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Telephone-Delivered Cognitive Behavioral Therapy for Insomnia in Patients with Cancer: A Randomized Controlled Trial

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TELEPHONE-DELIVERED COGNITIVE-BEHAVIORAL THERAPY FOR INSOMNIA IN PATIENTS WITH CANCER: A RANDOMIZED CONTROLLED TRIAL

by

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ABSTRACT

This study examined the efficacy and feasibility of a brief telephone-delivered CBT-I (TeleCBT-I) intervention in cancer patients compared to a control group. The study used a randomized controlled trial design. The TeleCBT-I program consisted of a brief four-week CBT-I program adapted for cancer patients. Patients completed assessment measures at pre-treatment, post-treatment and one-month follow-up. Out of 184 patients screened, 39 were randomly assigned, and 35 (TeleCBT-I, n = 19; Control, n = 16) completed pre- and post-treatment measures and were included in the analyses. Compared to control group, the TeleCBT-I group reported decreased insomnia severity symptoms ($p < .014$), improved sleep quality ($p < .023$), and reduced dysfunctional beliefs about sleep ($p = .039$) at post-treatment with sustained treatment effects at one-month follow-up. Sleep measures yielded large effect sizes (Hedges' g, 0.84-2.7). Although the TeleCBT-I group indicated improvements in fatigue, general functioning, physical well-being, functional well-being, and physical quality of life, effects at follow-up were observed only for fatigue, functional well-being and physical quality of life. No effects were found on depression at any of the time points. In terms of feasibility, TeleCBT-I demonstrated high adherence, high homework completion and high overall satisfaction. These results advance the empirical evidence of CBT-I in cancer patients and support the use of telephone-delivered CBT-I to widely disseminate and implement among patients with cancer.

Key words: CBT-I, Insomnia, Cancer, Telephone, Telehealth

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LIST OF ABBREVIATIONS

CBT-I	Cognitive Behavioral Therapy for Insomnia
CR	Cognitive Restructuring
DBAS	Dysfunctional Beliefs about Sleep
FACT	Functional Assessment of Cancer Therapy
HADS	Hospital Anxiety and Depression Scale
ISI	Insomnia Severity Index
PSQI	Pittsburg Sleep Quality Index
QOL-CSV	Quality of Life Patient Cancer Survivor Version
RCT	Randomized Control Trial
SC	Stimulus Control
SE	Sleep Education
SH	Sleep Hygiene
SR	Sleep Restriction
TeleCBT-I	Telephone-delivered Cognitive Behavioral Therapy for Insomnia
TSQ	Treatment Satisfaction Questionnaire

CHAPTER ONE: INTRODUCTION

Insomnia is a common and debilitating condition that can affect cancer patients at any time in the cancer continuum, from pre-diagnosis through long-term cancer survivorship. It is estimated that up to 80% of cancer patients experience sleep disturbances, while up to 30% to 60% suffer from insomnia (Savard, Ivers, Savard, & Morin, 2015, 2016; Sharma et al., 2012). If left untreated, insomnia is likely to become chronic, affecting the healing process and tumor progression in cancer populations (Cash et al., 2015). Insomnia has been associated with a number of negative physical and psychological consequences including: fatigue, pain, depression, anxiety, diabetes, cardiovascular disease, poor quality of life, and even early mortality (Palesh et al., 2017; Savard, Villa, Ivers, Simard, & Morin, 2009).

Considering that insomnia symptoms in cancer patients are often severe enough to warrant treatment, the American College of Physicians (ACP, Qaseem et al., 2016) guidelines recommend the screening and assessment of sleep complaints and treatment of insomnia during routine cancer care. Furthermore, the ACP asserted that all adult patients with cancer and comorbid insomnia symptoms receive cognitive behavioral therapy for insomnia (CBT-I) as the first line of treatment. Mounting evidence has demonstrated that CBT-I is effective to treat severe insomnia in adult populations, including cancer patients (Garland et al., 2014; Johnson et al., 2016; Zachariae, Lyby, Ritterband, & O'Toole, 2016). Emerging evidence suggests that CBT-I may also be beneficial in targeting other psychological outcomes in cancer patients, such as depression, anxiety and fatigue, as well as, quality of life (Dirksen & Epstein, 2008; Johnson et al., 2016).

Despite its high prevalence and negative impact in health, tumor progression, daily functioning, quality of life, and survival, insomnia is often under-recognized, under-diagnosed and under-treated in oncology settings (Geiger-Brown et al., 2015; Innominato et al., 2009; Johnson et al., 2016). Research has highlighted a number of challenges for cancer patients to receive CBT-I in a timely fashion, including lack of awareness of CBT-I, low clinician priority and referrals, limited trained providers, commute to treatment centers, and high cost and duration CBT-I (Manber & Simpson, 2016; Siefert, Hong, Valcarce, & Berry, 2014; Sivertsen, Vedaa, & Nordgreen, 2013). Another important challenge is that when treatment is offered, it generally consists of sleep medication (Sandlund, Hetta, Nilsson, Ekstedt, & Westman, 2017; Siefert et al., 2014), increasing the number of medications and side effects during cancer treatment.

Telehealth modalities have emerged as viable options to reduce barriers in care and improve clinical health outcomes (Perle & Nierenberg, 2013). The number of telehealth technologies and delivery formats is growing from live interactive video that allows providers to provide remote intensive home care to mobile applications that patients use to access health information and manage their health (Holmqvist, Vincent, & Walsh, 2014; Perle & Nierenberg, 2013). Given the empirical evidence demonstrating that CBT-I can help people sleep better, there is a growing interest in its widespread dissemination and implementation with all populations. Telehealth modalities can circumvent the challenges in disseminating CBT-I without reducing its effectiveness. Indeed, promising research indicates that both internet-based and telephone-delivered CBT-I programs are as effective as face-to-face individual and group modalities in adult samples (Arnedt et al., 2013; Ritterband et al., 2017; Zachariae et al., 2016).

Further research is needed to determine whether insomnia can be treated by delivering CBT-I through telehealth. Considering the huge potential of telehealth in increasing access, quality and efficiency in care (Chaet, Clearfield, Sabin, & Skimming, 2017), it is imperative to test CBT-I with different telehealth formats to improve patient health, particularly for individuals with chronic and debilitating conditions, such as cancer. Telehealth technologies may reduce barriers to disseminate and implement CBT-I in oncology settings. For example, patients can have access to CBT-I information and psychotherapy from the convenience of their home or work office, eliminating practical barriers, such as transportation issues, child care, as well as reduce overall cost and time invested in accessing care (Brenes, Ingram, & Danhauer, 2011; Chaet et al., 2017).

Although there is abundant interest in pursuing a widespread dissemination of CBT-I utilizing telehealth technologies, there is a lag in research with cancer patients. Telehealth research with CBT-I have largely focused on internet-based and mobile applications, despite telephone communication still being the most convenient, cost-effective, and ever-present form of communication in the United States and worldwide (Brenes et al., 2011).

To date, no research has examined CBT-I delivered through telephone communication with cancer patients. The present study adapted and tested a 4-week CBT-I program delivered via telephone to cancer patients. The main objectives were to test the efficacy and feasibility of a brief telephone-delivered CBT-I (TeleCBT-I) program in cancer patients. In this randomized controlled study, the effects of TeleCBT-I were compared to a treatment-as-usual control group. TeleCBT-I treatment gains over time were examined at one-month follow-up. The feasibility of telephone-delivered CBT-I in cancer patients was evaluated over the course of four weeks.

CHAPTER TWO: LITERATURE REVIEW

Insomnia

Insomnia is characterized by subjective complaints about difficulty initiating sleep, difficulty maintaining sleep, waking up too early in the morning or experiencing non-restorative or poor quality of sleep (Qaseem et al., 2016; Roth, 2007). As per the International Guidelines of Sleep Disorders (Thorpy, 2017), both reduced sleep time and impaired daytime functioning are important aspects in the diagnosis of insomnia disorder. The clinical diagnosis of chronic insomnia disorder according to the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) and the International Classification of Sleep Disorders, Third Edition, specify that symptoms cannot be associated with another sleep or medical disorder, must cause clinically significant functional impairment and be present at least three days in a week and for at least three months (American Psychiatric Association, 2013; Thorpy, 2017).

The prevalence of insomnia is higher among women than men and tends to increase as people age with a sharp spike among adults aged 55-64 years old as observed in the National Health Interview Survey from 2002-2012 (Ford, Cunningham, Giles, & Croft, 2015). The development and progress of insomnia seems to be determined by predisposing, precipitating, and perpetuating factors (Bastien, Morin, Ouellet, Blais, & Bouchard, 2004). Predisposing factors may include a person's genetics, gender, age, family history, trait anxiety, and predisposition to rumination (Bush et al., 2016; Hammerschlag et al., 2017; Harvey, Gehrman, & Espie, 2014), while precipitating factors consist of psychological and physical dysfunctions and

environmental, family and work-related circumstances. In cancer patients precipitating factors may include diagnosis of cancer, severity of disease, cancer treatment, side effects of cancer treatment, menopausal symptoms including pain or fatigue, and medications (Bastien et al., 2004; Savard et al., 2009). Perpetuating behavioral factors include long-term use of medications or use of inappropriate medications, and dysfunctional coping (i.e., inaccurate appraisal of sleep difficulties and quality) (Tremblay, Savard, & Ivers, 2009).

The American Academy of Sleep Medicine and Sleep Research Society consensus recommends seven or more hours of sleep to promote optimal health in adults. Aside from increasing the number of hours of sleep, the goal of treatment for insomnia is to improve sleep quality, as well as, to reduce day time impairment caused by the disorder (Schutte-Rodin, Broch, Buysse, Dorsey, & Sateia, 2008). Treatment options for insomnia include psychological therapy, pharmacologic therapy, or a combination of both (Qaseem et al., 2016). Psychological therapy options include CBT-I, multicomponent behavioral therapy or brief behavioral therapy for insomnia, and other interventions such as stimulus control, relaxation strategies, and sleep restriction. Among these interventions, CBT-I is considered the gold standard treatment for insomnia as per clinical guidelines and practice parameters of the American Academy of Sleep Medicine and the American College of Physicians (Qaseem et al., 2016; Sateia, Buysse, Krystal, Neubauer, & Heald, 2017).

Cognitive-Behavior Therapy for Insomnia (CBT-I)

The evidence that CBT-I is an effective treatment for insomnia and produces enduring effects lasting beyond treatment has been established. CBT-I was designed to improve sleep

disturbance by addressing psychological and behavioral factors involved in the development and maintenance of insomnia (Morin et al., 2015; Siebern & Manber, 2011). CBT-I combines components of cognitive and behavioral therapies. Cognitive therapy addresses dysfunctional beliefs and thoughts about sleep, while behavioral therapy targets behaviors and habits that do not promote sleep and are not conducive to healthy sleep patterns (Morin, 2010). The major components in CBT-I include: cognitive restructuring (CR), stimulus control (SC), sleep restriction (SR), sleep hygiene (SH), and relaxation techniques (RT) to improve sleep outcomes (Siebern & Manber, 2011; Annemieke van Straten et al., 2018). CBT-I is often provided individually or in group formats and traditionally is delivered during the course of eight to twelve sessions (Manber & Simpson, 2016; Siebern & Manber, 2011).

Accumulative evidence including randomized controlled trials, meta-analyses (Koffel, Koffel, & Gehrman, 2015; Sandlund et al., 2017; Trauer, Qian, Doyle, Rajaratnam, & Cunnington, 2015; Annemieke van Straten et al., 2018) and systematic reviews (Cunningham & Shapiro, 2018; Mitchell et al., 2014) established that CBT-I is an effective treatment for adults with chronic insomnia with clinically and statistically significant effect sizes. Indeed, a recent review and meta-analysis assessed the efficacy of face-to-face CBT-I on 20 randomized controlled trials and demonstrated that CBT-I at post-treatment improved sleep time by 7.61 (CI, -.51 to 15.74) minutes and sleep efficiency by 9.91% (CI, 8.09% to 11.73%) with sustained gains over time (Trauer et al., 2015).

Furthermore, emerging evidence supports the use of CBT-I in adults with comorbid medical or psychiatric conditions (Geiger-Brown et al., 2015). Although the efficacy and effectiveness of CBT-I is well-established, CBT-I is under-utilized in medical settings.

Therefore, researchers have called attention to the need of facilitating the dissemination and implementation of CBT-I to all populations, including cancer patients who may experience additional barriers to care. Moreover, current trends in the literature suggest reducing the length of CBT-I and establishing evidence for other forms of delivery in order to reach a greater number of patients (Morin, 2010; Sandlund et al., 2017; Zhou, Partridge, & Recklitis, 2017).

CBT-I for Cancer Patients

Compared to pharmacological treatment, CBT-I has been associated with substantial and sustained clinical benefits among cancer patients (Heckler et al., 2016; Peoples et al., 2017). A recent systematic review of CBT-I with patients of different types of cancers reviewed 12 trials (4 controlled and 6 uncontrolled) and found that CBT-I was associated with statistically and clinically significant improvements in subjective sleep outcomes (Garland et al., 2014). Additionally, this review demonstrated that CBT-I had positive effects in mood, fatigue, and overall quality of life. CBT-I was also successfully delivered through a variety of treatment modalities (e.g., self-help, videoconferencing and individual and group therapy). Moreover, Garland et al., (2014) concluded that studies with homogeneous cancer groups did not have a treatment advantage over studies that included mixed groups of cancer patients, suggesting that treatment effects may be similar irrespective of cancer stage and tumor location. Nonetheless, most research has been conducted with breast cancer patients, highlighting the need to investigate the effect of CBT-I concurrent with a broad range of cancer diagnoses. For example, in a recent meta-analysis of randomized controlled trials of CBT-I in cancer patients, three of the eight studies evaluated included patients with mixed cancer diagnoses (Johnson et al., 2016)

CBT-I for Breast Cancer Patients (BCS)

CBT-I is an efficacious treatment for people with comorbid breast cancer and insomnia. Using the main components of the CBT-I (i.e., SC, RT, SH, and CR), researchers have examined CBT-I delivered in individual, group and self-administered modalities with breast cancer patients. Studies included both uncontrolled and controlled trials. A multiple baseline single subject study evaluated CBT-I and fatigue management in women with breast cancer stages I-III (N =10). This study found that although sleep severity was significantly decreased at six-month follow-up, there was no significant decline in depression, anxiety, fatigue, or quality of life (Quesnel, Savard, Simard, Ivers, & Morin, 2003). Another study found that women with breast cancer stage I-III (N = 11) who participated in a self-administrated program of CBT-I reported significantly reduced insomnia severity, depression, and increased quality of life, but no significant reduction in anxiety and depression at three-month follow-up (Savard, Villa, Simard, Ivers, & Morin, 2011). These findings provide mixed evidence that CBT-I may have an effect on other psychological variables such as depression, anxiety, fatigue, and quality of life, and therefore more research is needed.

Most controlled trials showed positive outcomes associated with CBT-I in BCS. Dirksen & Epstein (2008) tested the efficacy of a multicomponent CBT-I in BCS compared to a control group that received sleep education and information on sleep hygiene. The study included 72 women who were at least three-month post-primary cancer treatment. Both groups sustained significant time effects for sleep onset latency, wake after sleep onset, time in bed, sleep efficiency and sleep quality after treatment. Although this study may have minimized the effect

of CBT-I over a psychoeducational sleep approach, it also indicates that low intensity sleep intervention may have a significant impact on BCS.

Other controlled trials have demonstrated that CBT-I reduced insomnia severity, depression, anxiety, and fatigue, and increased quality of life on women with breast cancer stages I-III (Barsevick et al., 2010; Casault, Savard, Ivers, & Savard, 2015; Mitchell, Gehrman, Perlis, & Umscheid, 2012; Savard et al., 2011). Similar treatment effects have been found even when CBT-I is delivered during chemotherapy treatment. Mitchell et al., (2009) examined the effects of individual CBT-I on a group of 219 women who were randomly assigned before chemotherapy treatment to CBT-I group or a health-eating control condition. Differences were found between groups in sleep quality and sleep efficiency at 30-days posttreatment, but only improved sleep quality was sustained at one-year follow-up. Together, these findings support that CBT-I is effective at improving insomnia symptoms in BCS. Additionally, these findings also highlight the need to investigate whether CBT-I is also helpful at targeting other psychological symptoms comorbid with insomnia and faced throughout the cancer treatment continuum.

Telehealth

Telehealth utilizes a broad range of electronic information and telecommunication technologies to provide long-distance clinical health care (Weinstein et al., 2014). Technologies include a wide range of options from low-cost applications such as telephone, video or home computers to more complex ones, such as telesurgery (Chaet et al., 2017; Porzsolt & Kaplan, 2006). The terms telehealth and telemedicine are often used interchangeably even by leading

telehealth and telemedicine organizations (American Telemedicine Association, 2016). The main difference is in the range of services provided, as telemedicine concerns with the delivery of diagnostic and clinical services, while telehealth extends to a broader range of services including patient care, self-management, and education (American Telemedicine Association, 2016).

Telehealth and CBT-I.

Given that the effectiveness of CBT-I in cancer patients is well documented, the next scientific venture is to make CBT-I more accessible and cost-effective for all populations. Telehealth supports novel applications to delivering CBT-I to individuals who would not otherwise have access to treatment.

Although limited, emerging research support the use of telehealth technologies to disseminate CBT-I. Growing evidence favors the use of internet-based applications of CBT-I. Several clinical trials demonstrated that web-based CBT-I delivered by an automated virtual therapist (Espie et al., 2008) or guided by a therapist (Blom et al., 2015; Kaldo et al., 2015; van Straten et al., 2014), as well as, self-help or self-administered interventions (Connelly, Gee, & Walsh, 2007; Lancee, van den Bout, van Straten, & Spoormaker, 2012; Ritterband et al., 2009; Ström, Pettersson, & Andersson, 2004). For example, a recent meta-analysis included eleven randomized controlled trials published from 2004 to 2015 and examined 1,460 participants, documenting that CBT-I delivered via telehealth improved insomnia symptoms at post-treatment with effect sizes (Hedges' g) for insomnia severity of 1.09, 0.58 for sleep efficiency, 0.49 for sleep quality and .021 for number of nocturnal awakenings (Zachariae et al., 2016). Treatment

outcomes were comparable with those found in face-to-face CBT-I interventions and were sustained at one-month to twelve-month follow-up.

Research on telehealth and CBT-I is fairly new and even more so with cancer patients. Out of the eleven studies included in a recent meta-analysis, only one was conducted with cancer patients (Zachariae et al., 2016). The sample included 28 cancer patients randomized to either internet-based CBT-I or waitlist control group (Ritterband et al., 2012). Findings indicated that participants in the internet-based CBT-I group showed improvements in insomnia symptoms at post-treatment compared to control group. Although encouraging, this evidence highlights the need to further investigate the efficacy of CBT-I delivered via telehealth modalities to cancer patients.

In this review of the literature only six empirical studies of CBT-I using some form of telehealth with cancer patient were found (Epstein & Dirksen, 2007; Ritterband et al., 2012; Savard, Ivers, Savard, & Morin, 2014; Savard et al., 2016, 2011; Zhou, Vrooman, Manley, Crabtree, & Recklitis, 2017). Table 1 presents a summary of the six studies. These studies examined a wide range of telehealth modalities, including: internet-based, self-administered animated videos, video conference, and a combination of group therapy with individual telephone calls, providing preliminary evidence for the use of telehealth to deliver CBT-I in cancer populations. Although promising, more research is needed to determine which telehealth format is more conducive to disseminate CBT-I without affecting its effectiveness in treating insomnia in cancer patients. Furthermore, although one study included telephone calls (Dirksen & Epstein, 2008), the telephone calls served as supplement to the actual group therapy and thus it does not constitute a true use of telehealth in providing CBT-I. These findings also highlight the

need to investigate whether telephone-delivered CBT-I is efficacious and feasible in cancer populations.

Telephone-delivered CBT-I

Telehealth application such as individual telephone calls is far more cost-effective and accessible to deliver than traditional face-to-face interventions and even more so than other forms of telehealth, such as video-conferencing and internet-based therapy (Brenes et al., 2011). Two studies have examined the use of telephone-delivered CBT-I. Bastien et al., (2004) compared face-to-face individual therapy, face-to-face group therapy and telephone consultations with 45 adults with insomnia. This study found that CBT-I was effective in reducing insomnia symptoms across treatment modalities and at six-month follow-up. Another study compared CBT-I delivered by telephone (n = 15) to passive control group (n = 15). The control group received an informational brochure (Arnedt et al., 2013). Both groups reported significant effect in all sleep measures. It is possible that the content of the brochure included some aspects of CBT-I, thus making it more therapeutic than intended. These findings suggest that some aspects of CBT-I could be beneficial as a stand-along intervention and potentially that a full dose of CBT-I is not warranted for all populations. Future research should explore the effect of telephone-delivered CBT-I compared to a control group, particularly to non-treatment control or wait-list control in order to discern whether changes between groups are greater for CBT-I delivered by telephone than a pure non-treatment group.

Telephone-delivered Interventions for Cancer Patients

Telehealth in the form of individual telephone calls or telephone consultations has been associated with positive outcomes and high levels of satisfaction among cancer patients receiving cancer genetic counseling (Zilliacus et al., 2010). Another study documented the use of a nurse-led telephone-based intervention to support cancer patients receiving oral chemotherapy (Barsevick et al., 2010). Although this intervention was not randomized, it provides exploratory evidence of telephone-based services for cancer populations. A recent study suggests that telephone-delivered cognitive behavioral therapy was comparable to face-to-face CBT for reducing anxiety and depression and improving coping skills in cancer patients (Watson, White, Lynch, & Mohammed, 2017). Furthermore, problem-solving interventions delivered via telephone have been effective in cancer patients as well (Watson et al., 2013).

In sum, the literature supports the use of CBT-I as the first-line of treatment for insomnia in cancer patients and encourages the use of telehealth to disseminate and implement CBT-I to all populations. Thus, given the proliferation of telehealth technologies and the growing evidence favoring the delivery of CBT-I through telehealth, it is imperative to examine which telehealth modality would be most efficacious and feasible in cancer populations. To our knowledge, no study to date has evaluated the efficacy of telephone-delivered CBT-I in cancer patients.

Table 1.
Summary of Studies Investigating Telehealth and CBT-I in Cancer Patients

Study	Sample Characteristics	Allocation	Diagnosis/ Stage	Type of Telehealth	Treatment Components	Sessions	Follow-up
Ritterband et al., 2012	Males and Females; Mean 56.7	CBT-I = 14, WLC = 14	State I-IV	Internet-based	SC, SR, SH, CR	6 session over 9 weeks (45-60 min)	None
Savard et al., 2011	Females; Mean 51.5 (37-74)	VCBT-I = 11	Breast Stage I-III	Self-administered animated DVD + Booklet	SC, SR, CR, SH, RP	6 videos, weekly (60 minutes) + 1 booklet	3-month
Savard et al., 2014	Females; Mean 54.4 (18-75)	Individual = 81, Video-based = 80, Control = 81	Breast; Stages 0-III	Self-administered animated DVD + Booklet	SC, SR, CR, SH	6 videos, weekly, (60 minutes) + 6 booklet; 6 individual sessions (50-minutes)	None
Savard et al., 2016	Females; Mean 54.4 (18-75)	Individual = 81, Video-based = 80, Control = 81	Stages 0-III	Video-based (animated 60-minute video + 6 booklets)	SC, SR, CR, SH	6 sessions; 6 weeks (60 minutes)	3-, 6-, and 12-month
Zhou et al., 2017	Males and females; Mean 28.1 (15-40)	In-person = 6, Videoconference = 4	Leukemia/ Lymphoma, Solid Tumor	Videoconference (Sessions 2 & 3)	SR, SC, SH, CR	3 sessions (60 minutes)	2- month
Epstein & Dirksen, 2007	Females; Mean 57.1 (29-74)	CBT-I = 34 Control = 38	Breast Stages I-III	Combined group with 2 phone conversations	SR, SC, SE, SH	4 weekly groups and 2 weekly telephone sessions (60-120-minutes group & 15-30 minutes telephone)	None

Note. Abbreviations: CBT-I, cognitive behavioral therapy for insomnia; WLC, wait list control; SC, stimulus control; SR, sleep restriction; SH, sleep hygiene; CR, cognitive restructuring; VCBT-I, video-based CBT-I; RP, relapse prevention; SE, sleep education.

Current Study

Based on the existing scientific knowledge, technological advance and practice patterns, the current study aims to contribute to the growing literature on the use of telehealth to effectively disseminate CBT-I to cancer patients. The goals of the study are to test the efficacy and feasibility of a brief telephone-delivered CBT-I program among patients with different types of cancer diagnoses. Although the effectiveness of CBT-I has been established (Manber & Simpson, 2016; Morin et al., 2015; Siebern & Manber, 2011) and its effectiveness in cancer patients is well-documented by previous studies (Dirksen & Epstein, 2008; Espie et al., 2008; Garland, Rouleau, Campbell, Samuels, & Carlson, 2015; Howell et al., 2014), its efficacy using telehealth has yet to be established. In order to build the strongest empirical evidence, this study was undertaken as a randomized controlled trial comparing telephone-delivered CBT-I (TeleCBT-I) to a treatment-as-usual control group and is reported in accordance with the CONSORT statement for non-pharmacological trials (Boutron et al., 2017).

As noted in the literature, the issue is no longer whether CBT-I is effective, but how to effectively disseminate it. Despite the evidence of CBT-I in reducing insomnia among cancer patients, CBT-I remains underutilized and largely inaccessible to cancer patients. Research demonstrated that insomnia is not routinely screened, assessed or diagnosed during the cancer treatment trajectory, and when diagnosed cancer patients are more likely to be offered medication treatment instead of a referral to non-pharmacological treatments (Siefert et al., 2014). Unfortunately, those who are referred to non-pharmacological treatment, such as CBT-I

face substantial challenges to access treatment in a timely fashion. For example, CBT-I may be delayed due to limited availability of trained providers, transportation costs, treatment duration, and cost of face-to-face treatment sessions (Morin, 2010; Siefert et al., 2014; Sivertsen et al., 2013). Aside from these common barriers, cancer patients face additional challenges to access CBT-I. For example, medical complications related to cancer treatment may limit their ability to engage in additional treatment services outside of their home or hospital. Furthermore, cancer patients may have exhausted social, financial, and work-related resources in their extensive cancer care.

Given the barriers to delivering CBT-I to cancer patients, there is an urgent need to investigate alternative treatment delivery options to improve CBT-I dissemination to cancer patients. To date, only three studies have evaluated the use of telephone-delivered CBT-I in adult populations and found positive clinical outcomes (Arnedt et al., 2013; Bastien et al., 2004; Holmqvist et al., 2014). However, no study has tested the use of telephone-delivered CBT-I in cancer patients.

Using a randomized controlled trial design, this study examined the efficacy and feasibility of a brief telephone-delivered CBT-I program in cancer patients compared to a treatment-as-usual control group. For the purpose of this study, a four-week CBT-I program was adapted for cancer patients. The main aims were twofold: (1) to test the efficacy of TeleCBT-I in reducing insomnia symptoms at post-treatment and one-month follow-up, and (2) to evaluate the feasibility of TeleCBT-I in cancer patients. Based on preliminary evidence suggesting that CBT-I may improve other comorbid psychological symptoms, the study also

examined whether TeleCBT-I had an effect on fatigue, depression, anxiety, general functioning, and quality of life.

The primary hypotheses were:

(1) Compared to control group, cancer patients in the TeleCBT-I group would show improvements in insomnia severity, quality of sleep, and beliefs about sleep at post-treatment.

(2) Compared to control group, TeleCBT-I group would report improvements in all sleep measures at one-month follow.

(3) Those in the TeleCBT-I group would be actively engaged by attending the four treatment sessions over the telephone and completing their homework daily or almost daily.

The secondary hypothesis was:

(4) Compared to control group, TeleCBT-I group would show beneficial changes in fatigue, anxiety, depression, general functioning and quality of life.

CHAPTER THREE: RESEARCH DESIGN AND METHODOLOGY

Participants

Eligibility Criteria

Patients met criteria to participate in the study if they were 18 years or older, were receiving medical treatment at Orlando Health UF Health Cancer Center (OH-UFCC), had a cancer diagnosis and concurrent diagnosis of insomnia. Insomnia diagnosis was assessed with the Structured Clinical Interview for DSM-5 Sleep Disorders Module (Taylor et al., 2018) and the Insomnia Severity Index (ISI) with a score of eight or higher (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006). Additional inclusion criteria were the ability to speak and read English. Exclusion criteria were other diagnosed sleep disorders (e.g., narcolepsy), as well as, other untreated pre-existing sleep disorders (e.g., sleep apnea), severe psychiatric diagnosis (e.g., schizophrenia), cognitive impairment or dementia, or neurological disorder, and active psychotic symptoms, suicidal ideation, intention or plan or substance use. Additionally, subjects were excluded if unable to attend at least three of the four TeleCBT-I sessions.

Recruitment

This study was reviewed and approved by the Orlando Regional Medical Center Internal Review Board and the University of Central Florida Internal Review Board. (See Appendix A). Participants were recruited from the patient population at Orlando Health UF Health Cancer Center (OH-UFCC) clinics. Recruitment flyers were displayed throughout the

different OH-UFCC clinics and distributed at group activities provided by the OH-UFCC's Integrative Medicine Department (See Appendix B). Patients were identified and referred by their medical providers if presenting with insomnia related complaints. Additionally, patients were able to self-refer to participate in the study. Patients were first screened by telephone to determine study eligibility before enrollment. Providers were informed about the study and recruitment procedures during staff meetings, didactic or grand rounds presentations. Furthermore, an information letter was disseminated every three to four months to oncology physicians and providers explaining the study aims, eligibility criteria and recruitment procedures (See Appendix C).

Among the patients that were approached (n = 184), 132 were deemed eligible to participate in the telephone screening. The telephone screening identified 53 patients that met criteria and were invited to complete a diagnostic clinical interview. A total of 47 diagnostic clinical interviews were completed and 39 patients were randomized to either the TeleCBT-I or control groups. Appendix D exhibits patient recruitment and study follow chart.

Sample Size Justification

A priori power analyses were performed to estimate the number of participants needed to test the primary hypotheses. Power analyses were computed with G Power 3.1.9.2. Previous research on telephone-delivered CBT-I reported large effect sizes ranging from .80 to 2.5. The number of participants needed to determine whether there is a mean difference between the CBT-I and the control group was computed with a significance level of 5%, statistical power of 80%, and a to-be-detected population effect size of .80 as reported by Arnedt et al., 2015. The

estimated total sample needed was 42 (n = 21 each group). Then, the necessary sample size to test whether there are mean differences between groups for time and group x time interactions was evaluated with the same statistical parameters as above. However, to capture a wider range effect size, a medium effect size for analyses of variance was computed (.25) (Cohen, 1992). The estimated total sample was 28 (n = 14 each group). Thus, ascertaining treatment effects with statistical confidence should require at least 14 participants in each group. As with any study, the larger the sample size, the higher the confidence in its results.

Telephone Screening

Appendix E presents the script and screening used to identify potential study participants over the telephone. Details about the study were further explained during the telephone screening. If interested in participating in the study, patients were asked to complete the Sleep Disorders Questionnaire (SDQ) over the telephone. The SDQ measures the potential of meeting clinical criteria for insomnia. Those screened positively for a potential insomnia diagnosis were deemed pre-qualified for the study and were invited to complete an in-person diagnostic interview at OH-UFCC. Those who were not interested in participating in the study after pre-qualification were given the option to receive the same CBT-I program in person. None of the patients opted to receive the CBT-I in person.

Study Design and Procedures

Study Design

This is a two-group (intervention and control), prospective, randomized, single-center experimental design study. This study is part of a larger study with multiple follow-up assessments. Patients received four treatment sessions of TeleCBT-I provided by three trained graduate-level clinicians supervised by a licensed psychologist. Patients had the option to receive a booster session after completing the last treatment session, an option taken by only two patients. Sessions were between 45-75 minutes each. In most cases, the first session, which included psychoeducation and information about the structure and procedures of the study, and the last session, which explained treatment expectations, follow-up procedures and post assessment took longer. Each patient completed measures at screening, pre-treatment, post-treatment and at one-month follow-up. The Consolidated Standards of Reporting Trails (CONSORT) and the recommendations for standard research and assessment of insomnia were applied (Buysse et al., 2006; Moher et al., 2010). Appendix F shows RCT procedures flow charts.

Study Setting

This study was conducted at Orlando Health UF Health Cancer Center (OH-UFCC) through its Integrative Medicine Department in Orlando, Florida. OH-UFCC is a state-designated Cancer Center of Excellence, which is one of the most prestigious state recognitions provided by the State Surgeon General and Secretary of Health to cancer care entities (Florida

Department of Health, Office of Communications, 2015). Its state-of-the-art facilities serve over 80,000 patients annually and offer inpatient and outpatient services throughout locations at Orlando and Gainesville. For the purpose of this study, enrollment was limited to patients receiving treatment in Orlando, Florida.

Diagnostic Clinical Interview

During the diagnostic clinical interview patients provided consent to participate in the study, and completed a structured clinical interview, pre-treatment measures and an intake and demographic questionnaire. Appendix G presents the intake and demographic questionnaire. Part of the consent process included obtaining medical clearance from patients' oncologist or medical provider. Thus, patients were asked to sign a medical clearance form, which was then used to collect the medical approval and clearance to participate in the study (See Appendix H).

The Structured Clinical Interview for DSM-5 Sleep Disorders Module was used to diagnosed insomnia disorder and rule out other sleep disorders. Only those who met DSM-5 criteria for insomnia disorder were enrolled in the study. Those assigned to the TeleCBT-I group were asked to complete a sleep diary for a minimum of two consecutive weeks prior to treatment. Patients were given the option to discontinue study participation at any time.

Randomization and Allocation

Eligible patients were randomized to either TeleCBT-I or control group. The RAND function of Microsoft Excel (Microsoft, version 2016) was used to generate unrestricted

randomly permutated codes prior to enrollment. Unrestricted or simple randomization assignment is similar to repeated coin tossing, and as a result, unequal group size is expected. In fact, it has been argued that forcing equal group size in simple randomized trials is merely cosmetic than scientifically (Schulz & Grimes, 2002). Thus, moderate discrepancy between groups was expected in accord to the essence of randomness as recommended by Schulz & Grimes (2002). Sealed envelopes were used to reveal allocation during the diagnostic interview. Initially, patients were randomized to three conditions (Group TeleCBT-I, Individual TeleCBT-I, and control group), but it was thereafter discontinued and the four patients that were assigned to the group TeleCBT-I format were re-assigned to individual TeleCBT-I.

Brief TeleCBT-I Program

After a comprehensive review of the literature, the brief TeleCBT-I program was developed using a multicomponent approach as tested in most clinical trials and clinical practices (Siebern & Manber, 2011). TeleCBT-I incorporated the most frequently used components of CBT-I: 1) sleep education, 2) sleep hygiene, 3) stimulus control, 4) sleep restriction, 5) cognitive restructuring, and 6) relaxation training (Manber & Simpson, 2016). Content components were condensed and separated into four sessions, instead of the usual eight to twelve CBT-I sessions. The resulting TeleCBT-I program consisted of four treatment sessions delivered once per week over the course of four weeks.

TeleCBT-I included a patient manual and workbook that was mailed to patients after completing the sleep diary and prior to initiating treatment. The manual was developed based

on existing CBT-I protocols (Edinger & Carney, 2008, 2015; Manber & Simpson, 2016). Additionally, it was tailored to address the unique needs of cancer patients by including scientific knowledge of how poor sleep affects patients with cancer and cancer survivors. Relevant information about patients' experiences with cancer treatment and poor sleep were also included throughout the different components. For example, cognitive restructuring included examples of dysfunctional thoughts of how lack of sleep would affect their health and cancer treatment. Table 2 presents an outline of the brief TeleCBT-I program components.

Table 2.
TeleCBT-I Program Outline

Week	Outline
1	• Welcoming and participant introductions • Overview of TeleCBT-I program and study protocol • Sleep education • Sleep hygiene, part 1 • Stimulus control • Review sleep diary • Set goals and provide week assignment
2	• Review of session 1 and homework • Review sleep diary • Sleep hygiene, part 2 • Relaxation techniques • Sleep restriction • Development of new sleep schedule • Set goals and provide week assignment
3	• Review of session 2 and homework • Review sleep diary • Adjust sleep schedule and calculate sleep efficiency • Cognitive restructuring • Set goals and provide week assignment
4	• Review of sessions 1 - 3 and homework • Review of sleep diary • Review and adjust sleep schedule as needed • Discuss sleep medications side effects and tapering strategy • Relapse prevention • Complete post-treatment measures • Review follow-up plan and schedule

Control Group

Patients allocated to the control group continued receiving treatment as usual. Patients were told that they needed to complete two sets of measures before beginning TeleCBT-I. Patients completed post-treatment and follow-up measures over the telephone at four- and eight-weeks, respectively. Patients were also given the choice to complete their measures in person or by mail. After completing the one-month follow-up measures, patients allocated to the control group were offered TeleCBT-I following the same procedures as those in the TeleCBT-I group.

Telephone Equipment and Protocol

The TeleCBT-I program was provided over the telephone using the OH-UFCC telephone service. Patients used their personal phones to participate in the sessions with no additional cost to them. Patients were asked to allot 60 to 90 minutes for the telephone-delivered CBT-I sessions. Safety measures were taken following telehealth guidelines recommendations. Specifically, patients provided information of current location and another telephone number to contact them in the event the telephone call was disconnected. Patients were also asked to ensure privacy by taking the telephone call from a private space (e.g., non-shared space within their home or office), and avoiding using the speaker mode if there is a possibility that another person could hear them.

Measures

Screening

Sleep Disorders Questionnaire (SDQ; Douglass et al., 1994). The SDQ includes 18 items designed to identify those who: 1) meet criteria for a sleep disorder, 2) report problems with sleep and 3) do not report sleep problems. Patients were asked to answer each question using a Likert scale ranging from 1 (Never) to 5 (Always). The SDQ has a sensitivity of 95% and specificity of 87% for insomnia. The SDQ has been used studies with cancer patients, but reliability scores were not reported (Garland, Carlson, Antle, Samuels, & Campbell, 2011).

Structured Clinical Interview

The Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Sleep Disorders (SCISD; Taylor et al., 2018). The SCISD is a brief clinician administered clinical interview that includes 20 to 51 questions and takes 10 to 20 minutes to administer. The interview assesses nine major sleep disorders, including insomnia as specified in the DSM-5. Taylor et al., (2018) reported the SCISD had an excellent interrater reliability for insomnia (1.0).

Sleep Measures

Insomnia Severity Index (ISI; Morin, 1993). The ISI is a brief measure of subjective sleep complaints and associated distress. The ISI examines global severity of insomnia based

on difficulty initiating or maintain sleep, and degree of dissatisfaction and daytime impairment associated with insomnia. It is comprised of seven items rated on 5-point Likert scale ranging from 0 (None) to 4 (Very Severe). Higher scores indicate greater impairment and a score of 8 indicates possible insomnia. The ISI has been shown to have high internal consistency (Cronbach's alpha = .90-.91) (Morin, Belleville, Bélanger, & Ivers, 2011) and has been validated for use with cancer patients (Cronbach's alpha = .90) (M. H. Savard, Savard, Simard, & Ivers, 2005). The ISI has also been found to be sensitive to therapeutic changes (Morin, Beaulieu-Bonneau, LeBlanc, & Savard, 2005). The Cronbach's alpha in this study was .53.

Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). The PSQI consists of 19 items and measures seven component scores (subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction) and a global score. Questions are scored on a 0 to 3 scale over a period of one-month. Evidence supports its sensitivity and specificity in detecting good and poor sleep quality (Garland et al., 2011). In a previous study, the Cronbach's alpha was .80 (Garland et al., 2011). In this study the Cronbach's alpha was .44.

Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS-16; Morin, Vallières, & Ivers, 2007). The DBAS-16 is an abbreviated measure designed to assess the disrupted cognition often seen in persons with sleep disturbance. Patients were asked to indicate the extent to which they agree with the statement on a Likert scale ranging from 0 (strongly disagree) to 10 (strongly agree). Scores of 4 or greater suggest unrealistic expectations for sleep or that dysfunctional thoughts about sleep have become a factor in the sleep problem. The DBAS-16 has been shown to have adequate internal consistency (Cronbach's alpha = .77),

and has been validated for use in different insomnia subgroups (Edinger & Carney, 2015). The Cronbach's alpha in this study was .79.

Sleep Diary (CSD; Carney et al., 2012). Sleep diaries are considered a reliable and valid measure of insomnia symptoms. The CSD was used in this study at pre-treatment and throughout the course of TeleCBT-I. The sleep diary provides night-by-night account of sleep pattern and quality of sleep. The sleep diary was used to calculate a subjective report of sleep efficiency throughout the course of TeleCBT-I.

Psychological Variables

Fatigue Symptom Inventory (FSI; Hann, Denniston, & Baker, 2000). The FSI is a 14-item self-report measure designed to assess physical and psychological aspects of fatigue, including perceived severity, frequency, and daily pattern of fatigue as well as its perceived interference with quality of life. Severity is measured on a separate 11-point scale (0 = not at all fatigued; 10 = as fatigued as I could be) that assess most, least, and average fatigue in the past week, as well as, current fatigue. The FSI has been validated with males and females with cancer diagnosis. Previous research determined that a mean score of 3 or greater indicate clinically meaningful fatigue. The Cronbach's alpha in a previous study was .95 (Stein, Jacobsen, Blanchard, & Thors, 2004). In this study the Cronbach's alpha was .92.

Functional Assessment of Cancer Therapy-General, Version 4 (FACT-G; Cella et al., 1993). The FACT-G is a 27-item instrument that measures four primary quality of life domains: Physical well-being (PWB), Social/Family well-being (SWB), Emotional wellbeing (EBW), and Functional well-being (FWB) The statements use a 5-point rating scale (0 = Not at

all; 1 = A little bit; 2 = Somewhat; 3 = Quite a bit; and 4 = Very much). Sample items include: "I feel sad" and "I have accepted my illness." FACT-G total score is computed as the sum of the four subscale scores with a possible range of 0-108 points. Higher scores are indicative of less dysfunction. In this study, missing values were not manipulated as the answer response for each patient was over 80% (more than 22 of 28 items). Normative data of adult cancer patients (N = 2,236) was used to determine better functional well-being for each subscale and composite score as follows: PWB (Normal, M = 16-27; Dysfunctional, $M \leq 15$, Better Functioning, $M \geq 28$), SWB (Normal, M = 17-22; Dysfunctional, $M \leq 16$, Better functioning, $M \geq 23$), EWB (Normal, M = 15-18; Dysfunctional, $M \leq 14$, Better functioning, $M \geq 19$), FWB (Normal, M = 13-19; Dysfunctional, $M \leq 12$, Better functioning, $M \geq 20$), and FACT General (Normal, M = 65-81; Dysfunctional, $M \leq 64$, Better functioning, $M \geq 82$) (Cella, 2007). The instrument developers reported a Cronbach alpha of .89. In this study the Cronbach's alpha was .44.

Quality of Life for Cancer Survivor Version (QOL-CSV; Ferrell, Hassey Dow, & Grant, 1995). The QOL-CSV was designed to measure the specific concerns of long-term cancer patients. The QOL-CSV is based on previous versions of the QOL instrument developed by researchers at the City of Hope National Medical Centre (Grant, Padilla, and Ferrell). The QOL-CSV consists of 41 items representing the four domains of quality of life incorporating physical, psychological, social, and spiritual well-being. Each item is rated on an anchored scale from 0 to 10. The higher the scores the better quality of life the individual endorses (Ferrell, Hassey Dow & Grant, 1995). In a previous study, the Cronbach's alpha was .93 (B. Ferrell, Hanson, & Grant, 2013). The Cronbach's alpha in this study was .80.

Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). The HADS consists of seven-item anxiety and depression subscales. Scores ranged from 0-3 with 21 as the maximum score for each subscale. Higher scores reflect higher anxiety or depressive symptoms. Scores between 0-7 = Normal, 8-10 = Borderline abnormal (borderline case) and 11-21 = Abnormal (case). Zigmond and Snaith (1983) reported a Cronbach alpha of .85 for the anxiety and .83 for the depression subscale, respectively. In this study the Cronbach's alpha were .86 for the overall scale, .76 for the anxiety subscale and .85 for the depression subscale.

Feasibility

Treatment Satisfaction Questionnaire (TSQ). The TSQ was developed for this study to assess patients' overall experience and satisfaction with the TeleCBT-I program (see Appendix I). The TSQ was administered at post-treatment only and consisted of closed- and open-ended questions. Patients were asked to rate nine statements evaluating specific aspects of the treatment experience. Statements were rated using a 3-point scale from 0 (Strongly Disagree) to 3 (Strongly Agree). Sample items include: "The program has motivated me to work on my sleep problems" and "I gained greater understanding of my sleep problem(s)." Items were averaged and summed to provide a total score. Negative scored items were reversed and higher scores were indicative of positive experience. Four statements examined clinicians' performance as perceived by patients using a 3-point scale from 0 (Strongly Disagree) to 3 (Strongly Agree). Sample items include: "The practitioner understood my sleep problems and concerns" and "The practitioner was good at her/his job." Items were averaged and summed to compute a composite score of clinician's performance.

Additionally, the TSQ measured treatment adherence based on the number of completed sessions and by asking patients how often they completed homework and practiced the treatment recommendations at post-treatment. Specifically, patients were asked *"Overall, how often did you practice the suggested homework or daily practice?"* with five possible answers (daily, almost daily [4-6 days/week], occasionally [1-3 days/week], rarely [0-1 days/week], never ([0 day/week]). Further, overall satisfaction with the TeleCBT-I program and helpfulness of program manual were each evaluated with one item using a 4-point scale from 0 (Very Dissatisfied or helpful) to 3 (Very Satisfied or Helpful). Moreover, patients were asked whether they would recommend the TeleCBT-I program to other patients using a 4-point scale from 0 (Not at all likely) to 4 (Extremely likely).

Qualitative questions to ascertain what aspects of the program patients liked or disliked included: "What did you find most helpful about the Sleeping Well Program?" and "What did you find least helpful about the Sleeping Well Program?" Responses were reviewed to identify major themes. Lastly, the TSQ included questions to determine major changes in patients' health, treatment and life circumstances that could affect treatment outcomes.

Demographics

Baseline demographic and medical characteristics included demographic (age, marital status, employment) and medical information (history of sleep problems, months since diagnosis, cancer type, cancer location, cancer stage, and treatment).

Post-treatment

All patients were asked to complete the post-treatment measures. The post-treatment measures were similar as the pre-treatment measures with the exception of the TSQ, which was developed for this study. Only those in the TeleCBT-I group were asked to complete the TSQ. The TeleCBT-I group completed the post-treatment measures during the last portion of their fourth treatment session, while the control group completed the post-treatment measures four weeks after the clinical interview. Patients were given the option to complete the measures in person or by phone. Following, patients were mailed a letter thanking them for their participation in the study. In addition, the letter included general sleep recommendations and patient's individualized scores on insomnia severity, sleep quality, depression and anxiety at pre- and post-treatment. Appendix J shows the template for the end treatment letter.

One-Month Follow-Up

Given that RCTs often estimate treatment effects by evaluating follow-up outcomes between treatment groups (Karlsson & Bergmark, 2015), both treatment groups were asked to complete follow-up measures. Patients in the TeleCBT-I group completed follow-up measures four weeks after completing treatment, while the control group completed follow-up measures four weeks after post-measures. Patients in the control group were offered the TeleCBT-I treatment after completing follow-up measures.

Statistical Analyses

Data Preparation

All analyses were performed using SPSS version 25 (IBM). Data was entered and verified independently by two research assistants. Examination of missing data, outliers and distributions was performed using standard procedures as outlined by Tabachnick & Fidell (2013). After inspecting data for accuracy, missing values were evaluated. Missing values detected were minimal and accounted for less than 5% on each of the few variables that had missing values. As a result, no missing data was imputed and missing cases were excluded using listwise deletion.

Normality was assessed by evaluating plots, and computing skewness and kurtosis. Considering the small sample size of this study ($N < 50$), skewness and kurtosis were evaluated using conventional and conservative standards as recommended by (Tabachnick & Fidell, 2007; Tabachnick & Fidell, 2013). Except for physical well-being, all variables had skewness and kurtosis scores below the absolute value of 3.29. Outliers were identified by evaluating studentized residuals at a multivariable level, including the two treatment groups and three time points together. Studentized residual values greater than the absolute value of 3.00 were considered outliers. Using this parameter, one case was identified as an outlier on HADS anxiety and QOL physical subscales at one-month follow-up.

Based on the pattern of relatively normal distribution across variables, parametric statistics were computed. Outliers were removed from analyses as appropriate and results with and without outliers were reported. The assumption of sphericity was evaluated using

Mauchly's test to determine whether the variances of differences were roughly equal. The Greenhouse-Geisser estimate was used when the sphericity assumption was not met as per recommended statistical parameters (Field, 2013; Tabachnick & Fidell, 2013).

Data Analyses

The TeleCBT-I and control groups were compared using *t*-tests, chi-square or Fisher's exact test analyses, as appropriate, on demographic, clinical variables and outcome variables at pre-treatment. Repeated measures analysis of variance (RM ANOVA) was used to evaluate the difference in the rates of change between the TeleCBT-I and control groups over the three time points. The basic model of group (coded as TeleCBT-I =1 and Control = 0), Time (pre-treatment, post-treatment, follow-up), and group x time as fixed effects. The outcome models included a treatment main effect to determine whether there is an overall difference between groups and a time main effect to determine whether scores changed over time. The main interest was in the group x time interaction effects to address the hypotheses that change by time differed by treatment group. Measures that demonstrated a significant treatment x time interaction were included in follow-up analyses.

Follow-up analyses followed the general linear model with three time points. Bonferroni adjusted post hoc tests were conducted to examine treatment differences in changes from pre-treatment to post-treatment and changes from pre-treatment to follow-up. Additionally, to demonstrate clinically meaningful changes at different time points, the insomnia severity scores were coded using its clinical cut off as: No clinically significant

insomnia (0-7), Subthreshold insomnia (8-14), Clinical insomnia (moderate severity) (15-21), and Clinical insomnia (severe) (22-28).

Effect Size

Partial eta^2 is commonly used in ANOVA designs as a measure of effect size and is often recommended particularly for repeated measures analyses (Field, 2013). In this study, partial eta^2 was used to estimate the percentage of variance in each of the effects (main effects and interactions). Results are interpreted as percentages of variance by moving the decimal point two places to the right. In addition, partial eta^2 is interpreted using cut offs for the magnitude of the effect as follows: .01 (small), .06 (medium) and .14 (large) (Cohen, 1988). Hedges' *g* was computed as an additional measure to estimate the magnitude of effect size by treatment groups. Hedges' *g* was chosen instead of Cohen's *d* because it accounts for small and unequal sample sizes (Hand, 2012). Hedges' *g* is interpreted using the Cohen's criteria for small (0.2), medium (0.5) and large (0.8) treatment effects.

Sample Size and Power Analyses

Repeated measures designs offer several benefits over independent measures designs (Field, 2013). Broadly, by including the same participants within each condition of the independent variables, the variance and bias caused individual differences is reduced. The results of the error term tend to be smaller producing greater statistical power. That is, if an effect exists, it is more likely to be detected. Lastly, repeated measures designs require a smaller number of participants (Field, 2013). Considering the merits of repeated measures

designed mentioned above, sensitivity analyses were computed to determine the population effect size for the study sample (Cohen, 1988).

Power analyses were computed with G Power 3.1.9.2. With an alpha level of .05, statistical power of .80, and a total sample size of 35, effect sizes > d = 0.86 could be detected when evaluating whether there is a mean difference between the TeleCBT-I and the control group (Cohen, 1988). Sensitivity analyses were also computed for the evaluation of mean differences between groups for time and group x time interactions using standard parameters (alpha = .05, power = .80) and sample size of 35 for three measures and two groups. With these statistical parameters, an effect size > d = 0.40 could be detected (Cohen, 1988).

Intention to Treat Analysis

The intention to treat (ITT) analysis is typically recommended for randomized controlled trials (Fisher et al., 2017; Ten Have et al., 2009) as it reflects real-world clinical practices where patients discontinue treatment or do not engage in treatment at all. ITT estimates treatment effects based on all randomized participants regardless of whether they adhered or completed the assigned treatment (Fisher et al., 2017; Hernán & Hernández-Díaz, 2012). The application of ITT analysis is critical for studies with substantial missing data resulting from lack of adherence and drop outs (Hernán & Hernández-Díaz, 2012). However, ITT also has its disadvantages as it may dilute the effects of a treatment due to noncompliance, and add heterogeneity in the sample by mixing together participants who are noncompliant, compliant, and drop outs. Further, it does not assess treatment efficacy accurately as it considers participants who have not received the intervention or have not completed the entire dose of an intervention or treatment (Gupta, 2011).

One alternative to ITT analysis is the as per-protocol (PP) analysis. PP analysis includes a subset of the ITT population by including participants who completed treatment without major protocol deviations and excluding those who did not complete treatment or did not receive the treatment (Gupta, 2011; Hernán & Hernández-Díaz, 2012). In fact, researchers have argued that it is advisable to exclude participants post-randomization if they did not receive the treatment and their allocation does not impact the chances of other participants to receive the treatment (Fergusson, Aaron, Guyatt, & Hébert, 2002). Thus, while ITT tends to make two treatments look similar, one advantage of PP is that it does a better job at reflecting treatment differences by analyzing data from participants who completed treatment and

provided outcome measures. Although PP estimates the true efficacy of a treatment, it may provide exaggerated treatment effects. Given the above mentioned strengths and limitations of these statistical analyses, the CONSORT guidelines for parallel group RCTs recommend that both ITT and PP analyses should be reported to allow participants to better interpret treatment effects (Moher et al., 2010)

Considering the entire randomized population for this study (N = 39), 35 patients completed pre-and post-treatment measures, 3 did not receive the TeleCBT-I treatment and only one 1 patient dropped out without completing the treatment, PP analysis was deemed more appropriate as the main goal of the study is to evaluate treatment efficacy. ITT analysis was also performed to adhere to the CONSORT guidelines and ascertain the potential for selection bias (Moher et al., 2010). ITT analysis was conducted using the last observation carried forward (LOCF) for the four patients who did not complete the intervention and post-treatment measures. Results from ITT analysis are presented after the main PP results.

CHAPTER FOUR: RESULTS

Demographic and Sample Characteristics

Patients were recruited in the study from January 2018 through March 2019. The total sample comprised 35 cancer patients who completed pre-treatment and post-treatment measures. Most patients were females (*n* = 30, 85.71%) with a mean age of 55.26 years (*SD* = 10.72; range 29-74). Over half of the sample self-identified as non-Hispanic Whites (*n* = 20, 57.1%), while a quarter as Hispanics (*n* = 9, 25.7%), and a small portion as Blacks/African Americans (*n* = 4, 11.4%) and mixed race/ethnicity (*n* = 2, 5.7%). Marital status was fairly distributed as patients reported being currently married (*n* = 13, 37.1%), divorced (*n* = 10, 28.6%), single (*n* = 8, 22.9%) or widowed (*n* = 4, 11.4%). Most patients were either full-time employed (*n* = 13, 37.1%) or retired (*n* = 12, 34.3%). Almost the entire sample had completed some college, higher education or more (*n* = 33, 94.3%). Patients' reported personal annual income ranged from less than $25,000 (*n* = 12, 34.2%) to $50,000 or more (*n* = 14, 40%).

Table 3 depicts the demographic and sample characteristics by treatment group. There were no statistically significant differences between treatment groups on demographic and sample characteristics variables, except for personal income.

Table 3.
Demographic and sample characteristics by treatment group

	TeleCBT-I (n = 19)		Control (n = 16)		
	Mean	SD	Mean	SD	
Variables	**No**	**%**	**No**	**%**	***p***
Age (years)	56.37	9.64	53.94	12.07	.512
	Range = 36 to 71		Range = 29 to 74		
Sex					.642
Female	17	89.5	13	81.3	
Race/Ethnicity					.377
Non-Hispanic White	12	63.2	8	50	
African American	2	10.5	2	12.5	
Hispanic	3	15.8	6	37.5	
Mixed	2	10.5	-	-	
Marital status					.440
Single	3	15.8	5	31.3	
Married	6	31.6	7	43.8	
Divorced	7	36.8	3	18.8	
Widowed	3	15.8	1	6.3	
Highest Level of Education					.239
High School or GED	-	-	2	12.5	
Some College	5	26.3	5	31.3	
Bachelor's degree	7	36.8	7	43.8	
Master's degree	7	36.8	2	12.5	
Employment					.490
Part-time	2	10.5	2	12.5	
Full-time	8	42.1	5	31.3	
Unemployed	2	10.6	1	6.3	
Retired	7	36.8	5	31.3	
Disabled	-	-	3	18.8	
Income					.048*
Less than $15,000	2	10.5	4	25	
15,000-24,999	3	15.8	3	18.8	
25,000-34,999	-	-	4	25	
35,000-49,999	4	21.1	-	-	
50,000-74,999	4	21.1	1	6.3	
75,000 or more	6	31.6	3	18.8	
Missing	-	-	1	6.3	

Note. Significance tests for continuous variables were determined with independent samples *t-tests* (2-tailed), while Fisher's exact tests were used for dichotomous and categorical variables.
Abbreviations: TeleCBT-I, Telephone-delivered cognitive behavioral therapy for insomnia; SD, standard deviation; No, frequency; %, percentage; GED, general educational development test.
Income (n = 34).
*p < .05.

Similarly, there was no difference between treatment groups on cancer related variables. In the total sample, patients reported having a cancer diagnosis of stage I (*n* = 12, 34.3%), stage II (*n* = 7, 20%), state III (*n* = 5, 14.3%), stage IV (*n* = 5, 14.3%), and some did not know their cancer stage diagnosis (*n* = 6, 17.13%). Most patients reported a breast cancer diagnosis (*n* = 20, 57.1%) and were diagnosed either two or more years ago (*n* = 17, 48.6%) or less than a year ago (*n* = 12, 34.3%).

In terms of past and current cancer treatment, most patients reported that they received surgery (*n* = 27, 77.1%), chemotherapy (*n* = 24, 68.6%), radiotherapy (*n* = 24, 68.6%), and hormonal therapy (*n* = 15, 42.9%). However, while a significant portion of patients were not undergoing cancer treatment at the time of the study (*n* = 16, 45.7%), more than half were receiving hormonal therapy (*n* = 9, 25.7%), chemotherapy (*n* = 4, 11.4%), radiotherapy (*n* = 4, 11.4%), and/or surgery (*n* = 4, 11.4%). Table 4 shows the cancer related information by treatment group.

Table 4
Cancer Related Information by Treatment Group

	TeleCBT-I (*n* = 19)		Control (*n* = 16)		
Variables	**No**	**%**	**No**	**%**	***p***
Cancer stage					.369
Stage I	7	36.8	5	31.3	
Stage II	6	26.3	2	12.5	
Stage III	3	15.8	2	12.5	
Stage IV	3	15.8	2	12.5	
Don't know	1	5.3	5	31.3	
Time since cancer diagnosis					.319
Less than one year	6	31.6	6	37.5	
One to two years ago	5	26.3	1	6.3	
Two or more years ago	8	42.1	9	56.3	
Cancer location					.406
Breast	13	68.4	7	43.8	
Brain	1	5.3	3	18.8	
Skin	-	-	1	6.3	
Colon	1	5.3	1	6.3	
Head and Neck	1	5.3	2	12.5	
Kidney	-	-	1	6.3	
Musculoskeletal	-	-	1	6.3	
Lung	1	5.3	-	-	
Blood	1	5.3	-	-	
Ovarian	1	5.3	-	-	
Past cancer treatments					
Chemotherapy	15	78.9	9	56.3	.273
Radiation therapy	13	68.4	11	68.8	>.05
Surgery	14	73.7	13	81.3	.700
Hormone therapy	10	52.6	5	31.3	.306
No past treatment	-	-	1	6.3	.457
Current cancer treatments					
Chemotherapy	3	15.8	1	6.3	.608
Radiation Therapy	2	10.5	2	12.5	>.05
Surgery	2	10.5	2	12.5	>.05
Hormone therapy	7	36.8	2	12.5	.135
No current treatment	6	31.6	10	62.5	.095

Note. Differences by group were determined with Chi-square and Fisher's exact tests.
Abbreviations: TeleCBT-I, Telephone-delivered cognitive behavioral therapy for insomnia; SD, standard deviation; No = Frequency; % = Percentage.

Pre-treatment Characteristics

Sleep Variables

At pre-treatment, the average insomnia severity score as measured by the ISI was 17.66 (*SD* = 4.07) indicating clinically significant insomnia with moderate severity for the entire sample. The average sleep quality as measured by the PSQI was 11.83 (*SD* = 3.44) and indicated poor sleep quality. Patients reported dysfunctional beliefs about sleep as measured by the DBAS-16 with a mean score of 5.24 (*SD* = 1.62). Further, about half of the patients were taking prescribed sleep medications prior to treatment (*n* = 18, 51.4%). There was no difference between groups on any of the sleep outcome variables at pre-treatment. Table 5 depicts the sleep outcome measures at pre-treatment for each treatment group.

Table 5.
Scores on Sleep Measures and Group Differences at Pre-treatment

	TeleCBT-I (*n* = 19)		**Control (*n* = 16)**				
Variables	**Mean**	**SD**	**Mean**	**SD**	***t* (33) / χ^2**	***p***	**95% CI**
ISI	17.79	3.57	17.50	4.71	.207	.837	[-2.56, 3.14]
PSQI	11.95	3.05	11.69	3.96	.219	.828	[-2.15, 2.67]
DBAS-16	4.98	1.50	5.55	1.75	-1.02	.315	[-1.68, 0.56]
Sleep Medication % (*n*)	52.6	10	8	50	.024	> .05	

Note. Significance tests were determined with independent samples t-tests (2-tailed) or chi-square tests. Abbreviations: TeleCBT-I, telephone-delivered cognitive behavioral therapy for insomnia; SD, standard deviation; ISI, insomnia severity inventory; PSQI, Pittsburgh sleep quality index; DBAS-16, dysfunctional beliefs about sleep.

Psychological Variables

In the entire sample, patients reported scores higher than three, indicating clinically significant levels of fatigue at pre-treatment (M = 4.74, SD = 2.01) as measured by the FSI. However, patients reported no clinical levels of anxiety (M = 8.14, SD = 4.35) and depression (M = 6.17, SD = 4.23) as measured by the HADS.

In terms of functional assessment of health-related quality of life, the FACT-G pre-treatment scores were examined using the normative data for cancer patients (Brucker, Yost, Cashy, Webster, & Cella, 2005). In the total sample, patients reported normal levels of general functioning (M =72.03, SD = 17.43), physical well-being (M = 19.37, SD = 4.96), social/family well-being (M = 19, SD = 6.27), emotional well-being (M = 17.06, SD = 4.63), and functional well-being (M = 16.6, SD = 5.31).

In terms of quality of life, patients reported scores slightly greater than the midpoint on the quality of life measure (QOL-CS) suggesting positive, but not optimal levels of overall quality of life (M = 5.72, SD = 1.45), physical QOL (M = 6.26, SD = 1.70), psychological QOL (M = 5.84, SD = 1.96), social QOL (M = 5.82, SD = 2.11), and spiritual QOL (M = 6.05, SD = 2.15). Table 6 presents the results for the psychological outcome variables by treatment group. No differences were found between groups in all psychological variables.

Table 6.
Scores on Psychological Measures and Group Differences at Pre-treatment

	TeleCBT-I (*n* = 19)		Control (*n* = 16)				
Variables	**Mean**	**SD**	**Mean**	**SD**	***t* (33)**	***p***	**95% CI**
FSI	4.60	1.62	4.90	2.44	-.422	.676	[-1.69, 1.11]
HADS-Depression	5.58	4.80	6.88	3.44	-.902	.374	[-4.22, 1.63]
HADS-Anxiety	7.89	4.22	8.44	4.62	-.363	.719	[-3.58, 2.50]
FACT-General	71.37	19.21	72.81	15.63	-.241	.811	[-13.64, 10.76]
Physical well-being	19.79	5.13	18.88	4.87	.538	.594	[-2.55, 4.37]
Social/Family well-being	18.42	6.68	19.69	5.88	-.590	.559	[-5.64, 3.10]
Emotional well-being	17.11	4.99	17	4.32	.066	.948	[-3.14, 3.35]
Functional well-being	16	5.88	17.31	4.63	-.723	.475	[-5.00, 2.38]
QOL-CSV Total	5.83	1.50	5.59	1.42	.469	.642	[-.78, 1.25]
Physical	6.23	1.64	6.3	1.81	-.115	.909	[-1.26, 1.12]
Psychological	5.86	2.25	5.82	1.63	.059	.953	[-1.34, 1.42]
Social	6.09	1.82	5.49	2.43	.826	.415	[-.87, 2.05]
Spiritual	5.96	2.30	6.16	2.02	-.272	.787	[-1.70, 1.30]

Note. Significance tests were determined with independent samples *t-tests* (2-tailed).
Abbreviations: TeleCBT-I, telephone-delivered cognitive behavioral therapy for insomnia; FSI, fatigue symptom inventory; HADS-Depression, depression subscale of hospital anxiety and depression scale; HADS-Anxiety, anxiety subscale of hospital anxiety and depression scale; FACT, functional assessment of cancer therapy; QOL-CSV, quality of life patient/cancer survivor version.

Post-treatment Outcomes

Sleep Variables

Insomnia Severity

The TeleCBT-I intervention resulted in significantly greater improvements in insomnia severity than the control group. The ISI mean decreased from 17.79 (*SD* = 3.57) to 7.58 (*SD* = 3.78) in the TeleCBT-I group reaching no clinically significant level at post-treatment. However, the ISI mean decreased from 17.50 (*SD* = 4.71) to 14.88 (*SD* = 5.82) in the control group sustaining clinically significant levels of insomnia severity at post-treatment. Hedges' *g* of the TeleCBT-I group was 2.72, while the Hedges' *g* of the control group was 0.48. There was significant within-subjects main effect across pre- and post-treatments, $F(1, 33) = 81.01$, $p < .001$, partial $\eta^2 = .711$, and a significant main effect between treatment groups, $F(1, 33) = 6.8$, $p = .014$, partial $\eta^2 = .171$. The significant Group x Time interaction, $F(1, 33) = 28.29$, $p < .001$, partial $\eta^2 = .462$, revealed that both groups reported decreased symptoms of insomnia severity at post-treatment. Post hoc comparisons revealed statistically significant differences between pre-treatment and post-treatment in both treatment groups, TeleCBT-I ($p < .001$) and control ($p = .018$). Figure 1 shows the mean scores on insomnia severity for the TeleCBT-I and control groups from pre-treatment to post-treatment.

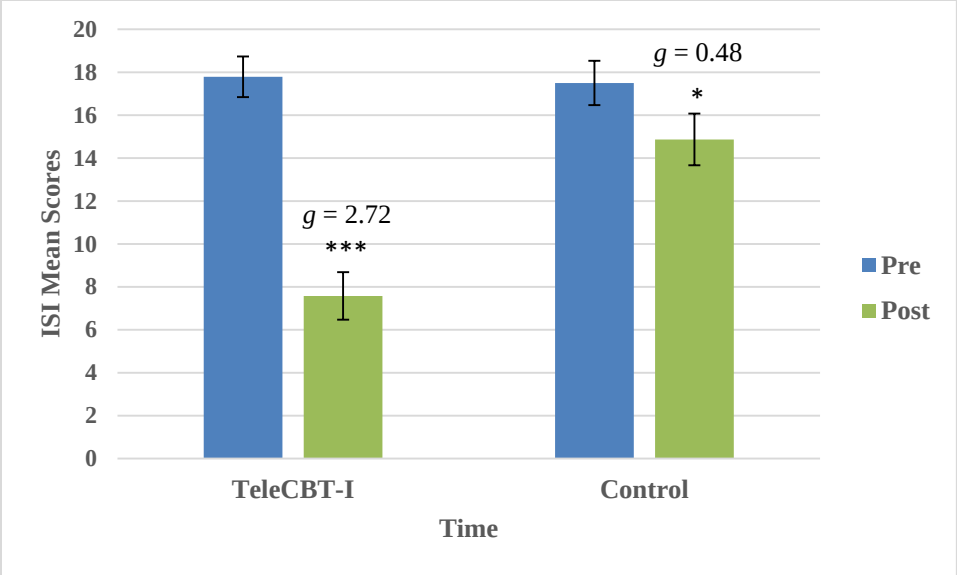

Figure 1.
Scores on Insomnia Severity by Group at Pre-treatment and Post-treatment

Note. Error bars represent 95% confidence intervals.
*$p < .05$, ***$p < .001$.

To examine meaningful clinical change in insomnia severity scores as a function of ISI clinical cut offs (0-7 = No clinically significant insomnia; 8-14 = Subthreshold insomnia, 15-21 = clinical insomnia/moderate severity, 22-28 = clinical insomnia/severe) from pre- to post-treatment, Fisher's exact tests were computed and demonstrated no difference between TeleCBT-I and control groups at pre-treatment. However, a statistical significance was observed between treatment groups at post-treatment where those in the TeleCBT-I group were more likely to endorse no clinically significant insomnia compared to control group (n = 12, 63.2% vs. n = 1, 6.3%), respectively (p = .001).

Sleep Quality

As shown in Figure 2, the TeleCBT-I group reported significantly greater improvements in sleep quality at post-treatment compared to the control group. The TeleCBT-I group showed a significant reduction from pre-treatment (M = 11.95, SD = 3.05) to post-treatment (M = 6, SD = 2.36), while the control group showed virtually no change from pre-treatment (M = 11.69, SD = 3.96) to post-treatment (M = 11.06, SD = 4.06) in sleep quality. Hedges' g of the TeleCBT-I group was 2.14, while the Hedges' g of the control group was 0.15. There was significant within-subjects main effect across pre- and post-treatments, $F(1, 33) = 37.67$, $p < .001$, partial $\eta^2 = .533$, and a significant main effect between treatment groups, $F(1, 33) = 5.65$, $p = .023$, partial $\eta^2 = .146$. There was also a significant Group x Time interaction, $F(1, 33) = 24.7$, $p < .001$, partial $\eta^2 = .428$. Post hoc comparisons revealed a statistically significant difference between pre-treatment and post-treatment in the TeleCBT-I group only ($p < .001$).

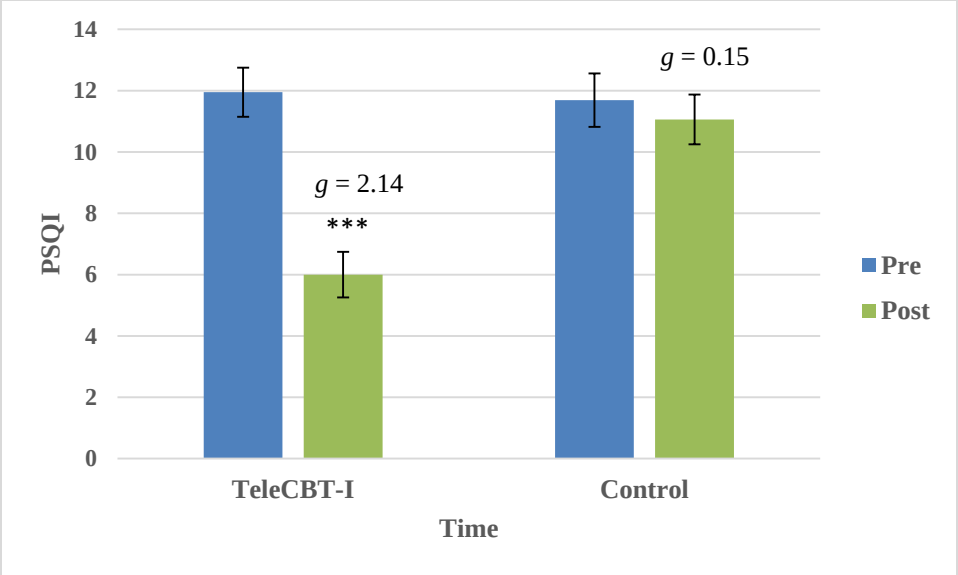

Figure 2.
Scores on Sleep Quality by Group at Pre-treatment and Post-treatment

Note. Error bars represent 95% confidence intervals.

****p* < .001.

Dysfunctional Beliefs about Sleep

The TeleCBT-I group showed reduced dysfunctional sleep beliefs from pre-treatment (*M* = 4.98, *SD* = 1.50) to post-treatment (*M* = 3.28, *SD* = 1.65), while the control group showed slightly similar levels of dysfunctional sleep beliefs from pre-treatment (*M* = 5.55, *SD* = 1.75) to post-treatment (*M* = 5.01, *SD* = 1.99). Hedges' *g* of the TeleCBT-I group was 1.06, while the Hedges' *g* of the control group was 0.28. There was a significant within-subjects main effect across pre- and post-treatments, $F(1, 33) = 22.32$, $p < .001$, partial $\eta^2 = .403$, and a significant main effect between treatment groups, $F(1, 33) = 4.63$, $p = .039$, partial $\eta^2 = .123$. There was also a significant interaction between treatment group and time, $F(1, 33) = 6.08$, $p =$

.019, partial η^2 = .156. Post hoc comparisons revealed a statistically significant difference between pre-treatment and post-treatment in the TeleCBT-I group only (p < .001). Figure 3 exhibits the mean scores on dysfunctional beliefs about sleep by treatment groups from pre-treatment to post-treatment.

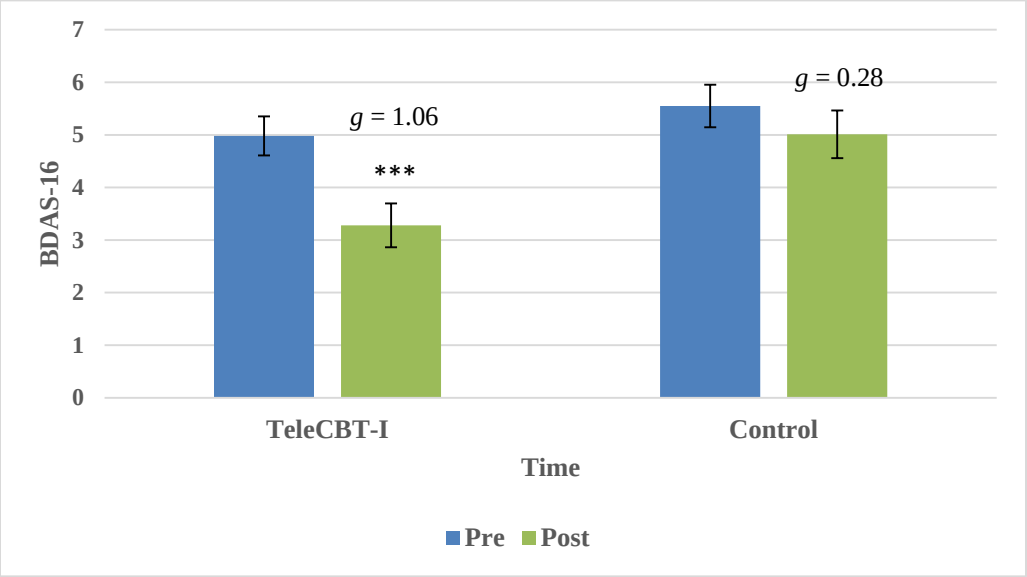

Figure 3.
Scores on Dysfunctional Beliefs about Sleep by Group at Pre-treatment and Post-treatment

Note. Error bars represent 95% confidence intervals.
***p < 0.001.

Sleep Medication

Patients in the TeleCBT-I group reported reduced use of sleep medication from pre-treatment (52.63%, n = 10) to post-treatment (15.79%, n = 3).

Table 7.
Scores on Sleep Measures by Group at Pre-treatment and Post-treatment and Treatment Effects

	Pre-treatment		Post-treatment			LMM Statistical Tests (Type III tests of fixed effects)								
						Time Effect			Group Effect			Group x Time Interaction		
Variables	*Mean*	*SD*	*Mean*	*SD*	*g*	***F*(1, 33)**	***p***	**Partial η^2**	***F*(1, 33)**	***p***	**Partial η^2**	***F*(1, 33)**	***p***	**Partial η^2**
ISI														
TeleCBT-I	17.79	3.57	7.58_a***	3.78	2.72	81.01	< .001	.711	6.80	.014	.171	28.29	< .001	.462
Control	17.50	4.71	14.88_a*	5.82	0.48									
PSQI														
TeleCBT-I	11.95	3.05	6_a***	2.36	2.14	37.67	< .001	.533	5.65	.023	.146	24.70	< .001	.428
Control	11.69	3.96	11.06	4.06	0.15									
DBAS-16														
TeleCBT-I	4.98	1.50	3.28_a***	1.65	1.06	22.32	< .001	.403	4.63	.039	.123	6.08	.019	.156
Control	5.55	1.75	5.01	1.99	0.28									

Note. TeleCBT-I (n = 19); Control (n = 16); Group effect sizes were computed as Hedges' g values.
Abbreviations: TeleCBT-I, telephone-delivered cognitive behavioral therapy for insomnia; ISI, insomnia severity inventory; PSQI, Pittsburgh sleep quality index; DBAS-16, dysfunctional beliefs about sleep.
Means with subscript ($_a$) are significantly different according to post hoc comparisons.
*p < .05, **p < .01, ***p < .001.

Psychological Variables

Fatigue

As presented in Table 8, the TeleCBT-I group mean was reduced from pre-treatment (*M* = 4.60, *SD* = 1.62) to post-treatment (*M* = 3.01, *SD* = 2.48), reaching no clinically significant level of fatigue at post-treatment. However, the control group showed slightly increased levels of fatigue from pre-treatment (*M* = 4.89, *SD* = 2.44) to post-treatment (*M* = 5.27, *SD* = 2.09). Hedges' *g* of the TeleCBT-I group was 0.74, while the Hedges' *g* of the control group was 0.16. The results revealed only statistically significant Group x Time interaction on fatigue, $F(1, 33) = 10.21$, $p < .003$, partial $\eta^2 = .236$. Post hoc comparisons yielded a statistically significant difference between pre-treatment and post-treatment in the TeleCBT-I group only ($p = .002$).

Depression

The TeleCBT-I group reported similar scores from pre-treatment (*M* = 5.58, *SD* = 4.80) to post-treatment (*M* = 5.37, *SD* = 5.93) on depression. However, the control group reported slightly increased symptoms of depression from pre-treatment (*M* = 6.88, *SD* = 3.44) to post-treatment (*M* = 7.13, *SD* = 4.23). Hedges' *g* of the TeleCBT-I group was 0.04, while the Hedges' *g* of the control group was -0.06. The effects of Time ($p = .975$), Group ($p = .314$), and Time x Group interaction ($p = .711$) were not significant on depression.

Anxiety

Both treatment groups reported slightly reduced scores from pre-treatment to post-treatment on anxiety. The HADS-Anxiety score decreased from 7.89 (*SD* = 4.22) to 6.53 (*SD* = 3.22) in the TeleCBT-I group and from 8.44 (*SD* = 4.61) to 7 (*SD* = 4.27) in the control group. Hedges' *g* of the TeleCBT-I group was 0.36, while the Hedges' *g* of the control group was 0.32. Although no main effects were observed by Group (p = .95) and Group x Time interaction (p = .69), there was a statistically significant Time effect on anxiety, $F(1, 33) = 5.90$, $p < .021$, partial $\eta^2 = .152$. However, post hoc comparisons were not statistically significant for both treatment groups.

Functional Assessment of Cancer Therapy

Table 8 shows the mean and standard deviations of FACT-G and its subscales by treatment group. The FACT general and subscales scores were within the normal range of functioning in both treatment groups at pre-treatment and post-treatment. Nonetheless, the TeleCBT-I group resulted in slightly increased scores, while the control group reported slightly decreased scores from pre-treatment to post-treatment on the FACT general and all its subscales. Hedges' *g* of the TeleCBT-I group for FACT general and all its subscales ranged from 0.24 to 0.45, while for the control group ranged was from 0.04 to 0.30. Overall, no main effects were observed in the FACT general and its subscales, except for Group x Time interaction on FACT general, $F(1, 33) = 6.4$, $p = .016$, partial $\eta^2 = .162$, physical well-being subscale, $F(1, 33) = 8.20$, $p = .007$, partial $\eta^2 = .199$ and functional well-being subscale, $F(1, 33) = 5.98$, $p = .020$, partial

η^2 = .153. Post hoc comparisons resulted in statistically significant differences between pre-treatment and post-treatment in the TeleCBT-I group for physical well-being (p = .017) and functional well-being (p = .051) subscales, while the control group revealed a statistically significant difference between pre-treatment and post-treatment only on the FACT general (p = .020).

Quality of Life in Cancer Patients

Table 9 shows the mean and standard deviations of QOL-CSV and its subscales by treatment group. A similar trend was found in quality of life as the TeleCBT-I group reported slightly improved quality of life from pre-treatment to post-treatment in QOL-CSV total and all its subscales. In contrast, the control group showed no changes on QOL-CVS total and its psychological and social subscales. Furthermore, the control group showed slightly decreased scores on QOL physical, but increased scores on QOL spiritual from pre-treatment to post-treatment. Hedges' g of the TeleCBT-I group for QOL-CVS Total and all its subscales ranged from 0.10 to 0.80, while for the control group ranged from was 0.01 to 0.36. No significant main and interaction effects were found on QOL-CVS total and all its subscales, except for the Group x Time interaction on QOL physical, $F(1, 33) = 15.05$, $p < .001$, partial η^2 = .313. The same pattern was observed when analyses excluded one outlier for the QOL physical subscale. That is, the QOL physical subscale showed significant Time x Group interaction, $F(1, 32) = 13.17$, p = .001, partial η^2 = .292, but no main effects. Post hoc comparisons yielded a statistically significant difference between pre-treatment and post-treatment in the TeleCBT-I group for QOL physical subscale only (p = .001)

Table 8.
Scores on Psychological Measures by Group at Pre-treatment and Post-treatment and Treatment Effects

						LMM Statistical Tests (Type III tests of fixed effects)								
	Pre-treatment		Post-treatment			Time Effect			Group Effect			Group x Time Interaction		
Variables	*Mean*	*SD*	*Mean*	*SD*	*g*	*F*(1, 33)	*p*	Partial η^2	*F*(1, 33)	*p*	Partial η^2	*F*(1,33)	*p*	Partial η^2
FSI														
TeleCBT-I	4.60	1.62	3.01 $_a$**	2.48	0.74	3.86	.058	.105	3.61	.066	.099	10.21	.003**	.236
Control	4.89	2.44	5.27	2.09	0.16									
HADS-Depression														
TeleCBT-I	5.58	4.80	5.37	5.94	0.04	.001	.975	.000	1.05	.314	.031	.140	.711	.004
Control	6.87	3.44	7.12	4.23	-0.06									
HADS-Anxiety														
TeleCBT-I	7.89	4.22	6.53	3.22	0.36	5.90	.021*	.152	.163	.689	.005	.004	.953	.000
Control	8.44	4.62	7	4.27	0.32									
FACT General														
TeleCBT-I	71.37	19.21	79.58	22.04	0.39	.326	.572	.010	.799	.378	.024	6.4	.016*	.162
Control	72.81	15.63	67.63 $_a$*	17.85	0.30									
Physical well-being														
TeleCBT-I	19.79	5.13	22.32 $_a$*	6.29	0.43	.000	.988	.000	3.56	.068	.097	8.20	.007**	.199
Control	18.88	4.87	16.38	7.27	0.06									
Social well-being														
TeleCBT-I	18.42	6.68	20.05	6.85	0.24	.045	.833	.001	.004	.951	.000	1.34	.256	.039
Control	19.69	5.88	18.56	5.93	0.19									
Emotional well-being														
TeleCBT-I	17.11	4.99	18.32	4.51	0.25	.732	.398	.022	.316	.578	.009	1.37	.251	.040
Control	17	4.32	16.81	4.35	0.04									
Functional well-being														
TeleCBT-I	16	5.88	18.89 $_a$*	6.56	0.45	.677	.417	.020	.256	.616	.008	5.98	.020*	.153
Control	17.31	4.63	15.88	4.91	0.29									

Note. Abbreviations: TeleCBT-I, telephone-delivered cognitive behavioral therapy for insomnia; FSI, fatigue symptom inventory; HADS-Depression, depression subscale of hospital anxiety and depression scale; HADS-Anxiety, anxiety subscale of hospital anxiety and depression scale; FACT, functional assessment of cancer therapy.
Means with subscript ($_a$) are significantly different according to post hoc comparisons; *$p < .05$, **$p < .01$.

Table 9.
Scores on Quality of Life by Group at Pre-treatment and Post-treatment and Treatment Effects

	Pre-treatment		Post-treatment			LMM Statistical Tests (Type III tests of fixed effects)								
						Time Effect			Group Effect			Group x Time Interaction		
Variables	*Mean*	*SD*	*Mean*	*SD*	*g*	*F*(1, 33)	*p*	*Partial* η^2	*F*(1, 33)	*p*	*Partial* η^2	*F*(1, 33)	*p*	*Partial* $\eta 2$
QOL-CSV Total														
TeleCBT-I	5.83	1.50	6.13	1.74	0.18	.232	.633	.007	.946	.338	.028	1.98	.169	.057
Control	5.59	1.42	5.44	1.12	0.11									
Physical														
TeleCBT-I	6.23	1.64	7.47_a**	1.38	0.80	1.86	.182	.053	2.66	.112	.075	15.05	< .001***	.313
Control	6.30	1.81	5.70	1.95	0.31									
Psychological														
TeleCBT-I	5.86	2.25	6.44	2.11	0.26	1.47	.234	.043	.316	.578	.009	1.54	.224	.045
Control	5.82	1.63	5.81	1.33	0.01									
Social														
TeleCBT-I	6.09	1.82	6.37	2.15	0.14	.241	.627	.007	1.23	.276	.036	.341	.563	.010
Control	5.49	2.43	5.47	2.14	0.01									
Spiritual														
TeleCBT-I	5.96	2.30	6.20	2.46	0.10	3.38	.075	.093	.372	.546	.011	.761	.389	.023
Control	6.16	2.02	6.84	1.65	0.36									

Note. Abbreviations: TeleCBT-I, telephone-delivered cognitive behavioral therapy for insomnia, QOL-CSV, quality of life-cancer survivor version.
Means with subscript ($_a$) are significantly different according to post hoc comparisons.
Hedges' *g* effect sizes were computed between pre-treatment and post-treatment scores by treatment group.
*****$p < .05$, ***$p < .001$.

Follow-Up Outcomes

Sleep Variables

Patients in the TeleCBT-I group indicated that the improvements observed from pre- to post-treatment in all sleep variables were sustained at one-month follow. Table 10 presents the observed means for all three time points and treatment effects by treatment groups. Only the measures that demonstrated statistically significant Group (TeleCBT-I and Control) x Time (Pre-treatment and Post-treatment) interactions were included in the follow-up analyses to assess differences between pre-treatment and follow-up and between post-treatment and follow-up.

Insomnia Severity

As shown in Figure 4, insomnia severity followed the same pattern as from pre-treatment to post-treatment. There was significant within-subjects main effect across the three time points, $F(2, 58) = 73.20$, $p < .001$, partial $\eta^2 = .716$, and a significant main effect between treatment groups, $F(1, 29) = 12.42$, $p = <.001$, partial $\eta^2 = .300$. There was also a significant interaction between treatment group and time, $F(2, 58) = 23.04$, $p < .001$, partial $\eta^2 = .443$, with post hoc tests revealing that there was a statistical significant difference in TeleCBT-I between pre-treatment and follow-up ($p < .001$), but not between post-treatment and follow-up ($p = .467$). However, there was a statistically difference in the control group between pre-treatment and follow-up ($p = .006$) and post-treatment and follow-up ($p = .043$).

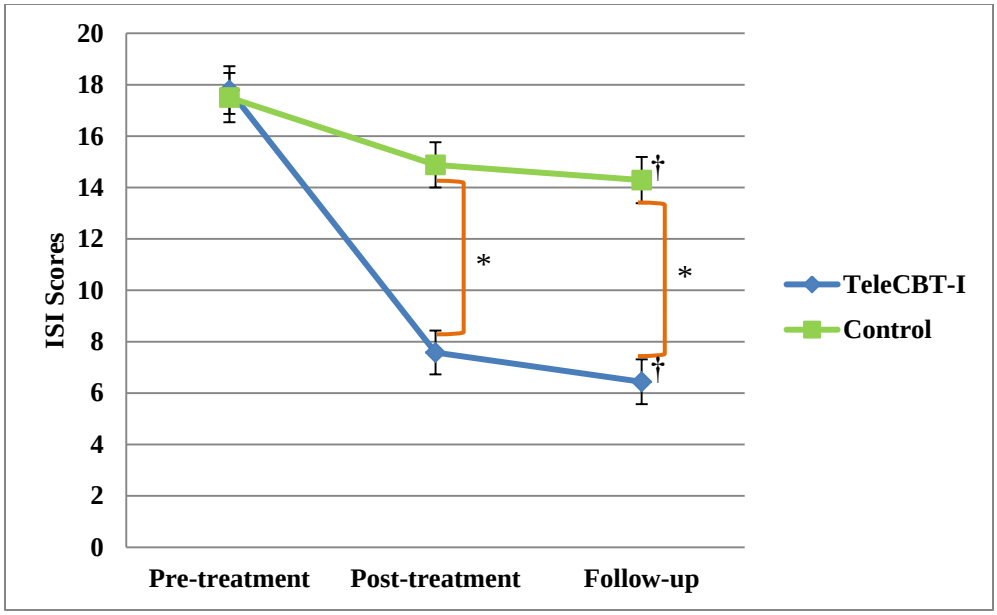

Figure 4.
Scores on Insomnia Severity across the Three Time Points

Note. Error bars represent 95% confidence intervals.
* = $p < .05$ for significant difference between groups.
† = $p < .05$ for significant main effect across times by treatment group.

Sleep Quality

Similarly, for sleep quality there was significant within-subjects main effect across the three time points, $F(2, 58) = 32.10$, $p < .001$, partial $\eta^2 = .525$, and a significant main effect between treatment groups, $F(1, 29) = 9.79$, $p = .004$, partial $\eta^2 = .252$. There was also a significant interaction between treatment group and time, $F(2, 58) = 18.88$, $p < .001$, partial $\eta^2 = .407$, with post hoc tests showing that there was a statistical significant difference in TeleCBT-I

between pre-treatment and follow-up ($p < .001$), but not between post-treatment and follow-up ($p > .05$). However, no statistically significance difference was found in the control group between pre-treatment and follow-up and between post-treatment and follow-up ($ps > .05$). Figure 5 presents the scores on sleep quality across all time points.

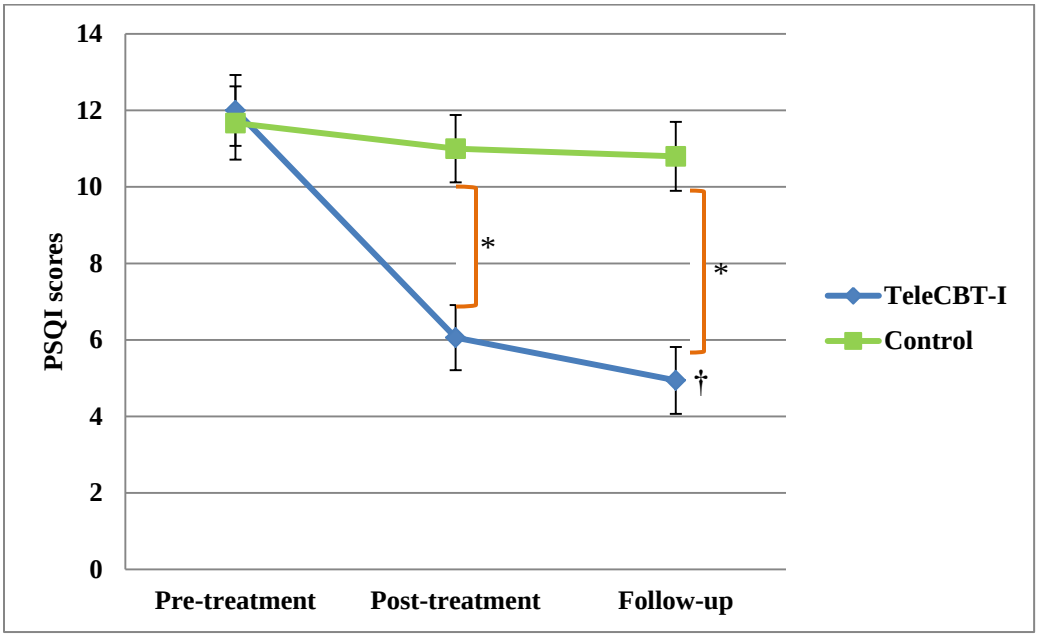

Figure 5.
Scores on Sleep Quality across the Three Time Points

Note. Error bars represent 95% confidence intervals.
* = $p < .05$ for significant difference between groups.
† = $p < .05$ for significant main effect across times by treatment group.

Dysfunctional Beliefs about Sleep

A similar pattern was observed in beliefs about sleep as in pre-treatment and post-treatment comparisons. There was significant within-subjects main effect across the three time points, $F(2, 58) = 13.77$, $p < .001$, partial $\eta^2 = .322$, and a significant main effect between treatment groups, $F(1, 29) = 4.96$, $p = .034$, partial $\eta^2 = .146$. There was also a significant interaction between treatment group and time, $F(2, 58) = 4.65$, $p = .013$, partial $\eta^2 = .138$, with post hoc tests showing that there was a statistical significant difference in TeleCBT-I for beliefs about sleep between pre-treatment and follow-up ($p = .002$), but not between post-treatment and follow-up ($p > .05$). However, no statistically significance difference was found in the control group between pre-treatment and follow-up and between post-treatment and follow-up ($ps > .05$). Figure 6 presents the scores on dysfunctional beliefs about sleep across all time points.

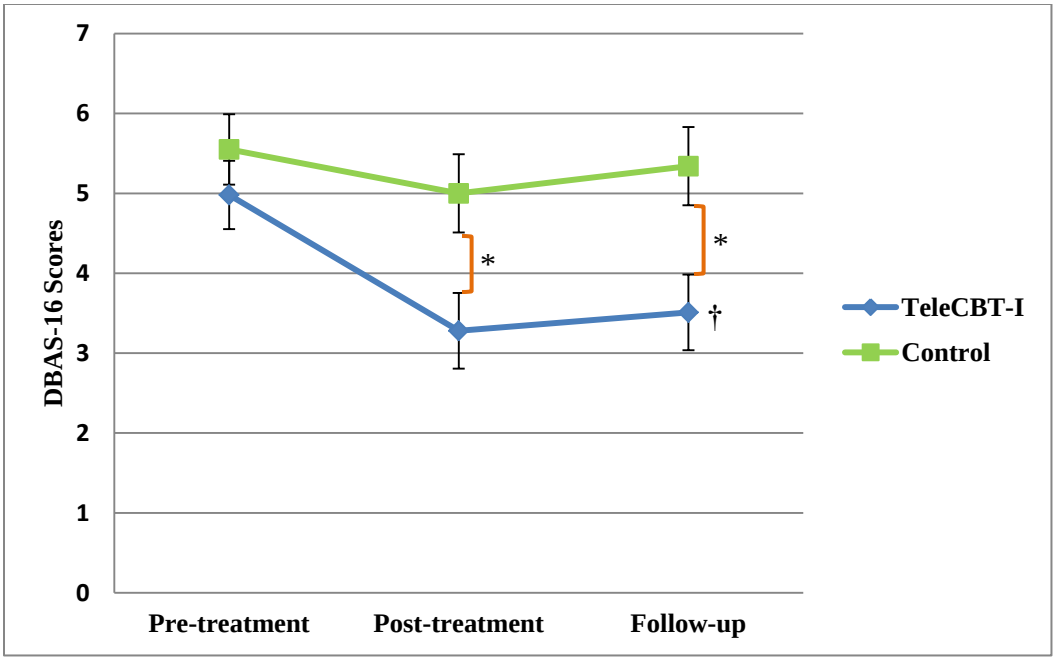

Figure 6.
Scores on Dysfunctional Beliefs about Sleep across the Three Time Points

Note. Error bars represent 95% confidence intervals.
* = $p < .05$ for significant difference between groups.
† = $p < .05$ for significant main effect across times by treatment group.

Psychological Variables

Fatigue

Although no significant main effect between treatment groups (p = .109) was found, results shown a significant within-subjects main effect across the three time points, $F(2, 58)$ = 3.16, p = .05, partial η^2 = .098 and a significant interaction between treatment group and time, $F(2, 58)$ = 3.89, p = .026, partial η^2 = .118. Post hoc tests showed that there was a statistical significant difference in the TeleCBT-I group for fatigue between pre-treatment and follow-up (p = .011), but not between post-treatment and follow-up (p > .05). However, no statistically significant difference was found in the control group between pre-treatment and follow-up and between post-treatment and follow-up (ps > .05). Figure 7 presents the scores on fatigue across all time points.

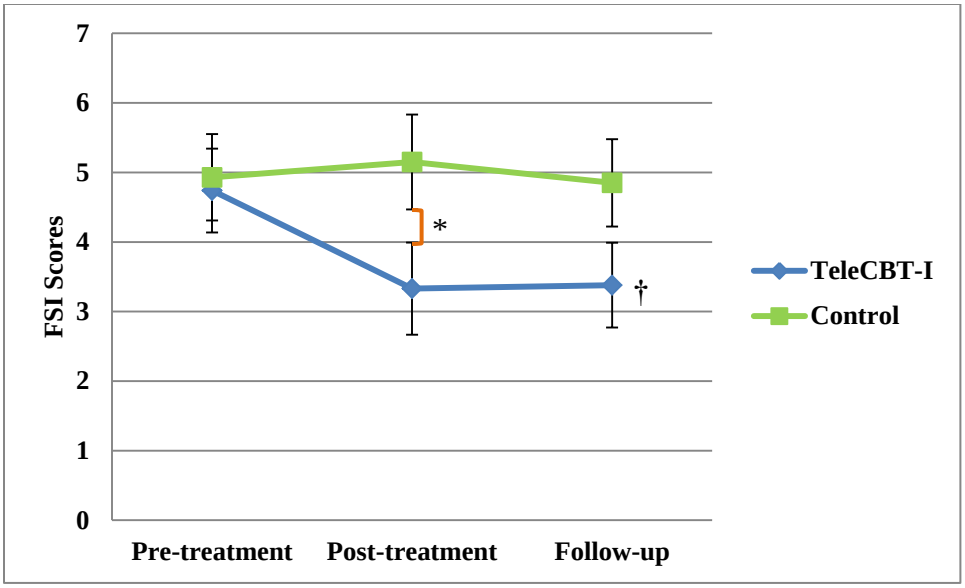

Figure 7.
Scores on Fatigue across the Three Time Points

Note. Error bars represent 95% confidence intervals.
* = $p < .05$ for significant difference between groups.
† = $p < .05$ for significant main effect across times by treatment group.

FACT General Functioning and Physical Well-Being

No statistically significant effects were observed for FACT general functioning and FACT physical well-being (*p*s > .05) at follow-up. However, FACT functional well-being showed statistically significant Group x Time interaction, $F(2, 58) = 3.92$, $p = .025$, partial $\eta^2 = .119$), but no Time and Group main effects. Nonetheless, post hoc tests revealed a statistically significant difference between pre-treatment and follow-up in the TeleCBT-I group ($p = .043$). Figure 8 depicts the scores on functional well-being across all time points.

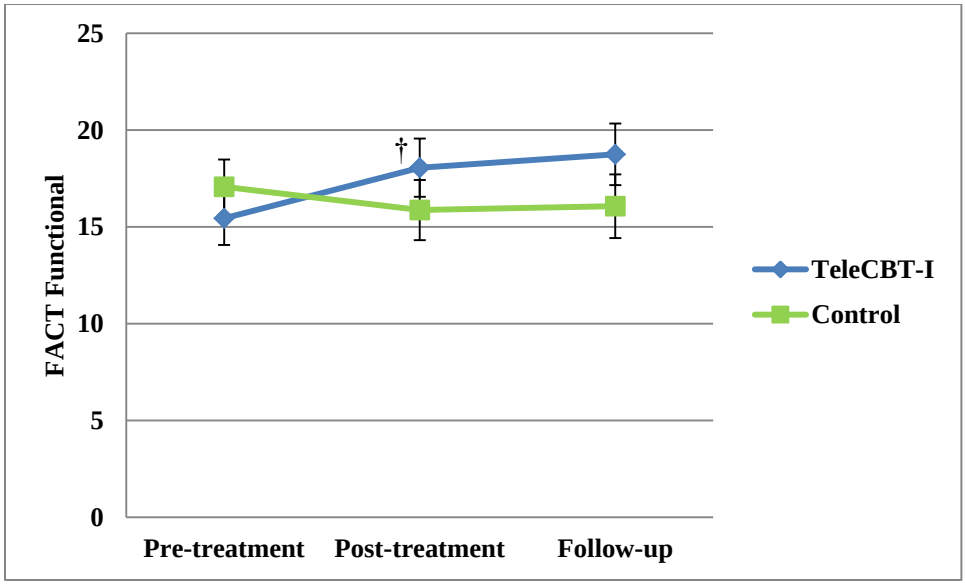

Figure 8.
Scores on Functional Well-being across All Three Time Points

Note. Error bars represent 95% confidence intervals.
† = $p < .05$ for significant change from pre-treatment to post-treatment.

Quality of Life Physical

Although there was not a statistically significant within-subjects main effect across the three time points ($p = .114$), there was a significant main effect between treatment groups, $F(1, 29) = 4.38$, $p = .045$, partial $\eta^2 = .131$. There was also a significant Group x Time interaction, $F(2, 58) = 14.24$, $p < .001$, partial $\eta^2 = .329$, with post hoc tests showing that there was a statistical significant difference in TeleCBT-I for physical QOL between pre-treatment and follow-up ($p < .001$), but not between post-treatment and follow-up ($p = .794$).

However, analyses conducted excluding one outlier revealed a slightly different pattern, as statistically significant differences were found for Time [$F(2, 56) = 3.27$, $p = .045$, partial $\eta^2 = .105$], and Time x Group interaction [$F(2, 56) = 12.30$, $p = .045$, partial $\eta^2 = .105$] effects, with similar results on post hoc tests showing statistical significant difference in TeleCBT-I for physical QOL between pre-treatment and follow-up ($p < .043$). Given the slight difference in results with and without outlier, analyses conducted without the outlier were interpreted. Figure 9 presents the scores on physical quality of life across all time points.

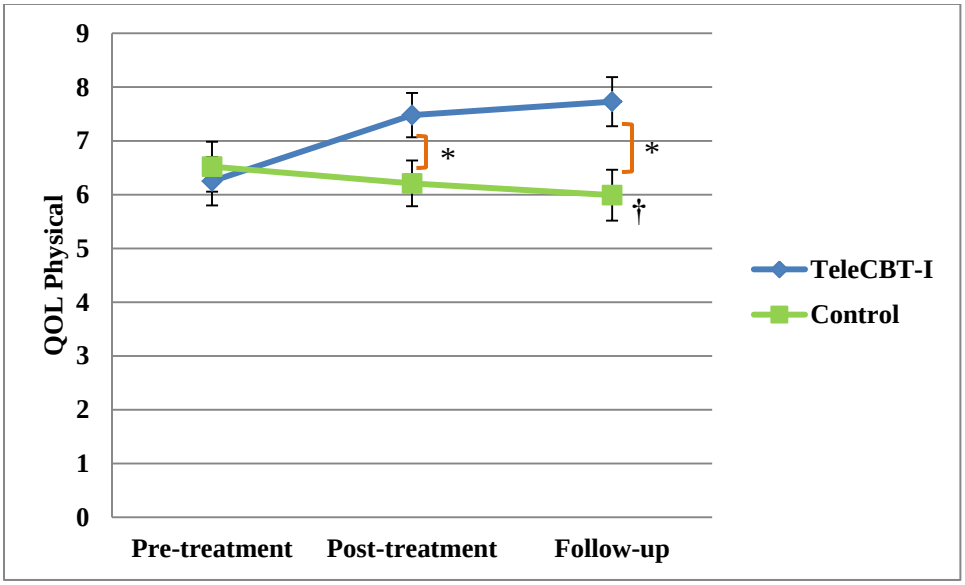

Figure 9.
Scores on Physical Quality of Life across the Three Time Points

Note. Error bars represent 95% confidence intervals.
* = $p < .05$ for significant difference between groups.
† = $p < .05$ for significant main effect across times by treatment group.

Table 10.
Sleep and Psychological Scores by Group for All Time Points, Treatment Effects, Effect Sizes, and Post Hoc Results

	Means and Standard Deviations			*p* values and Hedges' *g* in differences				*F*- Tests	
	Pre-treatment	Post- treatment	Follow- up	Pre-treatment and Follow-up		Post-treatment and Follow-up		Time x Group Interaction	Partial η^2
Variables				***p***	***g***	***p***	***g***		
ISI									
TeleCBT-I	17.75 (3.84)	7.37 (3.68)	6.44 (4.53)	< .001***	2.7	.467	0.22	$F(2, 58) = 23.04$	.443
Control	17.73 (4.77)	15.60 (5.22)	13.87 (5.64)	.006**	0.72	.043*	0.31	$p < .001$***	
PSQI									
TeleCBT-I	12 (3.31)	6.06 (2.46)	4.94 (2.72)	< .001***	2.3	.163	0.43	$F(2, 58) = 19.88$	.407
Control	11.67 (4.10)	11 (4.19)	10.80 (4.16)	.917	0.21	> .05	0.42	$p < .001$***	
DBAS-16									
TeleCBT-I	5.01 (1.60)	3.24 (1.78)	3.51 (1.93)	.002**	0.84	.661	0.14	$F(2, 58) = 4.65$	.138
Control	5.53 (1.81)	4.90 (2.01)	5.35 (1.86)	> .05	0.10	.169	0.23	$p = .023$*	
FSI									
TeleCBT-I	4.74 (1.74)	3.33 (2.56)	3.38 (2.05)	.011*	0.71	> .05	0.02	$F(2, 58) = 3.89$	.118
Control	4.93 (2.52)	5.15 (2.10)	4.85 (2.04)	> .05	0.03	> .05	0.14	$p = .026$*	
FACT General									
TeleCBT-I	70.31 (20.30)	77.56 (23.44)	77 (21.80)	.312	0.31	> .05	0.02	$F(2, 58) = 2.52$	.080
Control	72.53 (16.13)	68.27 (18.28)	73.40 (17.77)	> .05	0.05	.166	0.28	$p = .103$	
Physical well-being									
TeleCBT-I	19.31 (5.46)	21.75 (6.71)	21.56 (4.16)	> .05	0.45	> .05	0.03	$F(2, 58) = 2.84$	.089
Control	18.53 (4.84)	17.20 (6.70)	19.93 (5.23)	> .05	0.27	.030	0.44	$p = .067$	
Functional well-being									
TeleCBT-I	15.44 (6.13)	18.06 (6.80)	18.75 (7.09)	.043*	0.49	> .05	0.10	$F(2, 58) = 3.92$	.119
Control	17.07 (4.68)	15.87 (5.08)	16.07 (5.50)	> .05	0.19	> .05	0.04	$p = .036$*	
QOL Physical									
TeleCBT-I	6.25 (1.72)	7.48 (1.44)	7.73 (1.54)	< .001***	0.88	.789	0.16	$F(2, 56) = .12.30$	.305
Control	6.52 (1.76)	6.21 (1.444)	5.99 (1.53)	.359	0.31	> .05	0.14	$p < .001$***	

Note. Pre-treatment and post-treatment samples, TeleCBT-I ($n = 19$), Control ($n = 16$); Follow-up samples, TeleCBT-I ($n = 16$), Control ($n = 15$). Hedges' *g* effect sizes were computed between pre-treatment and follow-up and between post-treatment and follow-up scores by treatment groups. Abbreviations: TeleCBT-I, telephone-delivered cognitive behavioral therapy for insomnia, ISI, insomnia severity inventory; PSQI, Pittsburgh sleep quality index; DBAS-16, dysfunctional beliefs about sleep; FSI, fatigue symptom inventory; FACT, functional assessment of cancer therapy; QOL-CSV, quality of life-cancer survivor version.
*$p < .05$, **$p < .01$, *** $p < .001$

Feasibility

A total of 35 cancer patients (30 or 85.71% females) completed the study, indicating an overall 79.55% adherence rate for the entire sample. Two patients dropped out before initiating treatment and were considered lost to contact. Reason for discontinuation of the study is unknown for those lost to contact as they did not return outreach phone calls. During treatment, two patients dropped out, one due to medical complications related to cancer treatment (after session two), and one lost to contact (after session three). No adverse events were reported as a result of TeleCBT-I program. There were no statistically significant difference between dropouts and completers on insomnia severity and sleep quality as measured by ISI and PSQI (*p*s > .05).

Out of the 21 patients who initiated TeleCBT-I treatment, 19 completed the four TeleCBT-I sessions, resulting in 90.48% adherence rate for the TeleCBT-I group. Booster sessions were offered and two patients completed an additional booster session within 1-2 weeks post-treatment. One-month follow-up was assessed based on the last treatment session or booster session. Most patients reported that telephone-delivery format was convenient (79%; *M* = 2.79, *SD* = .42). Additionally, more than half (*n* = 11, 57.89%) reported that they completed homework and treatment recommendations almost daily, while the rest (*n* = 8) daily.

Patients reported high satisfaction with their overall TeleCBT-I program experience at post-treatment. Mean score for all nine items of the patient experience questionnaire was 2.73 (*SD* = .36). The results for each item are presented in Figure 10. Overall, patients reported high satisfaction (*M* = 3.68, *SD* = .75) with the program. Additionally, most patients reported that they will likely recommend the TeleCBT-I to other cancer patients (*M* = 3.79, *SD* = .42). Out of 19

patients, 14 indicated the program manual was very helpful. Clinician's performance was also rated highly (M = 2.73, SD = .36).

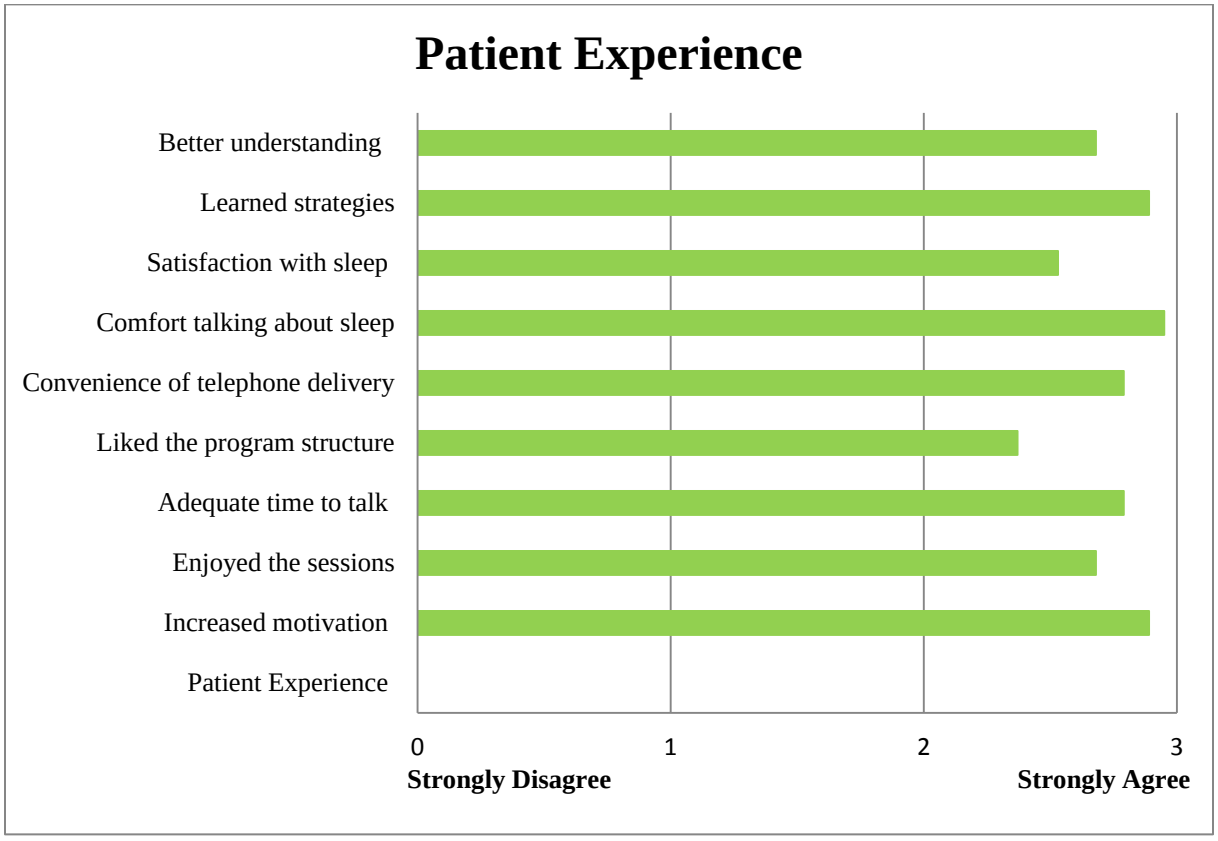

Figure 10.
Patient Reported Overall Experience and Satisfaction with TeleCBT-I

Qualitative questions yielded specific recommendations for the TeleCBT-I program. Overall, patients favored educational information of healthy sleep and how sleep is related to cancer, as well as, gaining self-awareness of sleep patterns (n = 9, 47.37%; e.g. *"I learned a lot!*

It changed my way of doing things and I told all my family", "It gave me more awareness of my sleep problems", "Realizing that sleep was important for cancer treatment, no other provider mentioned that to me"), sleep hygiene (*n* = 7; 36.84%; *"Tips on preparing to go to sleep, sleep hygiene")* and the combination of behavioral and cognitive techniques (*n* = 14, 73.68%; *"Different strategies to overcome negative sleep thoughts, [and] like covering my clock, it was a secret weapon!"*).

Although, a sizeable number of patients reported no improvements needed (*n* = 8, 42.11%; "All positive, life saver!", the majority provided specific recommendations to improve TeleCBT-I. Recommendations included reducing the overall amount of information and strategies as the program was potentially a source of additional anxiety (*n* =1), and improve the relaxation log as it was confusing (*n* =1). Patients also identified aspects of the program that they disliked, such as: Stimulus control (*n* = 2), sleep restriction (*n* = 1), sleep medication information (*n* = 1), and relaxation techniques (*n* =1). Additional recommendations included: To extend TeleCBT-I from four to six sessions (*n* =1), to include more relaxation techniques (*n* =1), and to offer CBT-I sooner, or right after a cancer diagnosis (*n* = 2).

These results underscore patients' overall high satisfaction with TeleCBT-I, and pointed three valuable recommendations: (1) to extend the TeleCBT-I to spread-out the information and allow more time to learn and practice the behavioral, cognitive and relaxation techniques, (2) to improve the self-monitoring logs by making them more user-friendly, and (3) to increase access to CBT-I by increasing dissemination efforts from the time of cancer diagnosis and throughout the cancer care continuum.

Intent to Treat Results

Intent to treat analyses were conducted using the full analysis set, which includes two patients that dropped out the study after completing pre-treatment measures and two patients who did not complete treatment. The last observation carried forward imputation method was used to assign post-treatment values. The tables presented in Appendix K detail the ITT results.

Overall, per protocol analysis produced similar findings as the intention-to-treat analysis, increasing the confidence in the study results (Moher et al., 2010). As observed in the main results as per-protocol, there were no differences between treatment groups on any of the demographic and cancer related information at pre-treatment, except for personal income (p = .042). Similarly, no differences were found on sleep and psychological measures at pre-treatment between the TeleCBT-I and Control groups (ps >.05).

Although the results from the repeated measures analyses of variance followed the same pattern as the per-protocol results, two differences were found. The Group effect on dysfunctional beliefs about seep (DBAS-16) was found not statistically significant as per ITT analyses, $F(1, 37) = 2.56$, $p = .118$, partial $\eta^2 = .065$, while functional physical well-being reached statistically significant values, $F(1, 37) = 4.57$, $p = .039$, partial $\eta^2 = .110$.

Feasibility analyses were not computed because this was only assessed at post-treatment. In sum, the ITT analyses revealed similar patterns as the as per-protocol analyses. Thus, ITT results demonstrated that the per-protocol results represent unbiased treatment effects.

CHAPTER FIVE: DISCUSSION

The current study tested the efficacy and feasibility of a brief telephone-delivered CBT-I program for the treatment of insomnia in cancer patients compared to a treatment-as-usual control group. The main study hypotheses that patients in the TeleCBT-I group compared to control would report beneficial changes in all sleep variables immediately after treatment and that these changes would be maintained at one-month follow-up were supported.

Patients in the TeleCBT-I group reported reduced insomnia severity, improved sleep quality and decreased dysfunctional sleep beliefs at post-treatment and one-month follow-up. Additionally, most patients in the TeleCBT-I group discontinued sleep medications at post-treatment, increasing the potential of experiencing less side effects and incurring in additional treatment costs. These findings are consistent with prior research supporting the effectiveness of CBT-I in patients with cancer compared to a treatment-as-usual control group (Bastien et al., 2004; Espie et al., 2008). Indeed, the magnitude of effects found at post-treatment for TeleCBT-I are comparable to those found in a recent meta-analysis for insomnia severity score (ISI) (Johnson et al., 2016). Further, these findings are also similar to studies examining CBT-I in cancer populations, providing further evidence of the effectiveness of CBT-I in cancer patients (Casault et al., 2015; Dirksen & Epstein, 2008; Espie et al., 2008; Matthews et al., 2014; Zhou, Partridge, Syrjala, Michaud, & Recklitis, 2017)

The hypothesis that TeleCBT-I would also have positive effects on fatigue, depression, anxiety, functioning, and quality of life was partially supported. Although patients in the TeleCBT-I group indicated greater improvements in fatigue compared to control at post-treatment, there were no time and group effects. However, results showed a statistically

significant interaction effect at post-treatment and follow-up, indicating significant differences between treatment groups and over time on fatigue. Further, patients in the TeleCBT-I group reported lower scores and reached subclinical levels at post-treatment, while patients in the control group reported slightly higher and clinical levels of fatigue at post-treatment.

Among cancer patients, fatigue is one of the most common complaints resulting from cancer treatment (Donovan, Jacobsen, Small, Munster, & Andrykowski, 2008). However, its presence and impairment are highly influenced by the course and type of cancer treatment that patients undergone. It is possible that fatigue may stay constant during the course of cancer treatment, and TeleCBT-I treatment improved patients' ability to cope with fatigue over time. Thus, improved perceived sleep quality and overall sleep, may increase a person's ability to cope with fatigue. Alternatively, changes in cancer treatments and recurrence in cancer symptoms may dilute TeleCBT-I treatment effect as this study did not exclude patients based on type or current cancer treatment. And therefore, patients could have experienced changes during the course of TeleCBT-I treatment. Nonetheless, the impact of CBT-I on fatigue in this study was similar as found in previous studies with cancer patients (Dirksen & Epstein, 2008; Heckler et al., 2016; Johnson et al., 2016). However, more research is needed to determine what aspects of CBT-I better target fatigue in cancer patients.

Importantly, both treatment groups reported normal to subclinical symptoms of anxiety and depression at pre-treatment. As a result, this study was unable to examine whether TeleCBT-I is also helpful to address anxiety and depressive symptoms. Nonetheless, while depressive symptoms remain the same in the TeleCBT-I group, a slight reduction of anxiety symptoms was observed at post-treatment in both treatment groups, suggesting that TeleCBT-I does not produce

negative effects on anxiety and depression. Alternatively, it is possible that TeleCBT-I has no effect on anxiety and depressive symptoms in cancer patients, and thus, the reduction of symptoms may be an artifact of the natural decline often observed in mental health symptoms. Previous research provide mixed evidence on the impact of CBT-I in other psychological variables, such as fatigue, anxiety and depression (Quesnel et al., 2003; Savard et al., 2016; Tremblay et al., 2009). This study provides further support of the need to investigate which aspects of CBT-I address anxiety and depressive symptoms and whether the same aspects apply to cancer patients.

Moreover, patients in the TeleCBT-I showed significant improvements in general functioning, physical well-being, functional well-being, and physical quality of life compared to those in the control group at post-treatment. However, treatment gains were only sustained at one-month follow-up in the functional subscale of general functioning and the physical subscale of quality of life. Importantly, these findings suggest that TeleCBT-I has a positive effect on daily functioning and physical quality of life in patients with cancer whose daily functioning and physical health is often significantly deteriorated during and after cancer treatment. Thus, these findings suggest the CBT-I may be beneficial to cancer patients as improvement in sleep may result in improvements in other aspects of physical health.

Overall, post hoc analyses revealed substantial changes across all time points. As expected, patients in the TeleCBT-I group demonstrated significant changes from pre-treatment to follow-up, but not from post-treatment to follow-up in all sleep measures. A further examination of the means indicated that these changes were all indicative of reduction of insomnia symptoms. Effect sizes (Hedges' *g*) between pre-treatment and follow-up were all large

(.84 – 2.7). These results suggest that TeleCBT-I is a viable option for treating insomnia in cancer patients. Additionally, patients in the TeleCBT-I group reported statistically significant improvement in fatigue, functional well-being, and physical QOL from pre-treatment to follow-up, suggesting that TeleCBT-I contributed to improvements in their perception of physical health and daily functioning.

As expected the control group showed no significant changes from pre-treatment to follow-up and from post-treatment to follow-up on all sleep and psychological measures, except for insomnia severity and physical well-being. That is, a statistically significant decline was observed in insomnia severity from pre-treatment to follow-up and from post-treatment and follow-up in the control group. In terms of physical well-being, only the increase of scores from post-treatment to follow-up was statistically significant. It is possible that these results in the control group are attributable to the typical improvement observed in mental health symptoms over time.

In terms of feasibility, previous research using telehealth modalities, provide encouraging evidence to further examine whether telephone calls, which are an inexpensive means of communication, can be used to provide evidence-based interventions, such as CBT-I. Indeed, this study demonstrated that telephone-delivered CBT-I produces similar improvements in insomnia symptoms as face to face delivered modalities. Overall, patient adherence was high (90%) and most patients completed all required treatment sessions. Additionally, patients reported high satisfaction with TeleCBT-I and indicated that they would highly recommend it to other cancer patients. Together, these results indicate the telephone-delivered CBT-I is not only effective at reducing insomnia symptoms, but also feasible in patients with cancer.

Strengths

Based on the existing literature, this is the first study that tests telephone-delivered CBT-I in a sample of patients with cancer. A major strength of this study was the randomized controlled design that followed the CONSORT guidelines (Moher et al., 2010) and compared the treatment group to a control group. Further, this study attempted to reflect the reality of clinical practice by using a limited exclusion criterion and therefore allowing patients with different types of diagnoses and stages of cancer to participate in the study. Additionally, patients were allowed in the study regardless of the cancer treatment they were undergoing. Current sleep medication was also allowed as many patients with cancer are prescribed sleep medication during cancer treatment. Another strength was the use of well-defined diagnostic criteria.

Although the main goal of the study was to test the use of telephone communication as a platform to provide CBT-I, patients were required to complete an in-person diagnostic interview to assess current insomnia symptoms and other co-morbid mental health conditions. The newly developed DSM-5 sleep module was used to determine insomnia diagnosis based on the DSM-5 criteria. Outcome measures were selected based on existing recommendations for insomnia research facilitating future replication and comparison of results with previous research. Another strength of the study is the use of an adapted CBT-I multicomponent program making it more relevant to the study population. Lastly, treatment and assessments were conducted over the telephone extending the use of telehealth to data collection practices and providing patients with a consistent platform throughout their involvement in the study.

Limitations

Although the innovative aspects of this study advance the evidence of CBT-I and its dissemination and implementation via telephone-delivery in a sample of cancer patients, the most notable limitation is the small sample size. Although sample size satisfied the minimal size requirement for the purpose of this study, future research should involve larger sample sizes in order to increase the statistical confidence of the results. Further, although the study included a wide range of cancer diagnoses, the small sample limited the ability to examine group differences based on type of cancer diagnosis and other variables of interest, such as age, race/ethnicity, cancer stage, and use of sleep medications. Additionally, some of the measures indicated a low reliability, which could be an effect of the combination of small sample size and small number of items.

In terms of sleep indicators, the study did not assess sleep onset latency, total sleep time, time awake after sleep onset, sleep efficiency and number of awakenings throughout the course of TeleCBT-I and across all time points. These measures provide a more detailed characterization of sleep patterns. Additionally, no objective sleep measures were used in the study. Although insomnia is diagnosed based on patients' perception of their sleep disturbance, daytime symptoms, and impairment in daily functioning, actigraphy and polysomnography identify other sleep problems (e.g., sleep apnea) that may be causing the underline sleep disturbance. Thus, this study is unable to confidently assert that the sample had only diagnosable insomnia with no presence of other sleep condition.

Treatment integrity as provided by three different clinicians was not assessed. However, clinicians were supervised by a licensed clinical psychologist and followed a manualized

program. In addition, patients received the same TeleCBT-I workbook, which provided instructions and information that guided each session. Nonetheless, larger trials would benefit from including fidelity measures.

The control group was deemed as treatment-as-usual, instead of a wait-list control group because patients and providers were allowed to make changes to sleep medications throughout the course of the study. Typically, wait-list control group are not offered or allowed any treatment associated with the researched treatment. Thus, it is possible that patients in the control group were actively using sleep medications or initiated or discontinued their sleep medication during the course of the study making significant changes in their perception of sleep problems. However, the study did assess for engagement in non-pharmacological treatments for insomnia at post-treatment and follow-up and this was considered a reason for discontinuation in the study.

Although the study provides evidence for sustained effects on insomnia improvement at one-month follow-up, future research investigating the effects of TeleCBT-I in cancer patients over extended periods of time are needed. Lastly, the findings of this study are not generalizable, but provide preliminary evidence for the efficacy and feasibly of using telephone calls to provide a brief program of CBT-I in patients with cancer. Although the TeleCBT-I group reported significant and sustained improvements in their sleep, more research is needed to understand among patients with cancer, who does and does not benefit from CBT-I delivered via telehealth platforms.

Conclusion

Insomnia can be treated successfully in cancer patients using telephone-delivered CBT-I. The four-week CBT-I program adapted for cancer patients led to decreased insomnia severity, improved sleep quality and reduced dysfunctional thoughts about sleep in patients with cancer with sustained gains observed at one-month follow-up. TeleCBT-I may have a positive impact on fatigue, anxiety, functioning and quality of life, but more research is needed. Lastly, telephone-delivered CBT-I is feasible and highly accepted among cancer patients.

APPENDIX A: IRB APPROVAL LETTERS FOR HUMAN RESEARCH

ORLANDO HEALTH
When it matters most.

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DATE:	January 30, 2018
TO:	Diane Robinson, PhD
FROM:	Orlando Regional Medical Center (ORMC) IRB
PROJECT TITLE:	[1182866-1] SLEEPING WELL: EVALUATING FORMAT EFFICACY FOR COGNITIVE-BEHAVIORAL THERAPY FOR INSOMNIA IN ADULT CANCER PATIENTS
REFERENCE #:	18.002.01
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
APPROVAL DATE:	January 30, 2018
STUDY EXPIRATION DATE:	January 29, 2019
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # 7

Thank you for your submission of New Project materials for this project. The following items were received:

- Advertisement - Sleeping Well Study Flyer_11-6-17.docx (UPLOADED: 01/15/2018)
- Advertisement - Advertisement-Study Materials Form.doc (UPLOADED: 01/15/2018)
- Consent Form - Consent Form -Sleeping Well Study_08Jan2018.docx (UPLOADED: 01/15/2018)
- Cover Sheet - Information Only - Other submissions Form Patient Materials.doc (UPLOADED: 01/15/2018)
- HIPAA Waiver - Waiver of Informed Consent-PHI WAIVER Form Screening survey.doc (UPLOADED: 01/23/2018)
- Letter - InformationSheetSleepingWell_11-06-17.doc (UPLOADED: 01/15/2018)
- Orlando Health - IRB Application - Orlando Health - IRB Application (UPLOADED: 01/15/2018)
- Other - Robinson Resource Review Committee Approval Letter 12.18.2017.docx (UPLOADED: 01/15/2018)
- Other - Phone Script _Sleeping Well_08Jan2018.docx (UPLOADED: 01/23/2018)
- Other - Follow Up Letter Sleeping Well.docx (UPLOADED: 01/15/2018)
- Other - End Letter Sleeping Well.docx (UPLOADED: 01/15/2018)
- Other - AppendixA_CBT-I Outline.docx (UPLOADED: 01/15/2018)
- Questionnaire/Survey - AppendixF_Sleep Diary Measure.pdf (UPLOADED: 01/15/2018)
- Questionnaire/Survey - AppendixE_Pre-Post MeasuresMissingSatisfaction.pdf (UPLOADED: 01/15/2018)

- Questionnaire/Survey - AppendixC_Sleep Disorders Questionnaire.pdf (UPLOADED: 01/15/2018)
- Study Plan - IRB Sleeping Well Study Protocol_08Jan2018.docx (UPLOADED: 01/15/2018)

The Orlando Regional Medical Center (ORMC) IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation. The Orlando Regional Medical Center (ORMC) IRB is organized and operates in compliance with DHHS regulations as described in 45 CFR part 46, i.e. The Common Rule, FDA regulations as described in 21 CFR Parts 50 and 56, and guidelines resulting from the International Conference on Harmonisation (ICH) E-6 Good Clinical Practice guidelines as appropriate.

In addition, the Orlando Regional Medical Center (ORMC) IRB operates in compliance with portions of the Health Insurance of Portability Act of 1996 (HIPAA Privacy Rule) that apply to research, as described in 45 CFR Parts 160 and 164 as appropriate.

The Orlando Regional Medical Center (ORMC) IRB has approved the waiver of documentation of informed consent (signature requirements) under 45CFR 46.117(C) for this project. **(Telephone screening ONLY.)**

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others (UPIRSOs) and SERIOUS and UNEXPECTED adverse events must be reported promptly to this committee. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this committee.

This project has been determined to be a Minimal Risk project. Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of January 29, 2019.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact the IRB Office at (321) 841-5895. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Orlando Regional Medical Center (ORMC) IRB's records.

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901, 407-882-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Notice that UCF will Rely Upon Other IRB for Review and Approval

From : **UCF Institutional Review Board**
FWA00000351, IRB00001138

To : **Diane Robinson**

Date : **March 21, 2018**

IRB Number: **SBE-18-13811**

Study Title: **SLEEPING WELL: EVALUATING FORMAT EFFICACY FOR COGNITIVE-BEHAVIORAL THERAPY FOR INSOMNIA IN ADULT CANCER PATIENTS**

Dear Researcher:

The research protocol noted above was reviewed by a University of Central Florida IRB Designated Reviewer on March 21, 2018. The UCF IRB accepts the Orlando Regional Medical Center (ORMC)'s Institutional Review Board review and approval of this study for the protection of human subjects in research. **The expiration date will be the date assigned by the ORMC Institutional Review Board and the consent process will be the process approved by that IRB.**

This project may move forward as described in the protocol. It is understood that the ORMC's IRB is the IRB of Record for this study, but local issues involving the UCF population should be brought to the attention of the UCF IRB as well for local oversight, if needed.

All data, including signed consent forms if applicable, must be retained and secured per protocol for a minimum of five years (six if HIPAA applies) past the completion of this research. Any links to the identification of participants should be maintained and secured per protocol. Additional requirements may be imposed by your funding agency, your department, or other entities. Access to data is limited to authorized individuals listed as key study personnel.

Failure to provide a continuing review report for renewal of the study to the ORMC **IRB could lead to study suspension, a loss of funding and/or publication possibilities, or a report of noncompliance to sponsors or funding agencies. If this study is funded by any branch of the Department of Health and Human Services (DHHS), an Office for Human Research Protections (OHRP) IRB Authorization form must be signed by the signatory officials of both institutions and a copy of the form must be kept on file at the IRB office of both institutions.**

This letter is signed by:

Signature applied by Jennifer Neal-Jimenez on 03/21/2018 02:32:02 PM EDT

Designated Reviewer

APPENDIX B: RECRUITMENT FLYER

Sleeping Well Study: Evaluating Format Efficacy for Cognitive-Behavioral Therapy for Insomnia in Adult Cancer Patients

Sleep Problems among Cancer Patients

- Sleep disturbances are among the most common and distressing symptoms endorsed by cancer patients.
- Up to 80% of cancer patients experience sleep disturbances, while up to 60% suffer from insomnia.
- The 2016 guidelines of the National Comprehensive Cancer Network (NCCN) and the American College of Physicians (ACP) recommend the screening and assessment of sleep complaints and treatment of insomnia during routine cancer care.
- The NCCN and ACP recommend that all adult patients with cancer and comorbid insomnia symptoms receive Cognitive Behavioral Therapy for Insomnia (CBT-I) as the first line of treatment.

Challenges to Providing CBT-I to Cancer Patients

- Insomnia is often untreated and when treatment is offered, it generally entails medication only.
- CBT-I is under-utilized and under-researched in cancer populations.
- Barriers include a lack of trained providers, commute to treatment centers, and treatment duration.

The ***Sleeping Well Study*** will address these challenges by providing a brief CBT-I intervention tailored to cancer patients via telephone! Participants will be randomized to either one of three groups: (1) individual telephone sessions, (2) group telephone sessions or (3) a wait-list control group. The CBT-I intervention consists of 3-4 sessions delivered 1 per week and over 1 month period. Participants will also be followed at 3 and 6-month after treatment.

For more information, please contact Andel Nicasio at 321-841-5056/Andel.Nicasio@orlandohealth.com

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APPENDIX C: PROVIDER STUDY INFORMATION SHEET

(Provider Information Sheet)

[Date]

Dear _____,

We are pleased to inform you about a new research study that your patients could take part in and benefit from. The research study is titled: ***Sleeping Well: Evaluating Format Efficacy for Cognitive-Behavioral Therapy for Insomnia (CBTI) in Adult Cancer Survivors*** [ORMC IRB# _____] and is being conducted by **Dr. Diane Robinson, Integrative Medicine Department.**

The study will test the efficacy of telephone-based delivery of a brief CBTI. CBTI is the recommended treatment for insomnia and can be provided alone or in conjunction with sleep medication. Untreated, sleep disturbance is likely to become chronic and affect the healing process and tumor progression in cancer populations[1].

The CBTI program consists of 3-4 sessions, one per week, provided by telephone. Eligible participants with sleep problems will be randomly assigned to individual telephone-based CBTI, group telephone-based CBTI or wait-list treatment as usual control group. Participants will be followed at 1-, 3- and 6-month after treatment.

We invite you to collaborate with us in offering this research opportunity to your patients. Participants can be referred by any of their healthcare providers (i.e., oncologist, physician, physician assistant, nurse, nutritionist, psychologist, and counselor) or self-referred.

Participant eligibility:

- Adult patients at the Orlando Health-UF Health Cancer Center.
- Participants identified by their healthcare provider as deemed in need of services for sleep disturbance - OR -
- Through the Health Inventory Intake or Distress Screening questionnaires by endorsing sleep problems.

Referral Process:

- You or someone from the medical team can refer participants to the study by:
  - Sending a Zsecure email to CancerSupportCommunity@OrlandoHealth.com with a subject line "Sleep Study" - OR by calling the Cancer Support Community at 321-871-5056.
  - Introducing the patient to one of our research assistants when they visit your clinic for study recruitment.

I will be grateful if you could discuss this research opportunity with your patients, as appropriate. If you have any questions, please contact me at (321) 841-7197. Thank you for your time and consideration.

Sincerely,

Diane C. Robinson, PhD

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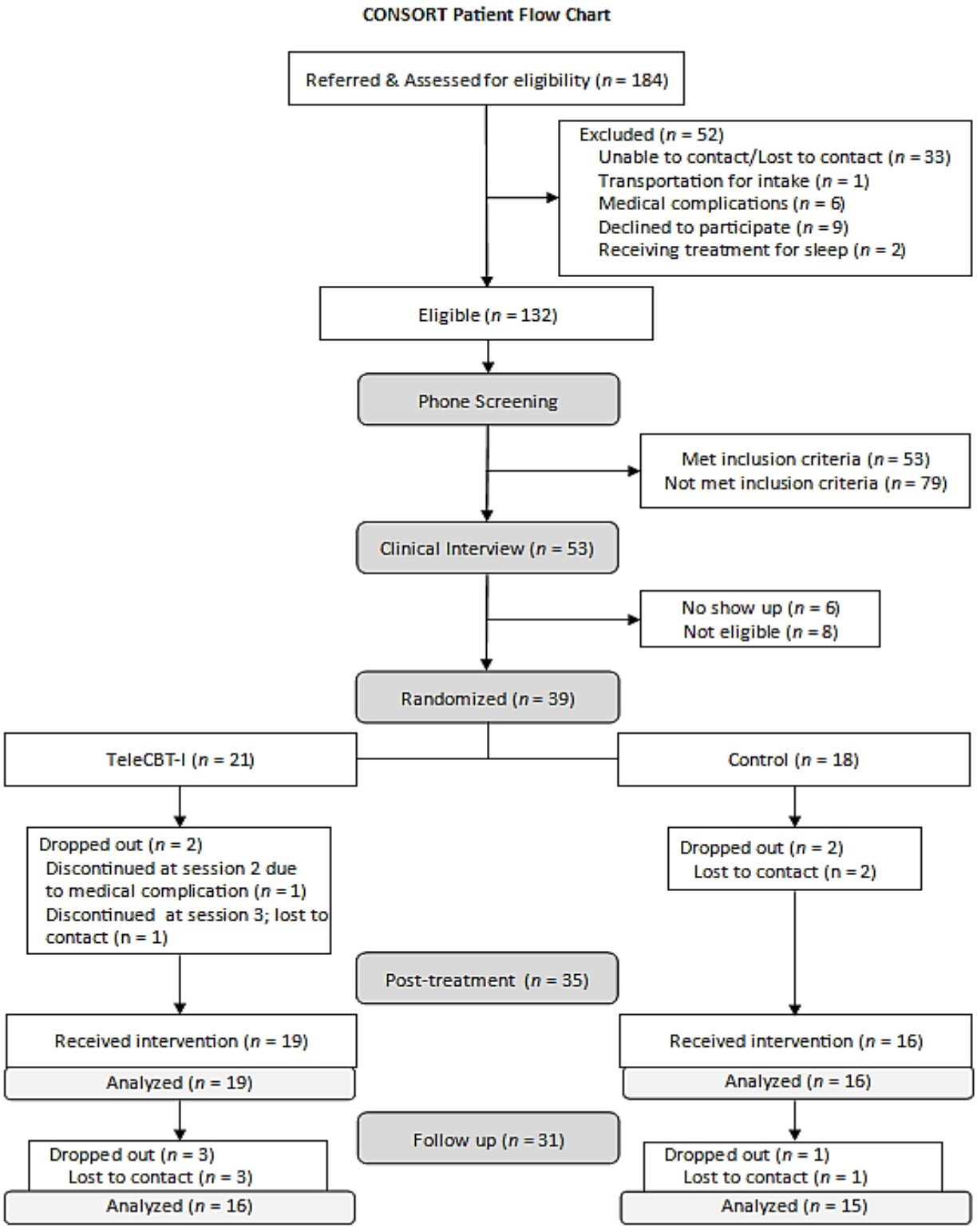
[1] Cash, E., et al. "Circadian disruption and biomarkers of tumor progression in breast cancer patients awaiting surgery." *Brain, behavior, and immunity* 48 (2015): 102-114.

APPENDIX D: PATIENT FLOW CHART


CONSORT Patient Flow Chart
Referred & Assessed for eligibility (n = 184)
Excluded (n = 52)
Unable to contact/Lost to contact (n = 33)
Transportation for intake (n = 1)
Medical complications (n = 6)
Declined to participate (n = 9)
Receiving treatment for sleep (n = 2)
Eligible (n = 132)
Phone Screening
Met inclusion criteria (n = 53)
Not met inclusion criteria (n = 79)
Clinical Interview (n = 53)
No show up (n = 6)
Not eligible (n = 8)
Randomized (n = 39)
TeleCBT-I (n = 21)
Control (n = 18)
Dropped out (n = 2)
Discontinued at session 2 due to medical complication (n = 1)
Discontinued at session 3; lost to contact (n = 1)
Dropped out (n = 2)
Lost to contact (n = 2)
Post-treatment (n = 35)
Received intervention (n = 19)
Analyzed (n = 19)
Received intervention (n = 16)
Analyzed (n = 16)
Follow up (n = 31)
Dropped out (n = 3)
Lost to contact (n = 3)
Analyzed (n = 16)
Dropped out (n = 1)
Lost to contact (n = 1)
Analyzed (n = 15)

APPENDIX E: TELEPHONE SCRIP AND SCREENING

Sleeping Well: Telephone Script

Phone Script for Screening **for Leaving Voicemail #1**

This message is for ____. This is ____ from the Cancer Support Community at Orlando Health. I'm calling to tell you about our Sleeping Well research study we are running here at the center. The study will be evaluating a brief talk therapy program tailored for adult cancer patients experiencing sleep problems. This form of talk therapy, called CBT, is the recommended treatment for sleep problems, but can also help reduce fatigue, anxiety and depression, and improve overall quality of life. It only requires one in-person visit with the rest of the study completed over the phone. We are currently seeking participants, so if you'd like to learn more about this study, please give us a call back at 321.841.5056. Thank you and have a great day.

Phone Script for Screening **for Leaving Voicemail #2**

This message is for ____. This is ____ from the Cancer Support Community at Orlando Health. I'm calling to find out if you might be interested in participating in a study evaluating a brief talk therapy program tailored for adult cancer patients experiencing sleep problems. This study is conducted over the phone and only requires one in-person visit to get started. If you'd like to learn more about this study, please give us a call back at 321.841.5056. Thank you and have a great day.

Phone Script for Screening **for Leaving Voicemail #3**

This message is for ____. This is ____ from the Cancer Support Community at Orlando Health. The reason for my call is to tell you about a Sleeping Well study we are conducting where we will be providing a brief talk therapy program for sleep problems in adult cancer patients. This study only requires one in-person visit with the rest completed over the phone. **This is the final phone call to you regarding this study**, so if you are interested in learning more about it, please give us a call back at 321.841.5056. Thank you and have a great day.

Phone script **for Live Call**

Hi. Is this ___? My name is ___ and I'm calling from the Cancer Support Community at Orlando Health. How are you today? [open response]. I'm calling today to tell you about our Sleeping Well Study that we're conducting through the center and I wanted to find out if you'd be interested in possibly participating.

[If No] – Ok. Just to let you know, the Cancer Support Community offers a variety of free support including mindfulness workshops, yoga, art & crafts, and support groups. We invite you to stop by and say hello.

[If Yes] OK Great, so this study will be using talk therapy tailored for cancer patients to help reduce sleep problems. We will be using Cognitive-Behavioral Therapy, also called CBT which is a form of talk therapy that has been recommended for treating sleep problems, particularly insomnia but it can also help with fatigue, anxiety, depression, and overall quality of

life. Basically, we will be evaluating the effectiveness of CBT treatments provided over the phone.

The study starts with a brief phone screening to see if you qualify. If you qualify, we will set up your in-person interview where we further evaluate sleep problems and any other emotional issues. You'll only need to attend this one interview as the rest can be completed over the phone. You will be randomly assigned to one of three groups. Group 1 will receive individual treatments over the phone; Group 2 will receive CBT-I treatments in a group conference call format; and group 3 will be waitlisted but given the option to receive CBT-I treatment over the phone or in person. The study includes 3 to 4 phone therapy sessions and a 1, 3, and 6 month follow-up phone call interview, each lasting approximately 1 hour.

Participation is completely voluntary and at no cost to you. Your participation in this study will not affect your current treatment at UF Health Cancer Center - Orlando Health. Do you have any questions about the study?

Would you be interested in participating in this study?

- **If Yes**… Proceed with the screening information.
- **If No**… Thank Her/Him for her/his time. **End of contact.**

Sleeping Well Study: Telephone Screening

1. **Are you 18 years old or older?**
   If Yes… Continue. | **If No**… Discontinue.

2. **Are you a cancer patient?**
   (Cancer patient could be any one with a diagnosis of cancer stages I-IV and who is receiving treatment or has recently completed treatment (< less than 5 years after completing treatment or that the person is in complete remission)
   If Yes… Continue. | **If No**… Discontinue.

3. **Are you a patient at Orlando Health UF Health Cancer Center?**
   If Yes… Continue. | **If No**… Discontinue.

4. **Do you currently have trouble sleeping?**
   If Yes… Continue. | **If No**… Discontinue.

5. **Have you ever been diagnosed with Sleep apnea?**
   If Yes… Ask if S/He is currently receiving treatment for Sleep Apnea.
   - If Yes, continue. | **- If No**… Discontinue.
   If No… Continue.

6. **Have you ever been diagnosed with Restless Legs Syndrome (RLS)?**
   If Yes… Ask if S/He has a current diagnosis of RLS and if S/He is currently receiving treatment for RLS.
   - If Yes for either question above … Discontinue.
   If No… Continue.

7. **Have you been diagnosed with Periodic Limb Movement Disorder (PLMD)?**
   If Yes… Ask if S/He has a current diagnosis of PLMD and if S/He is currently receiving treatment for PLMD.
   - If Yes for either question above… Discontinue.
   If No… Continue.

8. **Have you been diagnosed with Narcolepsy?**
   If Yes… Ask if S/He has a current diagnosis of Narcolepsy and if S/He is currently receiving treatment for Narcolepsy.
   - If Yes to either question above … Discontinue.
   If No… Continue.

9. **Are you able to attend an interview session at** UF Health Cancer Center-Orlando Health, Integrative Medicine Department?
   If Yes… Continue. | **If No**… Discontinue.

10. Are you able to attend 3-4 sessions, one per week, over the telephone?

If Yes… Continue. | **If No**… Discontinue.

Okay. Thanks for answering these questions. Now, I am going to ask you more specific questions about your sleep. We are almost done with the phone screening.

SQD Administration

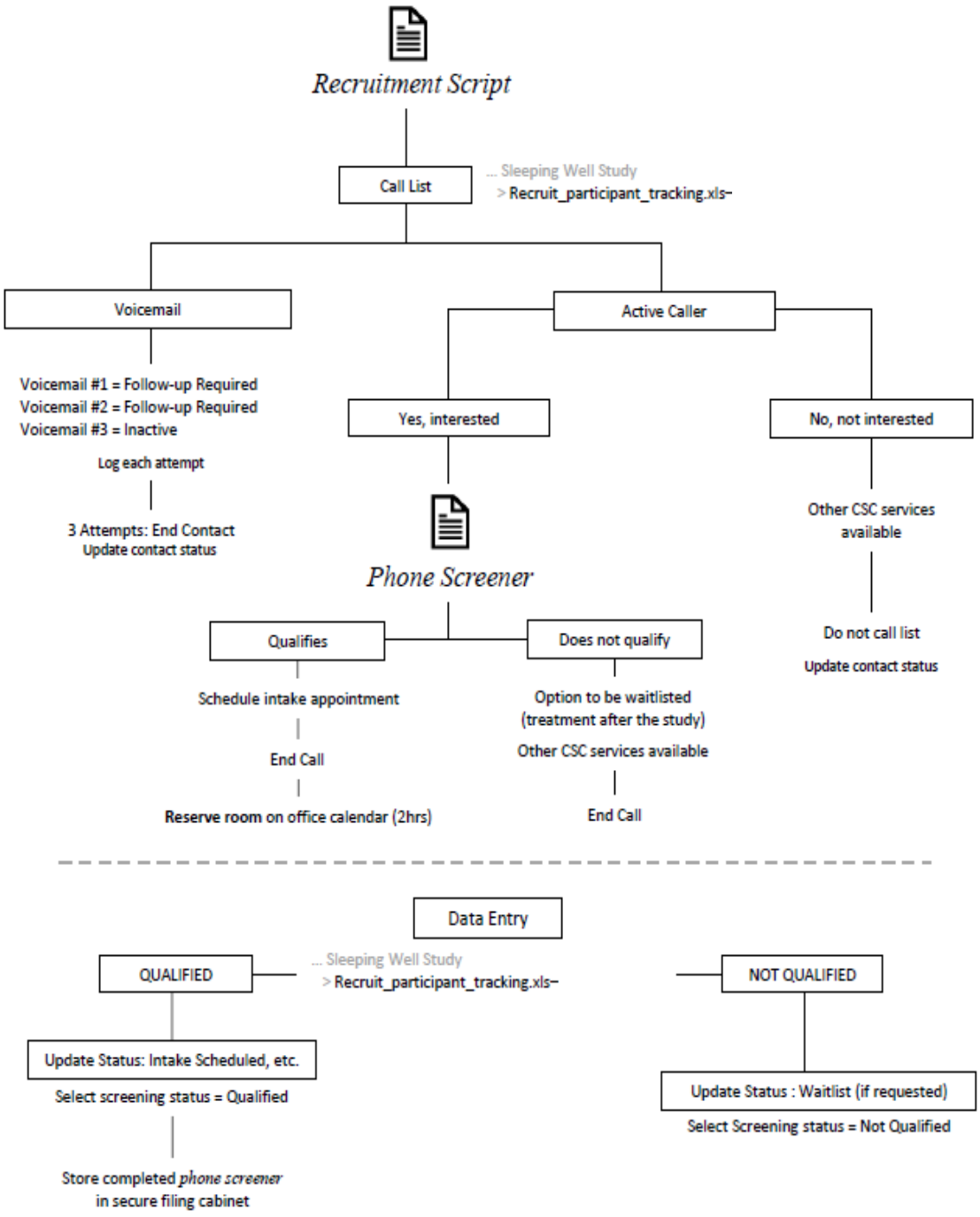
- **QUALIFIES IF**: Score of 3, 4 or 5 in any questions indicates possible insomnia or sleep problems.

We've finished the screening now, and you qualify for the study. The next step is to schedule the appointment for the in-person interview. This interview will further evaluate your eligibility and ask more questions about your sleep and potential emotional problems. You will also be assigned to one of the 2 groups.

Schedule Intake Appointment (in-person). Thank Her/Him for their time and provide the Cancer Support Community telephone number (321-841-5056) to call back if S/He has any questions.

- **DOES NOT QUALIFY IF**: Scores of 1-2 in all questions. Discontinue. Explain participant that S/He is not eligible for this study, but that S/He is welcome to enroll in other studies at UF Health Cancer Center-Orlando Health for which S/He qualifies in the future. Thank Her/Him for her/his time.

APPENDIX F: PROCEDURES FLOW CHARTS


Recruitment Script
Call List
... Sleeping Well Study
> Recruit_participant_tracking.xls~
Voicemail
Active Caller
Voicemail #1 = Follow-up Required
Voicemail #2 = Follow-up Required
Voicemail #3 = Inactive
Log each attempt
3 Attempts: End Contact
Update contact status
Yes, interested
No, not interested
Other CSC services available
Do not call list
Update contact status
Phone Screener
Qualifies
Does not qualify
Schedule intake appointment
End Call
Reserve room on office calendar (2hrs)
Option to be waitlisted (treatment after the study)
Other CSC services available
End Call
Data Entry
QUALIFIED
... Sleeping Well Study
> Recruit_participant_tracking.xls~
NOT QUALIFIED
Update Status: Intake Scheduled, etc.
Select screening status = Qualified
Store completed phone screener in secure filing cabinet
Update Status : Waitlist (if requested)
Select Screening status = Not Qualified

Preparing for Intake Appointment

Main objectives
1. Call to confirm appointment
2. Prepare all documents for appointment

Appointment Reminder Call
(1-2 business days prior to appointment)

FYI:
Check filing cabinet for already prepared intake folders… Just need to print out estimated appointment schedule

Intake Documents

- ❑ *During Intake Appointment Form*
- ❑ *Completed Phone Screener – or blank if not previously completed*
- ❑ *2 consent forms*
- ❑ *1 Medical release form*
- ❑ *1 SCISD DSM-V*
- ❑ *1 Demographic form*
- ❑ *1 Pre-Measures packet*
- ❑ *1 Randomization envelope*
- ❑ *Cancer Support Community Membership Form*
  (yellow sheet, found at front desk)

Don't forget a clipboard + 2 pens!

CONTROL participant	*OR*	INTERVENTION Participant	*OR*	INTERVENTION Participant (GROUP)
❑ *Estimated appointment schedule* *Enter intake date = autofill's future appointments. (Use as a guide)*		❑ *Estimated appointment schedule* *Enter intake date = autofill's future appointments. (Use as a guide)*		❑ *Assigned appointment schedule* *Based on group schedule*
❑ *Response score cards* !! NOTE: Only provide score cards – not all diary materials.		❑ *Sleep diary packet* *…See Sleep Diary Documents Folder*		❑ *Sleep diary packet* *…See Sleep Diary Documents Folder*

During Intake Appointment

(in-person appointment)
Time: approx. 1.5 - 2hrs

Main objectives

1. Conduct informed consent process
2. Confirm case of Insomnia
3. Eliminate other disorders
4. Doctor's name
5. Mailing address
6. Patient signatures

Don't forget a clipboard + 2 pens!

1. Informed Consent Checklist

- ❑ HAVE PATIENT READ THE CONSENT FORM
- ❑ Explain treatment schedule *(Use forecasting schedule)*
- ❑ Complete checklist form confirming consent form process was followed
- ❑ Have participant sign 2 consent forms, 1 for him/her and 1 for clinician

Date and Time of discussion _____/_____/____ _____ am | pm

Ask participant the following questions to verify they understand the study objectives and their responsibilities:

1. "Please describe what, if any, benefits you can expect by participating in this study?
2. Ask them to describe the study..."When you get home and your spouse/friends ask you about this, how will you describe the study to them?
3. Ask them to describe what is required of them, i.e. how many visits and what specific "tasks" they have to do.
4. Ask "What questions do you have?" (do not use "do you have any questions?")

People present during the discussion:	☐ **Researcher** _____ ☐ **Participant** _____ ☐ **Other:** _____
Enough time was provided for patient to read the consent form	☐ **YES** ☐ **NO**
Questions asked by participant:	
Participant verbalized understanding of the information and had the opportunity to ask questions, and agreed to participate	☐ **YES** ☐ **NO**
The most current version of the consent form was used	☐ **Version Date <u>01/08/2018</u>** If not, indicate which version _____
Participant SIGNED 2 consent forms	☐ **YES**
A copy of the consent form was provided to the patient	☐ **YES**

_____ _____

Name of researcher completing this checklist Signature

During Intake Appointment (cont.)

2. Administer forms

- ❑ Complete the SCISD DSM-V with patient as an interview format
- ❑ Have them complete the Pre-Assessment worksheet
- ❑ Have them complete the Demographics worksheet
  - ❑ Review Pre-Assessment worksheet HADS measures for mood symptoms. **If score s are ≥ 11**, offer counseling services at the end of the interview.

Does patient meet ELIGIBILITY CRITERIA?

Exclusion Criteria

- Pre-existing severe psychiatric diagnoses
- Taking antipsychotic medication
- Active psychotic symptoms or suicidal ideation
- Presence of another sleep apnea **unless** treatment is currently administered.
- Diagnosed with Restless Legs Syndrome
- Diagnosed with Periodic Limb Movement Disorder
- Diagnosed with Narcolepsy
- Cognitive impairment or dementia
- Neurologic disorder

What to do if they don't qualify... offer other CSC services/studies and offer counseling services for CBT-I outside of the study.

Inclusion Criteria

- English speaking patients at OH
- Adults 18-years-of-age or older
- Patients of any type of cancer, during or after treatment
- Endorse clinically significant sleep disturbance as measured by the SDQ
- Use of medication for insomnia is allowed, if stable (same dose for more than 3 weeks).
- Use of psychotropic medication (e.g. antidepressant) is allowed, provided that the does was not recently altered and has been stable for the past 6 weeks.
- Clearance from oncologist

3. Schedule next appointment

For a CONTROL participant

❑ **Explain response score cards** to be used for next appointment over the phone.

Schedule next appointment

...in 30 days (Post Assessment)

Participant leaves with:
- 1 consent form
- **Response score cards**
- Forecasting schedule (optional)
- Business card for front desk

For an INTERVENTION Participant

❑ **Explain sleep diary** packet
Requires 2 weeks of tracking before session #1.
Set start date and consider any vacation or any major change in his/her sleep routine.

Schedule next appointment

...in 14 days (Session #1)

Participant leaves with:
- 1 consent form
- **Sleep diary packet**
- Forecasting schedule (optional)
- Business card for front desk

For an GROUP Participant

❑ **Explain sleep diary** packet
Requires 2 weeks of tracking before session #1.
❑ Go over protocol for **missed CBTI sessions.**

Assign to Group Schedule

...(Session #1)

Participant leaves with:
- 1 consent form
- **Sleep diary packet**
- CBTI schedule
- Business card for front desk

APPENDIX G: INTAKE AND DEMOGRAPHIC QUESTIONNAIRE

Sleeping Well Study

Sleep and Demographic Information

All information on this sheet is strictly confidential.

Date: _____

Contact Information:
Last Name: _____ First Name: _____ Middle Initial: ____
Address: _____
Phone: _____ **Is it Okay to leave voice messages?** ❑ Yes ❑ No
Email: _____

Emergency Contact: _____ Phone Number: _____
Relationship to Emergency Contact: _____

Referring Physician or Medical Provider: _____

Sleep Information
What is your main sleep complaint? _____
_____
_____

Past Sleep Evaluation and/or Treatment:
❑ I have had a previous sleep disorder evaluation
❑ I have been prescribed PAP for home use
❑ I wear oxygen at night
❑ I have had a previous overnight sleep study
❑ I have had surgical treatment for a sleep disorder
❑ I have a family member with sleep apnea

Please list
1) Date of Prior Sleep Study: _____
2) Diagnosis: _____
3) Treatment if applicable: _____

Duration of Symptoms: _____months / years

Have you received any treatment for sleep problems?
❑ Yes ❑ No
If yes, please indicate below:
❑ Medication
❑ Relaxation techniques
❑ Psychotherapy
Other. Please describe: _____

Sleep Habits
❑ I usually watch TV in bed prior to sleep
❑ I usually read in bed prior to sleep
❑ I eat a snack at bedtime
❑ I work a rotating shift or I am a shift worker
❑ I smoke prior to bedtime or when I awaken during the night
❑ I eat if I wake up during the night
❑ I often travel across two (2) or more time zones
❑ I drink alcohol in the evening time to help get to / stay asleep

Bedroom Habits
❑ I sleep alone
❑ I share a bed with someone
❑ I share a dwelling but have separate bedrooms
❑ I share the bed with pets
❑ I have an uncomfortable bed or pillow
❑ I have an uncomfortable temperature in the bedroom
❑ I have a noisy bedroom or have too much light in the bedroom
❑ I have too many electrical devices in the bedroom

Sleep Pattern:
Typical bedtime _____ AM/PM
How many minutes to fall asleep _____
How many awakenings in the night? _____
Do you fall back to sleep easily? ❑Yes ❑ No
Typical wake-up time _____ AM/PM
Do you nap? ❑Yes ❑ No If yes, when / how long _____

Other relevant Information about Sleep:
_____
_____
_____

Cancer Diagnosis Information

With which type of cancer were you diagnosed?

- ❑ Breast cancer
- ❑ Lung cancer
- ❑ Non-Melanoma skin cancer
- ❑ Melanoma skin cancer
- ❑ Prostate cancer
- ❑ Bladder cancer
- ❑ Colon cancer
- ❑ Pharyngeal (Throat cancer)
- ❑ Melanoma
- ❑ Non-Hodgkin's Lymphoma
- ❑ Thyroid cancer
- ❑ Kidney cancer (renal cell)
- ❑ Leukemia
- ❑ Pancreatic cancer
- ❑ Endometrial cancer
- ❑ Other Please specify: _____

How long ago were you diagnosed with cancer?

- ❑ Less than 1 year ago
- ❑ 1 year ago to 2 years ago
- ❑ 2 years to 5 years ago
- ❑ _____ Include date if known or provided

At what stage were diagnosed?

- ❑ Stage I
- ❑ Stage II
- ❑ Stage III
- ❑ Stage IV
- ❑ Limited Stage
- ❑ Extensive Stage

Which of the following best describes your current condition?

- ❑ My stage has remained the same
- ❑ My stage has increased
- ❑ I am cancer free

Have you ever undergone any of the following cancer treatments to help reduce or control the spread of your cancer? (Check all that apply)

- ❑ Chemotherapy
- ❑ Radiation therapy
- ❑ Hormonal therapy
- ❑ Surgery
- ❑ Targeted drug therapy (Treatment targets changes in cancer cells)
- ❑ Stem cell transplant
- ❑ Clinical trial
- ❑ I have not undergone any cancer treatments
- ❑ Other. Please specify: _____

What type of cancer treatment are you currently receiving? (Check all that apply / See Next Page)

❑ Chemotherapy
❑ Radiation therapy
❑ Hormonal therapy
❑ Surgery
❑ Targeted drug therapy (Treatment targets changes in cancer cells)
❑ Stem cell transplant
❑ Clinical trial
❑ No cancer treatment at this time
❑ Other. Please specify: _____

When do you expect to complete your current cancer treatment? (If applicable)

_____

Are you using any other healing methods? Please check all that apply

❑ Acupuncture
❑ Chiropractor
❑ Energy Healing
❑ Physical Therapist
❑ Massage Therapy
❑ Medical Doctor
❑ Mental Health Professional
❑ Music or Art Therapy
❑ Other. Please describe: _____

<u>Mental Health History</u>

Have you ever been diagnosed with a mental illness?

❑Yes ❑ No
If yes, please indicate diagnosis: _____

Have you ever been hospitalized in relation to mental health?

❑Yes ❑ No
If yes, please describe: _____

<u>Pain</u>

On a scale of 0 (no pain) to 10 (extreme pain),

A. What is your level of pain right now? _____
B. What has your average pain level been over the past month? _____

Have you had a recent surgery (within the past 6 months)

❑Yes ❑ No
If yes, please describe: _____

Caffeine intake

Do you consume caffeine? ❑ Yes ❑ No

If Yes, do you consume ❑ Coffee ❑ Caffeinated drinks ❑ Caffeine pills

Estimate average cups of coffee per day? _____ Oz/ Cups

On a typical day, when do you drink coffee?

❑ Morning (6am-noon) ❑ Afternoon (noon-6pm) ❑ Evening 6pm-2am) ❑ Night (2am-6am)

Sodas, tea, Jolt®, Mountain Dew®, Red Bull ®, Monster®, ROCKSTAR Energy Drinks®

Estimate average number of caffeinated drinks per day? _____ Oz/ Drinks

On a typical day, when do you drink caffeinated drinks?

❑ Morning (6am-noon) ❑ Afternoon (noon-6pm) ❑ Evening 6pm-2am) ❑ Night (2am-6am)

Tobacco Intake

Have your ever smoked?

❑ Yes ❑ No

If Yes, how long have you smoked? _____ Years

How much? _____Number of cigarettes/Day (1 pack has 20 cigarettes; Export As has 25)

Have you quit smoking?

❑ Yes ❑ No

If Yes, Year Quit _____

If No, do you use cigarettes, smokeless tobacco, snuff, or other tobacco products?

_____

How much per day? _____

Alcohol Intake

Do you drink Alcohol?

❑ Yes ❑ No

If Yes, how much do you drink? _____ drinks

How frequent? ❑ Daily ❑ Weekly (_____times per week) ❑ Socially _____

What kind of alcohol? ❑ Beer ❑ Liquor ❑ Wine

Do you drink alcohol before going to bed frequently? ❑ Yes ❑ No

Do you use any other substances? ❑ Marijuana ❑ Cocaine ❑ Crack ❑ Other: _____

Do you use of these substances to help fall asleep or take it before going to bed? ❑ Yes ❑ No

Exercise

Do you exercise? ❑ Yes ❑ No

If Yes, how frequently? _____

Other Health History

Have you been diagnosed with a chronic or severe health condition? Please check all that apply.

- ❑ Asthma
- ❑ Back Pain
- ❑ Arthritis
- ❑ Chronic fatigue syndrome
- ❑ Diabetes
- ❑ Multiple Sclerosis
- ❑ Heart Condition
- ❑ High/Low Blood Pressure
- ❑ Headaches/Migraine
- ❑ Eating Disorders
- ❑ ADHD
- ❑ Anxiety
- ❑ Bipolar Disorder
- ❑ Depression
- ❑ Panic attacks
- ❑ PTSD
- ❑ Schizophrenia
- ❑ Other, please specify: _____

Current Medication

Please list all your current medications

Prescription Medication Name	How much?	How often?	Last taken?
Over-the-counter Medication Name	**How much?**	**How often?**	**Last taken?**
Herbal Remedy / Nutritional Supplement Name	**How much?**	**How often?**	**Last taken?**

General Demographic Information

Age: _____ DOB: _____

Gender:
❑ Female ❑ Male ❑ Other. Please specify: _____

What is your height? _____ Feet _____Inches
What is your weight today? _____ Weight one year ago? _____

Marital Status:
❑ Married ❑ Single ❑ Divorced ❑ Life Partner ❑ Separated ❑ Widowed
❑ Other. Please specify: _____

Race/Ethnicity:
❑ Asian/Pacific Islander
❑ Black or African American
❑ Hispanic or Latino
❑ Middle Eastern **(Arabs, Turks, Persians, Jews, etc.)**
❑ Native American or Alaska Native
❑ South Asian (India, Pakistan, Bangladesh, Nepal, etc.)
❑ White
❑ Other. Please specify: _____

Employment Status
❑ Active Duty Military
❑ Disabled
❑ Employed Full-Time
❑ Employed Part-Time
❑ Homemaker
❑ Not Employed
❑ Retired
❑ Self Employed
❑ Student Full-Time
❑ Student Part-Time
❑ Other. Please specify: _____

Highest Level of Education
❑ No schooling completed
❑ Some school, but less than 8th grade
❑ Completed 8th grade
❑ Some high school, no diploma
❑ High school graduate, diploma or the equivalent of GED
❑ Some college, no degree
❑ Trade/technical school/vocational training
❑ Associate degree
❑ Bachelor's degree
❑ Master's degree
❑ Professional degree
❑ Doctorate degree

Personal Annual Income
- ❑ Less than $15,000
- ❑ $15,000 – $24, 999
- ❑ $25,000 – $34,999
- ❑ $35,000 – $49,999
- ❑ $50,000 – $74, 999
- ❑ $75,000 or more
- ❑ Does not apply

Household Annual Income
- ❑ Less than $15,000
- ❑ $15,000 – $24, 999
- ❑ $25,000 – $34,999
- ❑ $35,000 – $49,999
- ❑ $50,000 – $74, 999
- ❑ $75,000 or more

Religious Preference
- ❑ Atheism/Agnosticism
- ❑ Buddhism
- ❑ Catholicism
- ❑ Christianity
- ❑ Hinduism
- ❑ Judaism
- ❑ Mormonism
- ❑ Islam
- ❑ Orthodox Church such as Greek or Russian Orthodox Church
- ❑ Protestantism
- ❑ Seventh-Day Adventists

Other. Please specify: _____

For Research Personnel Only

Referral Date: _____ By: _____
Med approval date: _____
Eligible: (Y/N): _____ Exclusion reason (if applicable): _____
Consented: (Y/N): _____ Date: _____
Randomization group: _____
Screening Date: _____
Baseline date: _____
Sleep Diary Start Date: _____
Session 1: Date: _____ Attendance (Y/N): _____
Session 2: Date: _____ Attendance (Y/N): _____
Session 3: Date: _____ Attendance (Y/N): _____
Session 4: Date: _____ Attendance (Y/N): _____
Post-Assessment Date (scheduled): _____ Completion date: _____
1 MONTH FU Date (scheduled): _____ Completion date: _____
3 MONTH FU Date (scheduled): _____ Completion date: _____
6 MONTH FU Date (scheduled): _____ Completion date: _____
Lost to contact: (Y/N): _____ **Date of last contact:** _____

APPENDIX H: MEDICAL CLEREANCE FORM

Research Study:
Sleeping Well: Evaluating Format Efficacy for Cognitive-Behavioral Therapy for Insomnia in Adult Cancer Patients

Request for Release to Participate

Orlando Health | UF Health Cancer Center ("UFHCC"), Integrative Medicine Department is conducting a research study to investigate the effects of a brief Cognitive-Behavioral Therapy (CBT) for sleep problems tailored for cancer patients. CBT is a form of talk therapy and is the recommended treatment for sleep problems, particularly insomnia.

About the study:

- This is a 4-week program delivered once a week over the telephone.
- Before starting the program participants attend an in-person interview to further evaluate sleep problems and any other emotional issues.
- Participants are randomized to participate in one of three groups: Group A receives the intervention via individual telephone calls, Group B receives the intervention via group telephone conferences, and Group C receives treatment as usual and is given the option to receive the intervention in a few months either in-person or by telephone.
- Follow-up assessments are collected via telephone at 1, 3 and 6 months after end of program.

By signing below, I acknowledge/represent the following:
I desire to participate in the Sleeping Well study (ORMC IRB# 10.002.01). I understand that during my participation I will be asked about personal matters regarding my sleep patterns. It is possible that I may feel tired, upset or anxious. If this happens, you can choose not to answer any or all the questions. Additionally, a clinician is available to speak to you. I certify that I voluntarily applied to participate in the study and am cognizant of all of the inherent dangers and risks that Cognitive Behavioral Therapy for sleep problems could offer to me.

My physician is signing below only to acknowledge ***that I am able to engage in cognitive behavioral therapy***, and that I am able to consent to participation in the study. In the event I have any questions or concerns about my health before, during, or after my participation in the study, I am responsible to seek appropriate medical attention.

As I understand my participation in the Sleeping Well study is voluntary, I agree to release UFHCC and anyone associated with these organizations (the "Released Parties") from all claims and damages that may occur due to my participation in the study.

Participant	**Physician**
Signature: _____	Signature: _____
Print:_____	Print: _____
Date: _____	Date: _____

APPENDIX I: TREATMENT SATISFACTION QUESTIONNAIRE

Sleeping Well: Treatment Satisfaction Questionnaire

Thank you for participating in the Sleeping Well Study. Please answer the following questions as honestly and accurately as possible. We appreciate your thoughtful feedback, as it will help us evaluate the effectiveness of Sleeping Well Program and help us make it even better for future participants!

Next to each statement below, please put a mark (X) to show whether you "strongly agree"; "agree"; "disagree"; or "strongly disagree" with the statements below.

Section 1: Your treatment Experience [Card # 47]				
During my contact with this treatment . . .	**Strongly Agree (3)**	**Agree (2)**	**Disagree (1)**	**Strongly Disagree (0)**
a. The program has motivated me to work on my sleep problems.				
b. I did not like *all* the program sessions I attended. *(reversed)*				
c. I did not have enough time to talk about my own sleep problems. *(reversed)*				
d. I have not liked some of the program rules or regulations. *(reversed)*				
e. I did not find it convenient to participate in the program via telephone. *(reversed)*				
f. I felt safe and comfortable talking about my sleep problems.				
g. I am satisfied with the accomplishments or changes I have made to improve my sleep.				
h. I have learned one or more strategies to improve my sleep.				
i. I gained greater understanding of my sleep problem(s)**.**				

Section 2. Questions about the practitioner	Strongly Agree (3)	Agree (2)	Disagree (1)	Strongly Disagree (0)
a. The practitioner understood my sleep problems and concerns.				
b. The practitioner gave me as much information as I wanted about what I could do to manage my sleep problems.				
c. The practitioner was good at her/his job.				
d. I was treated considerately and respectfully by the practitioner.				

Section 3: Overall Service Experience

1. How many sessions did you complete? _____

2. Overall, how satisfied or dissatisfied are you with the Sleeping Well Program?
❑ Very satisfied (4)
❑ Somewhat satisfied (3)
❑ Neither satisfied nor dissatisfied (2)
❑ Somewhat dissatisfied (1)
❑ Very dissatisfied (0)

3. Overall, how helpful or unhelpful was the program manual?
❑ Very helpful (4)
❑ Somewhat helpful (3)
❑ Neither helpful nor unhelpful (2)
❑ Somewhat unhelpful (1)
❑ Very helpful (0)

4. Overall, how often did you practice the suggested homework or daily practice?
❑ Daily (4)
❑ Almost daily / Most days (4-6 days per week) (3)
❑ Occasionally (1-3 days per week) (2)
❑ Rarely (0-1 days per week) (1)
❑ Never (0 days per week) (0)

5. How likely are you to suggest the Sleeping Well Program to another cancer patient?
❑ Extremely likely (4)
❑ Very likely (3)
❑ Somewhat likely (2)
❑ Not so likely (1)
❑ Not at all likely (0)

6. What did you find most helpful about the Sleeping Well Program?

_____
_____

7. What did you find least helpful about the Sleeping Well Program?

_____
_____

8. Please rate your overall experience with the Sleeping Well Program.

0	1	2	3	4	5	6	7	8	9	10
Very Dissatisfied										Very Satisfied

9. Do you have any additional comments, suggestions or concerns?

_____
_____
_____

Section 4. Physical health and Life Changes

Have you experienced any changes in your cancer treatment over the past month?
❑ No ❑ Yes; if Yes, please explain:

_____

Have you experienced any changes in your medication over the past month?
❑ No ❑ Yes; if Yes, please explain:

_____

2a.What about Sleep medications? Any changes over the past month?

_____
_____

Have you been diagnosed with a new condition over the past month?
❑ No ❑ Yes; if Yes, please specify:

_____

Aside from participating in the Sleeping Well Program, have you participated in another sleep program over the past month?
❑ No ❑ Yes; if Yes, please specify:
_____

Have you experienced any major life changes over the past 2 months?
❑ No ❑ Yes; if Yes, please review the list below and let us know which event and how much the event has affected your life by circling the appropriate number.

	Type of effect		Effect of Event on Your Life			
Event	Good	Bad	No effect	Some effect	Moderate effect	Great effect
❑ Going back to work or a new job	Good	Bad	0	1	2	3
❑ Being fired or laid off from work	Good	Bad	0	1	2	3
❑ Major change in your home conditions or living arrangements	Good	Bad	0	1	2	3
❑ Separation or divorce from spouse or partner	Good	Bad	0	1	2	3
❑ Death of a loved one	Good	Bad	0	1	2	3
❑ Family conflicts (e.g., parenting problems, problems with in-laws or relatives)	Good	Bad	0	1	2	3
❑ Change in your religious beliefs	Good	Bad	0	1	2	3
❑ Loss or damage to personal property	Good	Bad	0	1	2	3
❑ Took vacation	Good	Bad	0	1	2	3
❑ Major change in finances (increased or decreased)	Good	Bad	0	1	2	3
Other? _____	Good	Bad	0	1	2	3

Thank you! Please remember that we will be in contact with you to conduct the follow-up assessments over the phone at 1, 3, and 6 months.

If possible, please schedule the next telephone assessments:

1 month follow-up appointment: _____
3 month follow-up appointment: _____
6 month follow-up appointment: _____

End!!!

Thank you for taking the time to complete these questionnaires.

APPENDIX J: END OF TREATMENT LETTER

ORLANDO HEALTH | UFHealth CANCER CENTER

1400 S. Orange Ave. • Orlando, FL 32806
tel 321.841.1869 | OrlandoHealthCancer.com

Sleeping Well Study

[Date]

Dear _____,

Thank you for being a participant in the *Sleeping Well Study*! Your participation will help us learn whether telephone-based delivery of Cognitive-Behavioral Therapy for Insomnia is effective and feasible for cancer patients. We hope your experience with us has been one of positive learning and change. We wish you well in the unfolding moments of your life.

Remember to continue practicing the strategies and skills learned throughout the *Sleeping Well* program. Your continued healthy sleep practices will help you to improve your sleep and overall quality of life. If you would like to continue working on your sleep habits, we can help you to set up an appointment through the Integrative Medicine Department for individual and group therapy sessions. Furthermore, remember that you have access to many activities free of charge through the Cancer Support Community, including mindfulness-based stress reduction group, return to wellness group, yoga classes, and much more.

Below are some general suggestions for continued practice:

1. Keep a consistent sleep schedule.
2. Limit daytime naps to 30 minutes.
3. Avoid stimulants close to bedtime (e.g., caffeine, alcohol).
4. Exercise early and regularly to promote good quality sleep.
5. Stay away from food that can be disruptive right before sleep (e.g., fatty or fried meals, spicy dishes).
6. Balance fluid intake before going to bed (i.e., enough to keep from waking up thirsty, but not too much that you will be awakened by the need to go to the bathroom).
7. Ensure adequate exposure to natural light.

1039905 7/17

8. Practice a relaxing bedtime routine.
9. Make sure that your sleep environment is pleasant.
10. Be positive! Think about positive thoughts before going to sleep or practice gratitude by thinking about what you're grateful for.

Your Change Scores

You completed assessments of sleep, fatigue, depression, anxiety and quality of life before and after the program. The table below shows the change in your scores, whether for better, worse or no change. We will provide you the scores for the follow-up sessions as well at the end of the study in about six months.

	Before/Descriptor	**After/Descriptor**
Insomnia Severity	_____	_____
Sleep Quality	_____	_____
Sleep Efficiency	_____	_____
Depression	_____	_____
Anxiety	_____	_____

Thank you for your time and participation in the Sleeping Well Study. Your participation is valuable and very important to us. Please contact the Integrative Medicine Department for further questions or information.

Integrative Medicine Department
Telephone: (321)-841-5056
Fax: (321)-843-6777
22 W. Underwood St., 2nd Floor, MP 710-10
Orlando, FL 32806
UFHealthCancerOrlando.com

APPENDIX K: INTENT TO TREAT RESULTS

Intent to Treat Results

Table 11.
ITT Results for Demographic and Sample Characteristics by Treatment Group

	TeleCBT-I (*n* = 21)		**Control (*n* = 18)**		
	Mean	SD	Mean	SD	
Variables	No	%	No	%	*p*
Age (years)	55.05	10.15	52.28	12.32	.446
	Range = 36 to 71		Range = 29 to 74		
Sex					.647
Female	19	90.5	15	83.3	
Race/Ethnicity					
Non-Hispanic White	13	61.9	8	44.4	.142
African American	3	14.3	2	11.1	
Hispanic	3	14.3	8	44.4	
Mixed	2	9.5			
Marital status					
Single	3	14.3	5	27.8	.444
Married	7	33.3	9	50	
Divorced	8	38.1	3	16.7	
Widowed	3	14.3	1	5.6	
Highest Level of Education					
High School or GED	-	-	2	11.1	.079
Some College	5	23.8	6	33.4	
Bachelor's degree	7	33.3	8	44.4	
Master's degree	9	42.9	2	11.1	
Employment					
Part-time	2	9.5	2	11.1	.509
Full-time	9	42.9	6	33.3	
Unemployed	3	14.3	2	11.1	
Retired	7	33.3	5	27.8	
Disabled	-	-	3	16.7	
Income					
Less than $15,000	3	14.3	5	29.4	.042*
15,000-24,999	3	14.3	3	17.6	
25,000-34,999	-	-	4	23.5	
35,000-49,999	4	19	-	-	
50,000-74,999	5	23.8	1	5.9	
75,000 or more	6	28.6	4	23.5	

Note. Significance tests for continuous variables were determined with independent samples *t-tests* (2-tailed), while Fisher's exact tests were used for dichotomous and categorical variables. Income (n = 34). Abbreviations: TeleCBT-I, telephone-delivered cognitive behavioral therapy for insomnia; No, Frequency; %, Percentage.

Table 12.
ITT Results for Cancer Related Information by Treatment Group

	TeleCBT-I (*n* = 21)		Control (*n* = 19)		
Variables	**No**	**%**	**No**	**%**	***p***
Cancer stage					
Stage I	8	38.1	6	33.3	.327
Stage II	6	28.6	2	11.1	
Stage III	3	14.3	3	16.7	
Stage IV	3	14.3	2	11.1	
Don't know	1	4.8	5	27.8	
Time since cancer diagnosis					.699
Less than one year	7	33.3	7	38.9	
One to two years ago	5	23.8	2	11.1	
Two or more years ago	9	50	9	50	
Cancer location					.541
Breast	14	66.7	8	44.4	
Brain	2	9.5	3	16.7	
Skin	-	-	2	11.1	
Colon	1	4.8	1	5.6	
Head and Neck	1	4.8	2	11.1	
Kidney	-	-	1	5.6	
Musculoskeletal	-	-	1	5.6	
Lung	1	4.8	-	-	
Blood	1	4.8	-	-	
Ovarian	1	4.08	-	-	
Past cancer treatments					
Chemotherapy	16	76.2	10	55.6	.307
Radiation therapy	15	71.4	11	61.1	.734
Surgery	15	71.4	14	77.8	.726
Hormone therapy	11	52.4	5	27.8	.192
No past treatment	-	-	1	5.6	.462
Current cancer treatments					
Chemotherapy	4	19	2	11.1	.667
Radiation Therapy	3	14.3	2	11.1	>.05
Surgery	3	14.3	3	16.7	>.05
Hormone therapy	7	33.3	3	16.7	.290
No current treatment	7	33.3	12	66.7	.056

Note. Differences by group were determined with Chi-square and Fisher's exact tests.
Abbreviations: TeleCBT-I, telephone-delivered cognitive behavioral therapy for insomnia; No, Frequency; %, Percentage.

Table 13.
ITT Results for Sleep Measures and Group Differences at Pre-treatment

	TeleCBT-I (*n* = 21)		Control (*n* = 19)				
Variables	**Mean**	**SD**	**Mean**	**SD**	***t* (37) / χ^2**	***p***	**95% CI**
ISI	17.76	4.13	17.28	4.55	.348	.730	[-2.33, 3.30]
PSQI	12	3.23	11.94	3.93	.048	.962	[-2.27, 2.38]
DBAS-16	5.13	1.50	5.43	1.76	-.576	.568	[-1.36, 0.76]
Sleep Medication % (*n*)	52.4	11	47.6	10	.039	> .05	

Note. Significance tests were determined with independent samples t-tests (2-tailed) or chi-square tests.
Abbreviations: TeleCBT-I, TeleCBT-I, telephone-delivered cognitive behavioral therapy for insomnia; ISI, insomnia severity inventory; PSQI, Pittsburgh sleep quality index; DBAS-16, dysfunctional beliefs about sleep.

Table 14.
ITT Results for Psychological Measures and Group Differences at Pre-treatment

	TeleCBT-I (*n* = 21)		Control (*n* = 18)				
Variables	**Mean**	**SD**	**Mean**	**SD**	***t* (37)**	***p***	**95% CI**
FSI	4.73	1.63	4.97	2.31	-.381	.705	[-1.53, 1.04]
HADS-Depression	5.95	4.91	6.67	3.71	-.505	.616	[-3.58, 2.15]
HADS-Anxiety	8.38	4.69	8.28	4.48	-.070	.945	[-2.89, 3.09]
FACT General	69.81	19.91	71.72	15.40	-.331	.742	[-13.62, 9.79]
Physical	19.86	4.87	18.61	4.72	.808	.424	[-1.89, 4.37]
Social/Family	18.33	6.39	19.22	5.90	-.449	.656	[-4.90, 3.13]
Emotional	16.24	6.02	17	4.12	-.453	.653	[-4.17, 2.64]
Functional	15.33	6.61	16.94	4.49	-.875	.387	[-5.34, 2.12]
QOL-CSV Total	5.66	1.63	5.53	1.35	.264	.794	[-0.85, 1.11]
Physical	6.34	1.62	6.27	1.71	.126	.900	[-1.02, 1.15]
Psychological	5.64	2.39	5.73	1.56	-.134	.894	[-1.42, 1.24]
Social	5.72	2.11	5.18	2.47	.729	.471	[-0.95, 2.02]
Spiritual	5.84	2.53	6.29	1.95	-.606	.548	[-1.93, 1.04]

Note. Significance tests were determined with independent samples *t-tests* (2-tailed).
Abbreviations: TeleCBT-I, TeleCBT-I, telephone-delivered cognitive behavioral therapy for insomnia; FSI, fatigue symptom inventory; HADS-D, depression subscale of hospital anxiety and depression scale; HADS-A, anxiety subscale of hospital anxiety and depression scale; FACT, functional assessment of cancer therapy; QOL-CSV, quality of life patient/cancer survivor version.

Table 15.
ITT Results on Sleep Measures by Each Group at Pre-treatment and Post-treatment and Treatment Effects

					LMM Statistical Tests (Type III tests of fixed effects)						
	Pre-treatment		Post-treatment		Time Effect		Group Effect			Group x Time Interaction	
Variables	***Mean***	***SD***	***Mean***	***SD***	***F*(1, 37)**	***p***	***F*(1, 33)**	***p***	***g***	***F*(1, 33)**	***p***
ISI											
TeleCBT-I	17.76	4.13	8.52	5.23	61.26	< .001	4.61	.038	1.19	21.81	< .001
Control	17.28	4.55	14.94	5.54							
PSQI											
TeleCBT-I	12	3.23	6.62	3.29	32.13	< .001	4.17	.029	1.30	21.23	< .001
Control	11.94	3.93	11.39	4.06							
DBAS-16											
TeleCBT-I	5.13	1.50	3.58	1.85	20.81	< .001	2.56	**.118**	.72	5.81	.021
Control	5.43	1.76	4.95	1.95							

Note. Between-group effect sizes were computed as Hedges' *g* values.
Abbreviations: TeleCBT-I, TeleCBT-I, telephone-delivered cognitive behavioral therapy for insomnia; ISI, insomnia severity inventory; PSQI, Pittsburgh sleep quality index; DBAS-16, dysfunctional beliefs about sleep.

Table 16.
ITT Results on Psychological Measures by Group at Pre-treatment and Post-treatment and Treatment Effects

					LMM Statistical Tests (Type III tests of fixed effects)						
	Pre-treatment		Post-treatment		Time Effect		Group Effect			Group x Time Interaction	
Variables	***Mean***	***SD***	***Mean***	***SD***	***F*(1, 33)**	***p***	***F*(1, 33)**	***p***	***g***	***F*(1, 33)**	***p***
FSI											
TeleCBT-I	4.73	1.63	3.29	2.55	3.83	.058	3.24	.080	.88	9.95	.003
Control	4.97	2.31	5.31	1.98							
HADS-Depression											
TeleCBT-I	5.95	4.91	5.76	5.94	.001	.977	.397	.533	.21	.141	.710
Control	6.67	3.71	6.89	4.38							
HADS-Anxiety											
TeleCBT-I	8.38	4.69	7.14	4.01	5.83	.021	.009	.925	.03	.001	.970
Control	8.28	4.48	7	4.14							
FACT General											
TeleCBT-I	69.81	19.91	77.24	23.06	.347	.560	.515	.478	.49	6.33	.016
Control	71.72	15.40	67.11	17.18							
Physical											
TeleCBT-I	19.86	4.87	22.14	5.99	.002	.968	4.57	**.039**	.90	8.05	.007
Control	18.61	4.72	16.39	6.88							
Social/Family											
TeleCBT-I	18.33	6.39	19.81	6.59	.050	.825	.043	.837	.25	1.35	.254
Control	19.22	5.90	18.22	5.87							
Emotional											
TeleCBT-I	16.24	6.02	17.33	5.86	.750	.392	.007	.934	.10	1.39	.247
Control	17	4.12	16.83	4.15							
Functional											
TeleCBT-I	15.33	6.61	17.95	7.46	.702	.407	.036	.850	.36	5.93	.020
Control	16.94	4.49	15.67	4.67							

Note. Abbreviations: TeleCBT-I, TeleCBT-I, telephone-delivered cognitive behavioral therapy for insomnia; FSI, fatigue symptom inventory; HADS-D, depression subscale of hospital anxiety and depression scale; HADS-A, anxiety subscale of hospital anxiety and depression scale; FACT, functional assessment of cancer therapy; QOL-CSV, quality of life patient/cancer survivor version.

Table 17.
ITT Results on Quality of Life by Group at Pre-treatment and Posttreatment and Treatment Effects

					LMM Statistical Tests (Type III tests of fixed effects)						
	Pre-treatment		Post-treatment		Time Effect		Group Effect			Group x Time Interaction	
Variables	***Mean***	***SD***	***Mean***	***SD***	***F*(1,33)**	***p***	***F*(1,33)**	***p***	***g***	***F*(1,33)**	***p***
QOL-CSV Total											
TeleCBT-I	566	1.63	5.93	1.86	.244	.624	.506	.481	.35	1.98	.167
Control	5.53	1.35	5.39	1.07							
Physical											
TeleCBT-I	6.34	1.62	7.46	1.34	1.86	.180	3.56	.067	1.08	14.47	.001
Control	6.27	1.71	5.74	1.84							
Psychological											
TeleCBT-I	5.64	2.39	6.17	2.33	1.49	.230	.089	.767	.23	1.56	.219
Control	5.73	1.56	5.72	1.28							
Social											
TeleCBT-I	5.72	2.11	5.97	2.42	.247	.622	.916	.345	.35	.348	.559
Control	5.18	2.47	5.16	2.22							
Spiritual											
TeleCBT-I	5.84	2.53	6.06	2.67	3.33	.076	.849	.363	.37	.729	.399
Control	6.29	1.95	6.89	1.59							

Note. Abbreviations: TeleCBT-I, Telephone-delivered Cognitive Behavioral Therapy for Insomnia, QOL-CSV, Quality of Life-Cancer Survivor Version.

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