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TESTING A LOW-INTENSITY AND ACCESSIBLE COGNITIVE BEHAVIORAL
THERAPY FOR INSOMNIA (CBT-I) INTERVENTION IN INDIVIDUALS NEWLY
DIAGNOSED WITH CANCER

A dissertation submitted in partial fulfillment of the requirements for the degree Doctor of
Philosophy at Virginia Commonwealth University

by

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Abstract

TESTING A LOW-INTENSITY AND ACCESSIBLE COGNITIVE BEHAVIORAL THERAPY FOR INSOMNIA (CBT-I) INTERVENTION IN INDIVIDUALS NEWLY DIAGNOSED WITH CANCER

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of
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Virginia Commonwealth University, 2015

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Insomnia is defined as difficulty initiating or maintaining sleep, or nonrestorative sleep that lasts for at least one month *and* is accompanied by significant impairment in daytime functioning including fatigue, irritability, and/or difficulty concentrating. It is one of the most common complaints reported by individuals with cancer, especially around the time of cancer diagnosis and treatment. Yet it is often unrecognized and untreated, leading to adverse health consequences and increased healthcare costs. Cognitive Behavioral Therapy for Insomnia (CBT-I) has been recommended as the gold standard for treating insomnia among individuals with cancer. Multiple studies have tested and proven the efficacy and effectiveness of CBT-I among individuals with cancer. However, only one study has investigated the efficacy of CBT-I in individuals newly diagnosed with cancer who are undergoing cancer treatment. Moreover, previous studies have been limited by their focus on largely homogenous samples of White, well-educated women with breast cancer. The dissemination of CBT-I among individuals with cancer is greatly limited by the lack of available providers and resources needed to implement the standard face-to-face treatment. One strategy to address this shortage has been to abbreviate

standard CBT-I into low-intensity modalities that require fewer resources and can be self-administered on the Internet. The current study sought to examine the feasibility and acceptability, as well as the efficacy of one such program, an online low-intensity CBT-I intervention, Sleeping Healthy Using the Internet (SHUTi), supplemented with clinician support, in a sample of individuals newly diagnosed with heterogeneous malignancies who were undergoing chemotherapy and/or radiation. Results yielded support for the feasibility and acceptability of addressing individuals' insomnia with a low-intensity CBT-I intervention while they are undergoing cancer treatment. With regard to sleep, there were significant treatment effects observed on a global measure of insomnia severity and on subjective sleep consolidation. There were also significant treatment effects for depressive symptoms. Findings are discussed in the context of study limitations and for the purpose of expanding the literature on disseminating CBT-I early in the cancer care trajectory.

Testing a Low-Intensity and Accessible Cognitive Behavioral Therapy for Insomnia (CBT-I) Intervention in Individuals Newly Diagnosed with Cancer

Insomnia is defined as difficulty initiating or maintaining sleep, or nonrestorative sleep that lasts for at least one month *and* is accompanied by significant impairment in daytime functioning including fatigue, irritability, and/or difficulty concentrating (American Psychiatric Association, 2000). Insomnia is one of the most common complaints reported by individuals with cancer. Yet it is often unrecognized and untreated (Graci, 2005; J. Savard & Morin, 2001), leading to adverse health consequences and increased healthcare costs (Leger & Bayon, 2010; J. Savard & Morin, 2001; Wade, 2011). Insomnia prevalence ranges from 19% to 30% (Davidson, MacLean, Brundage, & Schulze, 2002; J. Savard & Morin, 2001), with the highest rates reported in breast cancer (38%) and lung cancer (37%) (Davidson et al., 2002). These rates are considerably higher than the prevalence in the general population, which is estimated at 10-15% (Roth, 2001). Individuals who have cancer and insomnia experience greater depression and mood disturbances (Bardwell et al., 2008; Donovan & Jacobsen, 2007; J. Savard, S. Simard, S. Hervouet, et al., 2005; Van Onselen et al., 2010), fatigue (Anderson et al., 2003; Beck, Dudley, & Barsevick, 2005; Davidson et al., 2002; Donovan & Jacobsen, 2007; Sarna, 1993), decreased quality of life (Davidson et al., 2002; Redeker, Lev, & Ruggiero, 2000; Vargas et al., 2010), and likely, increased mortality (J. Savard & Morin, 2001; Theobald, 2004). Thus, examining insomnia in the context of cancer is critical to improving outcomes for individuals with cancer, as is evidenced by the wealth of literature examining the co-occurrence of cancer and insomnia (K. K. Cheng & Lee, 2011; Espie et al., 2008; Fiorentino & Ancoli-Israel, 2006; Graci, 2005; O'Donnell, 2004; J. Savard, Simard, Blanchet, Ivers, & Morin, 2001).

The accumulated evidence has illuminated important aspects of the nature of insomnia in cancer. For example, insomnia tends to persist in individuals with cancer, such that as many as

75-95% of insomnia cases progress into chronic insomnia (Davidson et al., 2002; J. Savard et al., 2001), lasting for six months or more. Pain (Grond, Zech, Diefenbach, & Bischoff, 1994), fatigue (Balachandran, Faiz, Bashoura, & Manzullo, 2013; Roscoe et al., 2007), and mood symptoms (Van Onselen et al., 2010) have been identified as significant predictors of cancer-related insomnia. Individuals with clinically significant pain (Sharma et al., 2012) or fatigue (Davidson et al., 2002) are nearly three times more likely than others to experience sleep disturbances, whereas those with significant anxiety and depression are nearly five times more likely to report sleep problems (Sharma et al., 2012). Indeed, cancer-related insomnia rarely occurs in isolation; more often it presents as part of a symptom constellation consisting of pain, fatigue, and mood symptoms (Beck et al., 2005; Chen & Tseng, 2006; Donovan & Jacobsen, 2007; Hoffman, Given, von Eye, Gift, & Given, 2007; Sharma et al., 2012). One study found that as much as 18% of a sample of elderly individuals experienced concurrent insomnia, pain, and fatigue within weeks of their cancer diagnoses (Kozachik & Bandeen-Roche, 2008). The evidence further suggests that insomnia underlies important mechanisms in cancer symptom burden—it mediates the relationships between pain and fatigue (Beck et al., 2005), between depression and fatigue, and between depression and pain (Stepanski et al., 2009).

When it comes to the timing of insomnia treatment in cancer, the period immediately after cancer diagnosis and prior to treatment is increasingly being recognized as a critical period. While for many individuals with cancer, insomnia lingers through cancer survivorship and even years after cancer treatment (Gooneratne et al., 2007), studies indicate that for most individuals symptoms peak before and during early treatment (Buick et al., 2000; Phillips, Jim, Donovan, Pinder-Schenck, & Jacobsen, 2012; Thomas, Bower, Hoyt, & Sepah, 2010; Van Onselen et al., 2012). Longitudinal studies have found that insomnia is most prevalent (28%) within the first

two months after diagnosis, when surgery is completed and adjuvant treatment is initiated (J. Savard, Ivers, Villa, Caplette-Gingras, & Morin, 2011; J. Savard, Villa, Ivers, Simard, & Morin, 2009). Furthermore, individuals with insomnia at the beginning of treatment tend to experience a chronic course, while those with symptoms that do not reach the threshold for an insomnia diagnosis (i.e., sleep disturbances without daytime impairment) are much more likely to recover (J. Savard, Ivers, et al., 2011). Also, the disruption in circadian rhythms that precipitates sleep disturbances has been found to occur within the first week of a treatment cycle (J. Savard, Liu, et al., 2009). Taken together, these findings suggest that intervening to improve sleep at the outset of cancer treatment among those individuals with a comorbid insomnia diagnosis has the potential to make the greatest impact in terms of benefiting individuals' coping during treatment.

Despite the clinical significance of insomnia early in the cancer treatment trajectory, fewer studies have focused on understanding insomnia prior to radiation or chemotherapy treatment (Ancoli-Israel et al., 2006; Beck et al., 2010; Berger, Farr, Kuhn, Fischer, & Agrawal, 2007; Garrett et al., 2011; Miaskowski et al., 2011; Phillips et al., 2012; Van Onselen et al., 2010; Vargas et al., 2010). Much more attention has been given to insomnia and sleep disturbances during and after chemotherapy and/or radiation (Bardwell et al., 2008; Berger, 1997; Berger & Farr, 1999; Berger & Higginbotham, 2000; Carpenter et al., 2004; Costantini, Ale-Ali, & Helsten, 2011; Davidson et al., 2002; Kuo, Chiu, Liao, & Hwang, 2006; Moore, Berger, & Dizona, 2011; Payne, Piper, Rabinowitz, & Zimmerman, 2006; Rissling, Liu, Natarajan, He, & Ancoli-Israel, 2011; J. Savard, Liu, et al., 2009; J. Savard et al., 2001). Cognitive behavioral therapy for insomnia (CBT-I) is considered gold standard treatment for comorbid insomnia and its treatment effects are more durable than pharmacological treatments {Morin, 1999 #123; National Institutes of Health, 2005 #76}. However, there is only one

published study of CBT-I in individuals prior to chemotherapy initiation (Berger, Kuhn, Farr, Lynch, et al., 2009). Findings from this study showed that, although a CBT-I plan implemented before chemotherapy and reinforced during and after chemotherapy resulted in some benefits for sleep immediately and one year after, it did not confer significant improvements on critical subjective and objective sleep measures. One study limitation that likely contributed to these findings is that most participants (60%) reported fairly good or very good sleep at baseline, leaving little room for improvement. These findings underscore the importance of testing the efficacy of CBT-I among individuals who are experiencing significant sleep disturbances and daytime impairment (i.e., meet criteria for insomnia).

Intervening on individuals' sleep soon after cancer diagnosis and prior to treatment initiation is not without its challenges. Due to the large number of individuals presenting with insomnia during a time when engagement in intensive treatment is difficult, the best approach would likely include a stepped care model that includes low intensity/highly accessible treatments (self-help and abbreviated) as a first step (Mack & Rybarczyk, 2011). Self-help and abbreviated treatments have been highly tested in other insomnia groups (Edinger & Sampson, 2003; Rybarczyk, Mack, Harris, & Stepanski, 2011; Wagley, Rybarczyk, Nay, Danish, & Lund, 2012), but to our knowledge, only two self-help treatments have been tested in individuals with cancer (Ritterband et al., 2012; J. Savard, Villa, Simard, Ivers, & Morin, 2011) and neither study was conducted with newly diagnosed patients. Previous studies suggest that self-help approaches are 50-75% as effective as therapist delivered unabridged approaches. The proposed study will extend previous research (Berger, Kuhn, Farr, Lynch, et al., 2009; Ritterband et al., 2012) by examining the feasibility and efficacy of a low-intensity and accessible self-administered CBT-I intervention with clinician support in individuals with cancer. Participants

will be individuals newly diagnosed with non-advanced (i.e., curable) cancers who have yet to initiate their first course of chemotherapy or radiation therapy. They must report experiencing at least three episodes of sleep disturbance per week that is associated with daytime effects such as fatigue, irritability, or difficulty concentrating and has persisted for at least one month. This study will seek to address the following two complementary aims: 1) To assess the feasibility and acceptability of a low-intensity and accessible CBT-I intervention among individuals newly diagnosed with cancer; and 2) To determine the efficacy of the intervention in improving sleep and other quality of life outcomes during cancer treatment. In accomplishing these aims, the proposed study emphasizes increasing implementation and dissemination of CBT-I among individuals with cancer as suggested in the Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) model (Glasgow, Vogt, & Boles, 1999), by decreasing barriers related to time and cost (Glasgow & Emmons, 2007) while seeking to increase feasibility and acceptability (Klesges, Estabrooks, Dzewaltowski, Bull, & Glasgow, 2005).

Review of the Literature

Insomnia in Cancer

Insomnia is defined as difficulty initiating or maintaining sleep, or nonrestorative sleep, that lasts for at least one month (American Psychiatric Association, 2000). To meet diagnostic criteria, the sleep disturbance or associated daytime fatigue must cause clinically significant distress or impairment. Insomnia that occurs in the context of another medical condition like cancer is termed *Secondary Insomnia* or more appropriately, *Comorbid Insomnia* (American Psychiatric Association, 2000; National Institutes of Health, 2005). Comorbid insomnia is functionally equivalent to primary insomnia (Rybarczyk, Lund, Mack, & Stepanski, 2009) and warrants no less clinical attention. Indeed addressing comorbid insomnia in cancer, which

affects as many as one-third of all individuals with cancer (Davidson et al., 2002; J. Savard & Morin, 2001), is especially important because it is more likely to be undertreated due to the notion among patients and providers that the condition is a less significant (compared to cancer) and/or is a temporary disturbance for which few effective treatments exist (Fleming & Davidson, 2012). A first step to addressing cancer-related insomnia is to understand its etiology.

Etiological theory of comorbid insomnia in cancer. Much like primary insomnia, insomnia among individuals with cancer is explained through a diathesis-stress model. This model posits that a disorder like insomnia results when an environmental stressor triggers an underlying vulnerability (Morin & Espie, 2003; Spielman, Caruso, & Glovinsky, 1987). According to Spielman's 3-P model, insomnia develops when a *predisposition* or vulnerability to sleep disturbance (e.g., genetic and personality traits) is triggered by *precipitating* factors (e.g., life stressors, schedule changes), and is maintained when *perpetuating* factors (e.g., poor sleep hygiene, maladaptive beliefs about sleep) become entrenched (Spielman et al., 1987). Research has identified predisposing, precipitating, and perpetuating factors that while not unique to individuals with cancer, are especially relevant to the development and persistence of insomnia in this population. Of note, much of the evidence has focused only on precipitating factors.

Predisposing factors. Three of the most relevant predisposing factors for insomnia among individuals with cancer are psychiatric disorders, older age, and female gender. The co-occurrence of psychiatric disorders like anxiety and depressive disorders with cancer is one important factor that explains individuals' heightened predisposition to insomnia. Since insomnia or poor sleep is often part of the constellation of anxiety and depressive symptoms, it is believed that the increased prevalence of these psychiatric disorders in individuals with cancer, approximated at 49-53%, also increases risk for insomnia (Fleming & Davidson, 2012; J. Savard

& Morin, 2001). Regarding age, cancer incidence is highest among older individuals (Centers for Disease Control and Prevention, 2013), making the advanced age of most individuals with cancer another important predisposing factor (Fleming & Davidson, 2012; J. Savard & Morin, 2001). Finally, being female is a likely relevant predisposing factor for individuals with cancer (J. Savard, Villa, et al., 2009) given that insomnia is most prevalent in breast cancer (Fleming & Davidson, 2012). Also, anxiety and depressive disorders are more common in females (Leach, Christensen, Mackinnon, Windsor, & Butterworth, 2008), thus further increasing the burden of insomnia for females diagnosed with cancer.

Precipitating factors. Unlike predisposing factors, the factors that precipitate and perpetuate insomnia are much more amenable to intervention. For individuals with cancer, the most salient precipitating factor is the experience of being diagnosed with and treated for cancer. Although insomnia may pre-date cancer diagnosis for some individuals, it is also likely that for many, the stress and worry that accompany the emergence of cancer-related symptoms, the process of diagnosis, of surgery and active treatment is enough to trigger the onset of insomnia (Fleming & Davidson, 2012). Many individuals may respond with fear and distress to their unusual symptoms prior to diagnosis, which may disrupt their sleep; the extent of the disruption is likely related to the speed with which they seek medical attention and how quickly a diagnosis is made once such attention is sought (Fleming & Davidson, 2012).

Findings that insomnia symptoms peak soon after cancer diagnosis and immediately prior to treatment (Van Onselen et al., 2012) provide clear support for the notion that cancer diagnosis and treatment precipitate insomnia. Individuals are likely to experience much fear and anxiety during this period that may disrupt their sleep through various pathways. First, treatment may aggravate existing pre-treatment symptoms related to the distress of diagnosis (J. Savard, Liu, et

al., 2009). Second, surgery, often an initial step of treatment for patients, has been found to more than double the risk for insomnia in cancer (J. Savard, Villa, et al., 2009). This is partly attributable to the period of hospitalization associated with surgery as it is associated with concomitant environmental (e.g., noise, medication-dosing schedules), behavioral (e.g., daytime napping, modified bedtime routine), and psychological risk factors (e.g., isolation, fear) (Sheely, 1996). Individuals are also likely to experience distress as a result of undergoing an invasive procedure, which may result in loss in function or an altered appearance (Jacobsen, Roth, & Holland, 1998). Lastly, active treatment (i.e., chemotherapy, radiation therapy) is associated with significant physiological changes that can trigger insomnia. For instance, chemotherapy is thought to disrupt sleep by impairing patients' rest-activity circadian rhythms as early as after the first administration (J. Savard, Liu, et al., 2009), leading to decreased differentiation between daytime and night time activity (Fernandes, Stone, Andrews, Morgan, & Sharma, 2006; Levin et al., 2005; Parker et al., 2008; Pati et al., 2007), and daily dysfunction (Ancoli-Israel et al., 2006; Beck et al., 2010). Other biological agents in cancer therapies that contribute to insomnia are corticosteroids and biological response modifiers. Corticosteroids, like dexamethasone, used to treat cancer pain and other treatment related side effects, increase cortisol levels, thereby inducing insomnia (Kirkbride et al., 2000). Similarly, interferon and tumor necrosis factor, which are used to treat malignant melanoma, can also disrupt patients' sleep/wake cycles (J. Savard & Morin, 2001). Besides these biological effects, chemotherapy and radiation treatment have significant side effects that include pain, fatigue, and emotional distress, which are also implicated in insomnia. The sheer prevalence of these side effects means that few individuals with cancer are unaffected; when taken together with the considerable distress they cause, an examination of how these specific side effects impact insomnia is warranted.

An estimated 25% of newly diagnosed patients, 33% of those in treatment, and 75% of those with advanced cancer experience pain (Swarm et al., 2013). Cancer-related pain impairs patients' functioning while diminishing their quality of life, and when it is not adequately controlled early in cancer care, can shorten patients' survival (Swarm et al., 2013). As might be expected, cancer pain is one of the most feared symptoms by patients (Swarm et al., 2013). Insomnia from cancer-related pain can result from the pain in and of itself, or the medications used to treat the pain (Theobald, 2004). Experimental and clinical studies show that pain precipitates insomnia by causing micro arousals, thereby lightening sleep and lessening the restorative benefits of sleep. Individuals with persistent pain may also experience more nocturnal awakenings due to physiological changes related to pain. Pain can also induce insomnia by disrupting mood (Smith & Haythornthwaite, 2004).

Approximately 80% of individuals undergoing chemo- and/or radio-therapy report cancer-related fatigue (Hofman, Ryan, Figueroa-Moseley, Jean-Pierre, & Morrow, 2007). It is defined as a subjective, persistent, and distressing state of tiredness related to cancer or its treatment that interferes with usual functioning and is often unrelieved by rest (Berger et al., 2010). Patients on average consider cancer-related fatigue to be the most distressing symptom of cancer and its treatment (Berger et al., 2010). Research suggests that cancer-related fatigue is reciprocally associated with insomnia (Roscoe et al., 2007). Specifically, although fatigue can result from the physiological effects of cancer or cancer treatment (e.g., anemia) (Anderson et al., 2003), insomnia also increases daytime fatigue. It is also possible for decreased daytime activity and restless sleep to exacerbate fatigue, perhaps due to daytime napping and diminished circadian functioning as a result of inactivity (Berger & Higginbotham, 2000). Subjective and

objective measures of sleep confirm this complex relationship between insomnia and cancer-related fatigue.

Lastly, an estimated 50% of individuals with cancer have anxiety and/or depressive disorders that contribute to and co-vary with sleep disturbances (Phillips et al., 2012; J. Savard & Morin, 2001; Van Onselen et al., 2012; Woodward, 2011). For example, cancer surgeries that result in changes in patients' physical appearance or loss of function may produce greater emotional distress and thus increase risk for insomnia (J. Savard & Morin, 2001). In some cases, sleep disturbances can elevate patients' risk for depression (Fiorentino & Ancoli-Israel, 2014). Even though emotional distress and insomnia can be related and treating insomnia may improve emotional adjustment, it is important to note that for many patients, depression and anxiety may also require attention separate from insomnia treatment (Fiorentino & Ancoli-Israel, 2014).

Perpetuating factors. Chief among the behaviors that maintain insomnia once precipitated is poor sleep hygiene {Fiorentino, 2006 #17}. Insomnia persists when patients respond to its onset with maladaptive sleep behaviors that increase arousal and sleep effort, thereby inhibiting relaxation and sleep. For example, patients may spend more time in bed due to fatigue when not sleepy, perhaps engaging in activities that interfere with sleep, which weakens the association between their beds and sleep. Similarly, patients may weaken the association between sleep and/or relaxation and their bedroom when they repeatedly pair heightened arousal with their bedrooms by going to their bedrooms when in pain or distress (Fleming & Davidson, 2012). Also possible, patients may nap during the day in efforts to regain lost nighttime sleep, or may keep irregular sleep-wake schedules due to the side effects of treatment. While these behaviors are patients' attempts to cope with a stressful time period in their lives and may even be in keeping with treatment recommendations (Woodward, 2011),

insomnia becomes chronic when these behaviors become habits and persist after acute stressors, such as treatment, end.

Individuals may also develop faulty beliefs and attitudes about sleep that can perpetuate insomnia (J. Savard & Morin, 2001; Woodward, 2011). While not unique to individuals with cancer, one of the most common maladaptive beliefs about sleep that can perpetuate insomnia includes unrealistic expectations about sleep requirements (e.g., I need 8 hours of sleep each night). Others are erroneous causal attributions (e.g., If I don't sleep well, my cancer will come back); misattribution or exaggeration of the perceived consequences of insomnia (e.g., I'm always tired because I can't get a good night's sleep); and perceived diminished control or predictability of sleep (e.g., I feel like when and how I sleep is completely out of my control). These beliefs undermine sleep because they increase anxiety and other negative emotional responses, thereby increasing arousal at bedtime, which overrides the body's entrained sleep response.

Importance of treating insomnia early in cancer care trajectory. The importance of treating insomnia among individuals with cancer, especially early in the cancer care trajectory cannot be overstated. Left untreated, the consequences of insomnia for individuals can be severe. Individuals with concurrent cancer and insomnia experience greater symptom burden and poorer overall survival (Degner & Sloan, 1995). One study found that insomnia symptoms, which peaked within the first eight weeks after diagnosis, significantly increased the risk for death within the first year after cancer diagnosis (Kozachik & Bandeen-Roche, 2008).

According to the current state of the evidence, CBT-I is the treatment of choice for cancer-related insomnia. However, the efficacy and feasibility of CBT-I during this critical period of cancer treatment, namely the time surrounding cancer surgery and the initiation of

active treatment, remains unclear (J. Savard & Savard, 2013). Thus, an important avenue for research, and the purpose of the current pilot study, is to investigate whether CBT-I can be implemented as effectively during this time period as observed in other studies, and to examine whether it will be acceptable to individuals with cancer.

Treatment for Comorbid Insomnia in Cancer

The need for effective insomnia treatment in cancer has led to a proliferation of studies. First, it must be acknowledged that successful treatment of insomnia in cancer must include management of cancer-related symptoms such as pain and treatment side effects through pharmacological and non-pharmacological modalities. As discussed above, these symptoms contribute to and exacerbate insomnia. However, solely addressing these symptoms is insufficient, as the behaviors and thought patterns that perpetuate insomnia outlast these symptoms (J. Savard & Morin, 2001). Moreover, as the National Institutes of Health (NIH) (2005) State of the Science conference statement asserts, comorbid insomnia is a separate diagnosis that merits individualized attention. Thus, this review of the evidence on treating comorbid insomnia in cancer will focus on insomnia-specific treatment.

Pharmacological treatment. As in the general population (Morin & Jarrin, 2013), hypnotic medications are often prescribed to individuals with cancer who report insomnia. Recent estimates put hypnotic medication use in this population at 23%, with more than one-third of individuals initiating use at one point or another after their cancer diagnosis (Casault, Savard, Ivers, Savard, & Simard, 2012). Although hypnotic medications have been shown to be effective in the short-term in the general population (National Institutes of Health, 2005), they have yet to be studied in cancer populations (National Cancer Institute, 2013). Additionally, sleep experts recommend limiting use to two to four weeks (National Institutes of Health, 2005);

however, patients with cancer were found to be using these medications for an average of five years (Casault et al., 2012). Not only is evidence for such long-term use lacking (National Cancer Institute, 2013; J. Savard & Savard, 2013), but long-term use can also have adverse health consequences, including tolerance, dependence, residual daytime drowsiness, impaired cognitive functioning, and increased risks for falls and motor vehicle accidents (Glass, Lancot, Herrmann, Sproule, & Busto, 2005; J. Savard & Morin, 2001). Among individuals with cancer specifically, hypnotic medication use is associated with diminished quality of life and increased symptom burden (Paltiel et al., 2004). Moreover, sustained hypnotic medication use can actually precipitate insomnia by interfering with rapid eye movement sleep (National Cancer Institute, 2013), as well as perpetuate insomnia because individuals tend to overestimate their efficacy (Holbrook, Crowther, Lotter, Cheng, & King, 2000). Individuals may also adopt beliefs that only these medications can treat their insomnia, or that their sleep problems are permanent, due to their dependence on these medications or the unpleasant withdrawal symptoms they experience when they attempt to discontinue use. For these reasons, non-pharmacological treatment, specifically CBT-I, is recommended as first-line treatment for insomnia in individuals with cancer (National Cancer Institute, 2013).

Cognitive-Behavioral Treatment for Insomnia. CBT-I is a multiple-component behavioral treatment that aims to decrease the maladaptive behaviors and thought patterns that perpetuate insomnia (Morin, 2004). It is comprised of stimulus control, sleep restriction, sleep hygiene, and cognitive restructuring, as well as an optional relaxation training component used by some clinicians (Smith, Huang, & Manber, 2005).

Stimulus control operates on the notion that after numerous unsuccessful attempts to fall asleep, individuals with insomnia condition arousal by repeatedly pairing wakefulness with

bedtime and the sleep setting (Bootzin, 1973). Thus, the stimulus control component of CBT-I aims to repair the association between sleep and sleep stimuli (i.e., bedtime, bed, bedroom), as well as to restore synchronized circadian rhythms through five specific guidelines: 1) Go to bed only when sleepy; 2) Use the bedroom only for sleep or sex; 3) Get out of bed whenever unable to sleep after 15 minutes and only return to bed when sleepy; 4) Wake up at the same time each morning; and 5) Do not nap during the day (Bootzin, Epstein, & Wood, 1991; Morin, 2004).

Sleep restriction is guided by the principle that insomnia is maintained by the excess amount of time individuals with insomnia spend in bed not sleeping. Thus, limiting the amount of time spent in bed creates a temporary state of sleep deprivation or sleep pressure that is sufficient enough to overpower individuals' conditioned arousal (Morin, 2004). The goal of sleep restriction is to help individuals fall asleep faster, increase sleep continuity and improve sleep quality and ultimately, to enhance the efficiency of individuals' sleep. To determine an individual's sleep restriction regimen, a "sleep window" (i.e., bed- and wake-times) is established based on the average total sleep time estimated from sleep diaries (Morin, 2004). Adjustments are made to the "sleep window" over the course of treatment depending on the patient's progress and changes in sleep efficiency (Morin, 2004). For example, an individual's averaged total sleep time per night is five hours, and she must be up for work at 6 AM.

Therefore, she would be instructed to go to bed no earlier than 1 AM.

Sleep hygiene is the education component of CBT-I that entails teaching individuals about the external factors that promote and hinder sleep (Morin, 2004). For instance, individuals are educated about how environmental factors such as light and/or noise in the bedroom can disrupt sleep. They are counseled to avoid behaviors such as nighttime caffeine, alcohol, or

nicotine use. Alternatively, they are encouraged to engage in behaviors more conducive to sleep, including consuming a light snack before bed, and exercising daily.

Cognitive restructuring targets those beliefs, expectations and thought patterns that interfere with sleep by driving maladaptive behaviors (Morin, 2004). For instance, individuals may have misconceptions about the causes of insomnia (e.g., “My sleep is poor because I’m getting old”), have distorted perceptions that amplify the consequences of insomnia (e.g., “If I don’t get a full night’s sleep, I’ll be sick”), hold unrealistic expectations about sleep (e.g., “I have to get at least eight hours of sleep at night”), and/or may have dysfunctional beliefs about sleep-promoting practices (e.g., “I should just stay in bed and try harder to sleep”) (J. Savard & Savard, 2013; Woodward, 2011). These beliefs maintain insomnia by heightening individuals’ performance anxiety and by instilling a sense of learned helplessness around sleep, thereby increasing sleep effort and decreasing the likelihood of sleep (Morin, 2004). In addition to directly addressing these beliefs by challenging them, cognitive restructuring entails teaching individuals to: 1) never try to sleep; 2) not catastrophize after a poor night’s sleep; and 3) have realistic expectations about sleep (Morin, 2004).

Relaxation training can work in concert with the other components of CBT-I to reduce individuals’ physiologic and cognitive arousal, especially at night, thereby promoting sleep (Morin, 2004). There are a number of techniques for relaxation training, including progressive muscle relaxation, an exercise through which individuals are taught to tense and release different muscle groups to relax their bodies. Another option is guided imagery, in which through mental representations, individuals are guided to a peaceful scene where they are able to perceive the experience with their senses (Post-White, 2002).

Efficacy of CBT-I. The efficacy of CBT-I is well established, with studies yielding large effect sizes. On average, studies produce a 50-60% reduction in symptoms on key subjective and objective insomnia outcomes (J. D. Edinger, W. Wohlgemuth, R. Radtke, G. Marsh, & R. Quillian, 2001a; Espie, Inglis, Tessier, & Harvey, 2001; Morin, Colecchi, et al., 1999; Morin, Culbert, & Schwartz, 1994; Morin, Hauri, et al., 1999; Smith et al., 2002) among 70-80% of treated individuals (Woodward, 2011). Treatment gains can last for as long as two years (Morin, Colecchi, et al., 1999). Specifically, individuals typically report decreases in sleep onset latency (SOL), the period between laying down to sleep and sleep onset, and wake after sleep onset (WASO), the amount of time spent awake after sleep onset, to non-clinical levels after treatment (Edinger et al., 2001a; J. D. Edinger, W. K. Wohlgemuth, R. A. Radtke, G. R. Marsh, & R. E. Quillian, 2001b; Irwin, Cole, & Nicassio, 2006; Morin, Colecchi, et al., 1999; Morin, Kowatch, Barry, & Walton, 1993). Improvements in total sleep time (TST) have also been noted, with individuals reporting average increases of up to 45 minutes (Morin, Colecchi, et al., 1999; Morin et al., 1993). CBT-I also corresponds with improvements in quality of sleep or sleep consolidation, as measured by sleep efficiency (Edinger, Hoelscher, Marsh, Lipper, & Ionescu-Pioggia, 1992; Mimeault & Morin, 1999). Finally, individuals who undergo CBT-I report clinically significant improvements in their self-efficacy to address sleep problems and in their sleep satisfaction, as well as a decrease in their dysfunctional thoughts and beliefs about sleep (Edinger et al., 2001a; Edinger et al., 2001b; Morin, Blais, & Savard, 2002; Morin, Colecchi, et al., 1999).

When compared to pharmacotherapy, CBT-I is a more efficacious and durable treatment and it has the additional benefit of avoiding the side effects of pharmacological treatments. For instance, a meta-analysis showed that CBT-I recipients reported significantly greater

improvements in SOL than those treated with pharmacotherapy, 43% vs. 30% (Smith et al., 2002). The superior potency of CBT-I over pharmacotherapy is further supported by evidence that CBT-I alone is equally as, or more efficacious than combining pharmacotherapy with CBT-I (Jacobs, Pace-Schott, Stickgold, & Otto, 2004). Compared to those receiving pharmacotherapy, individuals treated with CBT-I are more likely to achieve normal sleep patterns after treatment, to be satisfied with their sleep, and to perceive their treatment as more effective, (Jacobs et al., 2004).

Effectiveness of CBT-I. Although requisite, establishing treatment efficacy is insufficient evidence for the feasibility or generalizability of CBT-I to real world settings. This is especially important given that in real world settings, individuals with insomnia also present with comorbid psychiatric and medical conditions (Morin, Stone, McDonald, & Jones, 1994). Compared to efficacy studies, the literature on the clinical effectiveness of CBT-I is less developed. Early evidence of the effectiveness of CBT-I came from case series studies of treatment-seeking patients from sleep clinics (Dashevsky & Kramer, 1998; Morin, Stone, et al., 1994; M Perlis et al., 2000; M Perlis, Sharpe, Smith, Greenblatt, & Giles, 2001), and also from primary care clinics (Espie, Inglis, Tessier, et al., 2001; Espie, Inglis, & Harvey, 2001; Espie, MacMahon, & Kelly, 2007). Nevertheless, the evidence is unequivocal that the efficacy of CBT-I is generalizable to more heterogeneous patient populations, including those with comorbid medical and psychiatric conditions (Smith et al., 2005). In particular, CBT-I was associated with 26-65% improvement in SOL, 48-50% improvement in WASO, 13-28% improvement in TST, and 14-33% improvement in SE (Okajima, Komada, & Inoue, 2011). Moreover CBT-I recipients reported decreases in hypnotic medication use (Espie, Inglis, Tessier, et al., 2001; Morgan, Dixon, Mathers, Thompson, & Tomeny, 2003; Morin et al., 2004; Morin, Colecchi,

Ling, & Sood, 1995) and on multiple quality of life indicators (Dixon, Morgan, Mathers, Thompson, & Tomeny, 2006; Morgan et al., 2003).

CBT-I Format. Despite its proven efficacy and effectiveness, CBT-I remains underused as a result of low availability and accessibility due to a lack of resources including limited availability of trained clinicians (Edinger & Means, 2005). This has prompted research into understanding the optimal dosing for treatment effect as well as the efficacy and effectiveness of abbreviated CBT-I, and into less resource-intensive treatment modalities. This line of research also extends the evidence on the effectiveness of CBT-I, as it tends to use more heterogeneous samples, with a goal of increasing dissemination of CBT-I.

Low-intensity CBT-I. Edinger et al. (2007) provided the basis for this line of scholarship, by demonstrating that contrary to expectations, one- and four-session CBT-I treatment outperformed the two- and eight-session treatments. Other studies have demonstrated that abbreviated CBT-I, constituting two to three sessions (face-to-face and over the telephone), is effective in significantly improving sleep among primary care patients (Buysse et al., 2011; Edinger & Sampson, 2003), psychiatric outpatients (Wagley et al., 2012), and among older adults with medical and psychiatric comorbidities (Germain et al., 2006). Overall, low-intensity CBT-I, including self-administered interventions, have been shown to be 50-75% as clinically effective as face-to-face unabridged treatments (Rybarczyk, Lopez, Schelble, & Stepanski, 2005; Rybarczyk et al., 2011).

Self-administered CBT-I. In addition to abbreviating sessions, research suggests that dissemination of CBT-I can be greatly expanded through self-administered modalities like Internet-based computerized programs. In fact, a recent meta-analysis found six different randomized controlled trials (RCTs) of computerized CBT-I, comprising 433 study participants

(S. K. Cheng & Dizon, 2012). Findings showed up to moderate effect sized improvements in the following outcomes: number of awakenings, WASO, TST, SOL, time in bed (TIB), SE, and sleep quality. There were also large improvements in subjective insomnia symptoms and consequences. Moreover, adherence among participants in computerized CBT-I was 78%, higher than the rates reported in face-to-face CBT-I (S. K. Cheng & Dizon, 2012).

Self-administered CBT-I with clinician support. Although comparable to standard CBT-I, self-administered CBT-I results in smaller treatment effects (J. Savard, Ivers, Savard, & Morin, 2013; van Straten & Cuijpers, 2009) that are clinically significant (Currie, Clark, Hodgins, & El - Guebaly, 2004). Augmenting self-administered interventions with clinician support is one strategy to address this limitation. Adding clinician support to self-administered CBT-I increases the intensity of the treatment, but it remains on the continuum of a low-intensity treatment. Several studies support that supplementing self-help CBT-I with clinician support enhances treatment effects (Ho, Chung, Yeung, Ng, & Cheng, 2014; Jernelöv et al., 2012; Kaldo et al., 2015). Most recently Kaldo and colleagues (2015) found that when compared to an active control treatment that entailed sleep hygiene, relaxation, mindfulness and general stress management, guided CBT-I resulted in clinically meaningful improvements in insomnia symptoms that was sustained 12 months post treatment.

Taken together, the evidence clearly supports abbreviated and computerized CBT-I as viable strategies for disseminating this efficacious and effective treatment. First, these treatment modalities help meet the varying needs of individuals with insomnia, as not all may require the full, intensive, treatment protocols. Secondly, they address the time- and resource-demands that make face-to-face CBT-I unfeasible in certain clinical settings or among certain patient-populations. Individuals with cancer who are about to initiate active cancer treatment fall into

this latter category. Given that cancer treatment is such a taxing time, individuals may find low-intensity CBT-I more acceptable. This line of research inquiry is supported by a small, but promising body of literature on the efficacy and effectiveness of CBT-I among individuals with cancer.

CBT-I in cancer. To date, there have been 15 published studies on the efficacy of CBT-I among individuals diagnosed with cancer (Berger, Kuhn, Farr, Lynch, et al., 2009; Davidson, Waisberg, Brundage, & MacLean, 2001; Epstein & Dirksen, 2007; Espie et al., 2008; Fiorentino & Ancoli-Israel, 2006; Garland et al., 2014; Matthews, Schmiede, Cook, Berger, & Aloia, 2012; Quesnel, Savard, Simard, Ivers, & Morin, 2003; Ritterband et al., 2012; J. Savard, Simard, Ivers, & Morin, 2005; J. Savard, Villa, et al., 2011; Simeit, Deck, & Conta-Marx, 2004). The strongest support for CBT-I among individuals with cancer is provided by RCTs. Nine of the published studies have been RCTs, with individual (Berger, Kuhn, Farr, Lynch, et al., 2009; Fiorentino & Ancoli-Israel, 2006; Matthews et al., 2012; J. Savard et al., 2013), group (Epstein & Dirksen, 2007; Espie et al., 2008; Garland et al., 2014; J. Savard, S. Simard, H. Ivers, et al., 2005), or computerized designs (Ritterband et al., 2012). Treatments have typically entailed four to eight 15- to 120-minute in-person sessions. These studies have proven the efficacy of CBT-I at improving sleep among individuals with cancer on key sleep parameters including SOL, WASO, and SE, and self-rated insomnia, as well as at conferring benefits in psychological well-being and quality of life. When tested, these therapeutic gains can be maintained for up to 12 months after treatment.

These studies are not without their limitations. First, the samples in these RCTs have been especially homogenous, as all or the majority of participants have been diagnosed with breast cancer. Second, all, but one of these studies, have been conducted among individuals who

are months or years post-diagnosis and -treatment. For example, in the first RCT published, Savard and colleagues (2005) randomized 57 breast cancer survivors who were on average 31 months post treatment, to an eight-session group CBT-I protocol or to a wait-list control. The CBT-I protocol was standard, including stimulus control, sleep restriction, sleep hygiene, and cognitive restructuring. Findings showed that compared to the control group, CBT-I recipients showed significantly greater improvement on subjective and some objective measures of sleep, with treatment gains maintained and even enhanced for some participants at the twelve-month follow-up. Additionally, CBT-I was associated with significant decreases in depression and anxiety, and increase in global quality of life. More recently, Fiorentino et al. (2009) reported similar results in a crossover design study of breast cancer survivors five to 24 months post treatment. After completing the six-session individual standard CBT-I protocol plus progressive muscle relaxation, 71% of participants experienced a remission in their sleep disturbances. There were significant improvements on subjective (i.e., WASO, SE) and objective (i.e., actigraph-measured WASO, sleep percentage) sleep measures.

Berger et al. (2009) completed the only RCT to date in individuals with cancer who were also undergoing chemotherapy. In the study, 219 individuals with breast cancer were randomly assigned to CBT-I or a healthy eating control treatment condition. Prior to chemotherapy, individuals in the CBT-I condition developed an Individualized Sleep Promotion Plan with a nurse, covering modified stimulus control and sleep restriction, sleep hygiene, and relaxation. The sleep plan was revised prior to each subsequent cycle of treatment, with reinforcements scheduled seven days after each revision. Post-CBT-I, individuals reported significantly fewer awakenings and higher sleep efficiency, as well as fewer actigraph-measured awakenings. Findings from this study support the feasibility and efficacy of implementing CBT-I prior to and

during active cancer treatment. Nevertheless, this examination of the benefits of CBT-I during this critical point of the cancer treatment trajectory was likely limited by the exclusion of individuals with chronic insomnia, leaving a largely non-clinical insomnia sample, a majority of whom self-identified as “fairly good” or “very good” sleepers.

Low-intensity CBT-I in cancer. Given its demonstrated efficacy, researchers in recent years have sought to increase the dissemination of CBT-I among individuals with cancer through self-help versions of CBT-I. Pioneering this kind of work, Savard et al. (2011) examined the feasibility of a self-help CBT-I intervention composed of a 60-minute video and a 20-page booklet on sleep hygiene, stimulus control, sleep restriction, and cognitive restructuring. In the single-group study design, participants were recruited during radiotherapy and were given the intervention materials after completing a two-week sleep diary. Participants were instructed to read a segment of their intervention booklet and to watch a segment of the video each week, for six weeks. There were significant, large effect-sized improvements in perceived sleep quality, SOL, WASO, and SE, moderate effect-sized improvements in depression and quality of life, as well as small effect-sized decrease in use of sleep medications, with many of these treatment gains generally maintained at the three-month follow-up. Moreover, these findings are especially promising in light of results that the self-reported adherence was 100%, while the attrition rate (18%) is comparable to that reported in a clinician-led intervention trial (16-18%) (Espie et al., 2008). However, the true efficacy of this self-help CBT-I has yet to be tested, as there was no control group to rule out the effects of time and/or treatment expectancies.

In the second self-help CBT-I study, Ritterband and colleagues (2012) evaluated the efficacy of Sleep Healthy Using The Internet (SHUTi), an individually-tailored, interactive Internet-based CBT-I treatment protocol, among cancer survivors who were on average, 48

months post-treatment. Of note, unlike previous studies, only individuals who self-reported that their cancer diagnosis or treatment precipitated or exacerbated their sleep problems were eligible to participate. The SHUTi program consists of six 45 to 60-minute cores covering stimulus control, sleep restriction, sleep hygiene, and cognitive restructuring. Participants are provided with individualized tailoring and feedback throughout the program based on sleep diary data that they enter. Additionally, automated emails are sent to participants to inform them of next steps and to encourage adherence. Post-intervention, the authors found that compared to the waitlist control group, SHUTi completers reported statistically significant and clinically meaningful improvements in multiple sleep outcomes. In particular, SHUTi produced 19% improvement in SE, 59% improvement in SOL, and large effect-sized improvement in self-rated sleep quality. Lastly, treatment effects for fatigue, ranging from moderate to large, was observed in the SHUTi group. Similar to the other self-help CBT-I study reviewed (J. Savard, Villa, et al., 2011), adherence was high, with 86% of participants completing the SHUTi program, which is comparable to adherence reported in a clinician-led intervention (Berger et al., 2003).

Both of these studies of self-help CBT-I had limitations that were similar to previous RCTs. In both studies participants were individuals with breast cancer who were months or years post-treatment. In fact, in one study, active cancer treatment was considered an exclusion criterion (J. Savard, S. Simard, H. Ivers, et al., 2005). As in other CBT-I studies among individuals with cancer, the study samples have lacked racial and ethnic diversity, as the majority have been well-educated Caucasian women. Despite these shortcomings, these studies have provided very favorable results about the efficacy and feasibility of implementing low-intensity CBT-I interventions among individuals with cancer. In addition to producing treatment effects on key insomnia outcomes comparable to those in face-to-face interventions, findings suggest

that these interventions can also produce clinically meaningful benefits on other psychosocial outcomes including fatigue and quality of life. These studies add to the growing knowledge base on effective strategies for translating and disseminating CBT-I among individuals with cancer.

Self-administered CBT-I with clinician support in cancer. There has been only one study that has tested the efficacy of a self-administered CBT-I supplemented with clinician support in individuals diagnosed with cancer. Building on previous work, Savard and colleagues (2013) compared the efficacy of a low-intensity CBT-I intervention, a video-based intervention with six booklets, supplemented with clinician support to a standard, face-to-face intervention in women who had undergone treatment for breast cancer. The authors found that the low-intensity intervention resulted in clinically significant improvements on several sleep parameters. These treatment effects were smaller than those found for the face-to-face intervention (J. Savard et al., 2013). Moreover, even though clinician support was offered, 9% of participants in the low-intensity treatment condition accessed this support.

Among the strongest arguments for these low-intensity CBT-I programs for patients, especially those already burdened with cancer, are their flexibility and convenience, which may enhance their acceptance and adherence. Preliminary data seem to support this, as the reported adherence rates have been higher than those reported in a face-to-face group CBT-I study. One research question that remains unanswered is the feasibility and efficacy of these low-intensity CBT-I interventions during the early stages of active cancer treatments, when patients are most likely to experience insomnia.

Considerations. In pursuit of the study aims, there were a number of considerations related to cancer and to Internet usage. The literature clearly supports treating individuals with cancer who also have comorbid insomnia with CBT-I, but there were a number of considerations

unique to the experiences of this population. The first has to do with the fatigue (Smith et al., 2005) and pain (National Cancer Institute, 2013) associated with cancer and its treatment. As described earlier, pain and fatigue can precipitate insomnia, as well as contribute to maladaptive thinking patterns and behaviors that perpetuate sleep disturbances. Thus, any CBT-I regimen for individuals with cancer, particularly if implemented during active cancer treatment, must address how these side effects impact sleep. For some patients, these cancer treatment side effects may require separate pharmacologic and non-pharmacologic management. For example, tricyclic antidepressants can be especially beneficial for treating sleep disturbances in patients with neuropathic pain and depression (National Cancer Institute, 2013). Additionally, non-pharmacologic strategies can be embedded in CBT-I treatment components. For instance, stimulus control and sleep hygiene can correct some individuals' tendency to respond to cancer-related pain and fatigue by spending additional time in bed by setting activity/exercise goals, and timing naps appropriately to limit their interference with nighttime sleep (National Cancer Institute, 2013; Smith et al., 2005). To reinforce those instructions, cognitive restructuring can also be used to adjust patients' misattributions of fatigue with sleep loss, while helping individuals distinguish between fatigue (i.e., decreased energy, such as a sense of heaviness in limbs, which may require rest but not necessarily sleep) and sleepiness (i.e., requiring effort to stay awake) (Smith et al., 2005). Also, relaxation techniques can be implemented in conjunction with pain management and to reduce conditioned arousal at bedtime.

Other considerations were related to cancer-specific psychological distress and age. Given the high co-occurrence of psychological distress, including depression and anxiety, with cancer and insomnia, these symptoms must also be appropriately managed in order to achieve the full benefit of CBT-I. Psychiatric symptoms were assessed to determine whether they

required separate psychotherapy or pharmacologic intervention (Smith et al., 2005). Lastly, older individuals with cancer and comorbid insomnia may have required important modifications to CBT-I protocols (National Cancer Institute, 2013). For instance, sleep hygiene and cognitive restructuring could be tailored to address the changes in sleep cycles that occur as part of the natural aging process. Thus, older patients were engaged in cognitive restructuring to develop more realistic expectations of their sleep.

Lastly, since that the current study examined the feasibility and efficacy of an online program, considerations regarding Internet access must be discussed. To accurately capture patients' CBT-I treatment preferences rather than their Internet access, prospective participants needed regular access to the Internet. Based on current evidence on Internet access, the potential for this requirement to have biased study findings was limited. An estimated 85% of American adults use the Internet (Pew Internet and American Life Project, 2011), with 72% of users having searched for health-related information (Fox & Duggan, 2013). Moreover, differences in access by socioeconomic status (SES) have decreased significantly (U.S. Government of Commerce, 2000) and access is similar across different racial and ethnic minority groups—86% of non-Hispanic Whites compared to 85% of non-Hispanic Blacks and 76% of Hispanic adults reported using the Internet in 2013 (Pew Internet and American Life Project, 2011). Given the increased rates of cancer among older adults, it is also important to note that Internet access is increasing in this segment of the population, with 83% of adults aged 50-64, and 56% of adults aged 65 and older using the Internet (Pew Internet and American Life Project, 2011; Zickuhr & Madden, 2012). These statistics further supported the importance of examining the acceptability and efficacy of an online CBT-I intervention, given that access to face-to-face CBT-I is limited.

Statement of the Problem

CBT-I is an evidence-based, efficacious and effective treatment for cancer-related insomnia. The treatment improves sleep, psychological and physical symptoms, with treatment gains that last for up to 12 months. With the utility of CBT-I in cancer firmly established, research efforts have recently turned to accelerating the translation and dissemination of CBT-I to a greater number of patients through low-intensity treatment modalities. To date, only two studies of a web-based and a video plus treatment booklet self-help interventions have been tested. One study added clinician support to the self-administered treatment. Overall, these studies have yielded very promising findings, demonstrating that CBT-I, even in its low-intensity forms, can have clinically meaningful and lasting effects on sleep, depression, quality of life, and fatigue. Moreover, participants appear to respond well to these treatments, with adherence rates higher than those reported in face-to-face studies, and comparable attrition rates. However, these findings are limited by the homogenous, non-representative nature of the study samples, when it comes to demographic characteristics and malignancy type. Second, despite evidence supporting the importance of treating CBT-I in the early phases of cancer treatment, only one CBT-I study and none of the low-intensity CBT-I studies, has been conducted during active cancer treatment.

This study aimed to address these gaps in the literature while extending previous research on accelerating the translation and dissemination of CBT-I among individuals with cancer through low-intensity treatment modalities. This study examined the feasibility, acceptability, and efficacy of a low-intensity and accessible CBT-I intervention delivered online, SHUTi, with therapist support provided as needed. Participants were individuals newly diagnosed with non-advanced (i.e., curable) cancers who were about to initiate their first course of chemotherapy or radiation therapy, and were experiencing at least three episodes of sleep disturbance per week

that was associated with daytime effects such as fatigue, irritability, or difficulty concentrating and had persisted for at least one month. The following complementary aims were examined:

Specific Aim 1: To assess the feasibility and acceptability of an online CBT-I intervention, Sleeping Healthy Using the Internet (SHUTi), in individuals newly diagnosed with cancer.

Specific Aim 2: To determine the efficacy of SHUTi at improving sleep and other quality of life outcomes during cancer treatment.

Statement of Hypotheses

Based on past evidence and the aims of the current study, the following hypotheses were proposed:

1. SHUTi will be a feasible and acceptable treatment for insomnia among patients newly diagnosed with cancer who are undergoing chemotherapy and/or radiation.
2. Compared to the treatment as usual (TAU) group, participants in the SHUTi group will report significantly better sleep after treatment, as indicated by lower Insomnia Severity Index (ISI) score, higher SE, decreased SOL, higher TST, and shorter WASO.
3. Compared to the TAU group, participants in the SHUTi group will report significantly better health-related quality of life and lower psychological distress (i.e., depression and anxiety) after treatment.

Methods

Study Design

The current study examined the feasibility and efficacy of a low-intensity and accessible CBT-I intervention delivered online, SHUTi, among patients newly diagnosed with cancer who

were treatment naïve and undergoing chemotherapy and/or radiation at an academic medical center. Participants were randomized to either the SHUTi condition or TAU group. All participants had a face-to-face meeting with the doctoral student at enrollment, when baseline self-report questionnaires were completed (see Measures section for further detail). As a pre-treatment assessment, all participants also completed a 1-week sleep diary. Participants randomized to SHUTi were enrolled in the program and provided with their login information at the end of the pre-assessment period. SHUTi participants were informed that they had the option of accessing the doctoral student's assistance to complete the program at any time during the study period. Specifically, she would be available to meet them at their weekly appointments to provide a tablet for them to complete the program cores either with her or independently during their appointments. Individuals randomized to TAU were contacted by telephone biweekly or in person if the doctoral student saw them during an appointment while she was meeting with another study participant. These phone calls and in-person visits mimicked the level of contact in the treatment condition to encourage participant engagement. However, during these contacts, no advice regarding sleep was given and if participants asked for help, they were encouraged to discuss their concerns with their oncologists. Individuals in the TAU group were also given the option of receiving SHUTi if interested at the end of the study period. However, none of the patients in the TAU condition chose to complete SHUTi. At the end of the study period, all participants completed a 1-week diary and the same standardized questionnaires completed at baseline. Participants in the SHUTi condition also completed a questionnaire about the acceptability of the program.

Participants

Twenty-eight adults (i.e., 18 years and older) diagnosed with non-advanced (i.e., curable) cancer who were about to initiate chemotherapy and/or radiation treatment for the first time participated in this study. None of the participants had widely disseminated (i.e., metastatic) disease at the time of recruitment. These individuals were eligible if they reported experiencing at least three episodes of sleep disturbance per week that was associated with daytime effects such as fatigue, irritability, or difficulty concentrating and had persisted for at least one month.

Participants were recruited from the Virginia Commonwealth University (VCU) Massey Cancer Center. The VCU Massey Cancer Center is an NCI-designated cancer center that provides comprehensive cancer care through multidisciplinary teams. These teams convene at weekly tumor board meetings to discuss patients and to design treatment plans. There are tumor board meetings for specific cancer sites: head and neck, ear, nose and throat; breast; chest; gastrointestinal; gynecological; and prostate and other urologic. In addition to these multidisciplinary teams, there is also a Fellows clinic, in which hematological/oncology medical fellows see patients, who are primarily indigent or uninsured, with various malignancies. Prior to their initial treatment appointments with their oncologist, potential participants were identified through case presentations at these tumor board meetings and at the Fellow's clinic, chart review, and oncologist referral.

Inclusion criteria were as follows: a) newly diagnosed non-advanced (i.e., curable) cancer; b) scheduled or planned to begin chemotherapy or radiotherapy; c) chemotherapy- or radiotherapy-naïve; c) meet diagnostic criteria for chronic insomnia (i.e., lasting for at least one month); d) interested in contributing to the understanding of insomnia in cancer; and e) have the permission of their oncologists to participate. Chronic insomnia has been defined in previous research (Edinger et al., 2004; Rybarczyk, Stepanski, et al., 2005) as the presence of (1) three or

more episodes of insomnia (i.e., ≥ 30 -minute SOL, ≥ 60 -minute WASO, or ≤ 6.5 hour-TST per night) of per week and (2) daytime effects of insomnia, such as irritability, difficulty concentrating, or fatigue for at least one month. Exclusion criteria were: a) untreated alcohol or substance abuse or dependence, bipolar, or psychotic disorder; b) medical conditions such as seizure disorder, restless leg disorder, or Parkinson's disease; and c) untreated sleep disorders such as sleep apnea. Other CBT-I efficacy and effectiveness trials have used these exclusion criteria (Smith et al., 2005) because sleep restriction may be riskier in bipolar or seizure disorder as it may precipitate a manic episode or lower the seizure threshold. Similarly, Parkinson's disease may cause sleep disturbances (Rybarczyk, Stepanski, et al., 2005).

The sociodemographic characteristics for the analytic sample (N=28) and for participants in the SHUTi (n=14) and TAU (n=14) conditions are presented in Table 1. F-tests (for continuous variables) and chi-square analyses (for categorical variables) were used to verify the success of randomization by examining whether there were any significant differences by condition at baseline. No significant differences were found between the SHUTi group and the TAU group with regard to gender, age, race, marital status, education, employment, income, and insurance status (all p values $> .05$).

Table 1. Sociodemographic characteristics of sample at baseline

Characteristic	Overall (N=28)	CBT-I (n=14)	TAU (n=14)
Gender, n (%)			
Females	22 (78.6)	11 (78.6)	11 (78.6)
Males	6 (21.4)	3 (21.4)	3 (21.4)
Age, <i>M (SD)</i>			
Range	23-63	37-49	44-56
Race, n (%)			
White	18 (64.3)	9 (64.3)	9(64.3)
Black	9 (32.1)	4 (28.6)	5 (35.7)
Asian	1 (3.6)	1 (7.1)	0
Marital status, n (%)			
Married	13 (46.4)	6 (42.9)	7 (50.0)
Single	7 (25.0)	5 (35.7)	2 (14.3)
Divorced/Separated/Widowed	8 (28.6)	3 (21.4)	5 (35.7)
Education, n (%)			
Some High School	1 (3.6)	0	1 (7.1)
High School	6 (21.4)	3 (21.4)	3 (21.4)
Some College	12 (42.9)	5 (35.7)	7 (50.0)
College	5 (17.9)	3 (21.4)	2 (14.3)
Graduate School	4 (14.3)	3 (21.4)	1 (7.1)
Employment, n (%)			
Full time	10 (35.7)	5 (35.7)	5 (35.7)
Part time	9 (32.1)	5 (35.7)	4 (28.6)
Unemployed	5 (17.9)	2 (14.3)	3 (21.4)
Disability	4 (14.3)	2 (14.3)	2 (14.3)
Income, n (%)			
<\$10, 000	8 (28.6)	4 (28.6)	4 (28.6)
\$10-29, 999	7 (25.0)	3 (21.4)	4 (28.6)
\$30-49, 999	2 (7.1)	2 (14.3)	0
\$50-74, 999	2 (7.1)	1 (7.1)	1 (7.1)
\$75-99, 999	2 (7.1)	1 (7.1)	1 (7.1)
\$100, 000	7 (25.0)	3 (21.4)	4 (28.6)
Insurance, n (%)			
Indigent/uninsured	5 (17.9)	3 (21.4)	2 (14.3)
Medicaid/VCC	5 (17.9)	1 (7.1)	4 (28.6)
Medicare	1 (3.6)	0	1 (7.1)
Private	17 (60.7)	10 (71.4)	7 (50.0)

Baseline insomnia- and cancer-related characteristics for the total sample and by group are presented in Table 2. F-tests and chi-square analyses found no significant differences

between the SHUTi group and the TAU group with regard to these characteristics including cancer site, stage, time since cancer diagnosis, and type of cancer treatment (all p values > .05).

Baseline descriptive statistics of the outcome variables (ISI, SOL, WASO, SE, FACT-G and its component scores, PHQ-9 and GAD-7) for the sample and by group at baseline are presented in Table 3. F-tests and chi-square analyses were performed to examine whether there were any significant differences in outcomes of interest by group. Since these tests are sensitive to violations of normality, variables found to be high on skewness and/or kurtosis were adjusted. Adjustments were performed by converting data points with z-scores greater than 1.96 ($p < .05$) to the next closest value that was under the cut-off value from the sample for that variable. This method maintains the shape of the sample distribution without distorting the data (Tabachnick & Fidel, 2007) and was determined to be the most appropriate way of addressing outliers given the small sample size (Taylor, Rybarczyk, Nay, & Leszczyszyn, 2015). Results showed that the two groups were equivalent with regard to all outcome variables (all p values > .05).

Table 2. Cancer- and insomnia-related characteristics at baseline

Characteristic	Overall (N=28)	CBT-I (n=14)	TAU (n=14)
Cancer site, n (%)			
Breast	10 (35.7)	3 (21.4)	7 (50.0)
Gastrointestinal	7 (25.0)	5 (35.7)	2 (14.3)
Head & neck	6 (21.4)	4 (28.6)	2 (14.3)
Gynecological	4 (14.3)	1 (7.1)	3 (21.4)
Other	1 (3.6)	1 (7.1)	0
Stage at diagnosis, n (%)			
I	6 (21.4)	4 (28.6)	2 (14.3)
II	6 (21.4)	1 (7.1)	5 (35.7)
III	9 (32.1)	6 (42.9)	3 (21.4)
IV	5 (17.9)	2 (14.3)	3 (21.4)
Other	2 (7.1)	1 (7.1)	1 (7.1)
Months since diagnosis, <i>M</i> (<i>SD</i>)	2 (1.8)	1.5 (0.85)	2.4 (2.3)
Surgery	18 (64.3)	8 (57.1)	10 (71.4)
Type of treatment, n (%)			
Chemotherapy	14 (50.0)	8 (57.1)	6 (42.9)
Radiation	3 (10.7)	0 (0)	3 (21.4)
Chemo-radiation	11 (39.3)	6 (42.9)	5 (35.7)
Duration of insomnia, n (%)			
≤ 5 months	14 (51.9)	10 (71.4)	4 (31.8)
6-12 months	3 (11.1)	1 (7.1)	2 (15.4)
1-5 years	1 (3.7)	1 (7.1)	0
≥ 6 years	10 (33.3)	2 (4.3)	7 (53.8)
Onset of insomnia, n (%)			
Before cancer diagnosis	21 (75.0)	9 (64.3)	12 (85.7)
After cancer diagnosis	7 (25.0)	5 (35.7)	2 (14.3)
Cancer caused insomnia, n (%)	11 (39.3)	8 (57.1)	3 (21.4)
Cancer affected sleep, n (%)	24 (85.7)	13 (92.9)	11 (78.6)
Told oncologist about sleep problems, n (%)	11 (39.3)	8 (57.1)	3 (21.4)
Use of sleep aid, n (%)	15 (55.6)	8 (57.1)	7 (53.8)

Table 3. Descriptive statistics of the outcome variables at baseline

Characteristic	Overall (N=28)	CBT-I (n=14)	TAU (n=14)
Insomnia Severity Index (ISI), <i>M (SD)</i>	13.6 (6.2)	13.7 (4.7)	13.4 (7.6)
Sleep Onset Latency in minutes (SOL), <i>M (SD)</i>	63.9 (58.9)	50.3 (33.5)	77.5 (75.5)
Wake Time After Sleep Onset in minutes (WASO), <i>M (SD)</i>	44.8 (35.1)	51.8 (40)	37.8 (29.2)
Sleep Efficiency % (SE), <i>M (SD)</i>	69.6 (17.3)	72.8 (15.8)	66.4 (18.9)
Total Sleep Time in minutes, <i>M (SD)</i>	372.2 (130.6)	419.8 (143.9)	324.6 (99)
Functional Assessment of Cancer Therapy-General (FACT-G), <i>M (SD)</i>	72.2 (16.1)	67.4 (15.6)	77.5 (15.6)
Physical Well-being Score	19.2 (5.9)	17.8 (6.3)	20.6 (5.1)
Emotional Well-being Score	15.8 (4.4)	15.3 (4.1)	24 (3.5)
Social/Family Well-being Score	22.6 (6.2)	21.3 (7.8)	24 (3.5)
Functional Well-being Score	14.7 (6.9)	12.9 (6.2)	16.4 (7.3)
Patient Health Questionnaire-9 (PHQ-9), <i>M (SD)</i>	10.2 (4.4)	10.6 (4)	9.8 (5.3)
Generalized Anxiety Disorder-7 (GAD-7), <i>M (SD)</i>	8.8 (5.1)	8.5 (3.9)	9 (6.3)

Procedure

The study protocol was approved by Massey Cancer Center's Protocol Review and Monitoring Committee (PRMC), MCC-14-1076, and the VCU Institutional Review Board (IRB), HM20002827.

Recruitment. Study participants were recruited between December 2014 and August 2015. Before recruitment for the study could begin, the doctoral student presented the study and eligibility criteria to the multidisciplinary teams at tumor board meetings and at the hematology/oncology Fellows' pre-clinic conferences. The doctoral student then attended these weekly tumor board meetings to identify potential study participants from the list of new patients that were discussed at each meeting. Other potential participants were identified at the

hematology/oncology Fellows' pre-clinic conferences, where patients who would be seen in the clinic that same day were discussed. Potential participants' ability to participate in the study was verified with their oncologists at the tumor board meetings and at the pre-clinic conferences. In addition to these active recruitment strategies, there was passive recruitment through fliers that were placed in areas of prominence at Massey.

The doctoral student approached patients during a pre-treatment appointment using a standardized verbal introduction to describe the study while also informing patients that their oncologists had given prior approval for their participation. This introduction took place either before or after patients had met with their oncologists. While these visits were usually one of the first times individuals were meeting with their oncologists, individuals were only approached after they had discussed their treatment plans with their oncologist. Interested individuals were formally assessed for other eligibility criteria, particularly, that they met diagnostic criteria for insomnia. Participants that met eligibility criteria and expressed interest in participating in the study were then consented into the study. The doctoral student reviewed consent forms with eligible individuals to ensure that they understood the study procedure and their rights as participants. After which, participants were asked to give written informed consent. After consent, enrolled participants were administered baseline assessments. In a few cases, potential participants were identified after they had already had a pre-treatment visit and did not have any upcoming appointments scheduled before their first treatment appointment. In those cases, individuals were approached about the study over the telephone and eligible individuals were also consented over the telephone, though written consent was obtained at the first meeting with the doctoral student. Baseline questionnaires were also completed over the telephone and these individuals were emailed their baseline sleep diaries so that they would have them completed

before they met up with the doctoral student at their first treatment appointment. Once consented, each patient was enrolled into either the SHUTi or TAU arm by random assignment.

Randomization. The randomization process was as follows. Prior to beginning the study, a random number generator (www.randomization.com) was used to produce a random permutation of integers from 1 to 30. This list was then matched with a systematic listing of 30 total treatment and control condition assignments (e.g., T, C, T, C, etc.) For example, if the random number generator produces 1, 23, 15, and 27, these numbers will determine the first four group assignments, so that first patient will be assigned to the treatment condition (T), the 23rd to the control condition (C), 15th to the treatment condition (T), and the 27th to the control condition (C). Thus at enrollment, the patient's assignment to the treatment or control condition was already determined.

At least one week after study enrollment, the doctoral student met with each study participant, whether in the SHUTi or TAU condition to collect baseline sleep diary data. This visit took place either before or at the first chemotherapy or radiation treatment appointment. At this meeting, individuals in the SHUTi condition were enrolled in the program and given their login information. Whenever possible, an introductory module that teaches users about the program and its features was also completed at this visit, to facilitate participants starting on the actual treatment portion of the program as immediately as possible. At this time, individuals were also asked about their preference for completing the treatment either independently or with the doctoral student's assistance. For participants who chose to work with the doctoral student, arrangements were made to meet at subsequent treatment appointments. For participants who chose to complete the program independently, the doctoral student monitored their progress with completing SHUTi Cores online and individuals were contacted either over the telephone or in

person if they failed to log onto the program for more than 1-2 weeks. Additionally, the option of completing the program at their treatment appointments with or without the doctoral student's assistance was presented again. In contrast, individuals in the TAU condition were told that they would be contacted biweekly, either on the telephone or in person, until the end of the study period once they completed the baseline sleep diary.

At the end of the study period, all participants completed the same questionnaires that they completed at baseline. Participants in the SHUTi condition also completed a questionnaire on the acceptability of the program. Questionnaires were completed either in person or over the telephone depending on the participants' availability. Participants were also asked to complete a 1-week sleep diary, which was either collected at a subsequent appointment or emailed to the doctoral student.

Compensation. To incentivize participation, individuals enrolled in the study were given two \$10 Visa gift cards. At enrollment, participants were informed verbally and through the written study consent form that they would be provided a small compensation for their participation. Participants who completed baseline questionnaires and returned a completed baseline 1-week sleep diary were given the first \$10 gift card. Participants received the second \$10 gift card after they completed post-treatment period questionnaires and returned a completed post-treatment 1-week sleep diary.

SHUTi. An overview of the SHUTi intervention is presented in Figure 3. The online program is made-up of six, weekly treatment Cores modeled after weekly face-to-face CBT-I sessions (Thorndike et al., 2008). Each Core began by providing a rationale for learning the material, explained the main content of the Core, and assigned homework with suggestions for improving sleep over the coming week. Each Core ended with a summary review of the main

points in the Core. The main content for each Core addressed myths about sleep, discussed in-depth information and vignettes, and used quizzes to evaluate users' learning in an interactive manner. As well as being interactive, SHUTi allowed for personalization. For instance, modifications were made to sleep recommendations based on participants' sleep diary data and individually set treatment goals.

The first Core of SHUTi is the Overview, which provided a review and rationale of insomnia and its treatment, including the impact of insomnia, its risk factors, and the effectiveness of CBT-I. Second is the Sleep Behavior Core, which introduced and implemented sleep restriction as well as stimulus control. The next Core is Sleep Behavior Core 2 and built on the previous Core by addressing concerns about sleep restriction while expanding on stimulus control instructions. The fourth Core is the Sleep Education Core, which focused on teaching sleep hygiene, particularly the lifestyle and environmental factors that influence sleep. The fifth Core is the Sleep Thoughts Core, aptly named for its focus on cognitive restructuring. Last is the Problem Prevention Core, which sought to synthesize information from the previous five cores to solidify users' knowledge and to prevent future problems by preparing users to cope with eventual increase in insomnia symptoms.

Each Core took approximately 45 to 60 minutes to complete. Cores were presented one at a time; the next Core became available to users a week after they completed one Core. However, users were able to revisit previous Cores as often as possible. Similar to an in-person CBT-I intervention, users were not required to keep sleep diaries after the baseline 1-week diary that was used to establish an initial sleep window. However, they were able to continue completing sleep diaries if they choose to, and the program used a built-in algorithm to make

necessary adjustments to users' sleep diaries if they continued to enter sleep diary data during the treatment.

Measures

All study measures were self-reported due to the unfeasibility and cost concerns of objective measures like polysomnography and actigraphy. The use of only self-report measures is not uncommon in insomnia studies like this (Smith et al., 2005). All study measures are included in the Appendix.

Study eligibility questionnaire. Individuals who expressed interest in the study after being approached by the doctoral student were administered a brief questionnaire to assess their eligibility. To be eligible, individuals had to have been diagnosed with non-advanced cancer and scheduled to undergo curative chemotherapy and/or radiation (i.e., not palliative). They also had to be chemotherapy and radiation naïve. This was verified via chart review. Regarding sleep, individuals had to report experiencing difficulty initiating (i.e., inability to fall asleep within 30 minutes) or maintaining sleep (i.e., awakening during the night for a total of 60 minutes), early morning awakenings (i.e., achieving less than 6.5 hours of sleep) at least three days a week. These sleep difficulties had to be associated with daytime consequences such as fatigue, irritability, or difficulty concentrating. All of these symptoms had to have persisted for at least one month. Thus, individuals had to answer “Yes” to all questions on the questionnaire to be eligible for participation. They also had to answer “No” to the exclusion criteria. Specifically, individuals were ineligible to participate if they reported untreated sleep apnea, seizure disorder, substance/alcohol use disorder, psychotic disorder, restless leg syndrome, or Parkinson's disease.

Participant information/Demographic questionnaire. The doctoral student administered a paper and pencil questionnaire to assess the history and current nature of

individuals' insomnia and cancer. In particular, the questionnaire asked about the time of cancer diagnosis and when treatment would/had begun. Participants were also asked about the duration of their sleep disturbance. The questionnaire also asked individuals about their perception of the relationship between their sleep difficulties and their cancer diagnosis. In particular, they were asked whether they believed their sleep difficulties pre-dated or developed subsequent to their cancer diagnosis. They were also asked whether they had talked to their oncologist about their sleep difficulties, and if they were taking a sleep aid. The questionnaire also collected participants' demographic information including age, education, income, and employment status.

Sleep diary. Standardized sleep diaries from SHUTi were used to measure and track key sleep quality indicators (Thorndike et al., 2008). Sleep diaries consisted of twelve questions including questions about the length of naps, use of sleep aids, bedtime, minutes to fall asleep, number and duration of nighttime awakenings, wake time, time of getting out of bed. Individuals were also asked about alcohol use and its timing. Lastly, participants were able to write in any comments about their sleep they found pertinent. Data from the sleep diaries were used to calculate SOL, WASO, TST, and SE.

Insomnia Severity Index (ISI). The ISI is an empirically valid seven-item global measure of perceived sleep difficulties (Bastien, Vallieres, & Morin, 2001) that has been also been validated in individuals with cancer (M. Savard, Savard, Simard, & Ivers, 2005). Respondents were asked to rate the perceived severity of their current sleep problems, satisfaction with their sleep, perceived sleep-related impairment, how noticeable they believe that impairment is to others, and the amount of distress associated with the sleep disturbance. All ratings were reported on a 0 to 5 scale, for a 0-28 total score, with higher scores indicating greater insomnia severity. The ISI has been evaluated as a reliable and validated measure of

insomnia that is sensitive to treatment response in clinical populations, including individuals with cancer (Bastien et al., 2001; M. Savard et al., 2005).

Patient Health Questionnaire-9 (PHQ-9). The PHQ-9 is a self-report version of the depression module from the PRIME-MD, a diagnostic measure for common psychiatric disorders (Kroenke, Spitzer, & Williams, 2001). It is a 9-item instrument used to measure depressive symptoms and functional impairment that is used to diagnose Major Depressive Disorder and to track treatment progress. Items correspond to DSM-IV-TR diagnostic criteria (American Psychiatric Association, 2000). The PHQ-9 has been found to be a valid and reliable measure and has diagnostic validity comparable to the original clinician administered instrument (Kroenke et al., 2001) and has been widely used to screen for depression among cancer individuals (Strong et al., 2008; Walker et al., 2011).

Generalized Anxiety Disorder-7 (GAD-7). The GAD-7 is a brief, 7-item self-report screening measure of generalized anxiety symptoms (Spitzer, Kroenke, Williams, & Lowe, 2006). The measure was developed from the DSM-IV-TR diagnostic criteria for Generalized Anxiety Disorder (American Psychiatric Association, 2000). The measure has been empirically validated (Lowe et al., 2008) and has been found to be an appropriate measure of anxiety symptoms among individuals with cancer (L. F. Brown, Kroenke, Theobald, Wu, & Tu, 2010; Kroenke et al., 2009).

Functional Assessment of Cancer Therapy-General scale (FACT-G). The FACT-G is a valid and reliable measure for evaluating general quality of life among individuals with cancer undergoing cancer treatment (Cella et al., 1993). Items assess individuals' symptoms and ability to perform activities in the following domains: Physical well-being, social/family well-being, emotional well-being, and functional well-being. The instrument has been used as an

outcome measure in numerous intervention studies among individuals with cancer (Rogers et al., 2009; Segal et al., 2009; Velikova et al., 2004).

Treatment acceptability questionnaire. To evaluate the acceptability of SHUTi among participants, a 12-item questionnaire was adapted from questionnaires used by Thorndike and colleagues (2008) for the initial evaluation of the utility and impact of SHUTi. Participants were asked to rate their perception of the suitability, ease of use, and effectiveness of SHUTi on a 5-point Likert scale where 1 corresponded “Not at All” and 5 corresponded with “Very.” Sample questions were, “How effective do you think this program will be as a long term cure?” and “How acceptable do you think the program would be for patients like you?” Participants were also asked to provide comments about their experiences with SHUTi.

Data Analysis

Statistical analyses were performed using IBM SPSS Statistics - Version 23 and G*Power – Version 3.1.9.2. Only the twenty-eight participants that completed all baseline measures were included in the analyses. Additionally, a “last observation carried forward” method was used to address instances of missing data. For two participants who completed the TAU period but failed to complete the post-treatment questionnaires and sleep diaries, their baseline data was used in place of post-treatment data. This is a conservative approach to addressing missing data due to attrition when analyzing treatment effects. The method limits attrition bias while strengthening any conclusions that can be made about the intervention (Kazdin, 2003). To verify results, a sensitivity analysis was also performed wherein the analyses were repeated with missing data and results were similar to results when the “last observation carried forward” was used.

To standardize effects for ease of interpretation, Cohen's d was reported as a measure of effect size. As a general rule, the cutoff is $d = 0.20$ for a small effect size, $d = 0.50$ for a medium effect size, and $d = 0.80$ for a large effect size (Cohen, 1988). Cohen's d was calculated using G*Power – Version 3.1.9.2. (Faul, Erdfelder, Lang, & Buchner, 2007).

Outline of Analyses by Hypotheses

Hypothesis 1. To test the first hypothesis that online CBT-I (i.e., SHUTi) would be a feasible and acceptable treatment for insomnia in individuals newly diagnosed with cancer who are undergoing chemotherapy and/or radiation, a number of indicators were examined. These indicators were: (1) Recruitment; (2) completion rate; (3) time to complete study and reasons for delays; (4) use and impact of doctoral student support; (5) SHUTi acceptability among participants; and (6) participants' comments about their experiences using SHUTi.

Hypothesis 2. To test the second hypothesis that compared to the group, participants in the SHUTi group would report significantly better sleep after treatment, repeated measures multivariate analysis of variance (MANOVA) was used. The independent variable (IV) was condition (SHUTi vs. TAU) and the repeated factor was time (baseline and post-treatment). The dependent variables (DVs) were the five indices of sleep quality—total score on the ISI, and the four sleep parameters calculated from sleep diary data, SOL, TST, WASO and SE. Follow-up repeated measures analyses of variance (ANOVAs) were also conducted to assess condition by time interactions for individual sleep variables.

Hypothesis 3. To test the third hypothesis that compared to the TAU group, participants in the SHUTi group would report significantly better health-related quality of life and lower psychological distress after treatment, repeated measures MANOVA was used. The IV was condition (SHUTi vs. TAU) and the repeated factor was time (baseline and post-treatment). The

DVs were total scores on the PHQ-9, GAD-7, and on the FACT-G and its individual components. Follow-up repeated measures ANOVAs were also conducted to assess condition by time interactions for individual outcome variables.

Results

Hypothesis 1: Study Acceptability and Feasibility

Recruitment. The recruitment and retention of study participants is illustrated in Figure 1. Study recruitment took place from December 2014 to August 2015. A total of 53 individuals were approached or responded to recruitment fliers posted for the study. Out of these individuals, 83% were screened for study eligibility. The reasons why patients refused to be screened for the study are presented in Table 4. Among the total number of patients who were screened, 68% were found to meet inclusion criteria. Most of the excluded patients (57%) were not experiencing sleep problems and if they were, they were not distressed by the symptoms and thus did not meet diagnostic criteria for insomnia. Only 14% of the excluded patients were excluded due to not having Internet or an email account. Although there was a study tablet available that patients could have used, they further explained that they were not comfortable using the Internet. Once screened and found to be eligible, 100% of these patients agreed to participate in the study and were consented.

Figure 1. Recruitment and Retention of Study Participants

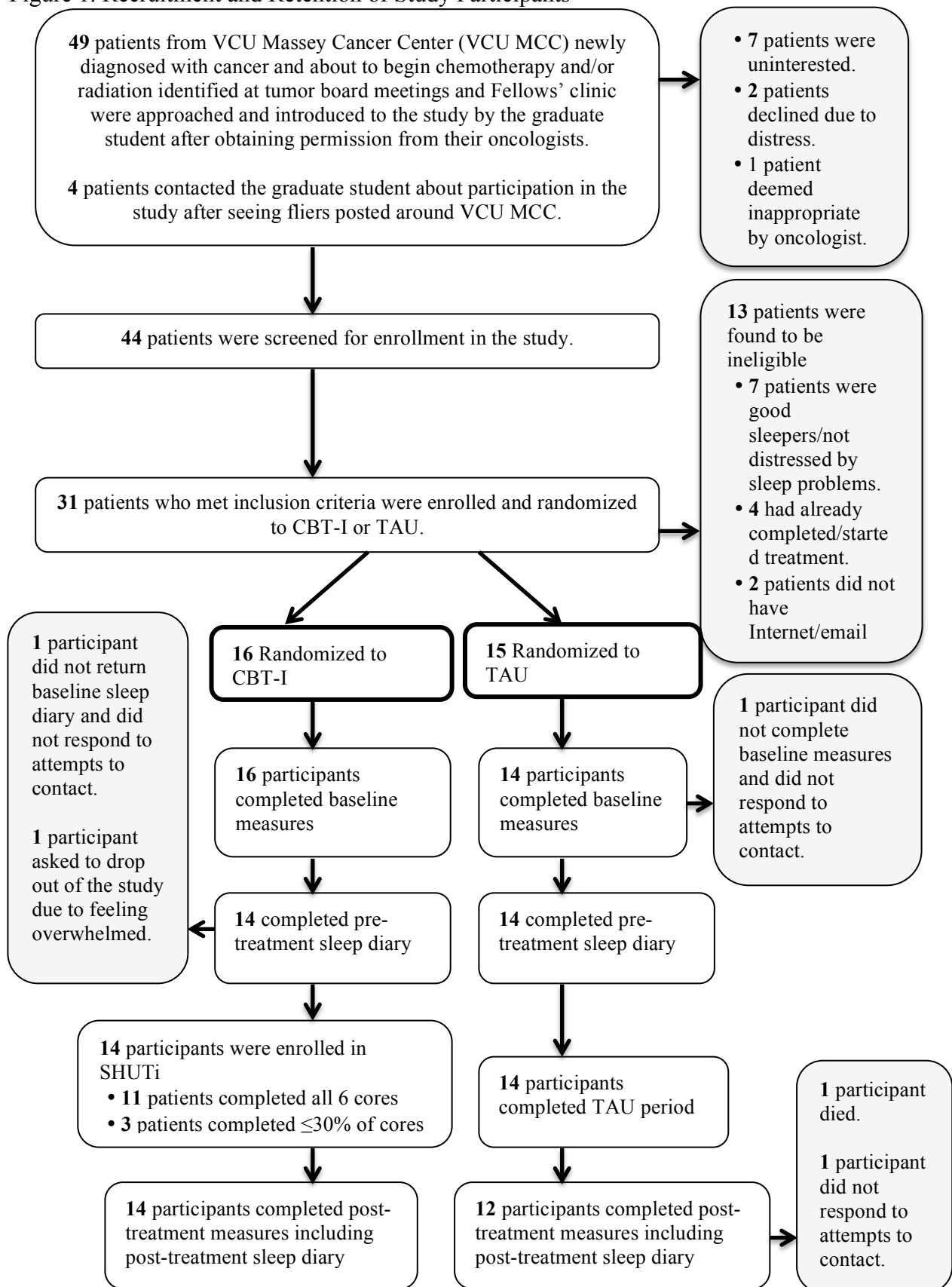


Table 4. Reasons for Deciding not to Participate in Study (n=10)

Reason	Number of Patients
Not interested in study	7
Feeling stressed about upcoming cancer treatment	2
Oncologist deemed patient to be inappropriate	1

Completion rate. Overall, 84% of the total number of participants that were randomized completed the study and all post-treatment questionnaires. This corresponds to a 13% attrition rate for the SHUTi group (n=3) and a 20% (n=3) attrition rate for the TAU group. In the SHUTi group, one participant completed the baseline questionnaires but failed to complete the baseline sleep diary and was subsequently lost to follow-up. Even though this patient was enrolled in SHUTi, only the training module was completed. Another participant randomized to SHUTi asked to drop out of the study before being enrolled in the program. Among the participants who were enrolled in SHUTi, 79% (n=11) completed all the six Cores. The rest of the participants completed at least 30% or two of the Cores. Reasons participants gave for not completing the program are enumerated in Table 5. In the TAU group, one patient never completed the baseline questionnaires or the sleep diary and was lost to follow-up. Among the participants who completed the TAU period, one participant died and thus post-treatment data was not collected. Another participant was lost to follow-up.

Table 5. Reasons for not Completing SHUTi (n=3)

Reason	Number of Patients
Program does not work well on cell phone	1
Sleep improved after initial increase in symptoms at diagnosis and beginning of treatment	1
Experienced treatment complications and found it difficult to continue program	1

Time to complete study and delays. The study period was initially planned to last nine to ten weeks for each participant. There would be a one-week pre-treatment period when patients would complete their baseline sleep diaries. The treatment period would last approximately six to seven weeks and then the post-treatment sleep diaries would be completed during week 9 or week 10. Instead, the study period lasted approximately four months on average and lasted as long as six months for some patients. However, the study period was equivalent between the SHUTi and TAU groups. Data collection was completed in December 2015.

There were a number of reasons for these delays. First, some participants experienced delays with beginning treatment. Approximately 13% of the study participants experienced treatment delays that lasted from one to several weeks. Immediately prior to beginning treatment, two participants' most recent scans showed disease progression and their disease had to be upstaged. Thus, adjustments had to be made to these participants' treatment plans. In another patient, treatment was delayed to allow for additional time for healing from neo-adjuvant surgery. In the last participant, treatment was delayed due to the participant becoming sick and requiring time for recovery.

Once treatment was initiated, there were additional delays due to side effects, infections, and participants' competing demands. Once participants began chemotherapy and/or radiation treatment, 37% of participants experienced some form of delay during the study period. For two of the participants, the onset of the side effects was within the first two treatments, and required hospitalization and for one of the participants, the hospitalization was for several weeks. In one participant, the severity of side effects was such that chemotherapy was discontinued prematurely; though the patient went on to receive radiation. This participant required additional

time to recover before resuming SHUTi. Another participant experienced further disruption in sleep due to high dosages of pain medications and decided to resume SHUTi after completing the part of the treatment regimen when pain medications were needed, so that a more regular sleep schedule could be maintained. One participant continued to work during treatment, making completing SHUTi less of a priority and contributing to delays with completing the program. Another participant, who was undergoing oral chemotherapy, was unresponsive to attempts to contact for approximately 1 month. Thus, the doctoral student was only able to reach the participant during a medical appointment.

Finally, collecting post-treatment was delayed by additional instances of hospitalizations and disease progression. One participant was hospitalized due to treatment-related complications and disease progression. For another participant, scans showed disease progression, which necessitated multiple appointments with different providers before it was eventually determined that palliative treatment and hospice care would be most appropriate. Another participant had a young child and other work responsibilities that contributed to some delay with completing post-treatment measures and the post-treatment sleep diary.

Doctoral student support and impact for SHUTi. Approximately 91% of the SHUTi participants who completed all six Cores did so with the assistance of the doctoral student. Among these participants, 60% initially accepted the doctoral student's assistance. She met with them during at least six treatment or other medical appointments and provided a tablet for them to complete the Cores. The level of assistance varied by participant. Some participants required as little assistance as setting up the Core and answering questions, whereas for one participant, the doctoral student completed each Core with the participant. The remaining 40% of the participants initially opted to complete the Cores independently. However, they experienced

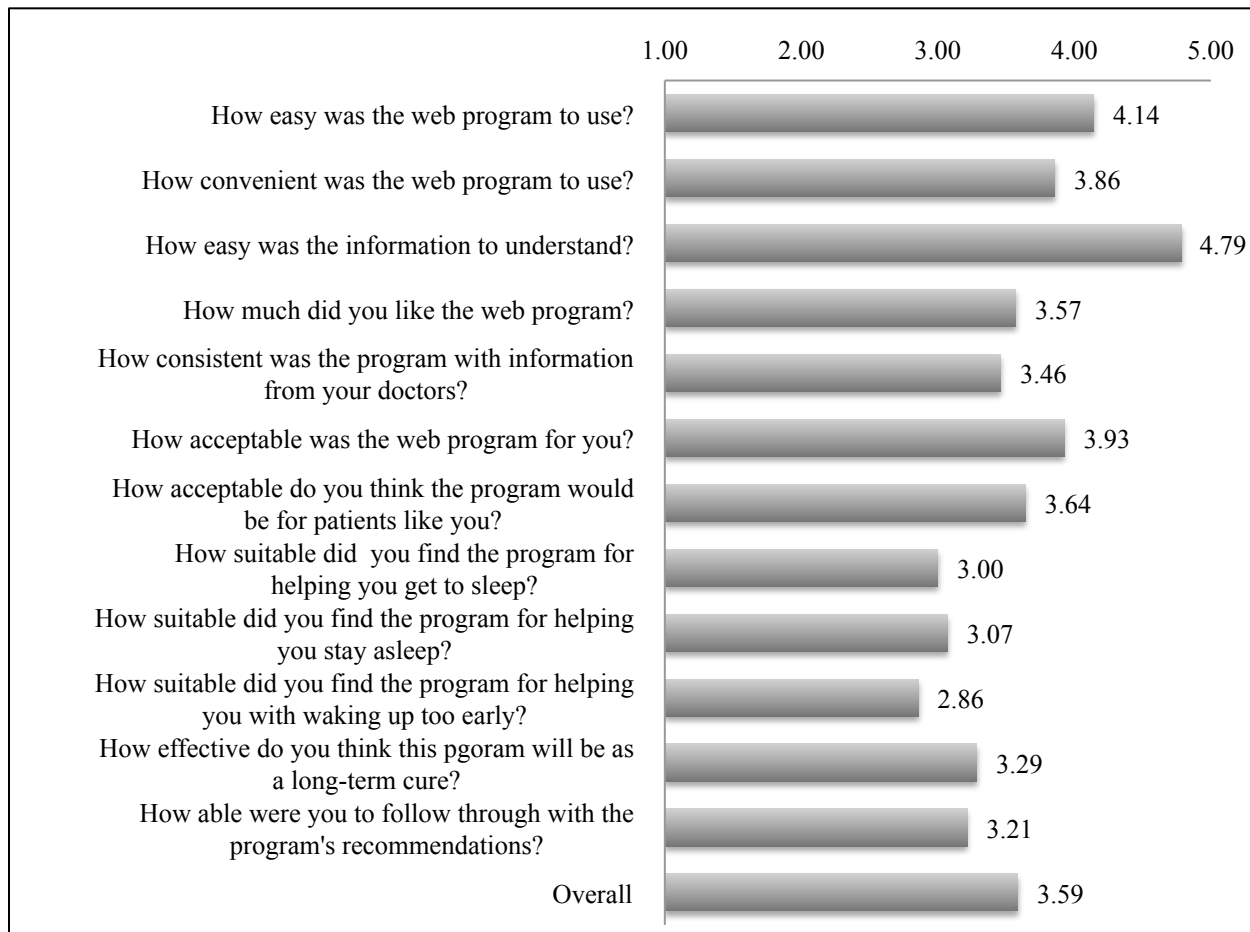
significant delay with completing the program. Three of the participants experienced delay due to disease-related complications and the other patient experienced an increase in distress such that attempts to contact were unsuccessful and the doctoral student had to wait for a medical appointment for face-to-face contact. Thus these participants were only able to complete the program with the doctoral student calling them weekly and working with them to complete the Cores over the telephone.

Thus, with regard to doctoral student support, participants who completed SHUTi can be classified into four different categories: (1) No support (9%); (2) Initially accepted moderate support (45%); (3) Initially accepted full support (9%); and (4) Initially refused but accepted full support due to unexpected delays (36%). These groups of participants differed in sociodemographic characteristics and in the time required for SHUTi completion. Participants who initially accepted the doctoral student's (moderate or full) support completed the program within ten weeks, while participants who initially chose to work independently took approximately four months to complete the program. As far as sociodemographic differences, approximately 67% of the participants who initially opted to complete the program with the doctoral student's assistance were African American. In other words, all African American participants in the SHUTi group initially opted to complete the program with the doctoral student's assistance. Participants who initially worked with the doctoral student also were more likely to be unemployed (33%) or on disability (33%). In comparison, participants who initially opted to work independently were more likely to have part-time (67%) or full-time (33%) employment.

SHUTi acceptability. Participants' ratings for the acceptability and utility of SHUTi are presented in Figure 2. Overall, SHUTi participants rated the program as being moderately

acceptable, with an average acceptability rating of 3.6 (1-5 scale). The highest rated items had to do with the program's ease of use (4.1) and comprehensibility (4.8). Participants rated the program acceptability for themselves and for others like them in the moderate range, 3.9 and 3.6 respectively. In contrast, the item that was given the lowest rating (2.9) was the item that asked about the program's suitability for helping with early morning awakenings. Similarly, items regarding the program's utility for addressing difficulty initiating (3.0) and maintaining sleep (3.1) received lower ratings. On average, participants reported moderate adherence to the program's recommendations (3.2).

Figure 2. Acceptance of SHUTi among Participants (n=14)



SHUTi participants' comments. Participants randomized to SHUTi provided comments on their experiences with the program. Among the favorable comments, one participant cited the sleep hygiene component as being particularly helpful, "The part I found most helpful about the program was the setup for my bedroom to make my room more comfortable and relaxing for good sleep." Another participant reported that completing the sleep diaries had been beneficial for correcting misperceptions about the amount of sleep, "I found it most helpful to realize how much I was actually sleeping because it was more than I thought." Two participants mentioned that the doctoral student had been a positive aspect of the program, with one reporting, "I don't know how acceptable or effective the program would have been without the counselor."

Participants also offered comments unique to the context of individuals with new cancer diagnoses navigating active treatment. One participant spoke about the fit of the program for patients, "I think it's a great program for people with insomnia. I don't think it was very helpful for people with illness." Another participant expressed concerns about the timing of the program, "I think within a month of diagnosis, it's natural to not be sleeping, it's a matter of time. I think it would be better if we were asked questions about sleep rather than a program. The program made it more a problem; it was more stress than needed. It would have been better once things had settled, after a treatment plan was set." Lastly, one participant spoke about the difficulty of completing the program while experiencing treatment side effects, "The program wasn't convenient to use because I wasn't feeling good. I didn't like that I had to access a computer because it wasn't great on my phone. I would have liked it better on paper or in person. I'm lazy, I like medications."

The remainder of participants' comments pertained to difficulties related to SHUTi-specific features. Three participants mentioned that it was difficult to try to complete the program on their cell phones, which made it inconvenient. One participant stated, "I didn't find completing the diaries intuitive, there was no default after completing a diary, so I had to change it every time I logged in. And it didn't work well on my cell phone."

Hypothesis 2: Change in Sleep Variables by Group.

A repeated measures MANOVA was performed to examine the second hypothesis that SHUTi would improve participants' sleep at post-treatment when compared to the TAU condition. Due to the assumptions underlying repeated measures MANOVA (Mayers, 2013), the data was first checked for any violations, including normality and multicollinearity. Initially, several variables were highly skewed and/or kurtotic (values outside the range of -1.5 to 1.5). Transforming several outliers addressed this violation. To identify outliers, standardized z-scores for baseline and post-treatment values of the outcome variables were calculated. This method entailed identifying values that corresponded to z-scores greater than 1.96 ($p < 0.05$) and converting them to the next closest value below the cut-off value (i.e., the value that corresponds to the highest non-significant z-score) for that variable. This method is appropriate for addressing outliers in small samples because it does not distort the data in order to maintain the sample distribution (Tabachnick & Fidel, 2007) and the method has been used previously in similar studies (Taylor et al., 2015). In all, ten total data points were converted. Baseline data points that were converted were ISI ($Z = 2.14$); SOL ($Z = 3.02$, $Z = 2.43$); TST ($Z = 2.08$); and WASO ($Z = 3.23$). Post-treatment data points that were converted were SOL ($Z = 4.76$); TST ($Z = 2.26$); and WASO ($Z = 3.51$, $Z = 2.29$, $Z = 2.03$).

Next, multicollinearity among the outcome variables was examined by running bivariate Pearson correlations. Results showed that SE was highly correlated ($r > \pm 0.7$, $p < 0.05$) with several other variables and Box's M Test of Equality could not be calculated due to this violation. Thus, SE was removed from the MANOVA and examined independently. When Box's M Test of Equality was calculated again without SE in the model, the assumption was found to be satisfied. To test the assumption of equality of error variances, Levene's Test of Equality of Error Variances values for the variables were examined. Results showed that with the exception of SOL, all values were nonsignificant ($p > 0.05$). However, because the sample sizes are equivalent between groups, the effects of this violation are mitigated. Nevertheless, Pillai's Trace will be the test statistic reported because it is robust to violations of the assumption of homogeneity of variance/covariance matrices when there are two equivalent groups (Field, 2009).

Results of the MANOVA model using TST, ISI, WASO, and SOL as dependent variables showed a significant time by group interaction, Pillai's Trace = 0.337, $F(4, 23) = 2.92$, $p < 0.05$. Follow-up repeated measures ANOVAs found a significant time by group interaction for ISI, Pillai's Trace = 0.262, $F(1, 26) = 9.25$, $p < .05$; and for WASO, Pillai's Trace = 0.195, $F(1, 26) = 6.31$, $p < .05$. See Figures 3 and 4. There were no significant time by group interactions for TST ($p = 0.323$) or SOL ($p = 0.908$). See Figures 5 and 6.

Before running the repeated measures ANOVA for SE, the assumption of sphericity or homogeneity of the variances between groups was verified by calculating Mulchy's Test of Sphericity. Results showed that all Epsilons were equal to 1, indicating that the assumption was met. When SE was examined independently in a repeated measures ANOVA, there was a trend

toward a significant time by group interaction, Pillai's Trace = 0.118, $F(1, 26) = 3.47$, $p = 0.074$.

See Figure 7.

Figure 3. Change in Insomnia Severity Index (ISI) Scores from Baseline to Post-Treatment in SHUTi and Treatment as Usual (TAU) Groups (N=28; Outliers Adjusted)

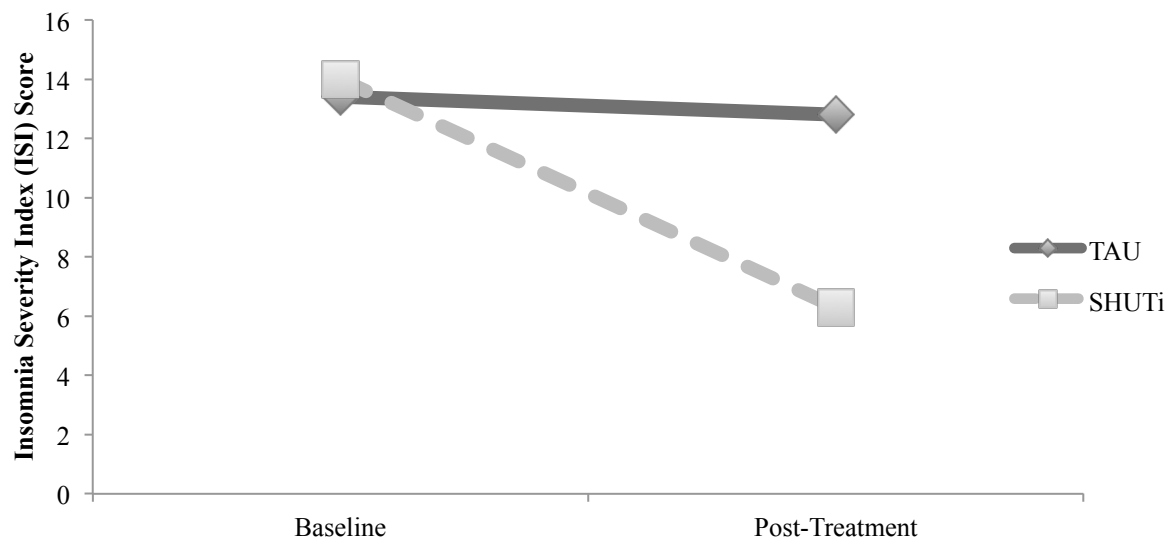


Figure 4. Change in Wake Time After Sleep Onset (WASO) in Minutes from Baseline to Post-Treatment in SHUTi and Treatment as Usual (TAU) Groups (N=28; Outliers Adjusted)

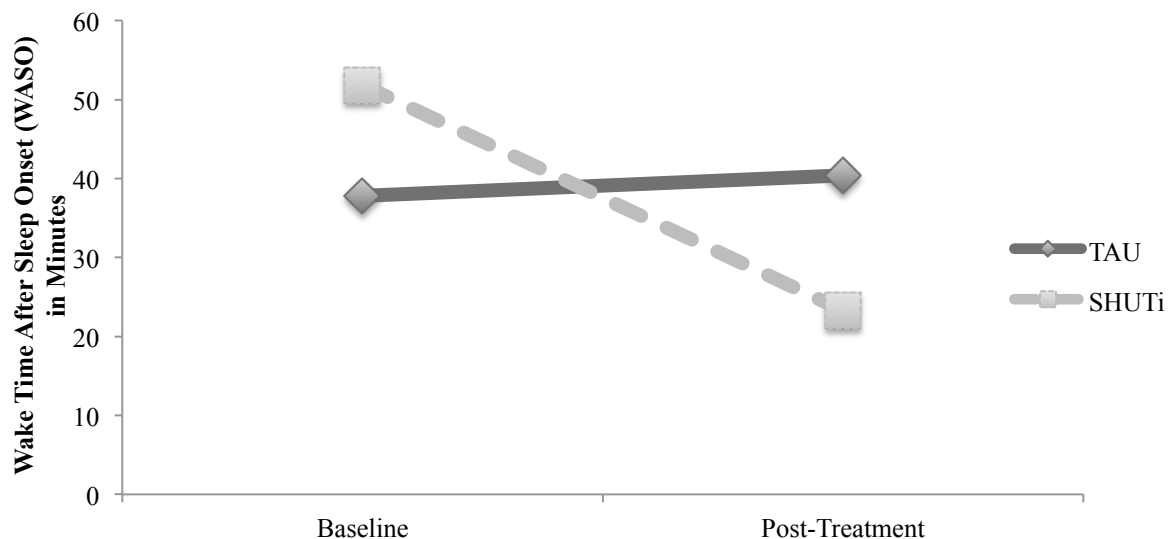


Figure 5. Change in Total Sleep Time (TST) in Minutes from Baseline to Post-Treatment in SHUTi and Treatment as Usual (TAU) Groups (N=28; Outliers Adjusted)

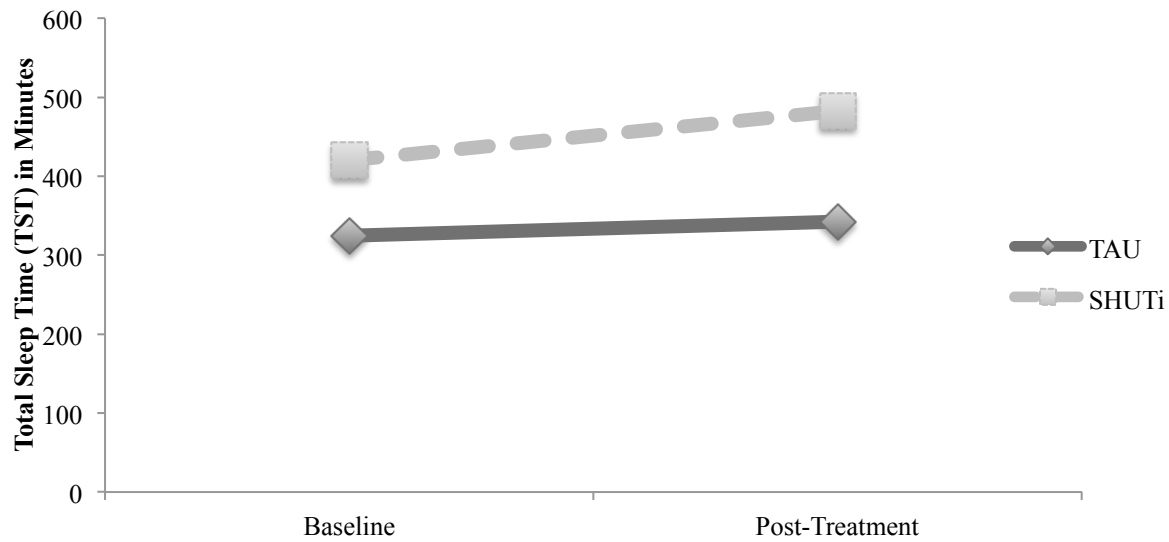


Figure 6. Change in Sleep Onset Latency (SOL) in Minutes from Baseline to Post-Treatment in SHUTi and Treatment as Usual (TAU) Groups (N=28; Outliers Adjusted)

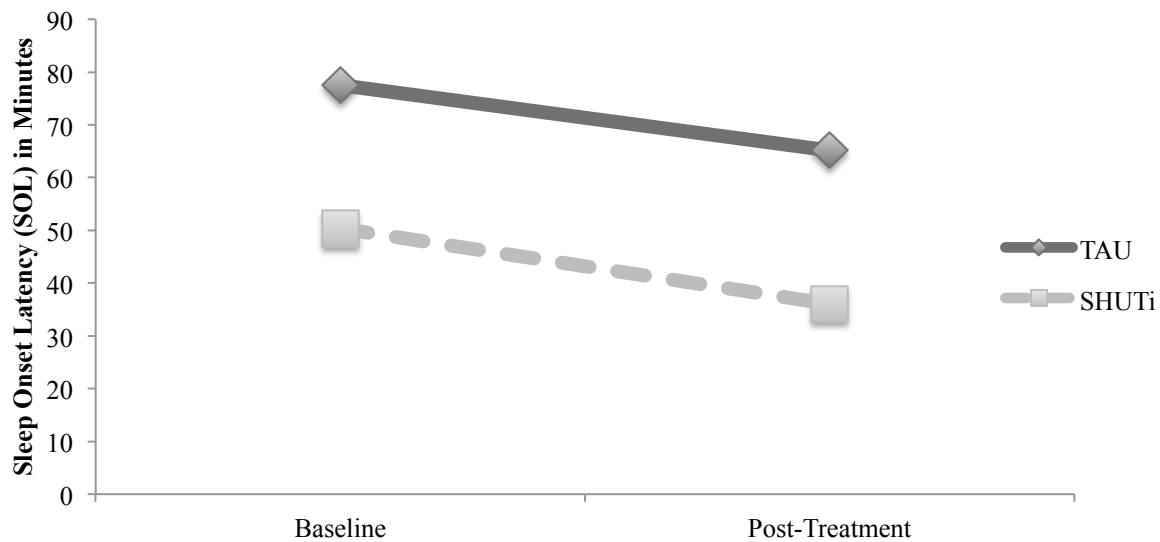
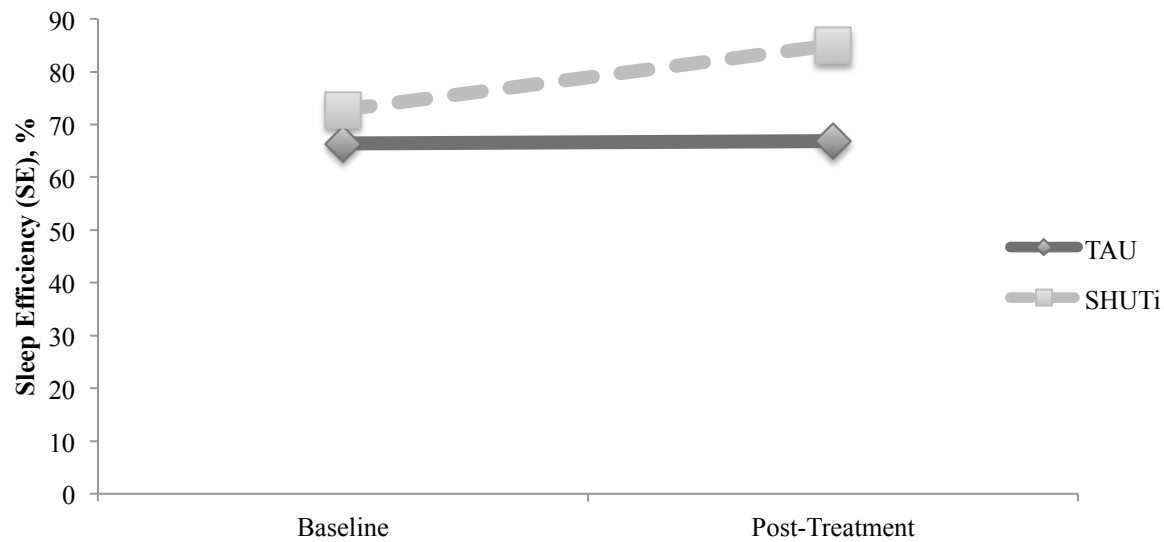


Figure 7. Change in Sleep Efficiency (SE), % from Baseline to Post-Treatment in SHUTi and Treatment as Usual (TAU) Groups (N=28; Outliers Adjusted)



With regard to effect sizes calculated with Cohen's d , there was a medium effect size observed for ISI (Cohen's $d = 0.60$) and for WASO (Cohen's $d = 0.49$). There were small effect sizes observed for SE (Cohen's $d = 0.37$), and TST (Cohen's $d = 0.20$). See Table 6.

Table 6. Means (Standard Deviation) and Effect Sizes of Sleep-Related Variables in CBT-I and TAU Groups at Baseline and Post-Treatment

	Baseline M (SD)		Post-Treatment M (SD)		Effect Size (d)
	CBT-I	TAU	CBT-I	TAU	
Insomnia Severity Index (ISI)*	14.0 (4.80)	13.4 (7.63)	6.3 (5.0)	12.8 (4.7)	0.60
Sleep Onset Latency (SOL)	50.3 (33.5)	77.5 (75.5)	36.0 (31.03)	65.1 (67.8)	0.03
Wake Time After Sleep Onset (WASO)*	51.8 (39.9)	37.8 (29.2)	23.3 (28.4)	40.4 (4.0)	0.49
Total Sleep Time (TST)	419.8 (143.9)	324.6 (99.0)	482.4 (123.0)	342.7 (102.1)	0.20
Sleep Efficiency (SE)	72.8 (15.8)	66.4 (18.9)	85.1 (12.1)	66.8 (21.9)	0.37

* $p < 0.05$

Hypothesis 3: Change in Depression, Anxiety, and Health-related Quality of Life.

A repeated measures MANOVA was performed to examine the third hypothesis that SHUTi would decrease participants' depression and anxiety while increasing their health-related quality of life at post-treatment when compared to the TAU condition. Due to the assumptions underlying repeated measures MANOVA (Mayers, 2013), the data was first checked for any violations, including normality and multicollinearity. Initially, several variables were highly skewed and/or kurtotic (values outside the range of -1.5 to 1.5). Transforming outliers addressed this violation. To identify outliers, standardized z-scores for baseline and post-treatment values of the outcome variables were calculated. This method entailed identifying values that corresponded to z-scores greater than 1.96 ($p < 0.05$) and converting them to the next closest value below the cut-off value (i.e., the value that corresponds to the highest non-significant z-score) for that variable. This method is appropriate for addressing outliers in small samples because it does not distort the data in order to maintain the sample distribution (Tabachnick & Fidel, 2007) and the method has been used previously in similar studies (Taylor et al., 2015). In all, five total data points were converted. Baseline data points that were converted were PHQ-9 ($Z = 2.33$) and GAD-7 ($Z = 2.40$). Post-treatment data points that were converted were PHQ-9 ($Z = 2.52$) and GAD-7 ($Z = 2.33, Z = 2.14$).

Next, multicollinearity among the outcome variables was examined by running bivariate Pearson correlations. Results showed that FACT-G was highly correlated ($r > -0.7, p < 0.05$) with PHQ-9 and GAD-7 scores. Thus, FACT-G was removed from the MANOVA and examined independently. To test the assumption, the correlation between the dependent variables is equal between the groups, Box's M Test of Equality was examined. Results from the test were not significant ($p > 0.05$), indicating that the assumption is satisfied. To test the

assumption of equality of error variances between the groups, Levene's Test of Equality of Error Variances values for the variables were examined. Results showed that none of the values were significant ($p > 0.05$). Thus this assumption was also satisfied. Nevertheless, Pillai's Trace will be the test statistic reported due to its robustness and for uniformity across analyses.

Depression and anxiety. Results of the MANOVA model using PHQ-9 and GAD-7 as dependent variables did not show a significant time by group interaction. However, there was a trend toward significance, Pillai's Trace = 0.180, $F(2, 25) = 2.74$, $p = 0.084$. Follow-up repeated measures ANOVAs found a significant time by group interaction for PHQ-9, Pillai's Trace = 0.159, $F(1, 26) = 4.93$, $p < 0.05$. There was no significant time by group interaction for GAD-7 ($p = 0.587$). See Figures 8 and 9. With regard to effect size, there was a small effect size observed for PHQ-9 (Cohen's $d = 0.43$). See Table 7.

Figure 8. Change in Patient Health Questionnaire-9 (PHQ-9) from Baseline to Post-Treatment in SHUTi and Treatment as Usual (TAU) Groups (N=28; Outliers Adjusted)

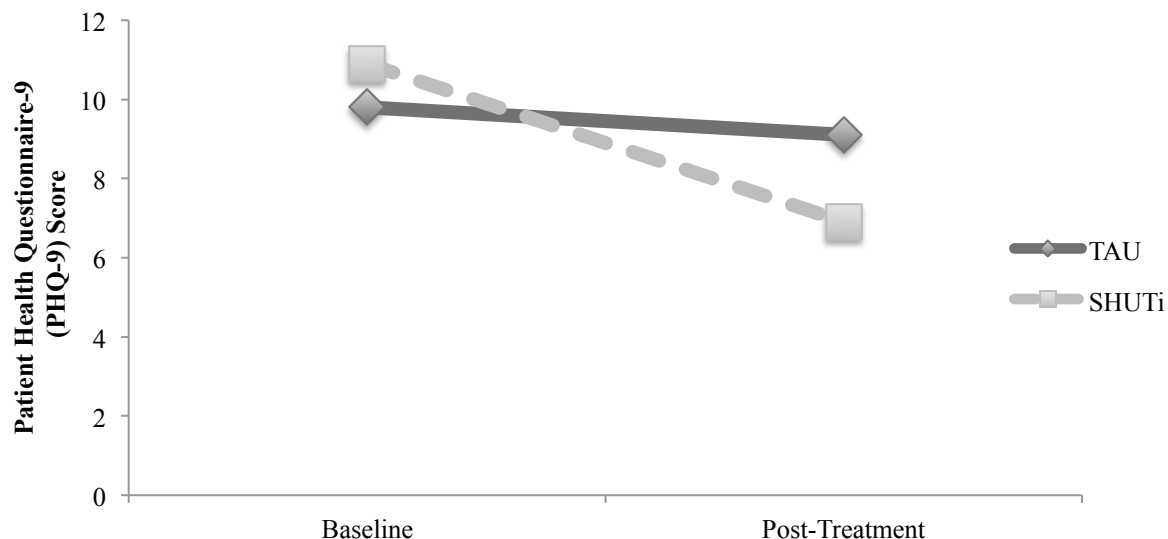


Figure 9. Change in Generalized Anxiety Disorder-7 (GAD-7) Scores from Baseline to Post-Treatment in SHUTi and Treatment as Usual (TAU) Groups (N=28; Outliers Adjusted)

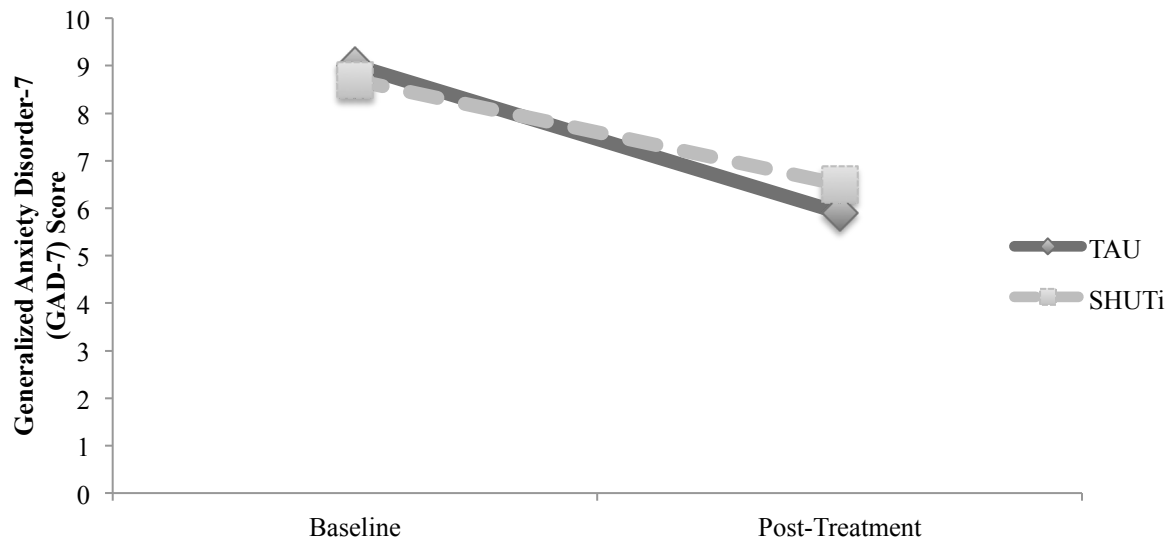


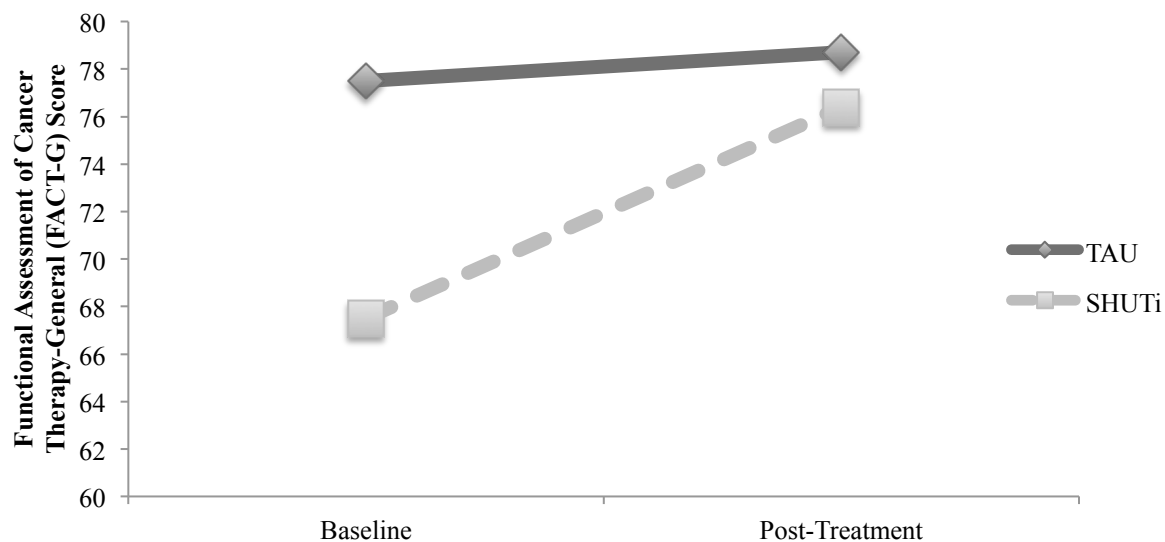
Table 7. Means (Standard Deviation) and Effect Sizes of Depression, Anxiety, and Health-Related Quality of Life in CBT-I and TAU Groups at Baseline and Post-Treatment

	Baseline <i>M</i> (SD)		Post-Treatment <i>M</i> (SD)		Effect Size (<i>d</i>)
	CBT-I	TAU	CBT-I	TAU	
Patient Health Questionnaire-9*	10.9 (4.1)	9.8 (5.3)	6.9 (4.5)	9.1 (5.0)	0.43
Generalized Anxiety Disorder-7 (GAD-7)	8.7 (4.0)	9.0 (6.3)	6.5 (5.3)	5.9 (5.2)	0.11
Functional Assessment of Cancer Therapy-General (FACT-G)	67.5 (16.1)	77.5 (15.6)	76.4 (20.0)	78.7 (17.7)	0.23
Physical Well-being	17.8 (6.3)	20.6 (5.1)	18.5 (6.5)	18.9 (5.6)	0.18
Emotional Well-being	15.3 (4.1)	15.3 (4.1)	19.1 (4.7)	17.5 (5.1)	0.31
Social/Family Well-being	21.3 (7.8)	23.9 (3.5)	22.3 (7.4)	25.5 (10.2)	0.03
Functional Well-being	16.5 (7.3)	12.9 (6.2)	16.8 (7.9)	15.8 (7.2)	0.22

* $p < 0.05$

Health-related quality of life. Results from Mulchy's Test of Sphericity showed that assumption of sphericity was satisfied in the model examining FACT-G individually. When FACT-G was examined independently in a repeated measures ANOVA, there was no significant time by group interaction, ($p = 0.244$). See Figure 7. This corresponded to a small effect size (Cohen's $d = 0.21$).

Figure 10. Change in Functional Assessment of Cancer Therapy-General (FACT-G) Scores from Baseline to Post-Treatment in SHUTi and Treatment as Usual (TAU) Groups (N=28; Outliers Adjusted)



Discussion

The current study sought to address two complementary aims. The first aim was to examine the feasibility and acceptability of implementing a low-intensity online CBT-I intervention, SHUTi, to address insomnia among individuals who had been newly diagnosed with cancer and were undergoing chemotherapy and/or radiation. Secondly, the study aimed to evaluate the efficacy of SHUTi in improving sleep outcomes and secondarily, in decreasing

psychiatric distress while increasing health-related quality of life. In pursuing these aims, the study adds to previous scholarship that has proven CBT-I to be an efficacious, effective, and durable treatment that can improve sleep and psychological well-being among cancer survivors. The current study is also in line with an emergent, yet promising body of work that shows that low-intensity versions of CBT-I such as self-directed treatment modalities, can achieve results comparable to standard treatments without the high resource demands (Ritterband et al., 2012; J. Savard et al., 2013). For instance, Savard and colleagues (2014) tested the efficacy of a low-intensity plus (optional) clinician support video-based CBT-I intervention and a face-to-face CBT-I intervention in a sample of 242 breast cancer survivors. They found that the low-intensity treatment resulted in small to large treatment effects on subjective sleep parameters that were comparable, though not equivalent to the treatment effects observed in the standard treatment. The remission rate in the low-intensity group (44.3%) was smaller than in the standard treatment group (71.3%) but still statistically significantly greater than in the control group (25.7%) (J. Savard et al., 2013). Yet, these studies have been plagued by limitations that threaten their generalizability. Published studies have focused on samples that are primarily White, female, and well educated (Berger, Kuhn, Farr, Von Essen, et al., 2009; Ritterband et al., 2012; J. Savard et al., 2013). Disease sites in these studies have also been homogenous, with breast cancer being overrepresented. Furthermore, previous studies have left the important question about the possibility of addressing insomnia during the early and critical period immediately after cancer diagnosis and during active treatment, largely unexamined. A literature search found only one study that has tested CBT-I in women newly diagnosed with breast cancer who were undergoing chemotherapy (Berger, Kuhn, Farr, Von Essen, et al., 2009).

Based on the current state of the evidence, it was hypothesized that implementing SHUTi, a low-intensity online CBT-I intervention, to treat insomnia among individuals who were newly diagnosed with cancer and undergoing chemotherapy and/or radiation would be feasible and would be found acceptable by participants. It was further hypothesized that SHUTi would improve sleep as well as decrease anxiety and depression while enhancing health-related quality of life. In all, these hypotheses were partially upheld. First, there was some support for the feasibility and acceptability of addressing insomnia among survivors early in the cancer trajectory. Second, there was preliminary evidence that a low-intensity intervention delivered online with clinician support can improve sleep and decrease psychological distress.

Feasibility and Acceptability of SHUTi

Recruitment. A major success of the current study and a key piece of evidence in support of feasibility is the successful recruitment of a diverse group of participants as they were navigating a highly stressful part of their disease management. Overall, 70% of the patients who were screened for the study were found to be eligible and of these patients, 100% initially agreed to participate in the study and were enrolled. Among these participants, 91% (n=28) of the participants completed all baseline assessments, constituting the final study sample that was included in all analyses.

The participation rate in the current study is higher than rates previously observed in similar studies. The only other published study that implemented CBT-I among individuals newly diagnosed with cancer as they were undergoing chemotherapy reported a 70% enrollment rate (Berger, Kuhn, Farr, Von Essen, et al., 2009) . Similarly, another intervention study targeting fatigue in newly diagnosed patients undergoing chemotherapy reported a 71% enrollment rate (Ream, Richardson, & Alexander-Dann, 2006). The high rate of participation

observed in the present study is particularly noteworthy given concerns about overwhelming and overburdening patients so early in their cancer diagnosis and treatment trajectory. In fact, this was often a concern encountered by the doctoral student when discussing the study with certain members of treatment teams. However, the rates of participation found in the current study as well as in the aforementioned intervention studies implemented during active cancer treatment have been higher than the rates (47-58%) found in other CBT-I studies that have addressed insomnia post-cancer treatment (Epstein & Dirksen, 2007; Fiorentino et al., 2009; Ritterband et al., 2012; J. Savard, S. Simard, H. Ivers, et al., 2005).

There are a number of features specific to the study design that likely contributed to the participation rate. Patients may be more willing to participate in interventions that target side effects and other psychological correlates of cancer during treatment because this phase is especially stressful and thus they may have greater need for these services. There is support for this hypothesis from a systematic review of studies on the unmet supportive care needs of people with cancer that found that levels of unmet needs were highest during treatment. Yet patients often fail to report their sleep difficulties to their oncologists (Engstrom, Strohl, Rose, Lewandowski, & Stefanek, 1999). In the current study 60% of participants had not talked to their oncologist about their insomnia. But that does not mean that patients are not seeking services and/or help from other sources, whether that is from family members (Engstrom et al., 1999) or from complementary and alternative medicine (CAM) modalities. Insomnia has been identified as one of the most reasons that cancer survivors use CAM treatments (Mao, Palmer, Healy, Desai, & Amsterdam, 2011). One study found that the greater the unmet need, the more likely a cancer survivor was to use a CAM treatment (Mao et al., 2008). More specifically, studies have reported that as many as 87 to 91% of individuals were using one or more

complementary treatments (i.e., in addition to conventional treatment) during active treatment (Yates et al., 2005). The addition of a CAM intervention was usually self-initiated rather than being recommended by an oncologist. This suggests that newly diagnosed patients are especially interested in adjunctive treatments during chemotherapy or radiation.

Nevertheless, recruiting newly diagnosed patients who have yet to begin treatment is particularly challenging (Balogun et al., 2011). It is likely that there were qualities about the current study that helped overcome some of these challenges. For one, the study employed a low-intensity treatment modality, addressing newly diagnosed patients' concerns about the accessibility and convenience of non-pharmacological interventions for insomnia (Davidson, Feldman-Stewart, Brennenstuhl, & Ram, 2007). It is noted that the two other studies of low-intensity CBT-I among individuals with cancer reported participation rates ranging from 50-55% (Ritterband et al., 2012; J. Savard, Villa, et al., 2011). Thus it is likely that it was the timing of the current study during treatment when need is high, as well as its low-intensity modality that helped boost the participation rate. The current study was also flexible. Participants were informed that the doctoral student could meet with them during their medical appointments, rather than requiring additional meetings. Participants who experienced delays in their treatment were also able to resume participation after their delays. Cancer survivors have cited flexibility as being key to participation in insomnia interventions (Davidson et al., 2007).

Sample diversity. In addition to being feasible in terms of the availability and willingness of the study population, the racial and ethnic diversity of the current study supports the feasibility of studying the efficacy of low-intensity CBT-I among minority cancer survivors. Racial and ethnic minorities made up approximately one-third of the current study sample (30% African American). This proportion is greater than has been included in past studies of CBT-I in

cancer, where racial and ethnic minorities, when included, have made up 4 to 18% of the studied samples (Berger, Kuhn, Farr, Von Essen, et al., 2009; Epstein & Dirksen, 2007; Fiorentino et al., 2009; Ritterband et al., 2012). The importance and challenge of recruiting minority participants to intervention studies is well established (Areán, Alvidrez, Nery, Estes, & Linkins, 2003; D. R. Brown, Fouad, Basen-Engquist, & Tortolero-Luna, 2000; Swanson & Ward, 1995; Yancey, Ortega, & Kumanyika, 2006). One factor that likely contributed to the success of recruiting African Americans in the current study is the race of the doctoral student. The doctoral student is Black and having her as the face of the study likely facilitated the participation of African American patients that were approached. There is evidence that suggests that race concordance between participants and interviewers corresponds to higher participant cooperation rates, especially among Black participants (Moorman, Newman, Millikan, Tse, & Sandler, 1999).

However, race concordance is not sufficient for successful minority recruitment (Areán et al., 2003). It is likely that the other features of the study, namely the availability of a tablet, the flexibility, and convenience of the study also contributed to the sample diversity. As previously stated, all African American participants in the SHUTi condition chose to meet with the doctoral student and use the tablet to complete cores during their appointments. The availability of the study tablet likely mitigated any barriers that may have been related to Internet access. In fact, one African American participant explained that the Internet access in her home became unreliable during the study period. Additionally, the flexibility and convenience of the study (i.e., no additional meetings) as previously described, likely contributed to a higher participation rate. In sum, providing participants with a tablet for use during their appointments and allowing them flexibility likely contributed to an overall higher rate of participation in the current study,

however, these factors (i.e., economic barriers, treatment schedule) have been shown to be more likely to influence minority participation in cancer studies (Giuliano et al., 2000).

Doctoral student support. When it comes to the study feasibility, the support of the doctoral student cannot be overstated. As one participant described, “I don’t know how acceptable or effective the program would have been without the counselor.” Of note, this is not the first study to employ clinician support as an adjunct to a self-help CBT-I intervention in individuals with cancer (J. Savard et al., 2013). However, in the previous study, very few of the participants accessed clinician support. Thus this is one of the first self-help CBT-I studies in individuals with cancer to report on how participants used clinician support. One of the most telling findings from the current study is that among SHUTi completers, when compared to participants who initially chose to complete SHUTi on their own (n=5), participants who initially accepted the doctoral student’s support (n=6) completed the program faster (10 weeks vs. 16 weeks). Moreover, a significant minority of participants randomized to SHUTi (27%; n=4) likely only completed SHUTi after much delay because of having the doctoral student’s support to assist in completing each core. This finding suggests that having the doctoral student’s support had a considerable impact on the completion rate as well as the time to complete. Meeting with patients at their weekly or biweekly medical appointments made it much less likely that patients would forget to complete a core, thereby cutting down on delays. It may also have served to maintain participants’ commitment to the program as meeting with the doctoral student was a frequent reminder that the study was ongoing.

Also worth discussing is how participants who initially accepted the doctoral support differed from the rest of the SHUTi group. These participants were more likely to be African American and to be from a lower socioeconomic class. Recruitment and retention of African

Americans and individuals from lower socioeconomic status is critical to ensuring the generalizability of observed treatment effects. Past studies have found that participation and retention rates tend to be lower among Black participants and those from lower socioeconomic classes (Murthy, Krumholz, & Gross, 2004). Yet the current study shows that when provided with the option of additional support, these participants may be more likely to access this support and with this additional support, they can demonstrate similar if not better participation and retention rates than other participants. Having the support of the doctoral student, who is Black, may have been especially effective at facilitating minority participation because it enhanced the qualities of research studies most likely to encourage participation among black and poor research participants—convenience of program location and timing, as well as the enthusiasm and trustworthiness of study staff (Gross, Julion, & Fogg, 2001).

Acceptability. An important indicator of a study's feasibility is its reception among its intended target population. Findings from the current study suggest that in general, participants found SHUTi to be an acceptable intervention for addressing their sleep difficulties. Put another way, 79% found the program to be mostly or very acceptable for themselves and 64% believed that it would be mostly or very acceptable for others like them. These findings suggest that despite some participants concerns about having a sleep intervention while they were in the early stages of cancer treatment, most participants had a positive response and felt the program would be helpful to others like themselves.

Other findings regarding the program's utility and effectiveness can be compared to findings from the only other study to examine the acceptability of SHUTi in a sample of individuals with insomnia (Thorndike et al., 2008). In the previous study, 100% of participants reported that SHUTi was mostly or very easy and convenient to use. Nearly all participants

(95%) indicated that the program was mostly or very understandable. The current study found somewhat similar results. Most participants (79%) found SHUTi easy and convenient to use. All participants indicated that the program was mostly or very easy to understand. On other hand, there were some discrepancies between the past and current findings. Whereas Thorndike and colleagues (2008) reported that 90% of their sample found SHUTi to be consistent with what they heard from their doctors, only 46% of participants in the current study found the program to be consistent. Similarly, 81% of the sample from the previous study rated the program as being mostly or very effective as a long-term cure, while 62% stated that they were mostly or very able to follow through with treatment recommendations. In contrast, only 36% of participants in the current study felt the program would be effective and only 36% reported being adherent. The discrepancy in how consistent SHUTi is with providers' recommendations may be partly explained by the inconsistency between oncologists' encouragement that patients rest during treatment and instructions from stimulus control to only go to bed when sleepy. Such inconsistencies may also help explain why so few patients felt they were able to adhere to the program's recommendation. One participant's comment that it did not seem like SHUTi was especially relevant for individuals who are medically compromised, lends further support to this argument. Participants may have been less adherent because they felt less capable of doing so because of physical limitations. Lastly participants may have been less confident in SHUTi as an effective long-term cure also because they were sick while undergoing the program. Most participants (86%) reported that their cancer diagnosis had adversely affected their sleep, thus they may have felt that only the successful treatment of their disease would effectively address their sleep problems. It is important to note that even though less than one-half of participants reported being adherent to the program and only a little over one-third indicated that the program

would be an effective long-term cure, SHUTi was proven to be efficacious at improving sleep and psychological distress among participants.

SHUTi Treatment Effects on Self-Reported Sleep

The baseline sleep parameters in the current study were somewhat comparable to those reported in a recent meta-analysis of 8 randomized controlled trials of CBT-I efficacy in cancer survivors (Johnson et al., 2016). The mean SE for participants randomized to SHUTi in the current study was 72.8% compared to 74.9% in previous studies. The mean WASO in the current study was 51.8 minutes compared to 61.5 minutes and the mean SOL in the current study was 50.3 minutes compared to 41.3 minutes in previous studies.

It is noteworthy that there was a small difference in mean ISI scores, 14.0 in the current study compared to 17.1 in previous studies. Given the similarities in other sleep parameters, this difference suggests that even though participants in the current study were reporting sleep parameters consistent with insomnia, they were not as distressed about these symptoms as has been observed in previous studies. This difference may be due to the fact that whereas most of the participants in previous studies have been months and years past their cancer diagnosis and treatment (Epstein & Dirksen, 2007; Ritterband et al., 2012), participants in the current study were on average within the first two months of their cancer diagnosis. One theoretical framework that has been advanced to understand how the co-occurrence of psychiatric and physical conditions influences the treatment of psychiatric symptoms is the “crowd-out effect” (Lê Cook, McGuire, Alegría, & Normand, 2011). This framework postulates that when patients experience both physical and psychiatric conditions concurrently, they may be more likely to focus on the physical condition as being more critical. This tendency to prioritize physical conditions over psychiatric symptoms may be even more pronounced in this sample given the

proximity of the cancer diagnosis. It is important to note that even though participants in the current study reported less insomnia-related distress than has been found in previous studies, their level of distress is nevertheless above the cut-off score (10) determined to differentiate between non-clinical and clinically significant sleep difficulties (Morin, Belleville, Bédard, & Ivers, 2011).

Findings from the current study showed that when compared to participants who received TAU, participants who completed at least 30% of SHUTi (79% had 100% completion rate) showed significant improvement on a global measure of insomnia and on several specific sleep parameters. On the ISI, considered by many to be the most reliable single measure of sleep (Smith & Wegener, 2003), there was a 55% decrease in the mean ISI score from 14.0 to 6.3 in the SHUTi group, compared to a 5% decrease from 13.4 to 12.8 in the TAU group. Research suggests that an ISI reduction of > 7 indicates moderate improvement while a reduction of > 8 indicates marked improvement (Morin et al., 2011). There was complete remission in the SHUTi group, as the mean ISI score was reduced from the clinical range to the non-clinical range while the mean for the TAU group remained in the clinical range. With regard to WASO, there was a similar 55% decrease in the SHUTi group (51.8 to 23.3 minutes) compared to a 7% increase in the TAU group. There was a marginally significant treatment effect found for SE. There was a 12-percentage point increase in the SHUTi group compared to a 0.4-percentage increase in the TAU group. The mean SE for the SHUTi group achieved the normal range cut-off of 85%.

Although there were larger improvements in SOL and TST in the SHUTi group than in the TAU group, there were no significant time by group interactions. There was a 28% decrease in the mean SOL in the SHUTi group (50.3 to 36 minutes) compared to a 16% decrease in the

TAU group (77.5 to 65.1 minutes). Nevertheless, the mean SOL for both the SHUTi and the TAU groups were above the generally accepted clinical cut-off of 30 minutes. The lack of a significant time by group interaction for SOL suggests that the improvement in SE is due to the decrease in WASO rather than the decrease in SOL. The mean TST for the SHUTi group increased by 63 minutes compared to an 18-point increase in the TAU group. Thus the lack of significant findings for these variables may have been due to limited power due to the small sample size even though this sample size is consistent with previous power analysis calculations (Ritterband et al., 2012).

To contextualize the current findings in the literature, there are a number of different comparisons. First, these findings can be compared to the broader literature on the effects of CBT-I among cancer survivors as reported in a recent meta-analysis (Johnson et al., 2016). However, this comparison is limited by the fact that all of these studies have been with cancer survivors rather than with individuals with new diagnoses who are undergoing treatment. To address this shortcoming, the present findings can be compared to the only other published study of CBT-I on patients with new diagnoses undergoing chemotherapy (Berger, Kuhn, Farr, Von Essen, et al., 2009). While this is not a perfect comparison, the study's use of a hybrid face-to-face and self-help model is similar to the current study's use of clinician support as an adjunct to online treatment. Third, the current findings can also be compared to a previous test of SHUTi in a group of cancer survivors (Ritterband et al., 2012).

Although overall similar, the effect sizes from the current study are smaller than have been reported in the larger literature on CBT-I in cancer (Johnson et al., 2016) and more comparable to findings reported in the previous trial of SHUT (Ritterband et al., 2012). For example, there were large effect sizes reported for ISI (1.74), WASO (0.98), and SE (0.99) in the

meta-analysis compared to moderate effect sizes for ISI (0.60) and WASO (0.49) and a small effect size for SE in the current study. In the previous SHUTi trial, the effect size for ISI was large (1.85) while the effect size for SE (0.72) was medium to large and was small for WASO (0.22). This is not unexpected, as all but one of the studies included in the meta-analysis are of standard, face-to-face CBT-I while SHUTi is a low-intensity version. The smaller effect sizes observed in the current study for ISI and SE when compared to the previous SHUTi trial may be partially explained by the fact that the current sample was more medically compromised. Post-treatment data for the current study was collected on average, 4 months after cancer diagnosis. A longitudinal study of the course of insomnia in cancer showed that among individuals with insomnia syndrome at diagnosis, there is a 92% persistence rate at 6 months after diagnosis compared to only a 38% 18 months after diagnosis (J. Savard, Ivers, et al., 2011). Previous intervention trials have also found variations in treatment effects by time since diagnosis and treatment status at time of intervention. Specifically, one study found that whereas an exercise intervention significantly improved sleep quality among participants who had indolent cancer, there were no treatment effects in participants with active disease (Courneya et al., 2012). While not focused on sleep-related outcomes, a meta-analysis of exercise interventions among predominantly breast cancer samples found that there were larger treatment effects on patient-reported outcomes during the post-oncology treatment phase than during treatment (Schmitz et al., 2005; Speck, Courneya, Mâsse, Duval, & Schmitz, 2010). Thus the current study provides support for the efficacy of CBT-I during the early stages of cancer diagnosis and treatment, while also demonstrating that given the acuity of distress (Carlson et al., 2004; Hanson Frost et al., 2000) during this period, treatment effects may be blunted.

Notably, the one exception was WASO, where the current study found a medium effect size whereas the previous SHUTi trial found a small effect size (Ritterband et al., 2012). In fact, there was no significant group by time effect in the previous trial. In the current study, this was the only sleep parameter wherein there was a slight worsening in the TAU group at post-treatment. The current findings also differ from results described in the only other study of CBT-I during active treatment (Berger, Kuhn, Farr, Von Essen, et al., 2009). In the previous study, the authors failed to find a significant group by time effect as found in the current study. However, they did find that only participants in the treatment group and not in the control group experienced a significant decrease in WASO. The current findings indicate that WASO may be a particularly relevant indicator of poor sleep during the early stages of cancer diagnosis and treatment. This assertion is supported by similar findings that without intervention, WASO increased during chemotherapy and only decreased after chemotherapy. Thus CBT-I is more likely to have an effect on WASO during this phase of the cancer trajectory. It is generally argued that differences in how insomnia symptoms are manifested (difficulties in initiating vs. maintaining sleep) are negligible due to the instability of these symptom differences (Hohagen et al., 1994) and consequently these differences are not given much consideration when it comes to designing interventions for treatment trials. Yet studies have consistently showed that there are variations in how CBT-I affects different sleep parameters. Past research indicates that while stimulus control and sleep restriction are the most effective components of CBT-I (Kyle et al., 2015; Morgenthaler et al., 2006; Smith et al., 2002), cognitive restructuring (i.e., changing unhelpful thoughts about sleep) and cognitive control (i.e., addressing thoughts, worries early in the evening) are especially helpful for consolidating sleep (Edinger et al., 2001b). There is also evidence that cognitive arousal is associated with more nighttime awakenings and greater sleep

fragmentation (Rasskazova, Zavalko, Tkhostov, & Dorohov, 2014). Thus the significance of WASO during cancer treatment and the larger effect of SHUTi on WASO in the current study in comparison to the previous SHUTi trial implicates the particular relevance of thoughts in this sample. There is evidence that supports the notion that cancer-related worry thoughts are especially salient soon after diagnosis and during treatment (Antoni et al., 2009).

In contrast, there were no significant treatment effects for SOL and TST. The findings regarding TST are in line with findings from the previous SHUTi trial (Ritterband et al., 2012). They are also similar to previous trials that have failed to find treatment effects to TST despite improvements in other sleep parameters (Espie et al., 2008; J. Savard et al., 2013). A possible explanation is that CBT-I initially aims to improve sleep efficiency by narrowing participants sleep window to consolidate sleep. Expanding the sleep window, which is more likely to have an impact on TST occurs later in treatment. Thus the current intervention may not have allowed a long enough study period to detect changes in TST (Espie et al., 2008). Unlike TST, SOL has typically been shown to be responsive to CBT-I (Ritterband et al., 2012; J. Savard et al., 2013). The null results in the current study along with the fact SOL was the only sleep parameter that remained in the clinical range in both the SHUTi and TAU group, may have to do with the prevalence of cancer-related physical symptoms. Physical symptoms including pain, which are a major precipitating factor for insomnia in cancer (Theobald, 2004), have been shown to specifically contribute to difficulty initiating sleep (Mercadante, Girelli, & Casuccio, 2004). Given that pain and other physical symptoms are more prevalent during treatment than after treatment (Van den Beuken-van Everdingen et al., 2007), it may explain why this sleep parameter was refractory to treatment in the current study. Furthermore, there is evidence that only face-to-face behavioral treatments for insomnia, as opposed to those delivered over the

Internet or over the telephone, improve sleep in patients with cancer or non-cancer pain (Tang et al., 2015).

SHUTi Treatment Effects on Depression and Anxiety Symptoms

Findings showed that SHUTi was associated with a significant and medium sized improvement in depressive symptoms. At baseline, participants in the SHUTi and TAU groups reported moderate depressive symptoms. Post-treatment, the SHUTi group exhibited a 4-point decrease in PHQ-9 scores, signifying a decrease in depressive symptoms from the moderate to mild range. In contrast, PHQ-9 scores in the TAU group were largely unchanged (-0.7 decrease), the mean score for the group is at the upper limit of the mild range and close to the recommended cut-off score (10) suggested for clinical attention (Morin et al., 2011). Post-treatment, only two participants in the SHUTi group (14.3%) reported a score that was above the clinical cut-off, compared to 4 or 28.6% in the TAU group. Previous trials of CBT-I in cancer have reported mixed findings with regard to treatment effects for depression. Some studies have failed to find a treatment effect (Matthews et al., 2012; Ritterband et al., 2012). Among the studies that have found a treatment effect for depression, the effect size has been in the medium range (Espie et al., 2007; J. Savard et al., 2013), while the effect size in low-intensity modalities have been more similar to the current results and have been in the small range (J. Savard et al., 2013). Ritterband et al (2012) found that while SHUTi did not have a significant effect on depressive symptoms, there was a medium treatment effect size.

There was no treatment effect for anxiety. There was a significant time effect that was similar across the two groups, such that there was a 2-point decrease in the mean GAD-7 score for the SHUTi group compared to a 3-point decrease in the TAU group. At post-treatment, both groups were reporting mild anxiety symptoms. This type of discrepancy in the treatment effects

of CBT-I on psychological symptoms is uncommon in the literature. For the most part, studies have found that the presence or absence of treatment effects has been similar for depression and anxiety. For example, Espie and colleagues (2007) found that group CBT-I was associated with a medium sized treatment effect for depression and anxiety, while Ritterband et al. (2014) found that SHUTi did not significantly improve depressive or anxiety symptoms. There is only one other study that found that whereas face-to-face CBT-I had a significant effect on depression and anxiety, video-based CBT-I significantly improved depression but not anxiety (J. Savard et al., 2013). An argument could be made that this difference is related to the intensity of the intervention, such that standard CBT-I may be more effective in addressing anxiety than depression. However, the fact that several standard CBT-I trials have failed to find treatment effects for anxiety and findings from the previous SHUTi trial also showed that there was no significant treatment effect on anxiety suggests that there may be another explanation. Instead, it seems more plausible that there may be a difference in the nature of depression versus anxiety that makes the former more responsive to CBT-I. In the current study, anxiety scores decreased for all participants, while depression only decreased in the SHUTi group. This idea is substantiated by findings from a recent meta-analysis of non-pharmacological sleep treatments in chronic pain that while treatment conferred benefits for depression post-treatment and at follow-up, there was no treatment benefit for anxiety (Tang et al., 2015). Similarly, another meta-analysis found a significant medium effect size for CBT-I on depression while the effect for anxiety outcomes was small and non-significant, suggesting that CBT-I is more effective for depression than for anxiety (Belleville, Cousineau, Levrier, & St-Pierre-Delorme, 2011; Sánchez-Ortuño & Edinger, 2012). Given the timing of the current study and its proximity to participants' diagnosis and treatment, patients' anxiety was likely more related to cancer, and

thus more responsive to the natural course of decreasing worry as patients adjust to their diagnoses and treatment.

SHUTi Treatment Effects on Health-related Quality of Life

At baseline, the mean FACT-G total score was 72.2. This score is lower than has been reported in normative data for a heterogeneous oncology sample (80.9) (Brucker, Yost, Cashy, Webster, & Cella, 2005) and in a previous study of CBT-I in cancer (80.1) (Espie et al., 2008), indicating worse health-related quality of life for the current sample. There were substantial differences between the mean component scores for the current study and normative data reported for individuals with cancer, such that for emotional and functioning well-being, the differences were clinically meaningful. These differences are consistent with the current sample being sicker.

There was no treatment effect observed for overall health-related quality of life or its components. There was no significant time effect, unlike in the case of sleep-related outcomes and psychological symptoms, suggesting that FACT-G total scores did not change from baseline to post-treatment. There was a 5-point increase in the mean total score for the entire sample, while there was a 9-point increase in the SHUTi group compared to a 1-point increase in the TAU group. It is likely that this difference may not have reached statistical significance due to the small sample size, especially since the increase in the SHUTi group was clinically meaningful. However, it is also possible that there is no treatment effect. A previous study of face-to-face CBT-I found medium to large effects for health-related quality of life. On the other hand, the previous SHUTi trial failed to find treatment effects for quality of life, but a video-based self-directed trial found a small positive effect. The current sample was sicker than has been studied previously and on the whole, reported worsening physical well-being at post-

treatment. It is possible that improvements in certain components of the FACT-G (i.e., emotional well-being) were canceled out by worsening physical well-being. Despite a slight and clinically non-significant increase in the mean physical well-being score for the SHUTi group (+0.7), the mean scores for both groups were substantially lower than the mean reported for a normative sample, 18.5 in SHUTi and 18.9 in TAU compared to 22.7 and for a sample with cancer, 21.3. The mean total FACT-G scores also remained lower than reported in normative data. Thus even at post-treatment, the sample continued to feel burdened by their disease, which makes sense since many were still engaged in active treatment.

Limitations

The current findings must be interpreted in the context of several limitations. First, the sample size was small and may have limited the ability to detect some treatment effects. This was particularly relevant when it came to outcomes like the TST and health-related quality of life wherein the mean scores for the SHUTi group differed considerably from the TAU group, yet there was no significant time by group interaction found. The current sample size was based on power calculations reported in previous studies. Moreover, the sample size in the current study is comparable to sample sizes that have been used in similar studies in the past (Fiorentino et al., 2009; Ritterband et al., 2012). However, the consistent time effects observed across most of the outcomes in the current study is consistent with past evidence that during this early phase of the cancer trajectory, there are substantial changes in patients' sleep and psychological well-being (Bárez, Blasco, Fernández-Castro, & Viladrich, 2009; J. Savard, Ivers, et al., 2011; Schroevers, Ranchor, & Sanderman, 2006). Thus, a larger sample size may be required to detect time by group interactions. However, this also makes the observed treatment effects that much more credible.

Another limitation of the current study is the use of only self-reported sleep parameters. The observed effects on sleep may have been even more convincing if they had been further substantiated by treatment effects on objective sleep measures. The inclusion of subjective and objective sleep measures is especially important given past mixed findings about differences in CBT-I effects by type of sleep measure (Lund, Rybarczyk, Perrin, Leszczyszyn, & Stepanski, 2013). However, this was a small pilot study and adding objective sleep measures was not feasible. Additionally, there are other studies in this area that have only used self-reported sleep measures (Matthews et al., 2014; Ritterband et al., 2012).

A third study limitation is the lack of a follow-up data to assess the durability of treatment effects. Studies that have evaluated study outcomes at follow-up have found that there are important changes in outcomes that contribute important information about treatment effects. Whereas some studies have found that some treatment effects diminish over time (Taylor et al., 2015), others have found that for some outcomes, the treatment effects are actually enhanced at follow-up (Espie et al., 2008; J. Savard, S. Simard, H. Ivers, et al., 2005). Thus follow-up data in the current study may have helped shed light on whether treatment effects would emerge or increase at follow-up when participants are likely done with their cancer treatment and thus may be more able to adhere to SHUTi recommendations. Yet this is not the first study in this area to exclude follow-up data (Epstein & Dirksen, 2007; Ritterband et al., 2012; J. Savard et al., 2013).

On a related note, the poor health status of some of the study participants likely contributed to the study delays and may have dampened some treatment effects. The study aimed to evaluate SHUTi during active cancer treatment, so it was expected that participants would be sick. However, 18% of the current sample had stage IV malignancies. These patients were not diagnosed with widely metastatic disease and thus were planned to undergo curative

treatment, making them eligible for the current study. This is not the first study of its kind to include participants with stage IV disease (Ritterband et al., 2012). But given that this study was during treatment, it is likely that stage IV disease was more impactful. The inclusion of these patients contributes further to the generalizability of the current findings.

A final limitation is that the doctoral student was responsible for randomization, data collection and implementing the intervention. Thus, blinding the experimenter was impossible, which may have contributed to demand effects (Orne, 1962). However, this threat to validity is mitigated by the fact that the intervention was a standardized program delivered online. Even though the doctoral student provided some support to all but one of the participants in the treatment condition, the core intervention was standardized.

Strengths

This study has several strengths. A major strength of the current study is the diversity of the sample, which enhances the external validity of findings. In recruiting a study sample that is diverse in race, socioeconomic status and type of malignancy, the current study addresses a significant gap in the literature. Previous samples have been primarily White, well-educated women with breast cancer. For example, this is one of the first studies to include patients with head and neck cancer. The current study suggests that online CBT-I can also be effective in other types of cancers as well as among Black individuals and those from lower socioeconomic strata.

Another strength of the present study is the inclusion of clinician support. There is previous support that low-intensity CBT-I interventions can be enhanced with the addition of clinician support (Ho et al., 2014; Jernelöv et al., 2012). However, previous trials that have included clinician support have found that participants have not taken advantage of this option (J.

Savard, Villa, et al., 2011). Evaluating clinician support was more feasible in the current study because the doctoral student was able to monitor participants' progress through SHUTi and there were multiple opportunities to offer support during participants' medical appointments. In the current study Black participants and those from lower socioeconomic status appeared to be more likely to initially accept the doctoral student's support. While it was not possible to test these hypotheses, it does suggest research questions for future inquiry. Also, flexibly offering clinician support rather than using randomization or having participants select an option at the beginning of treatment, more closely approximates how treatment would naturally unfold in a non-research clinical context.

Implications

Findings from the current study have implications for scholarship and clinical practice. Related to one of its primary aims, the first implication from the current study is about feasibility. Overall, the current findings support the feasibility of implementing a low-intensity CBT-I intervention to improve sleep among individuals newly diagnosed with cancer and undergoing active treatment. Future research should consider the following caveats. First, given that participants tend to be sicker during treatment, future studies should build in additional time to account for illness-related delays. There should also be flexibility to allow participants to continue the study if there are delays and building research activities around medical appointments substantially decreases the burden on participants, thus encouraging participation. On a related note, having a study tablet that allows participants to complete study activities during their medical appointments also facilitates participation. This also serves to increase participation by minority and low-income individuals. To that end, the current study adds to accumulated evidence that when minority and low income individuals are recruited and the

barriers to their participation minimized, they are just as likely if not more likely than other groups to participate in research studies (Wendler et al., 2005).

The treatment effects on self-reported sleep parameters and psychological functioning have significance for addressing insomnia during cancer treatment. Namely, low-intensity CBT-I can have a meaningful impact on sleep and depression even during this particularly stressful phase of the cancer care trajectory. Wake time after sleep onset may be especially responsive to treatment during this time, perhaps because intrusive thoughts are at a peak during this period. Yet, anxiety is less responsive to CBT-I likely because patients' anxiety is more closely tied to their disease. Health-related quality of life may be similarly unaffected by low-intensity CBT-I. These findings suggest that during cancer treatment, other outcomes may be more suitable for capturing the secondary effects of CBT-I. One possibility is fatigue. Fatigue has been examined as a secondary outcome in multiple CBT-I trials among individuals with cancer (Espie et al., 2008; Ritterband et al., 2012; J. Savard, S. Simard, H. Ivers, et al., 2005). Fatigue was also included in the previous evaluation of CBT-I during cancer treatment (Berger, Kuhn, Farr, Von Essen, et al., 2009). The current findings also highlight the importance of assessing multiple sleep parameters and not relying solely on global measures of insomnia. During the period immediately after diagnosis when they are about to embark on treatment, patients may underreport the distress related to their sleep difficulties because they may be more inclined to attend to their physical illness.

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Appendix

1. Study eligibility questionnaire
2. Clinical Interview
3. Sleep diary
4. Insomnia Severity Index (ISI)
5. Patient Health Questionnaire-9 (PHQ-9)
6. Generalized Anxiety Disorder-7 (GAD-7)
7. Functional Assessment of Cancer Therapy-General scale (FACT-G)
8. Treatment preference questionnaire

Study Eligibility Questionnaire

1. Have you been diagnosed with non-metastatic cancer?
2. Will you undergo chemotherapy or radiation treatment?
3. Is this the first time you will undergo chemotherapy or radiation treatment?
4. Do you experience at least three episodes of disturbed sleep per week *AND* daytime consequences such as fatigue, irritability, or difficulty concentrating that has lasted for at least one month?
 - a. An episode of insomnia is defined as:
 - i. An inability to fall asleep within 30 minutes
AND/OR
 - ii. Awakening during the night (after falling asleep) for a total of 60 minutes or more
AND/OR
 - iii. Achieving less than 6.5 hours of sleep per night

Participant information/Demographic questionnaire

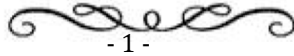
1. **When were you diagnosed with cancer?**
2. **When do you begin treatment?**
3. **For how long have you experienced the following symptoms?** ____years ____months
 - a) At least three episodes of disturbed sleep per week
AND
 - b) Daytime consequences such as fatigue, irritability, or difficulty concentrating?
4. **When did you first notice you were having problems with your sleep?**
____Before cancer diagnosis ____After cancer diagnosis
5. **Have you ever told your oncologist about these sleep problems?**
____Yes ____No
6. **Do you believe that your cancer diagnosis and/or treatment caused your sleep problems?**
____Yes ____No
7. **Do you believe that your cancer diagnosis and/or treatment has affected your sleep?**
____Yes ____No
8. **Are you taking any sleep aids, either prescribed or over the counter?**
____Yes ____No
9. **Please tell me your age:** ____
10. **Gender:** ____Male ____Female
11. **Marital status:** ____Married ____Single ____Divorced/Separated/Widowed
12. **Race/ethnicity:** ____Hispanic/Latino ____not Hispanic/Latino
____African American/Black ____Native Hawaiian/Other Pacific Islander
____American Indian/Alaskan ____White
____Asian ____Two or more races
13. **Education:**
____Some high school ____College
____High school ____Graduate school
____Some college
14. **Please indicate your household income**
____< \$10,000
____\$10-29,999

- ☐ \$30-49,999
- ☐ \$50-74,999
- ☐ \$75-99,999
- ☐ \$100,000+

15. What is your employment status?

- ☐ Full-time
- ☐ Part-time
- ☐ Retired
- ☐ Disabled
- ☐ Other

SLEEP DIARY INSTRUCTIONS



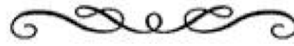
In order to better understand your sleep problem and monitor your progress while using SHUTi, it is important to collect some information on your sleep pattern.

General Instructions

- **What is a Sleep Diary?** A sleep diary is designed to gather information about your daily sleep pattern.
- **How often and when do I fill out the sleep diary?** It is necessary for you to complete your sleep diary every day. If possible, the sleep diary should be completed within one hour of getting out of bed in the morning.
- **What should I do if I miss a day on this paper version of the diary?** If you forget to fill in the diary or are unable to finish it, leave the diary blank for that day. If you complete this paper diary but do not enter it into SHUTi that day, you can enter up to 3 days worth of diaries at one time (today, yesterday, and the day before).
- **What if something unusual affects my sleep or how I feel in the daytime?** If your sleep or daytime functioning is affected by some unusual event (such as an illness, or an emergency) you may make brief notes on your diary.
- **What do the words “bed” and “day” mean on the diary?** This diary can be used for people who are awake or asleep at unusual times. In the sleep diary, the word “day” is the time when you choose or are required to be awake. The term “bed” means the place where you usually sleep.
- **Will answering these questions about my sleep keep me awake?** This is not usually a problem. You should not worry about giving exact times, and you should not watch the clock. Just give your best estimate.



SLEEP DIARY INSTRUCTIONS



- 2 -

Sleep Diary Instructions

Use the guide below to clarify what is being asked for each item of the Sleep Diary.

Question 1:

What time did you get into bed?

Write the time that you got into bed. This may not be the time you began “trying” to fall asleep.

Question 2:

What time did you try to go to sleep?

Record the time that you began “trying” to fall asleep. This is the time you go to bed with the intention of falling asleep. It should not include time in bed when you did not intend to fall asleep (that is included in Question 1). If you go to bed at 10:15 PM, but do not turn the lights off with the intention of going to sleep until 11:30 PM, you should enter 10:15 PM in Question 1 and 11:30 PM for this question. If you go to bed at 10:15 PM with the intention of going to sleep right away, but then do not fall asleep until 11:30 PM, you should write down 10:15 PM for both questions. The next question will capture how long it took to fall asleep.

Question 3:

How long did it take you to fall asleep?

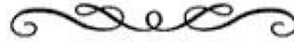
Beginning at the time you wrote in question 2, how long did it take you to fall asleep. Enter your answer in hours and minutes. Provide your best estimate of how long it took you to fall asleep once you got into bed and turned off the lights with the intention of going to sleep. If you go to bed at 10:15 PM with the intention of going to sleep, but then do not fall asleep until 11:30 PM, you should write down 1 hour 15 minutes (75 minutes total) in this space.

Question 4:

How many times did you wake up, not counting your final awakening? How many times did you wake up between the time you first fell asleep and your final awakening? This is the number of times you remember waking up during the night.



SLEEP DIARY INSTRUCTIONS



- 3 -

Question 5:

In total, how long did these awakenings last?

What was the total time you were awake between the time you first fell asleep and your final awakening. Enter your answer in hours and minutes. For example, if you woke 3 times for 20 minutes, 35 minutes, and 15 minutes, add them all up ($20+35+15=70$ min or 1 hr and 10 min). Estimate to the best of your knowledge how many minutes you spent awake for all awakenings combined. This should not include your very last awakening in the morning, as this will be logged in the next question (Question 6).

Question 6:

What time was your final awakening?

Record the last time you woke up in the morning. This is the very last time you woke up in the morning. If you woke up at 4:00 AM and never went back to sleep, this is the time to write. However, if you woke up at 4:00 AM, but went back to sleep for a brief period of time (for example, from 6:00 AM to 6:35 AM; this information would then be included in Questions 4 and 5), then your last awakening would be 6:35 AM.

Question 7:

What time did you get out of bed for the day?

What time did you get out of bed with no further attempt at sleeping? This may be different from your final awakening time (e.g., you may have woken up at 6:35 AM but did not get out of bed to start your day until 8:20 AM).

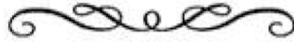
Question 8:

How would you rate the quality of your sleep?

"Sleep Quality" is your sense of whether your sleep was good or poor. Please use the following 5-point scale to indicate how you felt when you got up in the morning: (1=Very Poor, 2=Poor, 3=Fair, 4=Good, 5=Very Good)



SLEEP DIARY INSTRUCTIONS



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Question 9:

In total, how long did you nap or doze?

Estimate the total amount of time you spent napping or dozing, in hours and minutes. For instance, if you napped twice, once for 30 minutes and once for 60 minutes, and dozed for 10 minutes, you would answer 1 hour 40 min.

This should include all naps even if they were not intentional. For instance, if you dozed off in front of the TV for 30 minutes, this should be included. If you did not nap or doze, select 0 (zero).

Question 10a:

How many drinks containing alcohol did you have?

Enter the number of alcoholic drinks you had where 1 drink is defined as one 12 oz beer (can), 5 oz wine, or 1.5 oz liquor (one shot).

Question 10b:

What time was your last drink?

If you had an alcoholic drink yesterday, enter the time of day in hours and minutes of your last drink. If you did not have a drink, write "N/A" (not applicable).

Question 11:

Did you take any over-the-counter or prescription medication(s) to help you sleep? If so, list medication(s), dose, and time taken:

List the medication name, how much and when you took EACH different medication you took tonight to help you sleep. Include medication available over the counter, prescription medications, and herbals (example: "Zolpidem 10 mg 10 pm"). If every night is the same, write "same" after the first day.

Comments:

If you have anything that you would like to say that is relevant to your sleep feel free to write it here.

