse, psychotic symptoms, bipolar disorder, or a history of a seizure disorder or any seizure within the past year. Participants taking medication for insomnia were allowed to participate in the program if their medication regimen was stable and would be maintained during the program. Informed consent was obtained from all individual

participants included in the study. The study was approved by the cancer center’s IRB.

Intervention

The adapted intervention was comprised of three 60-minute group sessions delivered over 1 month and focused on addressing the cognitive and behavioral factors that perpetuate insomnia. The sessions were modeled after traditional treatment protocols [37] and involved the consolidation of content into the abbreviated format by a study author with training in CBT-Insomnia, with a subsequent review of materials by an experienced sleep psychologist. Specifically, we condensed the discussion of key components of CBT-Insomnia treatment in the group sessions and supplemented this much briefer explanation with a self-guided instructional workbook that provided further information and case examples to illuminate the session content. Further, our abbreviated program duration only allowed us to instruct participants about how to titrate their sleep but did not allow for the opportunity to provide ongoing guidance during sleep expansion, which traditionally occurs over the course of several months. To insure intervention consistency, all study sessions were conducted by a single, doctoral-level program facilitator with training and clinical experience in the delivery of CBT-Insomnia, utilizing the same session materials. A total of three group cycles (three sessions each) were offered, with 8, 16, and 14 participants in the first, second and third group cycle, respectively. Specific session content was as follows:

Session 1 (Week 1): Participants were provided an intervention overview and introduced to the 3-P model [38] of the etiology and maintenance of insomnia. The group was instructed on completion of sleep logs and how to use log data to track their progress. The self-guided workbook to supplement group content was introduced.

Session 2 (Week 2): Participants were introduced to the mismatch between sleep opportunity and need occurring in insomnia. They were introduced to the concept of sleep restriction and using their individual sleep log data, asked to develop a modified sleep schedule they would follow for the 2 weeks between Sessions 2 and 3. Stimulus control practices and maladaptive sleep cognitions were also discussed.

Session 3 (Week 4): Participants’ sleep logs were reviewed, and they were instructed on the gradual expansion of their restricted sleep, guided by their individual sleep logs. Challenges of CBT-Insomnia treatment adherence and the potential impact of cancer late-effects on sleep were discussed. Finally, basic sleep hygiene concepts were reviewed.

Measures

Screening Interview: A screening interview was conducted by study staff to ensure that participants met the

Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-V) criteria for insomnia disorder [39] and did not present contraindications for CBT-Insomnia treatment (e.g., bipolar disorder, history of a seizure disorder or any seizure within the past year, and active substance abuse). During their screening interview, participants reported on their demographic, medical and cancer-related variables, and their insomnia history.

Participants completed the following self-report measures at the beginning of Session 1 and end of Session 3.

Insomnia Severity Index (ISI) [40]: The ISI is a 7-item self-report measure of insomnia symptoms that has been validated in cancer populations [41] and is commonly used as an outcome measure in intervention trials [42]. ISI scores range from 0–28, and scores ≥ 15 are associated with clinical insomnia, while scores between 8–14 are associated with sub-threshold insomnia.

Pittsburgh Sleep Quality Index (PSQI) [43]: The PSQI is a 19-item self-report measure of sleep quality that has also been validated in cancer populations [44]. Overall PSQI sleep quality scores range from 0–21, with scores above 5 indicative of poor sleep quality [45].

Sleep Log: Participants completed daily sleep logs during the intervention period, which included data on time to bed, sleep latency, frequency of night awakenings, duration of night awakenings, actual wake time, and desired wake time. Sleep log data were used to calculate total sleep duration and sleep efficiency. A sleep efficiency $< 85\%$ was suggestive of disrupted sleep and behaviors that could be targeted by CBT-Insomnia.

Statistical analyses

To evaluate the impact of the intervention on sleep outcomes, we compared Session 3 to Session 1 scores with paired-samples *t*-tests and calculated Cohen's *d* as a measure of effect size. Participant's sleep log data from the first week and last week of the intervention were similarly compared.

Results

Over 1 year, a total of 79 cancer survivors either expressed interest in the program by initiating contact with study staff or were referred by their oncologists, with 75 survivors completing a study screen. Of these 75 survivors, 52 met program enrollment criteria. Twenty-two survivors were excluded for reasons including not having insomnia disorder ($n=12$), being on active cancer treatment ($n=8$), and being employed in a position requiring shift work ($n=3$). Among the 52 survivors who initially met program enrollment criteria, nine were not available during group session dates; two reported that their insomnia symptoms had resolved by the time the subsequent

intervention group was scheduled, and three could not be contacted, resulting in a total of 38 survivors who ultimately enrolled in the program and attended the first group session. Of these 38 survivors, nine dropped out reporting schedule conflicts ($n=5$) and health issues ($n=4$) as their primary reason. Seven participants dropped out following the first group session, and two following the second group session.

Data from the 29 participants who completed all three sessions are reported on here. They were an average of 52.2 years of age ($SD=12.0$ years), 6.0 years post-diagnosis ($SD=7.2$ years), and 3.6 years post-cancer treatment completion ($SD=6.0$ years). Participants were predominantly female (83.0%) and breast cancer survivors (58.6%), although there was a range of patients with a history of other cancer diagnoses who participated. See Table 2.

Participants reported having experienced insomnia symptoms for an average of 2.4 years (range=0.8 to 10.4 years), and 89.7% of the sample indicated that their cancer experience had caused or exacerbated their insomnia symptoms. Less than 1 in 3 (31.0%) of the survivors reported having discussed their insomnia symptoms with their oncology providers within the past year. At baseline, participants reported an average sleep efficiency of 77.3%, with significant symptoms of delayed sleep onset, night and early morning wakening. The sample's mean ISI (16.7) and PSQI (12.5) scores were both above threshold criteria used to indicate disrupted sleep. See Table 1. Following the intervention, participants reported statistically significant improvements across all sleep log variables (using paired-samples *t*-tests), resulting in an improvement in overall sleep efficiency from 77.3% to 88.5% ($t=-6.4$; $p<.001$). Specifically, participants reported significantly decreased sleep latency (from 43.7 to 13.7 min; $t=6.8$; $p<.001$), night awakening duration (from 68.4 to 31.3 min; $t=6.7$; $p<.001$), early morning awakening duration (from 19.1 to 8.2 min; $t=3.0$; $p=.005$), frequency of night awakenings (from 3.5 to 2.6 times per night; $t=3.6$; $p=.001$), and total sleep duration (from 6.3 to 5.8 h; $t=3.7$; $p=.001$). Participants similarly endorsed reduced insomnia symptoms (ISI; from 16.7 to 10.4; $t=6.9$; $p<.001$) and improved sleep quality (PSQI; from 12.5 to 6.5; $t=3.2$; $p=.004$). See Table 2.

Discussion

Results provide preliminary evidence supporting the feasibility and efficacy of this novel CBT-Insomnia intervention in a cancer survivorship program. Post-intervention, improvements were noted in insomnia symptoms and sleep quality, and sleep efficiency for the group was above the 85% cut-off used in clinical settings to indicate good sleep [37]. These pilot findings indicate that the core elements of CBT-Insomnia can be delivered effectively in

Table 1. Sleep variables at pre and post-intervention. *N* = 29

	Baseline \bar{x} (SD)	Post-Intervention \bar{x} (SD)	Effect Size (<i>d</i>)
Insomnia Severity Index			
Total Summary Score	16.7 (5.0)	10.4 (4.7)*	1.3
Pittsburgh Sleep Quality Index			
Total Sleep Quality Score	12.5 (4.1)	6.5 (2.6)*	1.7
Sleep Logs			
Sleep Latency (min)	43.7 (42.9)	13.7 (7.3)*	1.0
Night Awakening (min)	68.4 (52.2)	31.3 (26.8)*	0.9
Night Awakening (frequency)	3.5 (1.7)	2.6 (2.0)*	0.5
Early Morning Awakening (min)	19.1 (20.2)	8.2 (7.5)*	0.7
Total Sleep Duration (h)	6.3 (1.0)	5.8 (1.1)*	0.5
Sleep Efficiency (%)	77.3 (9.9)	88.5 (6.8)*	1.3

SD, standard deviation.

*Post-intervention values that significantly differ from baseline ($p < .05$) are shown in bold asterisk.ISI score: ≤ 7 (No clinically significant insomnia), 8–14 (Sub-threshold insomnia), ≥ 15 (Clinical insomnia.)PSQI score: > 5 (Poor sleep).**Table 2.** Sample demographic and disease-specific characteristics. *N* = 29

	n or \bar{x}	Range
<i>Demographic</i>		
Age (years)	52.2	22.5–73.3
Gender		
Male	5	
Female	24	
<i>Cancer-related</i>		
Primary diagnosis		
Breast cancer	17	
Hematologic malignancy	2	
Brain cancer	1	
Lung cancer	1	
Ovarian cancer	4	
Prostate cancer	2	
Rectal cancer	2	
Time since diagnosis (years)	6.0	0.6–29.0
Time since treatment (years)	3.6	0.8–28.0

condensed group-based format over the course of three sessions as the medium to large effect sizes ($0.5 < d < 1.7$) for sleep outcomes (e.g., sleep efficiency, ISI, and PSQI) were comparable to those seen in traditional CBT-Insomnia programs delivered in cancer populations [19].

As insomnia is so common in survivor populations, this novel intervention protocol provides an opportunity to maximize efficiency for the limited number of trained CBT-Insomnia providers. In conventional treatment, a single provider could only treat five survivors in 30 clinical hours (i.e., five patients \times six 1-hour sessions), whereas this group-based program can provide insomnia treatment for 10 times the number of patients in the same amount of clinician time (i.e., three 1-hour group sessions \times 10 groups of 5 survivors/group). Furthermore, this abbreviated approach serves to minimize the financial and time-related burdens associated with seeking individual, standard CBT-Insomnia treatment.

We note limitations of our pilot study that would benefit from future attention. First, 24% of survivors who enrolled did not complete all intervention sessions. Other CBT-Insomnia trials in oncology populations have reported comparable participant dropout rates [33,35], reflecting the health vulnerability of this patient population. In the current study, four of the nine study dropouts reported medical complications, including hospitalizations for cancer-related treatment. In addition, the inflexible group intervention schedule contributed to study dropout, suggesting that future interventions may need to implement variable scheduling or incorporate alternative delivery mechanisms (e.g., telephone or videoconference). Next, the lack of study follow-up beyond the third study session was not ideal from both a research and a clinical perspective. Research wise, we were unable to study the full impact and durability of the intervention effect. In particular, despite significant improvements to sleep outcomes, the sample reported a PSQI sleep quality score of 6.5 post-intervention, which is above a proposed cut-off score of 5 [45]. Clinically, study participants had just consolidated their sleep (with the expected decrease in total sleep duration as the survivors are experiencing briefer but less disrupted sleep) but were unable to receive ongoing guidance as they were expanding their sleep window. Further, we did not collect objective sleep data (e.g., actigraphy) from our study sample. Finally, although most participants had long-standing insomnia, the lack of a control group and a short assessment battery, which did not include an evaluation of factors that can affect insomnia symptoms (e.g., fatigue, depression, pain, alcohol intake, and sleep aid usage), in our pilot trial means their sleep improvements may be due to factors other than the intervention.

Despite these limitations, the adapted intervention tested here appeared to significantly improve survivors' sleep function and did so in an efficient three session window in patients across a range of cancer diagnoses. It is

critical that oncology providers actively discuss sleep function with survivors and that this conversation continues well into the survivorship period. In our sample, participants reported experiencing insomnia symptoms for over 2 years, on average, and the overwhelming majority indicated that the cancer experience had played a role in the development or exacerbation of insomnia. However, more than two-thirds of the survivors had not discussed their insomnia symptoms with their oncology provider within the past year, indicating that there are important concerns with patient awareness and screening for sleep disruption that must be resolved. Providers could consider the use of brief measures, such as the ISI, in their efforts to screen for insomnia for both clinical and research purposes.

In the future, it will be important to follow up on these encouraging findings by (a) improving our understanding of how travel burden plays a role in insomnia treatment seeking behavior, (b) testing a standardized treatment program in a randomized-controlled trial with longer follow-up, (c) examining treatment generalizability across

multiple cancer populations in different cancer centers, and in patients with varying demographic characteristics (e.g., ethnicity), (d) understanding the impact that improved sleep may have on health and cancer outcomes, (e) exploring ways to improve the intervention with additional cancer-specific content, and (f) investigating the enhanced use of technology in delivering the intervention to affected cancer survivors and caregivers who may have difficulty accessing even this adapted treatment program.

Acknowledgements

There is no funding to declare.

Conflict of interest

There are no conflict of interests to declare.

Ethics approval

This study was approved by the cancer center's IRB.

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