EVALUATION OF INTERNET-BASED VIDEOCONFERENCE INTERVENTION
OF COGNITIVE BEHAVIORAL THERAPY FOR INSOMNIA IN BREAST CANCER
SURVIVORS IN MEDICALLY UNDERSERVED AREAS OF COLORADO

by

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Approximately 30-50% of breast cancer survivors (BCS) experience insomnia versus 10-20% of the general population. This insomnia often originates with cancer treatment, but can become chronic and persist over the lifetime of the patient. Effects of chronic insomnia include decreased quality of life and an impaired immune system. Cognitive behavioral therapy for insomnia (CBTI) is an effective psychotherapy for insomnia, but rural BCS often lack access to this intervention.

The primary purposes of this six-week pretest-posttest design study were to 1) explore the feasibility and potential barriers of recruiting BCS with insomnia who live in rural areas of Colorado, and 2) to explore the effect of internet-based video conferenced (VC) CBTI on sleep and quality of life in this population.

Eighteen women were recruited into this study and underwent six weeks of VC CBTI. Primary sleep measures all improved significantly including: sleep efficiency (p < .001), sleep latency (p < .001), wake after sleep onset (p < .001) and total sleep time (p < .001). Global quality of life also improved significantly (p < .001), however the associated mental health measures of anxiety and depression remained unchanged. These findings suggest that an internet-based VC CBTI could be an effective tool for insomnia treatment in rural BCS.

The form and content of this abstract are approved. I recommend its publication.

Approved: Paula Meek
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CHAPTER I
INTRODUCTION

Background and Purpose

Insomnia is a pervasive disorder that affects 10-20% of the general population (Buysse, 2013). It is defined as difficulty initiating or maintaining sleep, or having non-restorative sleep for a period of at least one month in spite of having adequate opportunity to sleep (Buysse, 2013). This is often accompanied by associated daytime complaints including fatigue, sleepiness, mood and cognitive disturbances and impaired daily functioning (Ellis, Perlis, Neale, Espie, & Bastien, 2012). Insomnia can occur at any time, but it is can be precipitated by a trigger event such as a cancer diagnosis.

Insomnia disproportionately affects breast cancer survivors (BCS). Evidence suggests that approximately 30-50% of BCS experience insomnia (Savard, Villa, Ivers, Simard, & Morin, 2009) versus 10-20% of the general population (Berger, 2009). While patients with cancer experience insomnia at a higher rate, it is breast cancer survivors who are most affected (Savard, Ivers, Villa, Caplette-Gingras, & Morin, 2011). Often occurring during treatment, insomnia can become chronic and persist over the lifetime of the patient (Ahn et al., 2007; Savard, Simard, Blanchet, Ivers, & Morin, 2001). Effects of chronic insomnia include decreased quality of life (QOL), a depressed immune system and increased mortality (Innominato et al., 2009; Savard, Simard, Ivers, & Morin, 2005b).

Pharmacologic agents are often effective in managing acute insomnia; however, medications have long-term limitations (e.g. side effects, chemical dependency, etc.) and do not address the underlying contribution of cognitive and behavioral factors that give rise to persistent insomnia (Morin, Bootzin, Buysse, Edinger, Espie, & Lichstein, 2006; Savard &
Growing evidence suggests non-pharmacological management of insomnia after primary breast cancer treatment leads to improved sleep outcomes and quality of life.

Cognitive behavioral therapy for insomnia (CBTI) is an effective psychotherapy for insomnia (Buysse, 2013; Morin et al., 2009) in the general population as well as in the BCS population (Savard, Simard, Ivers, & Morin, 2005a; Tremblay, Savard, & Ivers, 2009). It has proven to be a more effective long term treatment than medication alone (Morin et al., 2009). Standard components of CBTI include sleep hygiene education, stimulus control, sleep restriction, relaxation training, and cognitive therapy (Buysse, 2013).

The internet is an emerging platform for the delivery of mental health services worldwide (Andersen & Svensson, 2013; Christensen & Petrie, 2013). It has the potential to bridge geographic and transportation challenges and to facilitate delivery of mental health services to patients in their homes. Internet-based CBT has been used in multiple interventions with promising results (Andersson, Stromgren, Strom, & Lyttkens, 2002; Cheng & Dizon, 2012; Macea, Gajos, Daglia Calil, & Fregni, 2010; Enander et al., 2015; Savard, Ivers, Savard & Morin, 2014; Spek, Cuijpers, Nyklicek, Riper, Keyzer, & Pop, 2007). Insomnia researchers have focused on the use of fully automated CBTI interventions over the internet (Espie, Kyle, Williams, Ong, Douglas, Hames, & Brown, 2012; Ritterband, Bailey, Thorndike, Lord, Farrell-Carnahan, & Baum, 2012; Savard et al., 2014; Vincent & Lewycky, 2009). This study proposed to evaluate a therapist driven CBTI delivered over the internet. For the purposes of this study, a therapist driven CBTI involves a therapist and a participant, conducting a CBTI session through a videoconference (VC) interface over the internet.
There is growing evidence to support the internet as an effective and secure delivery modality for CBT (Cheng & Dizon, 2012; Clarke et al., 2013). There are promising results when CBTI is delivered to adults with primary insomnia via a software module based internet delivery (Enander et al., 2015; Lancee, van den Bout, van Straten, & Spoormaker, 2012; Ritterband et al., 2009) and via an animated DVD (Savard et al., 2014), but none designed specifically for a rural breast cancer population with comorbid insomnia. A delivery of a therapist guided internet-based VC CBTI for BCS with chronic insomnia is a natural outgrowth of previous research.

Although CBT is an effective treatment for insomnia, it is unavailable to many rural BCS due to the high cost of individualized therapy and the lack of trained health care providers in rural areas. Yet rural cancer survivors suffer increased rates of anxiety and depression after treatment (Bettencourt, Schlegel, Talley, & Molix, 2007; Burris & Andrykowski, 2010), which have been strongly related to higher rates of insomnia (Baglioni, Spiegelhalder, Lombardo, & Riemann, 2010). Rural survivors are also more likely to report greater rates of overall psychological distress than urban survivors (Weaver, Geiger, Lu & Case, 2013). This is a significant problem because many Western states have urban centers where health care resources are clustered, and large areas of rural geography with few health resources.

In Colorado, 40-60% of the state is designated as Medically Underserved Areas (MUA) by the Health Resources and Services Administration (HRSA, 2013). MUAs are defined as counties or civil divisions in which there is a shortage of health care providers (HRSA, 2013). Internet based CBT has been shown to be effective in other studies, but rural BCS are an underrepresented demographic group. A study to target this population and treat
insomnia with CBTI has not been attempted. Given the percentage of MUAs in the state, Colorado is a logical place to test this intervention.

**Theoretical Basis for Research**

Classical conditioning is the theoretical basis for the perpetuation of chronic insomnia after breast cancer treatment. Formerly neutral stimuli that were originally associated with sleep are instead associated with arousal after being paired with acute insomnia during cancer treatment. For example, the rituals associated with bedtime (brushing teeth, washing face) can elicit wakefulness rather than sleepiness.

Spielman's 3 P Model of Insomnia was developed to explain the underlying causes of insomnia and the transition from acute to chronic insomnia (Spielman, Caruso, & Glovinsky, 1987). In this model, it is posited that there are predisposing, precipitating, and perpetuating factors that contribute to chronic insomnia. Predisposing factors are biopsychosocial determinants that contribute to a propensity toward insomnia. Precipitating factors can include any stressful event. In this study, the stress would likely be a breast cancer diagnosis and treatment. Perpetuating factors are cognitive and behavioral changes that an individual makes during acute insomnia. Examples of these perpetuating factors would include a decrease in exercise and an increase in napping due to fatigue associated with cancer treatment. These perpetuating factors then facilitate the transition from acute to chronic insomnia when they are inappropriately continued after the cancer treatment is completed.

**Purpose of Study**

The primary purposes of the study were to 1) explore the feasibility and potential barriers of recruiting BCS with insomnia who live in MUAs in Colorado, and 2) to explore the effect of internet-based VC CBTI in this population. There is a lack of research
evaluating the effect of CBTI on rural participants. Studying a population of BCS who live in MUAs would add to the existing research. This study is based on a parent study using in-person CBTI in BCS who lived in the Denver metro area. The parent (pilot) study served as a comparison group for this study (Matthews, Berger, Schmiege, Cook, McCarthy, Moore & Aloia, 2014).

**Design**

This study is a pretest-posttest design that will explore the effects of a 6-week internet-based VC CBTI intervention on the sleep, QOL and daily functioning of BCS in MUAs. The results of this intervention were then secondarily compared with the results from the parent study to determine if there were differences in the efficacy of the internet-based VC CBTI in a rural population, and the urban based in-person CBTI and Behavioral Placebo Therapy (BPT) interventions.

The primary outcomes are sleep efficiency (SE), sleep latency (SL), wake after sleep onset (WASO) and total sleep time (TST). These are traditional measures associated with insomnia and served as measures to determine if the participants responded to the CBTI intervention. Secondary outcomes included the measurement of quality of life (QOL) and daily functioning, which are both measures of daytime sequelae related to insomnia.

**Specific Aims**

Four specific aims are addressed in this study:

**Aim 1:** Evaluate and address the feasibility and the potential barriers to recruitment, retention, adherence, and delivery of internet based CBTI in BCS in rural MUAs.

**Aim 2:** Examine sleep/wake patterns, quality of life, and functional outcomes in individuals after a six-week internet-based VC CBTI intervention (pre/post within group differences).
H1: Women receiving internet-based VC CBTI intervention will demonstrate an improvement in sleep efficiency ([time asleep/time in bed] X 100) post CBTI intervention.

H2: Women receiving the internet-based VC CBTI intervention will self-report an improvement in QOL and perceived daily functioning post CBTI intervention.

Aim 3: Examine sleep/wake patterns, quality of life, and functional outcomes in individuals receiving an internet-based VC CBTI compared to those receiving standard, in-person CBTI and in-person behavioral placebo treatment (3 group design).

H1: Women receiving internet-based VC CBTI intervention will demonstrate an improvement in sleep efficiency ([time asleep/time in bed] X 100) compared to those receiving an in-person placebo treatment.

H2: Women receiving the internet-based VC CBTI intervention will self-report an improvement in QOL and perceived daily functioning compared to those receiving an in-person placebo treatment at the conclusion of the intervention.

H3: Women receiving internet-based VC CBTI intervention will demonstrate an improvement in sleep/wake patterns (SE, SL, TST) quality of life and functioning similar to the effect size seen in those receiving an in-person CBTI intervention (Cohen’s d = 0.34 - 0.67) (Matthews et al., 2014).

**Definition of Terms**

**Sleep Terms**

3 P Model of Insomnia - a model that proposes three categories of factors that contribute to chronic insomnia: predisposing, precipitating, and perpetuating (Spielman et al., 1987)

Sleep Efficiency (SE) - percentage of time a person is sleeping while in bed

([time asleep/time in bed] X 100)
Sleep Latency (SL) - time it takes for a person to fall asleep after turning out the lights and intending to sleep.

Total Sleep Time (TST) - total amount of time (in minutes) a person sleeps in one night.

Wake After Sleep Onset (WASO) - total amount of time (in minutes) a person is awake between falling asleep (initially) and waking up for the last time.

**Therapy Terms**

Behavioral Placebo Therapy (BPT) – a structured desensitization therapy in which participants identify behavioral and cognitive arousal items which are then paired with neutral items.

Bibliotherapy - a form of psychotherapy in which directed reading of books, articles, or handouts is used for therapeutic purposes.

Cognitive Behavioral Therapy for Insomnia (CBTI) - a structured psychotherapy that addresses both dysfunctional thoughts and maladaptive behaviors related to insomnia to individuals or groups.

In-person CBTI - CBTI delivered by a therapist to a patient(s) in the same room.

Insomnia - difficulty initiating or maintaining sleep, or having non-restorative sleep for a period of at least one month in spite of having adequate opportunity to sleep.

   - Acute - duration of less than one month
   - Chronic - occurs at least three nights per week; duration of greater than one month
   - Primary - insomnia is independent of any other cause (medical diagnosis, medication, substance abuse)
   - Secondary (comorbid) - insomnia occurs concurrently with or subsequent to a primary cause (medical diagnosis, medication, substance abuse)
Internet-based videoconference (VC) CBTI - CBTI delivered by a therapist to patient(s) via a computer. For the purposes of this study, the intervention will be delivered using a software program that allows the patient and the therapist to see and speak to each other in real-time.

Perpetuating Factors - cognitive and behavioral changes that an individual makes during the acute phase of insomnia that facilitate the transition from acute to chronic insomnia when they are inappropriately continued.

Telephone-based CBTI - CBTI delivered by a therapist to a patient(s) over the telephone. This includes an audio connection but no video connection.

Videoconference-based CBTI - CBTI delivered by a therapist to a patient(s) over the telephone. This includes both an audio connection and a simultaneous video connection.

Virtual Reality - computer simulated environment that can be prescribed or interactive, and can be used as a part of psychotherapy

Web-based Bibliotherapy - a form of psychotherapy in which directed reading of web pages is used for therapeutic purposes

**Geographic Terms**

Medically Underserved Area (MUA) - MUA is defined as a county or civil division in which there is a shortage of health care providers (HRSA, 2009). Approximately half of the State of Colorado qualifies as a MUA.

Rural - located outside a metropolitan statistical area (MSA) or located in a rural census tract of a MSA (HRSA, 2009). For the purposes of this study, non-urban based MUAs will be defined as rural.
General Terms

Breast Cancer Survivor (BCS) - people who have received a diagnosis of breast cancer. For the purposes of this study, BCS are women between the ages of 35-65 who are between 1-36 months post primary treatment.

Quality of Life (QOL) - "the individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns" (WHO, 1997).

Study Rationale

Patients who live in MUA's have limited access to health care which can impact health outcomes (Natale-Pereira, Enard, Nevarez, & Jones, 2011) and psychosocial distress (Weaver et al., 2013). A review of the literature showed that rural BCS regularly seek primary cancer treatment in urban areas, due to a lack of treatment options in their communities (Bettencourt et al., 2007). This extended stay away from home can disrupt family and social connections which can have ramifications when the BCS return home. Rural BCS report a lack of both formal mental health therapy and structured social support such as BCS support groups (Bettencourt et al., 2007; Burris & Andrykowski, 2010).

Insomnia is a common complaint after primary cancer treatment, which often persists for years. In a recent study of rural BCS, three years post treatment, 34% reported sleeplessness and 41% fatigue (Befort & Klemp, 2011). Insomnia is a prevalent comorbidity after treatment for breast cancer, with wide reaching ramifications. Breast cancer survivors (BCS) who have disordered sleep suffer multiple complications including an increased risk of cancer recurrence and death (Savard, Simard, Ivers, & Morin, 2005b). This study was designed to 1) explore the feasibility and potential barriers of recruiting BCS with insomnia
who live in MUAs in Colorado, and 2) to explore the effect of internet-based VC CBTI on this population.

**Significance**

**Practice**

This study was designed to pilot an internet-based VC CBTI to BCS with insomnia. The therapist was an advanced practice nurse with training in CBTI, and the participants are BCS who reside in MUAs in Colorado. CBTI is an established therapy for insomnia in BCS, but it is unavailable to many women in rural communities. An internet-based therapy could overcome geographic boundaries and provide access to mental health services for BCS in MUAs. The use of an advanced practice nurse as a CBTI therapist could provide a viable alternative to urban based sleep specialists.

**Theory**

This research is based on the 3 P Model of Insomnia (Spielman et al., 1987) which posits that chronic insomnia is comprised of predisposing, precipitating, and perpetuating factors. This study used an internet-based VC CBTI intervention targeting perpetuating factors leading to chronic insomnia, to improve sleep in BCS in MUAs.

**Research**

This study aimed to further two areas of research: the study of insomnia in rural BCS and the use of internet-based VC CBTI. There is evidence CBTI is an effective treatment in BCS (Savard et al., 2005a; Tremblay et al., 2009), but no studies to date have studied the effects of CBTI specific to rural BCS. Prior studies using internet-based VC CBTI have focused on a manualized self-help approach rather than a therapist driven intervention that mimics in-person therapy (Espie et al., 2012; Ritterband et al., 2012; Vincent & Lewycky,
One study provided 5-20 minute animated video segments on DVD in lieu of therapist time (Savard et al., 2014). Exploring the use of internet-based VC CBTI in a population of BCS who live in MUAs will further our understanding of both rural BCS with insomnia and a therapist driven internet-based VC CBTI.

**Policy**

Insomnia is a significant public health issue that affects 10-20% of the general adult population (Buysse, 2013), and 30-50% of BCS (Savard et al., 2009). While the financial ramifications of insomnia on BCS is not known, the fiscal aspect of insomnia has been studied in the general population. A recent survey estimated the cost of insomnia to businesses in the United States. They found that insomnia costs approximately $2200 per person in the workforce, for a total estimated cost of $63.2 billion annually (Kessler et al., 2011). In addition, sleep disruptions can have significant implications on health and survival in cancer survivors (Innominato et al., 2009; Innominato et al., 2012; Savard et al., 2005b).

**Summary**

Utilizing the 3 P Model of Insomnia (Spielman et al., 1987) this study seeks to evaluate the effect of internet-delivered CBTI on BCS in MUAs in Colorado. Additionally, it will explore the feasibility and potential barriers to recruitment in MUAs and the challenges associated with using an internet-based technology to deliver CBTI. The knowledge gained will contribute to the growing literature about effective treatments for insomnia in BCS, specifically the understudied rural BCS population. The use of an internet-based VC CBTI will serve as a pilot project to test the feasibility of this intervention.

In Chapter I, an overview of the problem of insomnia in BCS and the treatment of insomnia with CBTI were introduced. The purpose of this dissertation and the conceptual
framework were presented, and the specific aims of the study were outlined. Chapter II will
describe the current literature about insomnia in BCS in detail and the use of internet based
CBT, and Chapter III will present the study methodology.
CHAPTER II

REVIEW OF THE LITERATURE

The following literature review is categorized into several areas: 1) insomnia prevalence in BCS, 2) BCS in MUAs, 3) CBTI, and 4) face to face versus remotely delivered CBT.

Insomnia Prevalence in BCS

Insomnia disproportionately affects BCS compared to survivors of other cancers and the general public (Berger, 2009b; Davidson, MacLean, Brundage, & Schulze, 2002; Savard, et al., 2001a). This may be due, in part, to the tendency of older adults and women to have more sleep complaints, and the overrepresentation of these contributing demographic factors in breast cancer populations. Additionally, many breast cancer survivors receive hormonal treatments that result in sleep-disrupting menopausal symptoms. In one study, 51% of BCS reported insomnia symptoms after radiation therapy and 19% met the criteria for insomnia syndrome, suggesting greater severity and frequency of insomnia symptoms after primary cancer treatment (Savard, et al., 2001b). Subjective reports of insomnia in women after primary cancer treatment range from 20-70% (Fiorentino & Ancoli-Israel, 2006). In comparison, lower rates of insomnia symptoms were reported in surveys of the general populations of France and Italy (37.2%), the United States (27.1%) and Japan (6.6%) (Leger & Poursain, 2005).

Insomnia in BCS is often triggered by a cancer diagnosis or primary cancer treatment including surgery, chemotherapy, radiation, and hormone therapy (Berger, 2009b). This can be accompanied by anxiety, depression and fatigue (Minton, Alexander, & Stone, 2012), all of which can serve to perpetuate the insomnia. The insomnia can last long after treatment. A
recent study found that 18% of BCS still suffered from insomnia five years after treatment (Zucca, Boyes, Linden, & Girgis, 2012). Sequelae from the insomnia include memory and cognitive impairment (Caplette-Gingras, Savard, Savard, & Ivers, 2012) as well as a decreased immune system (Kamath, Prpich & Jillani, 2015; Miller, Ancoli-Israel, Bower, Capuron, & Irwin, 2008).

Common pharmacologic treatments for insomnia include prescribed benzodiazepines and sedative-hypnotics as well as over the counter antihistamines and unregulated nutritional supplements (Moore, Berger, & Dizona, 2011). Prescription sleep medications are generally indicated as a short-term treatment for transient insomnia, providing immediate relief during periods of high stress or grief. Long term use can result in diminishing effectiveness and dependence. Pharmacologic treatments don't address the underlying causes of insomnia. Non-pharmacologic therapies (e.g., sleep hygiene, relaxation therapy, stimulus control, and sleep restriction) address the underlying behavioral and cognitive barriers to good sleep. A recent study demonstrated that a combination of pharmacologic treatment with hypnotic medication and CBT was effective treatment for acute insomnia, but CBT alone was effective in the treatment of subsequent chronic insomnia (Morin et al., 2009).

In past studies of BCS with insomnia, urban areas were disproportionately represented as most studies originated in hospitals and universities in major cities. Two studies recruited participants from multiple Midwestern clinics in the United States, although the exact locations of the clinics were not disclosed so it remains unknown if rural areas were represented (Berger, 2009b; Berger, et al., 2003).
BCS in MUAs

The Health Resources and Services Administration (HRSA) has designated Medically Underserved Areas (MUA) as counties, civil divisions or urban census tracts in which there is a shortage of health care providers and personal health services (Figure 1) (CRHC, 2014). According to the Colorado Rural Health Center 13% of the state’s population live in rural or frontier counties and 77% of those counties are medically underserved (2013). Although urban BCS may not have adequate access to healthcare services because of lack of insurance coverage, this study will focus on rural BCS in MUAs in Colorado.

Rural BCS may experience survivorship differently than urban BCS. Studies have shown a decrease in satisfaction among women with psychosocial and medical support following primary breast cancer treatment due to a lack of care providers in rural areas (Gray, James, Manthorne, Gould, & Fitch, 2004; Weaver et al., 2013). Rural BCS overall have a lower quality of life (Lyons & Shelton, 2004; Reid-Arndt & Cox, 2010) than do urban BCS, and this can persist several years after treatment (Albert, Koller, Wagner, & Schulz, 2004).

In addition, rural providers report a deficit in adequate ongoing education regarding survivorship issues and challenges surrounding continuity of care after primary cancer treatment (Davis, Williams, Redman, White, & King, 2003; Gray et al., 2004; Pascal, Johnson, Dickson-Swift, McGrath & Dangerfield, 2015). It is also possible that rural BCS may perceive a stigma associated with seeking psychological services (Bettencourt et al., 2007). Treatment could be provided privately and remotely, but few studies have explored the willingness and technological ability of rural BCS. Additional investigations are warranted to understand the attitudes of rural BCS toward mental health treatment, as well as
their access and familiarity with the technology necessary to receive mental health treatment online.

Figure 1. Colorado Rural Counties (CRHC, 2014)

Cognitive Behavioral Therapy for Insomnia

CBTI is the front line psychosocial treatment for insomnia (Buysse, 2013), and interventions have been shown to improve sleep both immediately after therapy and up to 12 months after therapy in BCS (Berger et al., 2009; Epstein & Dirksen, 2007; Savard et al., 2005a). CBTI has been established as an effective treatment for both primary and comorbid insomnia (Morin et al., 2006), and as an effective co-treatment for patients attempting a stepped approach to discontinuing hypnotics (Belanger, Belleville, & Morin, 2009).
Previous studies of cognitive behavioral therapy for insomnia (CBTI) in BCS include randomized controlled trials (RCTs) (Arving, Sjoden, Bergh, Hellbom, Johansson, Glimelius, & Brandberg, 2007; Berger et al., 2009; Epstein & Dirksen, 2007; Fiorentino et al., 2009; Savard et al., 2005a) and pre-post group designs (Berger et al., 2003; Breland, Lee, & Muraki, 2005; Quesnel, Savard, Simard, Ivers, & Morin, 2003; Savard, Villa, Simard, Ivers, & Morin, 2011). The RCTs varied widely in size, ranging from 14 (Fiorentino et al., 2009) participants to 219 (Berger et al., 2009). Pre-post design studies uniformly had small samples, ranging from 10 to 21 participants (Berger et al., 2003; Quesnel et al., 2003; Savard et al., 2011). Urban areas were disproportionately represented as most studies originated in hospitals and universities in major cities. Two studies recruited from multiple Midwestern clinics in the United States, since the exact locations of the clinics were not disclosed, it remains unknown if rural areas were represented (Berger et al., 2009; Berger et al., 2003).

CBTI consists of four main components of therapy: stimulus control, sleep restriction, sleep hygiene education, and cognitive therapy (Perlis, Jungquist, Smith & Posner, 2005) (Table 1). Stimulus control (SC) is a therapy that limits the amount of time a person is in bed but not sleeping. In order to re-associate the bedroom with sleep, patients are advised to go to the bedroom only when sleepy and ready to fall asleep. If they cannot fall asleep within 15 minutes, they are instructed to leave the bedroom and not return until ready to sleep. Activities in the bedroom other than sleep and sexual activity are discouraged. Sleep restriction is a method in which the therapist limits the patient's scheduled sleep time based on recent total sleep averages. This is recommended to ensure that the patient is sleepy at bedtime. Sleep hygiene is an education about both sleep needs and counterproductive behaviors. Cognitive therapy challenges dysfunctional thoughts about
sleep and the daytime consequences (Perlis et al., 2005). A fifth therapy component, relaxation training, can be added to the CBTI intervention to educate the patient if hyper-arousal at bedtime is a problem.

Table 1

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<thead>
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<th>Standard Components of CBTI</th>
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<td><strong>Sleep Restriction.</strong> The goal of this behavioral strategy is to build up &quot;sleep drive&quot; by restricting sleep and excessive amounts of time in bed in an effort to compensate for sleep loss. As sleep becomes consolidated, the &quot;sleep window&quot; is extended, until a sleep schedule that optimizes daytime alertness is achieved.</td>
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<tr>
<td><strong>Stimulus Control.</strong> The primary goal of stimulus control is to re-establish the discriminative properties of sleep and sleep-compatible stimuli with the act of sleeping. This is typically achieved by avoiding sleep-incompatible behaviors in the bedroom, by reinforcing a regular sleep-wake schedule, and by strengthening the bed as a cue for sleep.</td>
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<td><strong>Sleep Hygiene Education.</strong> This psycho-educational intervention is not thought to be an effective “monotherapy,” however, sleep hygiene is generally considered to be an integral part of CBTI. Poor sleep hygiene is rarely the primary cause of insomnia, but it increases the likelihood of insomnia perpetuation.</td>
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<tr>
<td><strong>Cognitive Therapy.</strong> This component addresses dysfunctional beliefs held by most insomnia patients (e.g., mild sleep deprivation is detrimental to functioning), or it can address individualized concerns, unwanted intrusive ideation, or worry using a more traditional cognitive therapy model.</td>
</tr>
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Face to Face versus Remotely Delivered CBT

CBT is a standard therapy in traditional face to face practice. Research into remote delivery of this therapy continues, but it is not yet commonly available in practice. Remote delivery of CBT can include: bibliotherapy, web-based bibliotherapy, telephone, videoconferencing and virtual reality.

Bibliotherapy and web-based bibliotherapy using CBT can be further divided into three categories based on the amount of therapist guidance given: guided, minimal contact, and self-administered (Glasgow & Rosen, 1978). A recent review of the literature and meta-analysis found that bibliotherapy-based CBT for insomnia was effective using minimal contact and self-administered therapy, but was more effective using guided therapy (Farrand
& Woodford, 2013). Web-based bibliotherapy using CBT was not evaluated in this meta-analysis.

Several studies have evaluated the use of web-based bibliotherapy to treat insomnia. Sleep Healthy Using the Internet (SHUT-i) is a six session web-based bibliotherapy based on CBTI principles including education, sleep restriction, stimulus control, cognitive restructuring and relapse prevention (Ritterband et al., 2012; Thorndike, Saylor, Bailey, Gonder-Frederick, Morin, & Ritterband, 2008). SHUT-i is individually tailored based on participants' sleep diary entries, although all contact is automated instead of therapist guided. In a study of cancer survivors with insomnia, SHUT-i produced a clinically meaningful improvement in insomnia severity and a significant (Cohen's $d=0.72$, $p<0.01$) increase in sleep efficiency compared to the control group.

The Insomnia Assessment and Treatment Program (IATP) used a small handheld computer, to monitor sleep patterns and provide automated sleep restriction and stimulus control advice based on baseline sleep patterns (Riley, Mihm, Behar, & Morin, 2010). In a study of participants with primary insomnia, no significant differences in sleep outcomes were found between the IATP and the control group at six and 12 weeks post-treatment. The authors speculated that this may have been due to the common aspects of the interventions which included sleep hygiene, relaxation, and cognitive restructuring (Riley et al., 2010).

The largest study of web-based bibliotherapy using CBTI, occurred in a study of 118 adults with the diagnosis of chronic insomnia (Vincent & Lewycky, 2009). Participants in this study logged on to a website that provided a five session self-help CBTI intervention through the presentation of web pages, text, and video clips. Homework was assigned each week, but the therapy was not tailored based on homework results. The only patient contact
was at week three, when an electronic message was sent to participants inquiring about any technical difficulties. Both sleep quality and insomnia severity significantly improved in the CBTI group \( (p<0.0001) \) but not the control group (Vincent & Lewycky, 2009).

Virtual reality (VR) has been tested in conjunction with CBT as a method of exposure therapy in disorders such as PTSD, social anxiety, and panic disorder. In a systematic review of the literature of patients with PTSD, CBT plus exposure therapy via VR was effective in seven out of ten studies (Gonçalves, Pedrozo, Freire Coutinho, Figueira, & Ventura, 2012). Treatments for social anxiety and panic disorder both showed promising results when CBT was paired with VR (Meyerbroker & Emmelkamp, 2010; Yuen, Herbert, Forman, Goetter, Comer, & Bradley, 2013), more research is needed to determine the efficacy of the therapy.

The two most studied remotely delivered CBT modalities are the telephone and videoconferencing (VC). Twelve studies between 2002-2012 compared face to face treatment with either telephone or VC CBT. Six studies used the telephone to deliver CBT (Bastien, Vallieres, & Morin, 2001; Burgess et al., 2011; Day & Schneider, 2002; Glueckauf et al., 2012; Lovell et al., 2006; Mohr et al., 2012). Of these, two (Burgess et al., 2012; Lovell et al., 2006) conducted both initial and discharge meetings face to face, with subsequent sessions by telephone (13 and 8 sessions respectively). Four studies used a telephone therapy exclusively, with no face to face component. Glueckauf et al. (2012) conducted a series of 12 CBT sessions via the telephone; seven group and five individual sessions. Mohr et al. (2012) conducted 18 individual, 45-minute sessions over the telephone, while Bastien et al. (2004) used eight individual 20-minute sessions. Day & Schneider (2002) conducted five sessions of CBT delivered via a speaker phone in a clinic, then compared this therapy to both a face to face and a videoconference therapy. Given the mixed
designs of these studies, with different session lengths, number of sessions, and face to face sessions in some studies, it is difficult to conclude that telephone based CBT is effective.

Seven studies used VC to deliver the CBT. All VC sessions occurred at a clinic, with the therapist either in a different room or a different clinic. VC technology was provided and supported by the clinic. In five studies patients underwent the VC therapy while alone in a clinic room (Bouchard et al., 2004; Day & Schneider, 2002; Germain, Marchand, Bouchard, Drouin, & Guay, 2009; Mitchell et al., 2008; Ruskin et al., 2004). One study consisted of group CBT during which the participants would meet in a group at a clinic, then the therapist would lead the group via VC from another location (Morland et al., 2010). Another study involved children with depression and their primary caretakers. In this study the therapist met face to face with both parent and child before beginning eight weekly CBT sessions using VC at a medical center (Nelson et al., 2003). Unlike the telephone CBG, no VC therapy offered the participant an opportunity to have therapy at home.

Of the twelve studies that offered remotely delivered CBT, only two recruited individuals from rural areas (Bouchard et al., 2004; Germain et al., 2009). Further research needs to explore the feasibility of using a remotely delivered CBT to reach underserved rural populations. Together, these studies of VC delivered CBT indicate that additional study of VC technology needs to be undertaken. While these studies used VC technology only in a clinic setting, given the technology that exists today future studies need to explore the use of VC therapy in the home setting, with specific outreach to rural participants.

**Conceptual Framework**

Classical conditioning provides a theoretical basis for the perpetuation of insomnia. In classical conditioning, a previously neutral stimulus (e.g. the bedroom) is associated with
an unconditioned stimulus (e.g. arousal), eliciting a conditioned response. In the case of insomnia, the bedroom and thoughts about sleep are associated with arousal instead of sleepiness. For BCS this can originate during the initial diagnosis and treatment when sleep patterns are disturbed. The transition to chronic insomnia occurs when the acute treatment for breast cancer is finished, but the conditioned response to arousal at bedtime persists.

The Behavioral Model of Insomnia, or the "3 P Model of Insomnia" (Spielman et al., 1987) (Figure 2), informs the CBTI intervention. In this model, Spielman and colleagues hypothesize that predisposing, precipitating, and perpetuating factors lead to and maintain insomnia. Predisposing factors are biopsychosocial traits specific to an individual that make it more likely that person will experience insomnia. Precipitating factors are sudden life stressors such as divorce, job change, or medical diagnosis, which serve as triggers for acute insomnia. Perpetuating factors are dysfunctional thoughts and behaviors that an individual uses to manage insomnia. These may initially be useful for coping with acute insomnia, but can become the underlying cause of chronic insomnia. Examples of this include excessive time in bed while awake and napping (Perlis, et al., 2005).

Many BCS complain of insomnia that began or worsened with the cancer diagnosis, an undeniably stressful life event. Primary treatment for breast cancer can include surgery, radiation, and chemotherapy, all of which can cause changes to circadian rhythms (Liu et al., 2013). Decreased activity and increased napping behaviors are common coping methods used by this population during this stressful time. If these behaviors are continued past the acute phase of cancer treatment, maladaptive behaviors can become a part of a person's routine, and facilitate the transition to chronic insomnia.
If a person is predisposed to insomnia based on biopsychosocial traits (Spielman et al., 1987), then a diagnosis of breast cancer and the associated primary phase treatment can act as precipitating events that cause the BCS to suffer acute insomnia. During this time, if the BCS develops poor sleep habits such as napping and excessive time in bed to cope with the fatigue associated with primary cancer treatment then these behaviors can become habits which can then perpetuate the insomnia long after the acute treatment is completed. This can then lead to cognitive dysfunction about sleep, which triggers the autonomic arousal and emotional distress (Harvey, 2002) that in turn perpetuates the insomnia which reinforces the poor sleep habits. It is this combination of cognitive and behavioral stressors that drive the transition to chronic insomnia. It is not surprising, therefore, that CBTI is a frontline psychotherapy for insomnia as it addresses both mechanisms that perpetuate insomnia (Buysse, 2013; Williams, Roth, Vatthauer, & McCrae, 2013).
Summary

The state of the science indicates the importance of investigating remotely-delivered CBTI to BCS in MUAs. BCS suffer from insomnia at a higher rate than the general population (Berger, 2009b; Davidson et al., 2002; Savard et al., 2001). Insomnia can affect memory, increase cognitive impairment (Caplette-Gingras et al., 2012) and decrease the immune system (Miller et al., 2008). BCS in MUAs often experience a lower quality of life after cancer treatment (Lyons & Shelton, 2004; Reid-Arndt & Cox, 2010) and have fewer health care resources available (Gray et al., 2004). CBTI is an efficacious treatment for insomnia (Buysse, 2013) which has been proven in BCS (Quesnel et al., 2003; Savard et al., 2005a; Tremblay et al., 2009). Remotely delivered CBT shows promise as a method to reach rural participants (Bouchard et al., 2004; Germain et al., 2009). The literature supports research into an internet-based VC CBTI for BCS with insomnia in MUAs.

The 3P Model of Insomnia (Spielman et al., 1987) guides this research. It offers direction for hypothesis development and provides a framework for the CBTI intervention. The use of CBTI targets the perpetuating factors of insomnia. This study is designed to evaluate the use of CBTI over the internet to mitigate insomnia in rural BCS.
CHAPTER III

METHODS

Introduction

The primary purposes of this study were to: 1) explore the feasibility and potential barriers of recruiting BCS with insomnia who live in MUAs in Colorado, and 2) to explore the effect of internet-based VC CBTI on this population. The 3 P Model of Insomnia guided this intervention (Spielman et al., 1987). This model suggests that there are biological and psychological factors that increase vulnerability to insomnia (predisposing factors). When a stressor occurs, such as a breast cancer diagnosis and treatment (precipitating factors) the individual with predisposing factors is more likely to experience acute insomnia. Behavioral and psychological coping mechanisms, which can be helpful in the short term, such as napping and excess time in bed, perpetuate the insomnia and facilitate the transition from short term to chronic insomnia. Dysfunctional thoughts about sleep and consequences of insomnia can also perpetuate the problem.

Existing research suggests that CBTI is the front line therapy to treat insomnia in BCS (Buysse, 2013). The purpose of this study was twofold. The first purpose was to evaluate the feasibility of conducting a study of BCS in MUAs. This includes evaluating the potential barriers to recruitment as well as the technical and access issues in MUAs. The second purpose was to examine the effects of internet-based VC CBTI on BCS with insomnia living in rural MUAs in Colorado. Data was collected and compared to existing data from an in-person CBTI intervention conducted by Dr. Matthews (NIH 1K23NR010587; referred to as the parent study). The instruments and methodologies used were consistent with the parent study whenever possible for maximum comparability.
Research Questions and Hypotheses

The Specific Aims and Hypotheses were stated in Chapter 1 and are reiterated here.

**Aim 1:** Evaluate and address the feasibility and the potential barriers to recruitment, retention, adherence, and delivery of internet based CBTI in BCS in rural MUAs. There was no hypothesis as this was an exploratory aim.

**Aim 2:** Examine sleep/wake patterns, quality of life, and functional outcomes in individuals after a six-week internet-based VC CBTI intervention (pre/post within group differences).

H1: Women receiving internet-based VC CBTI intervention will demonstrate an improvement in sleep efficiency ([time asleep/time in bed] X 100) post CBTI intervention.

H2: Women receiving the internet-based VC CBTI intervention will self-report an improvement in QOL and perceived daily functioning post CBTI intervention.

**Aim 3:** Examine sleep/wake patterns, quality of life, and functional outcomes in individuals receiving an internet-based VC CBTI compared to those receiving standard, in-person CBTI and in-person behavioral placebo treatment (3 group design).

H1: Women receiving internet-based VC CBTI intervention will demonstrate an improvement in sleep efficiency ([time asleep/time in bed] X 100) compared to those receiving an in-person placebo treatment.

H2: Women receiving the internet-based VC CBTI intervention will self-report an improvement in QOL and perceived daily functioning compared to those receiving an in-person placebo treatment at the conclusion of the intervention.

H3: Women receiving internet-based VC CBTI intervention will demonstrate an improvement in sleep/wake patterns (SE, SL, TST) quality of life and functioning similar to
the effect size seen in those receiving an in-person CBTI intervention (Cohen’s $d = 0.34 - 0.67$) (Matthews et al., 2014).

**Design**

A quasi-experimental, one group pretest-posttest design was used for this study. Participants attended six weekly internet-based VC CBTI sessions. Measures of sleep, QOL, and daily functioning were evaluated prior to the CBTI intervention and at the end of the 6-week intervention. The results were then compared to the results of the parent study that used an in-person CBTI intervention and a placebo treatment (BPT).

**Sample**

The target sample for this study was female BCS (1-60 months post treatment) with insomnia (ages 35-65) who live in MUAs in Colorado. This sample was specifically chosen to age and treatment-stage match the parent study population. The age range is consistent with the general BCS population (>35 years of age). The upper age range was established as women over the age of 65 can have physiologic changes that contribute to insomnia. Participants must have been at least one month post primary cancer treatment (chemotherapy, radiation, surgery) as the acute treatment phase can increase chronic inflammatory responses which contribute to sleep disturbances (Liu et al., 2012; Wang et al., 2012). It was anticipated that 25 participants would be recruited for this study based on the need for 20 participants and the anticipation of 20% attrition.

The estimated incidence of female breast cancer in Colorado in 2012 was 64.5 per 100,000 women. Of these, 84% were White/Non-Hispanic, 10% were White/Hispanic, and 3% were Black (Colorado Department of Public Health and Environment (CDPHE), 2015).
It was estimated that the women recruited to this study would reflect these demographics. Participants were screened for insomnia using the Insomnia Severity Index (ISI), and additional criteria included residency in a MUA in Colorado and access to high speed internet. The participant's ability to consent was determined using a brief mental status screening over the telephone. Inclusion and exclusion criteria are found in Table 2.

Table 2

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
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<tbody>
<tr>
<td>Women ≥ 35 years of age up to age 65</td>
<td>Presence of a serious unstable physical illness other than cancer</td>
</tr>
<tr>
<td>1-60 months after surgery, radiation or chemotherapy for non-metastatic breast cancer and on a stable dose of anti-estrogen agent and medications for hot flashes</td>
<td>Presence of dementia, major depression, psychosis or other serious psychiatric disorder as determined by the Insomnia Interview Schedule (IIS) with questions adapted from the Structured Clinical Interview for DSM-IV)</td>
</tr>
<tr>
<td>Meets diagnostic criteria for chronic, comorbid insomnia</td>
<td>Presence of a sleep disorder other than insomnia. Based on self-report in initial interview (IIS) when asked about specific sleep disorders.</td>
</tr>
<tr>
<td>Speak and write English</td>
<td>Unstable doses of psychotropic medications (excluding hypnotics), opioids, anti-endocrine medications, or use of high dose steroids</td>
</tr>
<tr>
<td>Stable doses of psychotropic medications (excluding hypnotics), opioids, anti-endocrine medications, or use of high dose steroids* (&lt; 10% change in dosage/week)</td>
<td>Current evening/night shift employment</td>
</tr>
<tr>
<td>Residence in a rural MUA</td>
<td>Residence in an urban county of Colorado</td>
</tr>
<tr>
<td>Access to computer for videoconferencing meetings</td>
<td>No access to computer either at home or at a library or cancer outreach center within 30 miles.</td>
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</table>

Recruitment

COMIRB study approval was awarded in January 2014. Study recruitment ran between June 2014 and February 2016. Participants were recruited from rural cancer clinics, regional infusion centers, referrals from primary care providers in MUAs and through a partnership with the University of Colorado Cancer Center (UCCC). Rural communities in
Colorado are served by regional resources such as St. Mary's Regional Cancer Center in Grand Junction and St. Mary-Corwin Medical Center in Pueblo which are a part of the UCCC network. The P.I. contacted breast cancer patient navigators at these regional resources to educate them about the study and provide them with information to disseminate to potential participants. IRB approved flyers and brochures which included the P.I. and IRB-designated number, contact name and phone number, purpose of the research, primary eligibility criteria, and compensation information were provided.

Additional recruitment strategies that were explored included; recruitment through websites related to breast cancer survival, websites of trustworthy organizations (Morgan, Jorm, & Mackinnon, 2013) and Facebook (Lohse, 2013). While past studies have shown a disproportionately high Caucasian recruitment through these measures (Im, Chee, Tsai, Bender, & Lim, 2007; Lohse, 2013; Morgan et al., 2013), this is an appropriate method of recruitment to explore for this study. Website advertising mirrored the IRB approved flyers used in the clinics.

In recognition of their time and inconvenience, study participants received up to $50 for their participation. A $25 gift card was disbursed after the second session, and another $25 gift card was disbursed after the final survey results were completed.

**Setting**

The setting for the study was a videoconferencing platform: Adobe® Acrobat® Connect™ Pro (AACP). This provided a secure (SSL/TLS connection), easy to use method of internet-based software. The P.I. emailed each participant a hyperlink prior to each session. The participant then clicked on the hyperlink and was taken to a screen which prompted the user to enter their password. This ensured confidentiality, as each session cookie was invalidated...
immediately following a session. Once the password was entered, the session opened automatically on the participant's computer. The software worked with all webcams, and if the participant did not have a webcam one was provided free of charge. Possession of a computer and high speed internet access was a requirement for inclusion in the study. This choice was based on its security, encryption capabilities, ease of use, and compliance with HIPAA requirements (Adobe Systems Incorporated, 2013). The participant had the option of joining the videoconference (VC) from the privacy of her home or from a local library if no high speed internet was available at home. The only requirement was that the room be private to ensure confidentiality for the participant.

There were several encouraging statistics that made internet delivery of CBTI possible to BCS in MUAs in Colorado. It was estimated that 81% of adults in the U. S. regularly use the internet and of those 65% access the internet with a DSL, cable, or fiber optic connection (Pew, 2013). While it was anticipated that this percentage was lower in rural communities, it was believed there was increasing probability of a high number of households with high speed internet access.

**Procedure**

Potential participants were screened by the P. I. in an initial telephone conversation. At that time the P. I. used the IIS to establish insomnia severity and conduct a mental status screening. Qualified participants were oriented to the study and if interested mailed or emailed a copy of the Informed Consent and HIPAA forms. An Adobe Connect session was scheduled within one week to review these forms with the participant and gain informed consent (see below). This session also served to test the participant's internet connectivity and the participant’s comfort with necessary technology. The participant was asked to mail
back the signed informed consent. Once this was received, the participant received an email containing a sleep diary and a link to the surveys, and the six CBTI sessions were scheduled.

**Intervention**

The proposed and parent study intervention was based on an established in-person therapy to treat insomnia in breast cancer survivors (Epstein & Dirksen, 2007; Matthews et al., 2014; Savard et al., 2005a). The study used a six session CBTI therapy to evaluate the efficacy of internet-based VC CBTI on insomnia in BCS who reside in MUAs. This is consistent with the parent study and standard CBTI treatment suggested by Dr. Michael Perlis (Perlis et al., 2005). Sessions were held through a videoconferencing platform: **Adobe® Acrobat® Connect™ Pro (AACP)**, which was approved by the University of Colorado Denver. The first two sessions were approximately 30-45 minutes each. These sessions involved education on sleep restriction, stimulus control, sleep hygiene and cognitive therapy. Sessions three, four, and five consisted mainly of reviewing the sleep diary and making needed sleep schedule adjustments (20-30 minutes each). The final session focused on relapse prevention and lasted approximately 30 minutes (Table 3).
Table 3

<table>
<thead>
<tr>
<th>Week</th>
<th>Minutes</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>15-30</td>
<td>Informed Consent; Adobe Connect Session</td>
</tr>
<tr>
<td>1</td>
<td>30-45</td>
<td>Evaluation of Sleep Diary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Education: Sleep Restriction, Stimulus Control</td>
</tr>
<tr>
<td>2</td>
<td>30-45</td>
<td>Evaluation of Sleep Diary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Education: Sleep Hygiene, Cognitive Therapy</td>
</tr>
<tr>
<td>3</td>
<td>20-30</td>
<td>Evaluation of Sleep Diary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sleep Schedule Adjustments</td>
</tr>
<tr>
<td>4</td>
<td>20-30</td>
<td>Evaluation of Sleep Diary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sleep Schedule Adjustments</td>
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<tr>
<td>5</td>
<td>20-30</td>
<td>Evaluation of Sleep Diary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sleep Schedule Adjustments</td>
</tr>
<tr>
<td>6</td>
<td>30</td>
<td>Relapse Prevention</td>
</tr>
</tbody>
</table>

**Data Collection**

Participants were asked to keep a sleep diary as a daily log of their sleep characteristics. Study surveys were administered online using REDCap. REDCap is a Department of Health and Human Services (DHHS) supported, secure online tool designed to collect and manage data (Harris, Taylor, Thielke, Payne, Gonzalez, & Conde, 2009).

All survey responses were kept in a password protected, secure database on a University of Colorado Denver server, which was maintained by a professional technical support team. Participants completed the survey measures prior to beginning the CBTI therapy and after the last session (6 weeks). All of the primary measures were self-report. Participants were informed that all responses would be kept confidential.

**Consent and Authorization**

Informed consent was obtained from participants in compliance with human subjects’ protection and the Colorado Multiple Institutional Review Board (COMIRB). Consent was obtained during an initial Adobe Connect session. The participant was given the opportunity
to ask any questions she had, and informed at that time that participation was voluntary and she may withdraw from the study at any point. A copy of this consent was then mailed to the P.I. and a copy was kept by the participant. The first CBTI session occurred after the consent was returned to the P.I.; prior to the beginning of the study and before any data was collected for research purposes.

Women and minorities were welcome to participate in this study.

HIPAA Authorization - HIPAA authorization was obtained concurrently with the informed consent. The participant was informed that this project involved the use of protected health information (PHI). All information was de-identified and no personally identifiable PHI was disclosed to others outside of the facility.

**Risks and Benefits**

Confidentiality - participants faced a minimal risk of loss of confidentiality. All data was kept on a secure server in aggregate form.

Sleep loss - participants faced a risk of sleep loss due to the sleep restriction component of the CBTI. The goal of sleep restriction was to allow the participant the same amount of sleep time that she was sleeping prior to the study, based on her self-report. It was possible that the participant might under-estimate her current sleep time thus would lose sleep time based on the sleep restriction component. Symptoms of sleep loss are irritability, sleepiness, mood changes, and decreased mental acuity. These are self-limiting and should have been resolved with the next night's sleep.

Frustration/Anxiety - participants might have had some short term frustration or anxiety with the technology. University of Colorado Denver technical support was available to be contacted by the P.I. to help troubleshoot any problems with Adobe Connect.
The P. I. could contact the State of Colorado Mental Health Hotline at 800-273-TALK (8255) if there was any concern about the mental stability of a participant at any point in the study.

This study was designed to learn more about the effectiveness of an internet-based VC CBTI delivered to BCS living in MUAs in Colorado. This study was not designed to treat any illness or improve the health of the study participants.

This study was based on prior research that shows the efficacy of CBTI for BCS who have insomnia (Berger et al., 2009; Epstein & Dirksen, 2007; Matthews et al., 2014; Savard et al., 2005a). Additional research was needed to evaluate the efficacy of the internet delivered version of CBTI, and to evaluate the response of BCS who live in MUAs in Colorado so that they may also benefit from this therapy.

Potential benefits of this study outweighed the minimal risks.

**Instruments**

All measures proposed for this study were based on self-report. Participants logged into REDCap, an online data collection and measurement tool (Harris et al., 2009) to complete all questionnaires (Table 4). Questionnaires were given prior to the first session, and after the last (6th) session. The questionnaires were designed to take less than an hour to complete to minimize patient burden. Psychometrics for all formal measures can be found in Table 4.

**Screening and Characterization Measures**

Participants answered an initial demographic questionnaire that included questions on age, cancer stage (1-3), marital status, education, income, and cancer treatment. In addition, patients completed a medical history and current medication questionnaire.
**Hospital Anxiety and Depression Scale**

The HADS is a 14-item self-assessment tool designed to measure anxiety and depression over the last week. It has two subscales (anxiety, depression) of seven questions each. The questions are answered on a 0-3 scale, with 3 indicating higher symptom frequencies. A subscale score of 0-7 is normal, 8-10 is borderline abnormal, and 11-21 is an abnormal score (Zigmond & Snaith, 1983). Internal reliability of the HADS in a cancer patient population is established in both subscales: HADS-A ($\alpha = 0.93$) and HADS-D ($\alpha = 0.9$) (Moorey et al., 1991). Validity of the HADS was examined in a systematic review and meta-analysis of 28 studies determined that in cancer patients the HADS-D had a sensitivity of 0.86 (95% CI 0.76 to 0.93) for a threshold score of “7” and a specificity of .81 (95% CI 0.78 to 0.84) when screening for depressive disorder. The HADS-A had a lower sensitivity (0.73, 95% CI 0.68 to 0.77) and specificity (0.65, 95% CI 0.61 to 0.67) for a similar threshold score of “7-8” (Vodermaier & Millman, 2011). Concurrent validity was established by correlating scores from Beck’s Depressions inventory against the HADS-D and scores from Spielberger’s State-Trait Anxiety Inventory (STAI) against the HADS-A (Bjelland, Dahl, Haug & Neckelmann, 2002) (Table 4).

**Menopause Rating Scale**

The MRS is an 11-question self-assessment questionnaire in which respondents score the severity of menopausal symptoms. Response options were none (0), mild, (1) moderate (2), severe (3), very severe (4). The scale is broken down into three subscales: psychological (score 0-16), somatic (score 0-16), and urogenital (score 0-12). Menopausal symptoms can affect sleep, so this instrument was included as a characterization measure to evaluate for differences between groups. External reliability established with test-retest stability in a
population of women between 40-70 years of age ($r = .8-.96$). A methodological review found evidence of high internal reliability ($\alpha = 0.6-0.9$) across populations from Europe, North America and Latin America. Concurrent validity for the total MRS score was high when compared to the clinically used Kupperman Index ($r = 0.91$, 95% CI 0.89-0.93) but the authors suggest the lower correlations among sub-scales ($r = 0.5-0.7$) indicated that the sub-scales were not fully independent (Heinemann, Ruebig, Potthoff, Schneider, Strelow, Heinemann & Thai, 2004).

**Revised Piper Fatigue Scale**

The Revised PFS is a 22 item self-report questionnaire that is calculated on a 0-10 scale, with 0 being the least affected and 10 being the most. Representative questions include: “*To what degree is the fatigue you are feeling now causing you distress?*” and “*To what degree are you now feeling lively/listless?*”. There are four subscales, reliability of each was confirmed with Cronbach’s alpha: behavioral/severity (.89), sensory (.87), cognitive/mood (.87) and affective (.87). PFS total Cronbach's alpha of 0.97 indicates some remaining redundancy (Piper et al., 1998; Reeve et al., 2012). Construct validity was supported through item-subscale correlations ($r \geq 0.65$) and concurrent validity was supported through a positive correlation with the Profile of Mood States Fatigue subscale (POMS-F) ($r = 0.50-0.78$) (Cantarero-Villanueva, Fernandez-Lao, Diaz-Rodriquez, Cuesta-Vargas, Fernandez-de-las-Penas, Piper, Arroyo-Morales, 2014).

**Sleep Measures**

**Consensus Sleep Diary**

The Consensus Sleep Diary (CSD) is a subjective sleep assessment tool that standardizes instructions and core measures of sleep. It is used widely by sleep researchers
to track daily sleep patterns of patients and research study participants (Carney, Buysse, Ancoli-Israel, Edinger, Krystal, Lichstein, & Morin, 2012). In this study, participants were instructed to fill out the sleep diary every morning upon awakening. Items recorded included: time to bed, time to sleep, time awake, number of nighttime awakenings and WASO. This data was used to calculate sleep metrics including TST, SE, and SL. Reliability of self-reported sleep diaries has been supported with as little as three nights of data ($r = 0.80$) (Thomas & Burr, 2009). The CSD was created by 25 sleep experts who used focus groups to determine content validity of the tool. Concurrent validity was supported in the comparison of duration of sleep between the CSD and a Motion Watch accelerometer ($r = 0.49$) and the Pittsburgh Sleep Quality Index ($r = 0.75$) (Landry, Best & Liu-Ambrose, 2015).

**Insomnia Severity Index**

The Insomnia Severity Index is a seven question tool that is designed to measure the severity of an individual’s insomnia problems over the last two weeks. Scores on individual questions range from 0-4, with 0 being the least severe and 4 being the most severe. Interpretation of total score results are: 0-7 = *no clinically significant insomnia*, 8-14 = *subthreshold insomnia*, 15-21 = *clinical insomnia (moderate severity)*, and 22-28 = *clinical insomnia (severe)*. It has been shown to be a reliable tool in both the general (Cronbach's $\alpha=.90$) and known insomniac population (Cronbach's $\alpha=.91$). Concurrent validity was tested against the Pittsburgh Sleep Quality Index (PSQI) and the total scores were significantly correlated ($r=0.80$, $p<0.05$) (Bastien, Vallieres, & Morin, 2001; Morin, Belleville, Belanger, & Ivers, 2011).
Dysfunctional Beliefs and Attitudes about Sleep-16 (DBAS)

The Dysfunctional Beliefs and Attitudes about Sleep Scale-16 (DBAS-16) is a modified version of the original DBAS scale that measures patients' sleep related beliefs (Morin, Vallieres, & Ivers, 2007). Participants score each question (16) on a scale of 1-10, with 1 = strongly disagree and 10 = strongly agree. A total score is calculated as an average of all 16 questions. The DBAS is used in this study to evaluate participants who have faulty beliefs about sleep that can perpetuate insomnia.

The psychometrics show that this modified version is reliable in both clinical (Cronbach's $\alpha = 0.77$) and research samples (Cronbach's $\alpha = 0.79$) (Morin et al., 2007) and has the benefit of decreasing participant burden. A confirmatory factor analysis showed the 16 items loaded onto four factors: perceived consequences of insomnia, worry/helplessness about insomnia, sleep expectations, and medication (Morin et al., 2007). Concurrent validity of the DBAS-16 was shown through correlations with clinical and sleep items from established tests including the ISI ($r = 0.45$, $p < .001$), the Beck Anxiety Inventory ($r = 0.41$, $p < .001$) and the Beck Depression Inventory ($r = 0.42$, $p < .001$) (Morin et al., 2007).

PROMIS Short Form v1.0

The portion of the PROMIS Short Form v1.0 that is used in this study is comprised of two short forms, 8 questions each: Sleep-Related Impairment (SRI-8a) and Sleep Disturbance (SD-8b). Both forms are scored on a 5 point Likert scale and are designed to quantifiably measure qualitative aspects of sleep and sleep impairment (Yu, et al., 2011). Examples of questions include: “My sleep quality was” (SD-8b) and “I had a hard time getting things done because I was sleepy” (SRI-8a). Internal reliability of both scales was supported in a comparison with the longer versions: SD-8b ($r = 0.90$) and SRI-8a ($r = 0.90$).
Convergent validity of the SD8b ($r = 0.83$) and the SRI8a ($r = 0.68$) was determined through correlations with the Pittsburgh Sleep Quality Index (Yu et al., 2011).

**QOL and Functional Measures**

**EORTC Quality of Life Questionnaire C-30**

The EORTC QLQ-C30 v.3 is a 30 item self-administered questionnaire that was designed to measure health-related quality of life in a cancer specific population (Aaronson et al., 1993). It is comprised of five functional scales, three symptom scales, six symptom items, and a global QOL measure comprised of two items: health status and quality of life. The fatigue and symptom questions are answered on a four-point scale: $1 = \text{not at all}$, $2 = \text{a little}$, $3 = \text{quite a bit}$, $4 = \text{very much}$. Higher scores on the fatigue and symptom questions indicates more symptoms. The two global questions are answered on a seven-point scale: $1 = \text{very poor}$ and $7 = \text{excellent}$. Higher scores on the global questions indicate fewer problems.

Internal reliability of the EORTC QLQ-C30 v.3 was high when tested in breast cancer survivors ($\alpha = 0.84$-$0.88$) (Kluthcovsky, Urbanetz, de Carvalh, Pereira Maluf, Schlickmann Sylvestre, & Hatschbach, 2012). Concurrent validity of the Global QOL measure is supported when the EORTC QLQ-C30 v.3.0 is compared to the Psychosocial Adjustment to Illness Scale (PAIS) ($r = 0.63$) and the Profile of Mood States (POMS) ($r = 0.56$).

It has been validated for use in multiple languages and is regularly used as a QOL measure in BCS (Bjorneklett, Rosenblad, Lindemalm, Ojutkangas, Letocha, Strang, & Bergkvist, 2013; Koch et al., 2013).
**Attentional Function Index (AFI)**

The Attentional Function Index (AFI) is a 13 item self-report questionnaire designed to measure the constructs of directed attention and executive functions in a cancer survivor population. Subscales include perceived effectiveness of perception, action, and interpersonal communication. Question topics include concentration, forgetfulness, and annoyance/irritation and are scored from 0 (not at all) to 10 (extremely well). A higher score indicates better cognitive functioning. The AFI total score has been shown to have high internal reliability in a breast cancer survivor population (Cronbach's $\alpha=.92$). Divergent validity for the AFI total score was tested against the Confusion subscale of the Profile of Mood States. There was a significant negative correlation between AFI total score and the POMS Confusion subscale ($r = -0.59, p < 0.01$) (Cimprich, Visovatti, & Ronis, 2011).
<table>
<thead>
<tr>
<th>Study Measure</th>
<th>Reliability</th>
<th>Validity</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Screening and Characterization Measures</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital Anxiety and Depression Scale (HADS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety Subscale</td>
<td>$\alpha = 0.93$</td>
<td>Concurrent Validity$^2$</td>
<td>Determine pre and post anxiety and depression levels</td>
</tr>
<tr>
<td>Depression Subscale</td>
<td>$\alpha = 0.9$</td>
<td>STAI $^3$ $r = 0.64-.81$</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>BDI$^4$ $r = 0.62-.73$</td>
<td></td>
</tr>
<tr>
<td>Menopause Rating Scale</td>
<td>Women 40-70 yo$^5$</td>
<td>Concurrent Validity$^5$</td>
<td>Determine pre and post-menopausal symptoms</td>
</tr>
<tr>
<td></td>
<td>$\alpha = 0.6-0.9$</td>
<td>Kupperman Index $r = 0.91, 95%$ CI $0.89-0.93$</td>
<td></td>
</tr>
<tr>
<td>Revised Piper Fatigue Scale (PFS)</td>
<td>Breast Cancer Survivors$^6$</td>
<td>Construct Validity$^6$</td>
<td>Determine pre and post fatigue levels</td>
</tr>
<tr>
<td></td>
<td>$\alpha = 0.9$</td>
<td>Fatigue Dimensions $r \geq 0.65$</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Concurrent Validity$^7$</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>$r = 0.50-0.78$</td>
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</tr>
</tbody>
</table>

$^1$Moorey et al., 1991, $^2$Bjelland, Dahl, Haug & Neckelmann, 2002, $^3$State Trait Anxiety Index, $^4$Beck Depression Inventory, $^5$Heinemann, Ruebig, Potthoff, Schneider, Strelow, Heinemann & Thai, 2004, $^7$Cantarero-Villanueva et al., 2014
<table>
<thead>
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<th>Reliability</th>
<th>Validity</th>
<th>Purpose</th>
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</thead>
<tbody>
<tr>
<td><strong>Sleep Measures</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Consensus Sleep Diary</td>
<td>3+ Days of Data(^8)</td>
<td>Concurrent Validity(^9)</td>
<td>Daily self-report of sleep patterns</td>
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<tr>
<td></td>
<td>(r = 0.80)</td>
<td>MotionWatch (r = 0.49)</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>PSQI(^{10}) (r = 0.75)</td>
<td></td>
</tr>
<tr>
<td>Insomnia Severity Index</td>
<td>General Population (\alpha = 0.90)</td>
<td>Concurrent Validity (PSQI ; r = 0.80)</td>
<td>Measures insomnia severity over last 2 weeks</td>
</tr>
<tr>
<td></td>
<td>Insomniac Population (\alpha = 0.91)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dysfunctional Beliefs and Attitudes about Sleep-16</td>
<td>Clinical Population (\alpha = 0.77)</td>
<td>Concurrent Validity (ISI ; r = 0.45)</td>
<td>Measures dysfunctional beliefs that can influence sleep</td>
</tr>
<tr>
<td></td>
<td>Research Population (\alpha = 0.79)</td>
<td>BAI-SI(^{12}) (r = 0.41)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>BDI-SI(^{13}) (r = 0.42)</td>
<td></td>
</tr>
<tr>
<td>PROMIS Short Form v1.0 SRI-8a SD-8b</td>
<td>General Population (r = 0.90)</td>
<td>Concurrent Validity (PSQI ; r = 0.83)</td>
<td>Measures sleep quality and sleep impairment</td>
</tr>
<tr>
<td></td>
<td>(r = 0.90)</td>
<td>PSQI (r = 0.68)</td>
<td></td>
</tr>
</tbody>
</table>

\(^8\)Thomas & Barr, 2009, \(^9\) Landry, Best & Liu-Ambrose, 2015, \(^{10}\)Pittsburgh Quality Sleep Index, \(^{11}\)Morin et al., 2007, \(^{12}\)Beck Anxiety Inventory-Sleep Items, \(^{13}\)Beck Depression Inventory-Sleep Items, \(^{14}\)Yu et al., 2011
| Study Measure                        | Reliability | Validity                      | Purpose                                                        |
|-------------------------------------|-------------|-------------------------------|                                                               |
| **QOL and Functional Measures**     |             |                               |                                                               |
| EORTC QLQ-C30 v.3.0                 | Breast Cancer Survivors<sup>15</sup>  
<sup>α</sup> = 0.84-0.88 | Concurrent Validity<sup>15</sup>  
PAINS r = 0.63  
POMS r = 0.56 | Measures health-related quality of life in a cancer population |
| Attentional Function Index           | Breast Cancer Survivors<sup>16</sup>  
<sup>α</sup> = 0.92 | Divergent Validity<sup>16</sup>  
POMS Confusion subscale r = –0.59 | Measures perception of cognitive function |

<sup>15</sup>Kluthcovsky et al., 2012,  
<sup>16</sup>Cimprich, Visovatti, & Ronis, 2011
Treatment Fidelity Measures

**Patient Knowledge Test (PKT)**

The PKT is a 15 item questionnaire designed to assess knowledge about sleep and behaviors that perpetuate poor sleep. It was developed by Dr. Ellyn Matthews and used in the parent study to assess knowledge gained during the intervention. Questions in this test are related to maladaptive behaviors and dysfunctional thoughts addressed in CBTI. This can be used as a treatment fidelity measure as participants who are adherent to treatment should score more highly than those who do not adhere to treatment because information learned in treatment should inform participant answers. It is used in this study to both assess knowledge and for comparison to the two groups from the parent study.

**Patient Satisfaction Questionnaire**

The patient satisfaction questionnaire consisted of two questions written by the investigator: “Did you feel comfortable communicating using this technology?” and “Would you recommend this study to a friend?”.

**Data Analysis**

Power analysis for this study was based on a previous randomized control trial of CBTI intervention in BCS (Savard et al., 2005a). In this study Savard et al. (2005a) utilized an eight session CBTI (n=27) and a waiting-list control condition (n=30). Similar to this dissertation study, they combined stimulus control, sleep restriction, cognitive therapy, sleep hygiene, and fatigue management. They reported effect sizes for sleep efficiency of $r = 0.55$ ($F_{1,52} = 22.59; p < .0001$ [Cohen's $d = 1.32$]), or large effect based on the interaction between group assignments and time (Savard et al., 2005a). For the purposes of this study, at 80% power with 20 participants per group (using the parent study for the second group) and an $\alpha$
= .05 using a two-tailed t-test calculator it is possible to detect effect sizes as small as Cohen's d=.91. Frequency tables were used for the descriptive analysis of categorical variables, while measures of central tendency were used for continuous variables. Homogeneity of variance was evaluated in the distribution of scores on the dependent measures.

**Aim1:** Evaluate and address the feasibility and the potential barriers to recruitment, retention, adherence, and delivery of internet based CBTI in BCS in rural MUAs.

Descriptive statistics were used to describe recruitment, retention, attendance and adherence to the CBTI. The P.I. kept a log of session attendance and the sleep diary was used to track participant adherence to treatment. Technical difficulties and participation barriers were also recorded in the treatment log. Technical difficulties were analyzed against participant response to evaluate if there was a significant difference between groups with and without technical difficulties.

**Aim 2:** Examine sleep/wake patterns, quality of life, and functional outcomes in individuals after receiving a six-week internet-based VC CBTI.

A dependent t-test was run to evaluate the differences in sleep efficiency scores between time (pre and post CBTI) in the internet-based VC CBTI group.

**Aim 3:** Examine sleep/wake patterns, quality of life, and functional outcomes in individuals receiving an internet-based VC CBTI compared to those receiving standard, in-person CBTI and in-person behavioral placebo treatment (3 group design).

A one-way analysis of covariance (ANCOVA) was run to evaluate the differences in sleep efficiency scores between time and group. Pretreatment sleep efficiency scores and baseline demographic differences that might have an effect on sleep efficiency scores were
controlled for in analysis. Component measures of sleep efficiency including WASO, TST, SL, and subjective ratings of sleep quality were examined using univariate analysis.

An ANCOVA was run to evaluate the differences in QOL between time and group. Pretreatment QOL scores and baseline demographic differences that might have an effect on QOL were controlled for in analysis. Component measures of QOL including degree of fatigue-related interference with daily activities and perceived cognitive functioning were examined using univariate analysis.

**Summary**

This chapter described the design, sample, recruitment methods, setting, procedure, intervention, data collection, study consent and authorization, associated risks and benefits, instruments, data analysis and limitations of this study. CBTI is the front line therapy to treat insomnia in BCS (Buysse, 2013), yet BCS in MUAs have difficulty accessing this therapy. Consequently, the CBTI intervention in this and the parent study were identical with the exception in-person vs. video delivery. The purpose of this study was twofold: to evaluate the feasibility of conducting a study of BCS in MUAs and to examine the effects of internet-based VC CBTI on sleep, quality of life and daily functioning in BCS living in rural MUAs in Colorado.
CHAPTER IV

RESULTS

This chapter is organized into four parts: study measure results, Aim 1, Aim 2, and Aim 3. The Aim 1 section details the feasibility of recruiting and delivering an internet-based VC CBTI intervention to rural BCS with insomnia. This includes the potential barriers to delivery of internet-based VC CBTI including technical problems and rural internet access issues. The Aim 2 section examines the differences in sleep and QOL outcomes in individuals over a six-week internet-based VC CBTI intervention. Aim 3 examines the differences in significant sleep and QOL outcomes between rural BCS who received an internet-based VC CBTI intervention and urban BCS who received an in-person BPT or CBTI intervention.

Study Measures Results

Study measure results are presented in tables by type of study measure. All results will be discussed in Chapter V. Primary outcomes with significant differences will be included for analysis against outcomes from the parent study in Aim 3.

Screening and Characterization Measures

Demographics Results

Table 5 depicts the demographic characteristics of the study sample. The average age of the participants (n=18) was 57.72 years old (SD = 6.49) and average cancer diagnosis was either Stage I (n=9) or Stage II (n=7) breast cancer. Most had undergone radiation therapy (n=16) and half (n=9) had chemotherapy during treatment. The majority were college
educated (n=13) and the median annual household income was $60,000-$80,000. There were no significant differences between groups.

Table 5
Demographics of Study Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>VC CBTI Group (n=18)</th>
<th>CBTI Group (n=24)</th>
<th>BPT Group (n=16)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean  SD</td>
<td>Mean  SD</td>
<td>Mean  SD</td>
</tr>
<tr>
<td>Age (years)</td>
<td>57.72  6.49</td>
<td>52.88  6.15</td>
<td>52.86  9.33</td>
</tr>
<tr>
<td>Cancer Stage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>9</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>II</td>
<td>7  7</td>
<td>5  3</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>2  4</td>
<td>3  1</td>
<td></td>
</tr>
<tr>
<td>Radiation</td>
<td>16  11</td>
<td>11  11</td>
<td></td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>9  11</td>
<td>8  8</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>10  8</td>
<td>8  8</td>
<td></td>
</tr>
<tr>
<td>Employed Full Time</td>
<td>7  6</td>
<td>7  7</td>
<td></td>
</tr>
<tr>
<td>College Educated</td>
<td>13  9</td>
<td>10  10</td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$0-$20,000</td>
<td>0  2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>$20,000-$40,000</td>
<td>5  5</td>
<td>1  1</td>
<td></td>
</tr>
<tr>
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<td>3  3</td>
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<td>3  3</td>
<td></td>
</tr>
<tr>
<td>$80,000-$100,000</td>
<td>1  1</td>
<td>1  1</td>
<td></td>
</tr>
<tr>
<td>$100,000-$150,000</td>
<td>3  2</td>
<td>1  1</td>
<td></td>
</tr>
<tr>
<td>$150,000 or greater</td>
<td>1  2</td>
<td>2  2</td>
<td></td>
</tr>
</tbody>
</table>

Hospital Anxiety and Depression Scale Results

In this sample, the pre intervention HADS Anxiety scores ranged from 7-16 ($M = 10.61, SD = 2.81$) and post intervention scores ranged from 8-13 ($M = 11.16, SD = 1.10$). Pre intervention HADS Depression scores ranged from 6-12 ($M = 8.61, SD = 1.46$) and post intervention scores ranged from 6-11 ($M = 7.78, SD = 1.90$). There were no statistically significant differences between pre and post intervention scores on either subscale (Table 6).
Menopause Rating Scale Results

Total MRS scores ranged from 19-38 ($M = 27.89$, $SD = 5.51$) pre intervention to 17-30 ($M = 21.67$, $SD = 3.11$) post intervention. There was a significant difference between pre and post intervention scores in the total MRS score and on all subscales (Table 6).

Revised Piper Fatigue Scale (PFS) Results

The pre intervention PFS Total Fatigue Score ranged from 1.82-7.91 ($M = 5.54$, $SD = 1.71$) then decreased to a post intervention range of 1.27-7.19 ($M = 3.44$, $SD = 1.86$) which represents a statistically significant decrease in fatigue ($M = 2.10$, $SD = 1.72$, $p = .000$) (Table 6).

Table 6
Group Differences Pre/Post CBTI Intervention – Screening and Characterization Measures

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th></th>
<th>Post Intervention</th>
<th></th>
<th>Time Condition Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>t</td>
</tr>
<tr>
<td>HADSAnx</td>
<td>10.61</td>
<td>2.81</td>
<td>11.17</td>
<td>1.10</td>
<td>-.832</td>
</tr>
<tr>
<td>HADSDep</td>
<td>8.61</td>
<td>1.46</td>
<td>7.78</td>
<td>1.90</td>
<td>1.47</td>
</tr>
<tr>
<td>MRS Total</td>
<td>27.89</td>
<td>5.51</td>
<td>21.67</td>
<td>3.11</td>
<td>4.71</td>
</tr>
<tr>
<td>MRSPsych</td>
<td>10.17</td>
<td>3.35</td>
<td>7.78</td>
<td>1.87</td>
<td>3.94</td>
</tr>
<tr>
<td>MRSSom</td>
<td>10.83</td>
<td>1.98</td>
<td>8.61</td>
<td>1.29</td>
<td>4.21</td>
</tr>
<tr>
<td>MRSUro</td>
<td>6.89</td>
<td>2.56</td>
<td>5.28</td>
<td>1.53</td>
<td>2.88</td>
</tr>
<tr>
<td>PFS</td>
<td>5.54</td>
<td>1.71</td>
<td>3.44</td>
<td>1.86</td>
<td>5.18</td>
</tr>
</tbody>
</table>

Sleep-Related Measures

Insomnia Severity Index Results

Pre intervention scores on the ISI ranged from 8-26 ($M = 14.78$, $SD = 4.63$), while post intervention scores ranged from 3-23 ($M = 7.83$, $SD = 5.73$). There was a significant
difference between pre and post intervention scores ($M = 6.94, SD = 5.44, p = .000$) (Table 7). Clinical significance is discussed in Chapter V.

**Dysfunctional Beliefs and Attitudes about Sleep-16 Results**

Pre intervention scores on the DBAS ranged from 2.71-7.77 ($M = 5.79, SD = 1.57$), while post intervention scores ranged from 2.47-7.51 ($M = 4.27, SD = 1.52$). The mean DBAS score decreased by 1.52 points which was a significant difference between pre and post intervention scores ($M = 1.52, SD = 1.63, p < .001$) (Table 7).

**PROMIS Short Form v1.0 Results**

PROMIS Short Forms are scored using a raw score that is converted to a T-score for clinical purposes. The raw scores were calculated in SPSS and the T-scores could be calculated based on the PROMIS authorized conversion tables (Yu et al., 2011). Mean PROMIS SRI scores decreased significantly from ($M = 42, SD = 7.50, p = .000$) to ($M = 15.39, SD = 4.07, p = .000$) as did the PROMIS SD scores ($M = 29.5, SD = 5.07, p = .000$) to ($M = 19.89, SD = 5.67, p = .000$).

Table 7
**Group Differences Pre/Post CBTI Intervention – Sleep-Related Measures**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline Mean</th>
<th>Baseline SD</th>
<th>Post Intervention Mean</th>
<th>Post Intervention SD</th>
<th>t</th>
<th>df</th>
<th>p</th>
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</thead>
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<tr>
<td><strong>Sleep Measures</strong></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
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<tr>
<td>ISI Total</td>
<td>14.78</td>
<td>4.63</td>
<td>7.8</td>
<td>5.73</td>
<td>5.42</td>
<td>17</td>
<td>.000</td>
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<td>DBAS</td>
<td>5.79</td>
<td>1.57</td>
<td>4.27</td>
<td>1.52</td>
<td>3.95</td>
<td>17</td>
<td>.001</td>
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<td>PRO-SRI</td>
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<td>7.50</td>
<td>15.39</td>
<td>4.07</td>
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<td>PRO-SD</td>
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<td>5.07</td>
<td>19.89</td>
<td>5.67</td>
<td>6.50</td>
<td>17</td>
<td>.000</td>
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</table>
Quality of Life and Functional Measures

EORTC Quality of Life Questionnaire C-30 Results

Pre intervention scores on the Global QOL subscale of the EORTC QLQ-C30 ranged from 16.67-100 ($M = 58.80$, $SD = 23.13$), while post intervention scores ranged from 41.67-100 ($M = 80.10$, $SD = 19.83$). The mean Global QOL score increased by 21.29 points which was a significant difference between pre and post intervention scores ($M = 21.29$, $SD = 23.78$, $p < .001$) (Table 6). Complete results of functional and symptom scales, as well as individual items are reported in Table 8.

Attentional Function Index (AFI) Results

Scores on the AFI decreased slightly from pre intervention ($M = 5.95$, $SD = 1.81$) to post intervention ($M = 5.00$, $SD = 2.28$) but it was not a statistically significant change ($p=.306$) (Table 8).
Table 8
*Group Differences Pre/Post CBTI Intervention – QOL and Functional Measures*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline Mean</th>
<th>Baseline SD</th>
<th>Post Intervention Mean</th>
<th>Post Intervention SD</th>
<th>t</th>
<th>df</th>
<th>p</th>
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</thead>
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<tr>
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<tr>
<td>Global QOL</td>
<td>58.80</td>
<td>23.13</td>
<td>80.10</td>
<td>19.83</td>
<td>-3.80</td>
<td>17</td>
<td>.001</td>
</tr>
<tr>
<td>Physical</td>
<td>88.52</td>
<td>19.78</td>
<td>91.11</td>
<td>20.20</td>
<td>-1.32</td>
<td>17</td>
<td>.202</td>
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<tr>
<td>Role</td>
<td>85.19</td>
<td>23.50</td>
<td>91.67</td>
<td>21.58</td>
<td>-2.36</td>
<td>17</td>
<td>.030</td>
</tr>
<tr>
<td>Emotion</td>
<td>60.19</td>
<td>21.87</td>
<td>73.61</td>
<td>14.64</td>
<td>-4.56</td>
<td>17</td>
<td>.000</td>
</tr>
<tr>
<td>Cognition</td>
<td>63.89</td>
<td>24.42</td>
<td>78.70</td>
<td>14.91</td>
<td>-3.92</td>
<td>17</td>
<td>.001</td>
</tr>
<tr>
<td>Social</td>
<td>74.07</td>
<td>74.07</td>
<td>88.89</td>
<td>24.92</td>
<td>-2.68</td>
<td>17</td>
<td>.016</td>
</tr>
<tr>
<td>Symptom Scales</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>39.50</td>
<td>15.82</td>
<td>27.16</td>
<td>22.62</td>
<td>2.87</td>
<td>17</td>
<td>.011</td>
</tr>
<tr>
<td>N/V</td>
<td>3.7</td>
<td>7.13</td>
<td>.93</td>
<td>3.93</td>
<td>1.84</td>
<td>17</td>
<td>.083</td>
</tr>
<tr>
<td>Pain</td>
<td>37.03</td>
<td>23.26</td>
<td>21.30</td>
<td>24.80</td>
<td>3.80</td>
<td>17</td>
<td>.001</td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>11.11</td>
<td>19.80</td>
<td>11.11</td>
<td>19.80</td>
<td>.000</td>
<td>17</td>
<td>1.000</td>
</tr>
<tr>
<td>Insomnia</td>
<td>66.67</td>
<td>22.87</td>
<td>40.74</td>
<td>29.27</td>
<td>6.02</td>
<td>17</td>
<td>.000</td>
</tr>
<tr>
<td>Appetite</td>
<td>3.70</td>
<td>10.78</td>
<td>3.70</td>
<td>10.78</td>
<td>.000</td>
<td>17</td>
<td>1.000</td>
</tr>
<tr>
<td>Constipation</td>
<td>7.41</td>
<td>18.28</td>
<td>9.26</td>
<td>22.30</td>
<td>-.566</td>
<td>17</td>
<td>.579</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>7.41</td>
<td>18.28</td>
<td>5.56</td>
<td>12.78</td>
<td>.369</td>
<td>17</td>
<td>.717</td>
</tr>
<tr>
<td>Financial</td>
<td>22.22</td>
<td>30.25</td>
<td>14.81</td>
<td>23.50</td>
<td>1.29</td>
<td>17</td>
<td>.215</td>
</tr>
<tr>
<td>AFI</td>
<td>5.95</td>
<td>1.81</td>
<td>5.00</td>
<td>2.28</td>
<td>1.06</td>
<td>17</td>
<td>.306</td>
</tr>
</tbody>
</table>
Treatment Fidelity Measures

**Patient Knowledge Test (PKT) Results**

There was no significant change in PKT score pre and post intervention \( (M = 0.17, SD = 0.92, p = .760) \).

**Patient Satisfaction Questionnaire Results**

This questionnaire was only asked post intervention and all participants answered “yes” to each question.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline Mean</th>
<th>Baseline SD</th>
<th>Post Intervention Mean</th>
<th>Post Intervention SD</th>
<th>Time</th>
<th>Condition</th>
<th>Interaction</th>
<th>t</th>
<th>df</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>PKT</td>
<td>6.28</td>
<td>2.29</td>
<td>6.11</td>
<td>1.37</td>
<td>.310</td>
<td>17</td>
<td>.760</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Specific Aim 1**

**Aim 1**: Evaluate and address the feasibility and the potential barriers to recruitment, retention, adherence, and delivery of internet based CBTI in BCS in rural MUAs.

The specific metrics for evaluation of feasibility and barriers can be analyzed in three broad categories: recruitment, acceptability of treatment (retention & adherence), and technology (delivery). Each will be addressed in this section. Descriptive statistics were used to describe recruitment, retention, attendance and adherence to the CBTI. The P.I. kept a log of session attendance and the sleep diary was used to track participant adherence to treatment. Technical difficulties were recorded in the treatment log.
Table 10

Specific Metrics to Evaluate Feasibility

<table>
<thead>
<tr>
<th></th>
<th>Recruitment</th>
<th>Technology</th>
<th>Acceptability of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of potential participants recruited through primary care providers, breast cancer navigators, and online advertisements</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Number of potential participants with access to high speed internet</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of potential participants with access to computer with video camera</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of potential participants that complete baseline online surveys</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of technical issues during sessions</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average number of minutes related to technical issues during treatment sessions</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average number of treatment sessions completed by participants</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Participant adherence to sleep/wake times</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Estimated Cost Savings to Participants</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

**Recruitment**

Feasibility of recruitment was assessed with two measures: the total number of eligible participants that inquired about participation compared to the number who chose to participate and the methods by which these eligible participants were recruited. Recruitment spanned 18 months, from June 2014 to January 2016. A total of 32 potential participants contacted the PI, and 18 participants consented and finished the intervention (Figure 3).

Participants of this study were recruited through multiple mediums which are summarized in Table 11. The most successful method of recruitment was a direct mail campaign from an urban provider. This provider identified patients who met eligibility criteria for the study and mailed a study flyer to each patient. A total of 28 flyers were
mailed, and ten people responded (36%). Of these respondents, seven consented to participate in the study. The second most successful method of recruitment was Public Service Announcements (PSA) broadcast from three different rural radio stations. Each PSA ran twice a day for three weeks, and a total of nine BCS contacted the PI for more information. Of these, one declined to participate indicating the time required was too burdensome, two were ineligible, and six were consented and received the intervention.

Additional discussion on feasibility of recruitment of rural study participants will occur in Chapter V.

Table 11

<table>
<thead>
<tr>
<th>Methods of Participant Recruitment</th>
<th>Responded</th>
<th>Consented</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Mail from Provider</td>
<td>10</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Rural Radio Stations (3) PSAs</td>
<td>9</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Referrals from Rural Providers</td>
<td>8</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Participant Referrals</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Community Flyers</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Local Newspaper Advertisements</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Direct Mail to Knitting Stores</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Email to Specialty Groups (2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Church Bulletin Advertisements</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Urban Radio Interview</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Press Release</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Figure 3. Screening and Enrollment Flow Chart
Technology

Participants in this study were required to have access to a computer with high speed internet, either at home or through a local library or provider's office. All 32 potential participants that contacted the PI for additional information on the study indicated that they had access to a computer and that they had high speed internet at home. Two participants did not have a webcam, so webcams were provided for them. As shown in Figure 3, two eligible potential participants declined to participate based on discomfort with required technology.

The feasibility of an online survey was determined by the number of participants that were able to successfully complete the baseline online survey. An invitation to complete the baseline survey was emailed to participants with a hyperlink to the survey embedded in the email. The survey could be completed in one or multiple sittings, but was configured to require answers to each question. All 18 participants that were consented for the intervention completed both the baseline and post-treatment online surveys.

The number of technical issues and average time spent on technical issues during study sessions is presented in Table 12. Technical issues occurred for 11 out of 18 participants. Most issues were related to either audio (6) or video (8) connection, and required the PI to spend initial minutes of the intervention session helping the participants to resolve the issue. Only one session was interrupted by a failure in an internet connection, and that failure was due to the urban based internet connection, not the rural internet connection. Levene’s test found no significant variances in sleep outcomes between participants with technical trouble and those without. Additional discussion on the feasibility and barriers of technology used in this study will occur in Chapter V.
Table 12  
*Technical Difficulties Encountered by Participants*

<table>
<thead>
<tr>
<th>Participant</th>
<th>Audio</th>
<th>Video</th>
<th>Internet Connection</th>
<th>Total Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Session 1 – 5 min</td>
<td>Session 1 – 6 min</td>
<td></td>
<td>11</td>
</tr>
<tr>
<td>2</td>
<td>Session 1 – 10 min.*</td>
<td>Session 2 – 5 min.</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>Session 2 – 10 min.*</td>
<td>Session 4 – 7 min.*</td>
<td>Session 3 – 5 min.</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>Session 4 – 7 min.*</td>
<td></td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>5</td>
<td>Session 1 – 5 min.</td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>8</td>
<td>Session 2 – 6 min.*</td>
<td></td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>10</td>
<td>Session 3 – 5 min.*</td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>11</td>
<td>Session 1 – 7 min.*</td>
<td>Session 1 – 7 min.*</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>13</td>
<td>Session 1 – 6 min.</td>
<td></td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>15</td>
<td>Session 1 – 6 min.</td>
<td>Session 2 – 5 min.</td>
<td></td>
<td>11</td>
</tr>
<tr>
<td>16</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>17</td>
<td>Session 2 – 3 min.</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>18</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>30 minutes</td>
<td>51 minutes</td>
<td>5 minutes</td>
<td>86 minutes</td>
</tr>
</tbody>
</table>

* Unresolved, used telephone connection for audio  
** Unresolved, used audio connection only (no video)

**Acceptability of Treatment**

Acceptability of treatment was determined using both attendance at treatment sessions and participant adherence to prescribed bed times, wake times, and total time in bed (TIB) between sessions (Figure 4). All participants (n=18) attended the six required sessions. Three participants required an additional week, so attended six sessions over seven weeks. The remaining participants (n=15) completed the six sessions in the expected six weeks. Adherence to prescribed bed times, wake times, and TIB were calculated as weekly means and are presented in Figure 4. These prescribed times are based on the sleep
restriction component of CBTI which is introduced in the first session of treatment. Therefore, sessions 2-6 were used to calculate participant adherence to the prescribed component of treatment (sleep restriction). Adherence to bed time and wake time was defined as going to bed and rising not more than 15 minutes before the prescribed time. Adherence to total TIB was defined as not more than 30 minutes above the prescribed TIB. This is consistent with an adherence definition established in previous studies of insomnia in a BCS population (Matthews, Schmiege, Cook, Berger, & Aloia, 2012; Tremblay, et al., 2009). It is important to note that there was no statistical difference between average adherence to prescribed bed times, wake times, and TIB in the VC CBTI group and the CBTI group in the parent study. Participants in this study were adherent five nights or more per week after the second week.

Figure 4. Adherence to Treatment
Specific Aim 2

Aim 2: Examine sleep/wake patterns, quality of life, and functional outcomes in individuals receiving an internet-based VC CBTI.

H1: Women receiving internet-based VC CBTI intervention will demonstrate an improvement in sleep efficiency ([time asleep/time in bed] X 100) post CBTI intervention.

Sleep/Wake Patterns

Sleep/wake pattern data was obtained from self-reported weekly sleep diaries. A dependent t-test was run to determine whether there was a statistically significant mean difference in the primary measurement of SE before and after the six-week internet-based VC CBTI intervention. There was a statistically significant increase in SE scores post intervention ($t=7.969, p=.000$) (Table 13). The mean SE score increased from 77.79% ($SD = 12.13$) pre intervention to 88.05% ($SD = 5.80$) post intervention ($p = .000$). The clinically recommended SE is above 85%, therefore this represents a significant clinical change. This finding was supported by other sleep metrics collected from the sleep diaries which are reflected in Table 13.
Table 13

Sleep Diary Differences Pre/Post CBTI Intervention

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>Post Intervention</th>
<th>Time Condition Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>SE</td>
<td>77.79</td>
<td>12.13</td>
<td>88.05</td>
</tr>
<tr>
<td>SL</td>
<td>36.81</td>
<td>30.81</td>
<td>16.02</td>
</tr>
<tr>
<td>WASO</td>
<td>44.42</td>
<td>29.64</td>
<td>25.27</td>
</tr>
<tr>
<td>TST</td>
<td>385.31</td>
<td>70.59</td>
<td>423.48</td>
</tr>
<tr>
<td>Awakenings</td>
<td>2.37</td>
<td>1.06</td>
<td>1.70</td>
</tr>
</tbody>
</table>

H2: Women receiving the internet-based VC CBTI intervention will self-report an improvement in QOL and perceived daily functioning post CBTI intervention.

Quality of life, as measured by the Global QOL subscale of the EORTC QLQ-C30, increased significantly after the CBTI intervention as discussed above (\( M = 21.29, SD = 23.78, p < .001 \)) (Table 8).

Perceived daily functioning is measured with the Functional Scales of the EORTC QLQ-C30 and the AFI. The Physical Function scale did not improve significantly, but the Role, Emotion, Cognition, and Social scales all improved significantly (Table 8). The AFI total score did not significantly change.

Specific Aim 3

**Aim 3:** Examine sleep/wake patterns, quality of life, and functional outcomes in individuals receiving an internet-based VC CBTI compared to those receiving standard, in-person CBTI and in-person behavioral placebo treatment (3 group design).
H1: Women receiving internet-based VC CBTI intervention will demonstrate an improvement in sleep efficiency ([time asleep/time in bed] X 100) compared to those receiving an in-person placebo treatment.

A one-way analysis of covariance (ANCOVA) was run to evaluate the differences in sleep efficiency scores between time and group. Pretreatment sleep efficiency scores served as covariates. Component measures of sleep efficiency including WASO, TST, SL were examined using univariate analysis.

Table 14
Means and Standard Deviations of Sleep Diary Measures by Group and Time

<table>
<thead>
<tr>
<th>Measurement</th>
<th>CBTI (n=24)</th>
<th>BPT (n=16)</th>
<th>VC CBTI (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td>Pre</td>
</tr>
<tr>
<td>SE</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>75.28 (17.14)</td>
<td>88.45 (6.46)</td>
<td>78.31 (6.69)</td>
</tr>
<tr>
<td>SL</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>38.69 (40.63)</td>
<td>14.10 (8.68)</td>
<td>27.52 (20.02)</td>
</tr>
<tr>
<td>WASO</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>42.35 (37.74)</td>
<td>2.99 (20.96)</td>
<td>46.59 (21.31)</td>
</tr>
<tr>
<td>TST</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>384.48 (87.66)</td>
<td>409.18 (47.13)</td>
<td>388.66 (65.92)</td>
</tr>
<tr>
<td>Awakenings</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>2.43 (1.10)</td>
<td>1.84 (1.10)</td>
<td>2.77 (1.21)</td>
</tr>
</tbody>
</table>
Table 15
Analysis of Covariance of Post-Test Sleep Diary Outcomes with Pre-Test Scores as Covariates

<table>
<thead>
<tr>
<th>Measures</th>
<th>df</th>
<th>SS</th>
<th>MS</th>
<th>F</th>
<th>p</th>
<th>η²</th>
</tr>
</thead>
<tbody>
<tr>
<td>SE</td>
<td>2</td>
<td>235.94</td>
<td>117.99</td>
<td>4.26</td>
<td>.019</td>
<td>.136</td>
</tr>
<tr>
<td>SL</td>
<td>2</td>
<td>272.30</td>
<td>135.15</td>
<td>1.42</td>
<td>.250</td>
<td>.050</td>
</tr>
<tr>
<td>WASO</td>
<td>2</td>
<td>884.82</td>
<td>442.41</td>
<td>1.41</td>
<td>.252</td>
<td>.253</td>
</tr>
<tr>
<td>TST</td>
<td>2</td>
<td>19026.77</td>
<td>9513.38</td>
<td>4.57</td>
<td>.015</td>
<td>.145</td>
</tr>
<tr>
<td>Awakenings</td>
<td>2</td>
<td>0.66</td>
<td>0.33</td>
<td>0.53</td>
<td>.590</td>
<td>.019</td>
</tr>
</tbody>
</table>

A post hoc analysis using Least Significant Difference (LSD) was conducted for all measures that had a statistically significant difference between the adjusted group means.

SE was statistically significantly greater in both the CBTI ($M = 88.53, SE = 1.08, 95\% CI [0.171, 7.108], p = .040$) and the VC CBTI ($M = 90.16, SE = 1.24, 95\% CI [1.561, 8.872], p = .006$) groups compared to the BPT group ($M = 84.94, SE = 1.32$).

TST was statistically significantly greater in the VC CBTI group ($M = 450.32, SE = 10.75$) compared to the CBTI group ($M = 409.49, SE = 9.31, 95\% CI [12.31, 69.36], p = .006$) and the BPT group ($M = 414.26, SE = 11.41, 95\% CI [4.63, 67.51], p = .025$).

**H2:** Women receiving the internet-based VC CBTI intervention will self-report an improvement in QOL and perceived daily functioning compared to those receiving an in-person placebo treatment at the conclusion of the intervention.

An ANCOVA was run to evaluate the differences in QOL between time and group. Pre intervention QOL and function scores served as covariates. Component measures of QOL including degree of fatigue-related interference with daily activities and perceived cognitive functioning were examined using univariate analysis.
Table 16
Means and Standard Deviations of QOL Measures by Group and Time

<table>
<thead>
<tr>
<th>Measurement</th>
<th>CBTI Pre Mean (SD)</th>
<th>CBTI Post Mean (SD)</th>
<th>BPT Pre Mean (SD)</th>
<th>BPT Post Mean (SD)</th>
<th>VC CBTI Pre Mean (SD)</th>
<th>VC CBTI Post Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFS</td>
<td>5.17 (1.68)</td>
<td>3.75 (1.93)</td>
<td>5.70 (1.26)</td>
<td>4.47 (1.83)</td>
<td>5.54 (1.71)</td>
<td>3.43 (1.86)</td>
</tr>
<tr>
<td>ISI Total</td>
<td>17.25 (3.69)</td>
<td>9.14 (5.67)</td>
<td>17.09 (4.03)</td>
<td>12.00 (4.83)</td>
<td>14.78 (4.63)</td>
<td>7.83 (5.73)</td>
</tr>
<tr>
<td>DBAS</td>
<td>5.39 (1.51)</td>
<td>4.01 (1.44)</td>
<td>5.76 (1.40)</td>
<td>4.62 (1.73)</td>
<td>5.79 (1.51)</td>
<td>4.27 (1.52)</td>
</tr>
<tr>
<td>EORTC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global QOL</td>
<td>66.49 (13.44)</td>
<td>74.28 (14.41)</td>
<td>59.80 (25.21)</td>
<td>70.10 (22.26)</td>
<td>58.80 (23.13)</td>
<td>80.09 (19.83)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>41.30 (22.02)</td>
<td>25.60 (17.86)</td>
<td>45.75 (21.47)</td>
<td>33.99 (21.33)</td>
<td>39.51 (15.82)</td>
<td>27.16 (22.62)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>82.61 (24.35)</td>
<td>36.96 (28.41)</td>
<td>78.43 (20.21)</td>
<td>57.84 (22.14)</td>
<td>66.67 (22.87)</td>
<td>40.74 (29.27)</td>
</tr>
<tr>
<td>Pain</td>
<td>27.54 (24.93)</td>
<td>24.64 (25.56)</td>
<td>31.37 (26.93)</td>
<td>39.22 (33.82)</td>
<td>37.04 (23.26)</td>
<td>21.30 (24.79)</td>
</tr>
<tr>
<td>Role</td>
<td>76.81 (26.94)</td>
<td>83.33 (23.57)</td>
<td>71.57 (35.73)</td>
<td>80.39 (29.60)</td>
<td>85.19 (23.49)</td>
<td>91.67 (21.58)</td>
</tr>
<tr>
<td>Emotion</td>
<td>75.36 (15.54)</td>
<td>81.52 (14.64)</td>
<td>61.27 (24.99)</td>
<td>67.16 (24.38)</td>
<td>60.19 (21.87)</td>
<td>66.26 (35.99)</td>
</tr>
<tr>
<td>Cognition</td>
<td>66.67 (21.32)</td>
<td>77.54 (21.09)</td>
<td>66.18 (24.38)</td>
<td>71.08 (22.07)</td>
<td>63.89 (24.42)</td>
<td>74.13 (26.75)</td>
</tr>
<tr>
<td>Social</td>
<td>63.77 (32.04)</td>
<td>84.78 (24.05)</td>
<td>75.49 (31.80)</td>
<td>71.57 (31.60)</td>
<td>74.07 (31.43)</td>
<td>85.24 (32.13)</td>
</tr>
</tbody>
</table>
Table 17  
Analysis of Covariance of QOL Post-Test Outcomes with Pre-Test Scores as Covariates

<table>
<thead>
<tr>
<th>Measures</th>
<th>df</th>
<th>SS</th>
<th>MS</th>
<th>F</th>
<th>p</th>
<th>η²</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFS</td>
<td>2</td>
<td>7.66</td>
<td>3.83</td>
<td>1.49</td>
<td>.235</td>
<td>.052</td>
</tr>
<tr>
<td>ISI Total</td>
<td>2</td>
<td>95.71</td>
<td>47.86</td>
<td>1.93</td>
<td>.156</td>
<td>.069</td>
</tr>
<tr>
<td>DBAS</td>
<td>2</td>
<td>1.89</td>
<td>0.95</td>
<td>0.501</td>
<td>.609</td>
<td>.019</td>
</tr>
<tr>
<td>EORTC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global QOL</td>
<td>2</td>
<td>1171.05</td>
<td>585.52</td>
<td>2.13</td>
<td>.129</td>
<td>.073</td>
</tr>
<tr>
<td>Fatigue</td>
<td>2</td>
<td>438.72</td>
<td>219.36</td>
<td>0.598</td>
<td>.553</td>
<td>.022</td>
</tr>
<tr>
<td>Insomnia</td>
<td>2</td>
<td>5210.51</td>
<td>2605.26</td>
<td>4.34</td>
<td>.018</td>
<td>.139</td>
</tr>
<tr>
<td>Pain</td>
<td>2</td>
<td>4356.76</td>
<td>2178.38</td>
<td>5.49</td>
<td>.007</td>
<td>.169</td>
</tr>
<tr>
<td>Role</td>
<td>2</td>
<td>145.95</td>
<td>72.98</td>
<td>0.208</td>
<td>.813</td>
<td>.008</td>
</tr>
<tr>
<td>Emotion</td>
<td>2</td>
<td>2043.51</td>
<td>1021.76</td>
<td>1.750</td>
<td>.183</td>
<td>.061</td>
</tr>
<tr>
<td>Cognition</td>
<td>2</td>
<td>387.67</td>
<td>193.83</td>
<td>0.396</td>
<td>.675</td>
<td>.014</td>
</tr>
<tr>
<td>Social</td>
<td>2</td>
<td>3080.51</td>
<td>1540.26</td>
<td>2.096</td>
<td>.133</td>
<td>.072</td>
</tr>
</tbody>
</table>

A post hoc analysis using Least Significant Difference (LSD) was again conducted for all measures that had a statistically significant difference between the adjusted group means.

The EORTC item for Insomnia was statistically lower in the CBTI group ($M = 33.73, SE = 5.18$) compared to the BPT group ($M = 56.80, SE = 5.95$, 95% CI [-38.82, -7.32], $p = .005$). There were no statistically significant differences between the CBTI and the VC CBTI groups ($M = 45.85, SE = 5.94$, 95% CI [-28.25, 4.02], $p = .138$) or the BPT and the VC CBTI groups (95% CI [-6.002, 27.91], $p = .201$).
EORTC item for Pain was statistically significantly lower in the VC CBTI group \((M = 16.99, SE = 4.73)\) compared to the BPT group \((M = 39.40, SE = 4.83, 95\% CI [-35.98, -8.85], p = .002)\). There was no statistically significant difference between the VC CBTI and the CBTI groups.

Table 18

<table>
<thead>
<tr>
<th>Measures</th>
<th>CBTI</th>
<th>BPT</th>
<th>VC CBTI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cohen’s d</td>
<td>SD</td>
<td>Cohen’s d</td>
</tr>
<tr>
<td>Insomnia</td>
<td>.553</td>
<td>32.65</td>
<td>.263</td>
</tr>
<tr>
<td>Pain</td>
<td>.105</td>
<td>17.87</td>
<td>.249</td>
</tr>
</tbody>
</table>

This reflects that the in-person CBTI intervention impacted insomnia \((ES = .553)\) and the VC CBTI impacted pain \((ES = .425)\), but the small study sample size limited interpretation of these results.

H3: Women receiving internet-based VC CBTI intervention will demonstrate an improvement in sleep/wake patterns (SE, SL, TST), quality of life and functioning similar to the effect size seen in those receiving an in-person CBTI intervention \((\text{Cohen’s d} = 0.34 - 0.67)\) (Matthews et al., 2014).

Table 19

<table>
<thead>
<tr>
<th>Measures</th>
<th>CBTI</th>
<th>BPT</th>
<th>VC CBTI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cohen’s d</td>
<td>SD</td>
<td>Cohen’s d</td>
</tr>
<tr>
<td>Sleep Efficiency</td>
<td>.175</td>
<td>15.91</td>
<td>.090</td>
</tr>
<tr>
<td>Sleep Latency</td>
<td>.636</td>
<td>38.88</td>
<td>.357</td>
</tr>
<tr>
<td>Total Sleep Time</td>
<td>.064</td>
<td>85.98</td>
<td>.069</td>
</tr>
<tr>
<td>WASO</td>
<td>.434</td>
<td>30.18</td>
<td>.317</td>
</tr>
<tr>
<td>Awakenings</td>
<td>.242</td>
<td>1.17</td>
<td>.313</td>
</tr>
</tbody>
</table>
SE, TST, and number of nighttime awakenings had low effect sizes (.069 -.313) while SL and WASO had medium effect sizes (.317-.636) (Table 19).

**Summary**

The results of the study were reviewed in detail in this chapter. The feasibility of and barriers to recruitment, retention, adherence and delivery of VC CBTI were discussed. Most successful methods of recruitment included provider direct mail and in-person referrals and public service announcements broadcast over local rural radio stations. Participants were able to access technology to receive the intervention, and were adherent to treatment at least five nights per week, similar to participants who enrolled in the in-person CBTI.

The internet-based VC CBTI intervention did show significant gains pre to post intervention in all sleep diary measures (SE, SL, TST, WASO, awakenings) as well as insomnia, fatigue, pain and psychosocial scales from the EORTC. Depression and anxiety were not significantly improved post intervention.

An ANCOVA was run to compare mean group differences adjusted for pre intervention scores and both insomnia and pain showed significant differences between groups. The CBTI group improved significantly more in insomnia, and the VC CBTI group improved in pain.

The small sample size and lack of power inhibited interpretation of the results.
CHAPTER V
DISCUSSION

Specific Aim 1

**Aim 1:** Feasibility of and Barriers to Recruitment, Retention, Adherence and Delivery of Internet-based VC CBTI.

The specific metrics for evaluation of feasibility and barriers can be analyzed in three broad categories: recruitment, technology (delivery) and acceptability of treatment (retention & adherence). Each will be further discussed in this section.

**Recruitment**

In this study the most effective recruitment method was a direct mail campaign from an oncology office. HIPAA precluded the PI from accessing Patient Medical Information (PMI) directly, but inclusion criteria were shared with an employee from the oncologist’s office who ran a search in the patient database to identify eligible potential participants. Participation invitations were then direct mailed to these individuals at two different time points for a total recruitment of seven participants. The second most effective recruitment method was PSAs broadcast by local radio stations. These were short (20-30 second) announcements that were read by on-air personalities at three rural radio stations twice per day for three weeks.

According to Cudney, Craig, Nichols & Weinert (2004) the challenges to rural recruitment include: the uniqueness of the rural culture and context, lack of a local research infrastructure and higher costs of recruitment. There may exist resistance to participating in research conducted by an “outsider” who is not familiar with the patterns and social norms of the rural community (Cudney et al., 2004). To combat this outsider bias, the PI attempted to
partner with multiple providers at cancer care clinics throughout rural Colorado. No rural clinics or cancer care centers agreed to partner on a direct mail campaign, but seven cancer care clinics and oncologists’ offices agreed to display brochures in their waiting rooms to advertise the study. Thirty brochures were given to each office for a total of 210 brochures. This resulted in eight BCS contacting the PI for more information and three study participants.

Another recruitment strategy employed was local advertising through newspapers, community flyers, and church bulletins. This was suggested as a recruitment method because it reaches potential participants “where they live” in local communities and helps to combat outsider bias (L. Pedro, personal communication, January 2015). This did not result in any study participants, but the concept of reaching into a community and recruiting through local means might help to explain the success of the radio PSA recruitment method.

There is evidence to suggest that rural BCS have higher expectations of self-sufficiency and lower acceptance of mental health services (Bjorklund & Pippart, 1999; Koopman, Angell & Turner-Cobb, 2001) which may have influenced willingness to participate in this study. Rural communities are not homogenous and they can vary greatly from one area to another. A better understanding of the context of the rural survivors (Pedro & Schmiege, 2014) might have allowed for a more targeted recruitment strategy.

**Technology**

Technology related challenges in this study took two forms: delivery and recruitment. Delivery challenges were minimal. Evidence for that includes the fact that no participant had more than 12 minutes of disrupted communication (Table X), and no participant found the technology so burdensome that they dropped out of the study.
Discomfort with technology was given as the reason two potential participants refused to participate in the study, but it is unknown how many potential participants never contacted the PI because of discomfort with technology.

Access to high speed internet, a requirement for this study, is still a challenge for many rural communities. The move toward accessing the internet using satellite technology will help many rural communities upgrade their internet connection, but mountainous regions face unique challenges due to topography that blocks satellite signals. It is unknown how many eligible potential participants did not contact the PI because they did not have the necessary access to receive the intervention.

One area in which technology provided a clear benefit to this study was in the questionnaire response rate (100%). The pre and post intervention questionnaires were built and delivered through RedCap. The questionnaires were designed to require a response to every question, but did allow participants to save their work and return to finish the survey at a later time if necessary in order to minimize participant burden. The parent study used pen and paper questionnaires in which questions could be missed or not answered. In the parent study the questionnaires were direct mailed back and forth between the PI and participants. This could have contributed to a delay in initiating participation in the study after a participant indicated interest. Likewise, the post intervention survey was direct mailed and response rates may have suffered if the participants perceived that their role in the study was completed at the end of treatment. In the current study, a link to the questionnaire was emailed to participants after consent was obtained, and directly after the last session. This immediacy may have contributed to the 100% response rate.
Acceptability of Treatment

Acceptability of treatment was determined by attendance at treatment sessions and adherence to prescribed sleep and wake times and total time in bed. All participants completed the six sessions of the intervention and after week 2 were compliant at least five nights of the week (Figure 4).

The use of an internet based VC technology to deliver the intervention allowed for a richer quality of communication than telephone or therapist guided web-based bibliotherapy. An early attempt to define the influence that technology can have on the quality of communication was introduced by social psychologists (Short, Williams and Christie, 1976) with the term "social presence". They hypothesized that each method of mediated communication would have inherent advantages and disadvantages that would impact the way in which an individual would be willing to communicate through that technology. This was defined as the "degree of salience of the other person in the interaction and the consequent salience of the interpersonal relationships" (Short, Williams & Christie, 1976, p. 65). Understanding this quality of social presence is essential when attempting to form a therapeutic relationship between patient and provider using the internet. Studies involving counseling have shown that a high degree of social presence is correlated with session satisfaction (Hashimoto, Hashimoto, Onozawa, Hosoya, Harada & Okunaka, 2007; Zilliacus, Meiser, Lobb, Kirk, Warwick & Tucker, 2010), which may have influenced study outcomes.

Specific Aim 2

Aim 2: Examine sleep/wake patterns, quality of life, and functional outcomes in individuals after receiving a six-week internet-based VC CBTI.
H1: Women receiving internet-based VC CBTI intervention will demonstrate an improvement in sleep efficiency ([time asleep/time in bed] X 100) post CBTI intervention.

All sleep measures recorded in the sleep diary (SE, SL, WASO, TST, Awakenings) showed significant improvement after the six-week VC CBTI intervention. Clinically arguably the most important sleep outcome is SE. This is the primary outcome that is targeted in CBTI. A SE score of 85% is the clinical threshold for determining a good sleeper from a bad one (Perlis et al., 2005). The improvement in SE from 78% to 88% pre and post intervention indicates a clinically important step from inefficient sleep to efficient sleep. A key teaching of CBTI is that spending time in bed while awake is counterproductive. Both SL and WASO represent minutes spent awake in bed that can be harmful to forming good sleep habits. Both measures improved significantly pre and post intervention, for a mean gain of almost 40 minutes less awake time during the night (Table 13).

The literature supports CBTI as an effective treatment for insomnia comorbid with cancer (Garland et al., 2014). The sleep diary measures from this study all improved significantly, indicating that an internet-based VC is a viable method of delivery of CBTI that should be more fully explored. In addition, outcomes of subjective sleep measures support the interpretation that internet-based VC CBTI is an effective treatment for insomnia in rural BCS.

The statistically significant decrease in the ISI score that was shown in Chapter IV must also be considered in terms of clinical significance. The mean pre intervention ISI score of 14.78 indicated clinical insomnia of moderate severity, and the mean post intervention ISI score dropped to 7.8 which would be considered no to subthreshold insomnia. In a recent article validating the psychometric indicators of the ISI as a treatment
response tool the authors concluded that a change score greater than seven would be considered moderately improved, and a change score greater than nine would indicate marked improvement (Morin et al., 2011). In this study the mean change score of 6.94 is close to the recommended change score of seven and thus the treatment response could at best be considered a moderate clinical improvement in insomnia severity.

There was also a statistically significant decrease in participants’ total fatigue scores as measured by the PFS. The mean PFS score decreased from 5.54 (moderate fatigue) to 3.44 (mild fatigue). The single item “fatigue” measure on the EORTC-QLQ also decreased significantly \( (M = 12.34, SD = 6.8, p = .011) \) (Table 6). Approximately one in four BCS suffers from severe fatigue, which is an independent but often co-occurring construct from insomnia. It appears that BCS who are diagnosed with Stage II or III cancer and who undergo chemotherapy are at higher risk for fatigue (Abrahams, Gielissen, Schmits, Verhagen, Rovers & Knoop, 2016). CBTI has been shown to reduce cancer related fatigue (Fleming, 2014; Heckler et al., 2016), although it is unknown whether this is independent of or related to the associated decrease in sleep disturbances. In this study, the decrease in fatigue is consistent with the improvement in sleep measures.

H2: Women receiving the internet-based VC CBTI intervention will self-report an improvement in QOL and perceived daily functioning post CBTI intervention.

Participants reported a significant increase in QOL post intervention as measured by the Global QOL subscale of the EORTC QLQ-C30 \( (M = 21.29, SD = 23.78, p < .001) \) (Table 6). Further examination of the EORTC subscales revealed an interesting pattern related to functional improvement. Functional scales that reflect psychosocial dimensions (role, emotion, cognition, social) showed significant improvement. Physical scales and items
(physical, N/V, dyspnea, apnea, constipation, diarrhea) did not reflect any significant improvement after the intervention. The symptom subscale of pain did reflect significant improvement post intervention ($M = 15.73, SD = 1.54, p < .001$), which could be related to the known interaction between sleep and perception of pain (Matre et al., 2015).

A recent study looked at pharmacological and behavioral interventions in 797 women experiencing hot flashes during and after menopause. Researchers found that symptom clusters emerged including disrupted sleep, pain, and mood. It is possible that the improvement in reported pain is influenced in part by improved sleep and/or decreased time awake during the night experiencing hot flashes (Woods et al., 2015).

The AFI total score decreased post intervention ($M = 0.95, SD = .92, p = .306$) but the change was not significant. There are several reasons that could explain why the intervention had no significant effect on the AFI. The AFI is designed to measure an individual’s self-perception of effectiveness in functioning at the time of administration (Cimprich et al., 2011). It is possible that the participants either did not experience or did not recognize any change in effectiveness in functioning after the intervention. There is no proven correlation between sleep and the perception of how effectively one functions so this result could suggest that no correlation exists. This result could also suggest that the online administered AFI is not a sensitive tool to recognize changes in perceived daily functioning in a BCS population.

Rural areas throughout Colorado can vary greatly in access to community and perceived isolation (Pedro & Schmiege, 2014) which can influence depression and hopelessness (Koopman et al., 2001). The mean HADS Anxiety and Depression scores did not change significantly in this study, but both approached clinical significance pre and post
intervention. The HADS Anxiety score was borderline to clinically abnormal and the HADS Depression score was borderline at both time points. This is consistent with a recent study that shows fatigue and insomnia decrease after CBTI, but changes in anxiety and depression may take longer to manifest (Fleming, Randell, Harvey & Espie, 2014).

A study of 116 cancer survivors examined the differences in mental health functioning between rural and non-rural cancer survivors 1-5 years after treatment. They found that rural cancer survivors scored higher on the HADS Anxiety (ES = .70) and Depression (ES = .47) scales than non-rural survivors (Burris & Andrykowski, 2010). It is possible that the HADS is not a sensitive tool in the rural cancer survivor population, but it is also possible that the online VC CBTI that was focused on sleep improvements was not an effective tool for treating underlying anxiety or depression. In the parent study neither anxiety nor depression reached significance, but both trended down at follow up time points of three and six months after treatment (Matthews et al., 2014). It is possible that improving sleep habits does influence anxiety and depression in the long term, but this would require a longer term study with more outcome points to establish.

**Specific Aim 3**

**Aim 3:** Examine sleep/wake patterns, quality of life, and functional outcomes in individuals receiving an internet-based VC CBTI compared to those receiving standard, in-person CBTI and in-person behavioral placebo treatment (3 group design).

Specific aim 3 compared the outcomes between three groups: in-person CBTI, in-person BPT, and internet-based VC CBTI. An ANCOVA was run to compare adjusted group means with pre-test scores as covariates and two items were identified as statistically significant: insomnia and pain. The adjusted insomnia mean score in the in-person CBTI
group was significantly lower than in the BPT and VC CBTI groups. Conversely, the adjusted pain mean score was significantly lower in the VC CBTI group compared to the CBTI and BPT groups. CBTI is an established in-person treatment for insomnia in BCS. The observation that insomnia improved in the in-person CBTI group is not unexpected. The significant difference in the mean pain score in the VC CBTI group is less supported. It is possible that given the small sample size a high baseline rating of pain in a few participants could have skewed the sample. Overall it is difficult to conduct a meaningful interpretation of the data given the small sample size and associated lack of power.

**Study Limitations**

This study was designed to recruit BCS from rural areas in Colorado as defined by HRSA, but did not take into consideration the characteristics of different rural areas and the disparities between BCS in those areas (Pedro & Schmiege, 2014). More detailed information and stratification of participants by rural areas would have allowed for a richer analysis. A stronger commitment from rural providers to recruit patients could have resulted in a larger, more meaningful sample.

This study was based on a parent study that used in-person CBTI as a therapy for BCS. While this study replicated the parent study in session number and session length, there are other differences between the two studies. The dissertation study used an internet-based VC CBTI to reach BCS in MUAs. Demographics were compared between groups, but there may be subtle differences between the predominantly urban and rural groups which were not captured using traditional demographics. There is evidence to show that rural BCS have a different experience of survivorship (Davis et al., 2003) and capturing that information is beyond the scope of this study.
CBTI was provided by an advanced practice nurse trained in the intervention, who was enrolled in a nursing doctoral program. The CBTI in the parent study was provided by an associate professor at a large university. The therapist from the parent study trained and supervised the doctoral student, and efforts were made to adhere to the fidelity of the CBTI to lessen the differences between the two therapists. Still, there could have been differences in the delivery of the therapy that limited comparability.

Mental health resources are limited in many rural areas, and there may be a stigma associated with participating in the CBTI intervention (Bettencourt et al., 2007). It is possible that the BCS in MUAs who agreed to participate in this study do not reflect the attitudes of rural BCS as a whole.

The technology required for participation in this study might have limited the sample. Participants were required to either have a computer with high speed internet access or to use a computer at a local library or referring clinic. It is also possible that BCS who were not comfortable with technology did not participate in the study, resulting in a non-representative sample.

Aim 3 was intended to compare VC CBTI against in-person CBTI and BPT, but the small sample size and subsequent lack of power did not allow for meaningful comparisons between groups.

**Implications for Practice**

This study supports the use of CBTI as a front-line behavioral treatment for insomnia in BCS (Morin et al., 2006). Unfortunately, it is not as readily accessible to rural survivors in MUA’s due to a lack of trained psychologists who are geographically available. In this study a trained nurse provided the VC CBTI intervention over the internet to rural BCS.
Statistically significant decreases to insomnia, fatigue, and sleep diary measures (SE, SL, WASO, TST) support the investigation of using internet-based VC CBTI to rural survivors as a treatment for insomnia. This could provide a valuable tool for helping to increase healthcare access to people in rural areas.

Technology-mediated interventions are an increasingly important component of comprehensive health care. Health care providers must find a way to leverage technology to reach underserved individuals. Technology is increasingly incorporated into provider education (Skiba, 2015) and providers need to actively seek new methods of outreach to patients. VC CBTI is one example of how a gold-standard treatment for insomnia can be provided to rural BCS who would otherwise have no access to the treatment.

**Future Research**

There are many areas that can be researched based on the findings of this study. In-person CBTI is an effective treatment for insomnia in BCS. Future studies should compare in-person CBTI, VC CBTI, and web based bibliotherapy CBTI to compare therapeutic outcomes and evaluate cost savings between the groups. It is possible that different demographic groups would show an affiliation to one delivery method over another.

Technology has evolved to provide a myriad of ways in which we can communicate. A mobile device based CBTI could provide another method for study. Future studies should enroll a larger sample size to increase power for more meaningful statistical conclusions.

Another rich area for research is the differences in the rural contexts. This study combined all participants into the category of “rural”, but there could be vast differences between the rural experience as lived in a tourist town versus a small ranching community.
Recruiting in rural areas proved challenging in this study. Future research could identify better methods to reach rural participants.

**Conclusion**

Feasibility studies are designed to provide necessary information to determine if an efficacious intervention can be effective when provided to a community based population or via a different medium (Bowen et al., 2009). This study evaluated a known intervention (CBTI) delivered via a different method (VC CBTI) in order to reach a rural population. VC CBTI appears to provide a viable method of delivering therapy to rural BCS who would otherwise likely not receive the therapy due to geographical limitations and a lack of providers. Reducing insomnia in BCS can positively affect QOL and have long reaching health and wellness implications.
REFERENCES


