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Feasibility of an Online Cognitive Behavioral Therapy Program to Improve Insomnia, Mood, and Quality of Life in Bereaved Adults Ages 55 and Older

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Feasibility of an online cognitive behavioral therapy program to improve insomnia, mood, and quality of life in bereaved adults ages 55 and older.

A Dissertation Presented By

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Abstract

Objective: To determine the feasibility of an online cognitive behavioral therapy for insomnia (CBT-I) in bereaved older adults.

Participants: The study participants include adults aged 55 and older (*N* = 30) that lost a loved one within the past five years and are currently experiencing symptoms of insomnia.

Methods: This study used an experimental design and was guided by the Transitions Theory developed by Meleis. Descriptive statistics and *t*-tests were used to measure changes within and between groups. Experimental arm had the CBT-I online treatment and the control arm had attention controlled online tasks. Intervention fidelity was measured.

Results: The online CBT-I intervention is a feasible intervention for bereaved older adults with insomnia. High retention rates were shown in both groups, and both groups' insomnia and mood symptoms improved at post- study measurement. There were no statistically significant differences seen in any measure between groups.

Conclusions: Transitions in older adult life includes loss of friends and family as well as development of sleep issues. The Transitions Theory is useful for informing the design of behavioral interventions in this older population. Further research is needed to understand how sleep can be improved by cost effective online interventions that might not include solely CBT-I.

Keywords: online cognitive behavioral therapy, insomnia, older adults, depression, anxiety, quality of life

Proposal

Introduction to the Problem and Specific Aims

Loss of sleep has negative consequences on mood and physiological health (Carroll et al., 2015; Harvey et al., 2018). It is identified as a risk factor for health conditions such as cardiac disease, stroke and diabetes (Grandner et al., 2016; Lin, Chien, Chung and Wu, 2018).

Insomnia is common after the loss of a loved one (Richardson, Lund, Caserta, Dudley, & Obray, 2003; Simpson, Allegra, Ezeamama, Elkins, & Miles, 2014). It can include difficulty falling asleep, multiple nighttime awakenings, and early morning awakening, all of which are frequently observed during bereavement (Simpson, Allegra, Ezeamama, Elkins, & Miles, 2014). Studies have shown sleep issues caused by bereavement can last up to five years (Jonasson et al., 2009) after the death of a loved one.

Insomnia is often treated with over the counter (OTC) sleep aids, or prescription sedative-hypnotic medications (Maust, et al., 2019). In fact, about a third of all older adults in the United States use sleep medications to induce or prolong sleep (Maust, et al., 2019). However, sleep aids have the potential to compromise cognitive functioning and increase the risk of falls (Albert, Roth, Toscani, Vitiello & Zee, 2015). There is also some evidence that the anticholinergic effects of some of these sleep medications can increase the risk of dementia (Gray et al., 2015). Increased risk of stroke and overdoses may also result from taking sleep aids (Petrov et al., 2014). Pursuing non-pharmacologic interventions might be an option for older adults who are at increased risk for falls, strokes, and overdoses. There is therefore an opportunity to improve

quality of life in older adults by addressing their sleep health using means other than medication.

Some examples of nonpharmacologic treatments for insomnia include biofeedback, mindfulness, and tai chi (Frame & Alexander, 2013; Hubbling, Reilley-Spong, Kreitzer, & Gross, 2014; and Irwin et al., 2015). A biofeedback study in older adults found that a 30-minute audio-visual stimulation program over four weeks (n=8) showed significant improvement in insomnia symptoms and sleep quality (Tang, Vitiello, Perlis, Mao & Riegel, 2015). In a study by Black, O'Reilly, Olmstead, Breen and Irwin (2015), a sample of 25 older adults with a mean age of 66.3 years, found that both insomnia symptoms and depression symptoms significantly improved following the mindfulness education intervention. Irwin et al. (2015) have also found that tai chi reduced symptoms of insomnia in an older adult sample.

While the above nonpharmacologic treatments do show benefits, they can be costly and involve a great deal of training that might be challenging to implement widely. Psychotherapy has been shown to significantly reduce symptoms of insomnia in some populations (Kanady et al., 2018). One type of psychotherapeutic modality —considered the gold standard psychotherapy for insomnia —is Cognitive Behavioral Therapy for Insomnia (CBT-I), which is traditionally administered in personal sessions between patient and therapist (Feuerstein et al., 2017). CBT-I has been linked not only to improvements in sleep, but also to decreases in a variety of mental health symptoms. For example, CBT-I has improved symptoms related to Post-Traumatic Stress Disorder (PTSD) and suicidal ideation in veteran populations (Kanady et al., 2018; Trockel, Karlin, Taylor, Brown, & Manber, 2015). Following a CBT-I intervention, fear of sleep in

veterans diagnosed with PTSD (N=45) improved, resulting in a decrease in waking episodes after sleep onset and increased total sleep time (Kanady at al., 2018). In another study with 407 veterans, Trockel, Karlin, Taylor, Brown and Manber (2015) found that the Insomnia Severity Index (ISI) decreased from a mean of 20.4 at baseline to a mean of 10.7 at session 6, meaning insomnia was initially of moderate severity and it decreased to sub-threshold insomnia. Another study of veterans (N=22) found that alcohol-dependent veterans exposed to CBT-I had a decrease in insomnia symptoms compared to the monitor-only group (Chakravorty et al., 2019) - the differences between the groups was significant for the insomnia severity index with monitor-only compared to the CBT-I group. Although sleep improved, behaviors associated with alcohol use did not significantly change.

The benefits of CBT-I in the bereaved has also been studied (N=11), in a sample of primary caregivers of patients who died of cancer, aged 42 through 80 with a mean of 56, with statistically significant improvements in sleep as measured by the Pittsburg Quality Sleep Index (Carter, Mikan, & Simpson, 2009). Another study that looked at hospice and palliative care nurses (N=13) with sleep disturbances who were chronically bereaved (Carter, Dyer, and Mikan, 2013) found that CBT-I did not change sleep components, including sleep latency, efficiency and total sleep between time points; however the levels of depression were reduced, although the significance of these results was not discussed by the authors.

Even though there has been some evidence of improvement in insomnia and mood symptoms in the bereaved, **online CBT-I intervention has not yet been explored in an older bereaved adult population, although it has shown promise in**

use with other populations. An online intervention for older adults with sleep disturbances has the potential to improve access to those in need of treatment. Other telemedicine programs like critical access care have helped improve accessibility to healthcare services (Kuperman, Linson, Klefstad, Perry, & Glenn, 2018). There has also been telepsychiatry for neurocognitive screening for older adults that has had favorable outcomes with no differences in cognitive scoring between in-person and remote screening (Vahia et al., 2015). Another study involved community based telepsychiatry for older adults living in rural areas and they found that participants in the outpatient setting were satisfied (Dham, Gupta, Alexander, Black, Rajji & Skinner, 2018). Online treatment programs might also lead to longer term cost savings as shown in an online interactive program for sleep symptoms (Thiart et al., 2016). More research on the cost savings possible with online CBT-I needs to be pursued in order to inform clinicians and health care insurances about the efficacy of treatment that would be prescribed and paid for by stakeholders (Botteman, 2009).

Therefore, the purpose of this feasibility study is to examine the usefulness of CBT-I delivered online versus the existing standard of care in bereaved adults ages 55 and older. In this study, bereaved older adults are defined as those who are deeply saddened by the loss of a close loved one within the past five years. This age group was chosen for two reasons: (a) because insomnia in older adults can lead to high levels of functional problems, including poor memory and attention, and slower response times (Ancoli-Israel & Cooke, 2005) and (b) age 55 and older is the cut-off age which aligns with other psychiatric studies involving older adults (Chen, Stevinson, Fang, Taun and Ku, 2019; Morita, Sasai-Sakuma, and Inoue, 2017). Use of online CBT-

I programs in older adults has not been explored, and there are differences with this population, i.e., verbal learning, subjective organization, environment cue dependence, that might impact the benefit they receive from participation in the program (Chan & Yan, 2018; Kurtz & Zimprich, 2014).

Using the transitions theory (Meleis, 2010) to frame the study, the specific aims are to:

a. Explore the preliminary efficacy of an **online** CBT-I sleep program including its feasibility **[nursing therapeutics]** on insomnia, cessation of sleep medication, neuropsychological changes including mood and anxiety, and quality of life **[personal conditions]** in bereaved adults **[change trigger]** ages 55 and older.
b. Describe the time to recruitment, rate of retention, acceptability and barriers associated with the use of an online CBT-I sleep program among bereaved adults ages 55 and older.
c. Describe the treatment fidelity associated with an online CBT-I sleep program.

Background and Significance

Transitions in life pose new obstacles and changes that require adjustment. Bereavement following the loss of a loved one is one type of transition that adults of all ages experience. Quality of life and psychological health often worsen during this period and sleep becomes disrupted, with significant reductions in total sleep time and increased rates of insomnia (Richardson, Lund, Caserta, Dudley, & Obray, 2003). This is especially true in older adulthood. Adjusting to a new way of life can be particularly difficult as one ages. The transition from life with a loved one to a life without this person is something that needs to be better understood. More specifically, the issues

associated with this transition and sleep problems needs to be examined in this population so that appropriate and effective interventions can be designed and implemented in order to ward off cardiovascular disorders and psychological issues like worsened cognition (Lao et al., 2018; Porter, Buxton & Avidan, 2015).

Insomnia

Insomnia, or lack of sleep with difficulty in initiating sleep and/or staying asleep throughout the night and/or possible early morning awakenings, is a concept that has been studied in a number of disciplines including psychology (e.g., McCurry, Logsdon, Teri, and Vitiello, 2007), nursing (e.g., Brandt & Piechocki, 2013), and medicine (e.g., Buenaver, Townnsend, & Ong, 2019; McCrae et al., 2018). Various disciplines including nursing have been interested in issues surrounding sleep because of the hypothesized connection with health outcomes (Sandlund, Hetta, Nilsson, Ekstedt, & Westman, 2017). There have been a number of treatments that have been developed to treat insomnia symptoms.

Cognitive Behavioral Therapy for Insomnia

The most commonly used behavioral intervention used to treat insomnia is known as cognitive behavioral therapy for insomnia (CBT-I). This modality originates from the discipline of psychology and incorporates the cognitive distortions and maladaptive behaviors from traditional CBT but goes further to tackle insomnia and issues surrounding this phenomenon. The therapy is typically carried out in a face-to-face session (either one-on-one or in psychotherapy groups with others who are learning the material) and is provided by a clinician with specialized training in CBT-I known as behavioral sleep medicine (BSM; Perlis and Smith, 2008). The duration of the

therapy varies in length, with most CBT-I interventions delivered in six to eight sessions (Matthews, Arnedt, McCarthy Cuddihy, & Aloia, 2013). The duration of sessions is also variable (Carter, Mikan & Simpson, 2009; Pfoff, Zarotney & Monk, 2013), although some studies describe four or more contacts as the minimum required to receive an adequate dose (Edinger et al., 2007; Trauer, Qian, Doyle, Rajaratnam, & Cunningham, 2015).

Traditional in-person CBT-I programs have been instrumental to improving insomnia across populations. These improvements have been evidenced across the lifespan from adolescence through geriatrics (Bruin, Bogels, Oort & Meijer, 2015; Irwin et al., 2015), and with populations with various comorbidities like post-traumatic stress disorder (PTSD; Kanady et al., 2018; Trockel, Karlin, Taylor, Brown, & Manber, 2015) and HIV (Safren et al., 2016).

There have also been a few studies that looked at bereaved adults with insomnia who received traditional CBT-I. In one study with 11 bereaved family members who received in-person CBT-I from a nurse therapist, insomnia decreased over 5 weeks (p<0.02; Carter, Mikan, & Simpson, 2009). Another study found that hospice nurses who are exposed to chronic bereavement benefited from a CBT-I intervention (Carter, Dyer, & Mikan, 2013).

Recently, internet-based CBT-I programs have been developed that allow patients to participate in therapy within their homes. A popular online program is SHUTi (Ellis, Seed, Bastien & Grandner, 2017). SHUTi contains six core CBT-I learning modules. Each core module is time released over a 6-week period. The core modules include: Get Ready, Sleep Window, Behaviors, Thoughts, Education, and Looking

Ahead (www.myshuti.com). The program is accessed remotely from any computer using an internet connection and the participant is involved in interactive content, reading materials, and sleep diaries during the six weeks to help them learn about CBT-I and how to incorporate it into his/her life.

The SHUTi program has been shown to reduce symptoms associated with insomnia including sleep efficiency with the CBT-I group showing a 19% improvement from baseline ($t(12)=-6.83$, $p<.01$) in a cancer survivor population ($N=22$) and large effect sizes for depression and anxiety ($d=.54$ and $d=.42$, respectively) pre- and post-intervention (Ritterband et al., 2012). Another study found insomnia significantly decreased ($p<0.0001$) after the SHUTi intervention in a sample of 1,149 non-clinically depressed participants (Christensen et al., 2016).

There are other virtual CBT-I programs available. One of them is CBT-I Coach which is a smartphone application that patients use to track their sleep (Koffel et al., 2018). It has been found to be feasible in a veteran population; however, it is important to know that this program is designed to be an adjunct to face-to-face CBT-I (Koffel et al., 2018). It does have the limitation of not providing timestamps for when patients submitted their daily sleep scores. Another online program for insomnia is called Sleepio (www.sleepio.com). It is an online platform that has been found in one research study to improve participants' sleep time and quality (Espie et al., 2012). There are fewer studies that involve this specific platform compared to CBT-I Coach and SHUTi. No matter what platform that is used, there is a consensus that more studies are necessary to fully evaluate the use of the online CBT-I program across different patient populations.

There have been limitations to the online CBT-I programs including the inability for the PI to track the participants' timestamped use of the program (Espie et al., 2012; Kofell et al., 2018). In a meta-analysis study, researchers found the average drop-out rates of online CBT-I of 24.7% versus the in-person CBT-I that studies have reported from 0% to 33% drop-out rate, which have been attributed to not having the accountability of researchers communicating with them (Zachariae, Lyby, Ritterbannd & O'Toole, 2016). In an attempt to improve retention, one study (utilizing Sleepio) involved use of an online community to engage participants; however, this introduced additional challenges, including negative experiences when participants read "horror" stories posted by others (Coulson et al., 2016) and complaints that the community involvement as time intensive.

In the current study, the SHUTi program has the ability to track the participant's use of the program, i.e., when they logged into the system and how long they were active within the program. Participants can ask questions directly to the PI versus communicating with other participants in the online community, as there is no online SHUTi community, which helps to negate sharing of "horror" stories. Retention will be managed by having the PI contact the participants by phone at baseline to increase interpersonal connection between researcher and participant. The PI will also email participants weekly as well as being available for technical support throughout the study.

Mental Health

Sleep appears to play a significant role in alleviating the symptoms of mental disorders including anxiety (Gosling et al., 2018). In a sample of 1149 community-

dwelling adults (Gosling et al., 2018), those with higher levels of anxiety experienced greater reductions in anxiety following a sleep intervention (t=-6.77, df =724.27, p<0.001). Sleep allows for rest of the physical body, but it also allows the brain to filter extraneous proteins that might be detrimental to health (Haydon, 2017). It also permits time to process information, assists with memory consolidation (Goerke, Muller, & Cohrs, 2017), improves attention (Chua, Fang & Gooley, 2017), and decreases reaction time (Wlodarczyk, Jaskowski & Nowik, 2002). For all of its biological benefits, sleep is essential for the overall mental well-being and functioning of the patient (Britton, McKinney, Bishop, Pigeon, & Hirsch, 2019; Lin et al., 2018). In a retrospective cohort study that looked at patients across the lifespan, including one group aged 45-64 and another group aged 65 and older, they found that there was a significantly higher risk of suicide attempts in insomnia patients compared to those without insomnia (Lin et al., 2018). Those in the 65 and older age group had a higher risk of suicide compared to the younger group. Another study found that middle and older-aged adults aged 44-87 who had attempted suicide suffered from more severe insomnia than other depressed, non-suicide attempt groups (Kay et al., 2016).

During bereavement, emotional stressors are high and mood can be labile with increased anxiety. Without sleep to take care of biological processes that are hypothesized to occur during sleep, there is the potential for depressive and anxiety symptoms to be especially pronounced during waking hours.

Mental health symptoms are common in people experiencing bereavement and the presence of symptoms without appropriate treatment can lead to disability or morbidity (Ghio et al., 2015). Older adults with depression and anxiety are at a

particularly high risk of failing to receive treatment for mental health symptoms because there are societal influences that portray older adulthood and mental health disorders as inevitable, despite findings that contradict this conception (Xiang, Danilovich, Tomasino, & Jordan, 2018). Another issue is that older adult men are at high risk of suicide, particularly when there are changes in mood (Almeida et al., 2016). This is especially concerning when there is a loss of a loved one. Studies support mental health symptoms that commence and/or intensify in severity following the death of a loved one can last for at least five years (Jonasson, 2009). If adequate sleep is not being obtained, the likelihood of improving psychiatric symptoms drastically declines as evidence by multiple studies (Britton, McKinney, Bishop, Pigeon, & Hirsch, 2019; Kay et al., 2016; Lin et al., 2018).

Quality of Life

The assessment of quality of life encompasses a number of domains of a person's life including social connectedness and environmental supports (Uchmanowicz, Koltuniuk, Stephien, Uchmanowicz & Rosinczuk, 2018). This is of relevance to older adults suffering bereavement because they have recently lost a major support in their life: their partner/spouse, parent, sibling, child, grandchild, or close friend. Older adults who lose one of their primary supports can have a difficult time adjusting to a new way of life and social isolation and loneliness are common for adults who are alone in older adulthood (Victor, Scambler, Bond & Bowling, 2000). They might not have the energy, motivation, or be in the mood to socialize, which is where mental health symptomatology plays a critical role. The older adult can have difficulty in getting out of the house or even maintaining the social connections they once had prior

to their loss (Ayotte, Margrett, & Hicks-Patrick, 2010). Their environment can become more limited because they are not participating in their community as much as they did prior to bereavement.

Less physical movement from sitting in the home can lead to negative physical health outcomes (Fernandez-Alonso, Muoz-Garcia & La Touche, 2016). Chronic health conditions can develop and/or be exacerbated by limited movement. Comorbidities such as physical and psychological health problems can become more serious, and lead to increased mortality. In fact, a study of 198 older adults aged 80 to 98 years old showed a reduced risk of mortality for active older adults compared to their sedentary counterparts two years later (Beta=-0.679, p=.32; Beta=-1.20, p=.26, respectively; Chipperfield, 2008). Another study that looked at depressed adults with insomnia (N=37) with a mean age of 52.9 years old (Shimodera et al., 2014) found that a CBT-I intervention administered over four weeks helped to improve physical functioning (p = 0.006), social functioning (p = 0.002) and mental health (p = 0.041).

Theoretical/Conceptual Framework

The transitions theory proposed by Afaf Meleis (2010) will be used to guide this study. This theory describes the interactions between nurses and patients during a change in the patient's life and will be used in this study to explain how a transition can impact health and well-being (Meleis, 2010). In this study, the loss of a partner/spouse, parent, sibling, child, grandchild, or close friend marks the transitional period for the patient into bereavement.

Transitions theory has four components: (1) the nature of the transition or ***change trigger***; (2) ***conditions that impact the transitions*** in one's personal life,

community and/or society; (3) ***nursing therapeutics or interventions*** that can help the patient transition; and (4) ***patterns of responses*** (behaviors, feelings, well-being, health). For the purposes of this study the phenomenon of interest is insomnia during the period of bereavement and therefore the components of transitions theory can be considered: (1) loss of a loved one is the change trigger — it is development in nature and is a single (oftentimes) critical event; (2) insomnia is the personal condition that inhibits the transition; (3) the attention-control, online CBT-I program, and nurse CBT-I therapy will be the therapeutic interventions; and (4) diminished insomnia will be considered a positive pattern of response (with the CBT-I interventions hypothesized to improve insomnia).

Other patterns of response, or outcomes of interest besides insomnia, will include depression, anxiety, and quality of life (QOL). Consideration of the community and societal conditions that impact the transition will also be assessed using a quality of life measure.

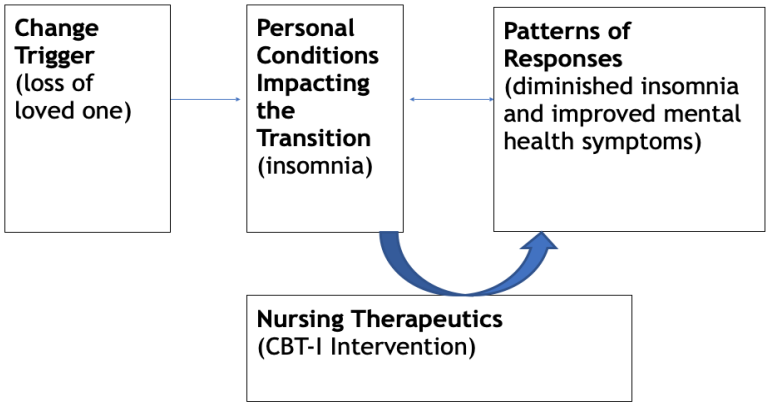

Figure 1

Adapted Model of Transitions Theory (Meleis, 2010).

Methods

Design

This study will use a randomized controlled trial design. Subjects will be randomized 1:1 to:

Arm 1 — attention control

Arm 2 — online SHUTi CBT-I program

A statistician will generate the random number sequence and will place the treatment assignments into opaque envelopes that the Principal Investigator (PI) I will use to randomly assign subjects to the study treatment.

Sample

The accessible population for this study is older adults in bereavement groups in New Hampshire, New York, Massachusetts, Rhode Island, and Connecticut, with an expected total accessible population of 5,000 people based on figures estimated by group leaders. There are multiple groups that meet throughout these states and each have varying group sizes (5–30). The participants will be adults aged 55 years old and older. Both men and women will be included in this study. The participants will be from the Northeastern part of the United States.

Table 1.

List of the inclusion/exclusion criteria for this study

Inclusion	**Exclusion**
Aged 55 or older	Current experience of suicidal/homicidal ideation or intent to harm self or others

Speak and write in English – *SHUTi is currently only available in English*	Previous mental health treatment or current (past) taking of antipsychotic medications, mood stabilizers, or substance use replacement therapy medications. Diagnosis from a healthcare provider or therapist of serious mental illness, i.e. bipolar disorder, schizophrenia or schizoaffective disorder, current substance use disorder or alcohol use disorder, or personality disorders.
At least one loved one who passed away within the past 5 years	Inpatient psychiatric hospitalization within the 12 months
Currently experiencing symptoms of insomnia	
Wants to improve insomnia symptoms	
Access to a computer for at least 3 hours weekly for 8 weeks	
Ability (physical and mental) to use a computer mouse, keyboard, and audio	
Reliable internet access	
Working email address to receive study materials	

Setting

Study procedures will take place in the participants' homes or friend/family's homes for both study arms. A quiet, private space with a computer is important so that the participant can focus on the content on the screen.

Procedures

IRB approval will be secured before any study procedures take place. Recruitment at the sites indicated in Table 2 will occur once approval has been secured by each specific organization. Information about the study will reach potential participants in the following ways: live informational session by PI [dependent on PI proximity to bereavement group location], email blasts, newsletters, and social media

announcements. Participants will call the PI using the phone number provided on the paper advertisements or on the virtual web announcement. Inclusion and exclusion criteria will be assessed over the phone by the PI, and those who meet the study requirements will be verbally consented and assigned a unique identification number. An IRB approved fact sheet will be sent to them by email. For those who do not meet inclusion criteria, only their age, sex, reason for refusal, and specific inclusion criteria that is not met will be recorded. Once the participant has met all of the inclusion criteria, they will be randomly assigned to a study arm. Participants will be made aware as part of the information sheet not to disclose information about their study treatment to others in their bereavement communities. Both arms will be expected to complete measurements at the time points outlined in Table 2.

Table 2.

Outline of study arms and measurements at timepoints.

	Baseline Measures obtained: Demographics, WHOQOL-BREF, ISI, and DASS-21	**Modules 1 through 6 (for both experimental and attention-control groups)**	**Week 8 Measures obtained: WHOQOL-BREF, ISI, and DASS-21, Final Survey Questionnaire (Appendix L)**	**Week 8 Intervention Receipt Measure**
Arm 1	X	X	X	X
Arm 2	X	X	X	

Recruitment. Approval to use recruitment organizations will be obtained and secured in writing before recruitment will proceed. This is to ensure that the site agrees

to use recruitment materials and/or talks by the PI at their facility. See Table 3 for the recruitment plan. These recruitment sources are chosen due to the population (*age and likelihood of having lost a loved one recently)*. From these recruitment sites combined including bereavement groups, it is expected to reach approximately 5,000 potential participants.

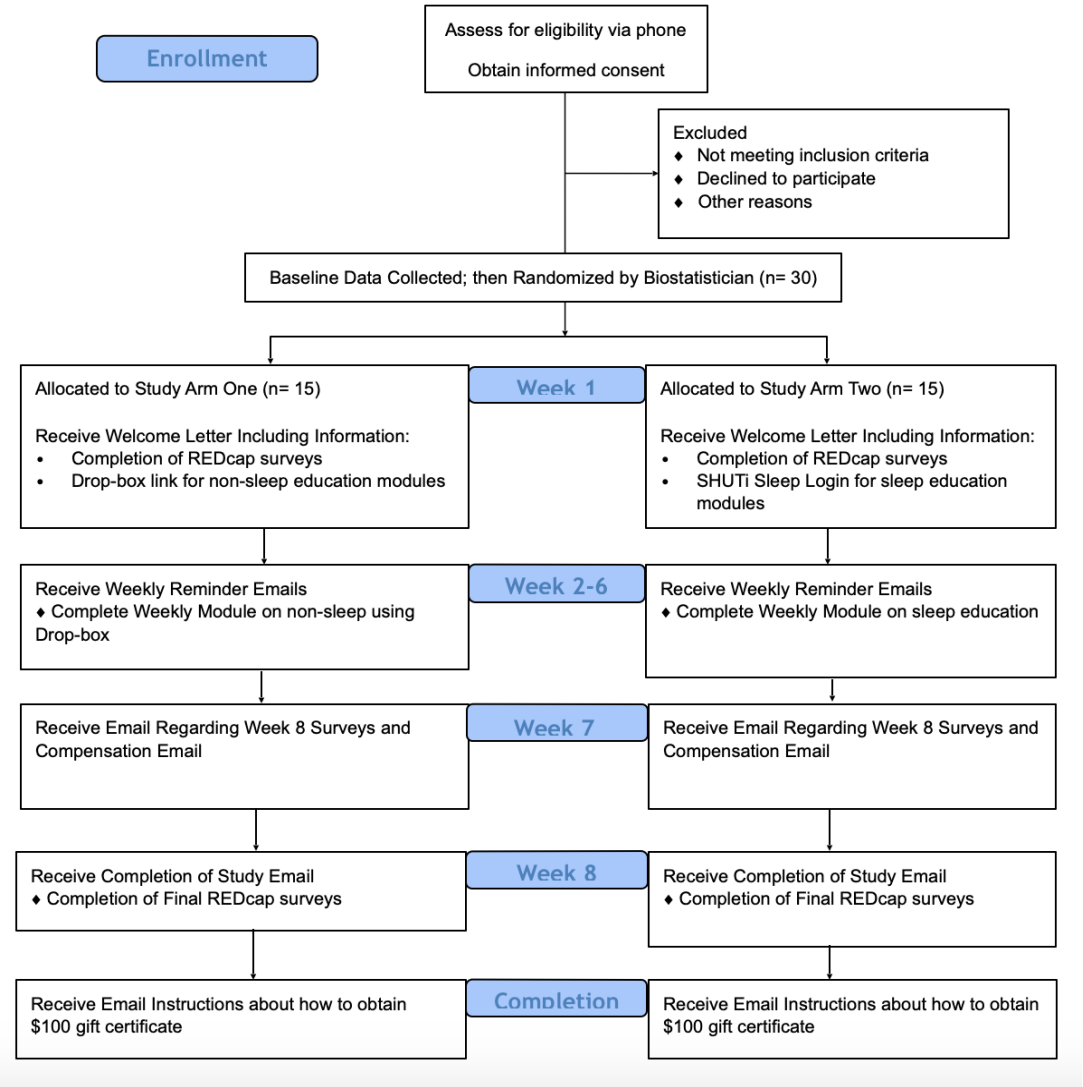

Figure 2.

Study Procedures.

Table 3.

Agencies where recruitment will occur

Location	Modality of recruitment
Visiting Nurses Association (VNA) Bereavement Groups of Massachusetts, New Hampshire, and Maine	Email blast from VNA coordinator; posters and flyers at the physical sites; and live informational sessions done by the PI.
Care Dimensions of Massachusetts— Hospice, Palliative Care, Support Services	Email blast of study from their Research coordinator; and posters and flyers at the physical sites.
The Meadows and The Gables Residential living - Independent, Assisted, and Memory Care Facility in Vermont	Email blast from Program coordinator; posters and flyers at the physical sites; and live informational sessions done by the PI.
Hospice Foundation of America	Newsletter Announcement to Members [including clinicians and patients]; and informational post on their Facebook page.
Massachusetts Funeral Homes – Dignity Memorial, Ruggerio Family Memorial Home, Davis Funeral Home, and Graham Putney & Mahoney Funeral Partners	Email blast from funeral home coordinators; and posters and flyers at the physical sites.
Facebook Bereavement Groups— The Bridge: A Center for Hope and Healing, Empty Arms Bereavement Support, My Bereavement Companion Counseling & Support, Grieving the loss of a loved one Support Group	Email blast of study from their site administrator coordinator.

All interested potential participants will call the number (answered by the PI) listed on the recruitment materials. There will be a recorded message (see Appendix O) that allows for those interested to leave a voicemail (in the event that the PI does not answer the call). The PI will return the call within 24 hours and immediately delete the potential participant's voicemail. At the time the PI and potential participant speak live

over the phone, the PI will screen the participant for inclusion and exclusion criteria using the Screening Tool (see Appendix E). Informed consent will then be obtained over the phone. The participants will be sent an email copy of the study fact sheet and informed consent. If inclusion/exclusion criteria are met and informed consent is obtained, baseline data will be collected by the PI and entered into a secure database on the University of Massachusetts Medical School (UMMS) server. Once baseline data is collected, subjects will be randomly assigned to a study arm and unique identification number using the previously generated random assignment envelopes (prepared by the biostatistician; see Figure 2 for study procedures).

The participant will receive study materials associated with the procedures for their specific study arm. These materials will be emailed after baseline data are collected to the email address the participant provided on the demographics form. The materials within this “Welcome to the Study” email will appear as displayed in Table 4. Copies of the emails can be found in Appendix F.

Table 4.

Contents of the “Welcome to the Study” email

		Arm 1	**Arm 2**
Welcome and Copy of study fact sheet		X	X
Drop-box Module Links (Non-Sleep Education)		X	
SHUTi Login and Password			X

Study arm one. The participants will conduct time-matched module exercises on healthy life practices including nutrition and exercise. The training will consist of six modules that the participants can access via drop-box. It will include videos, readings, and interactive activities to complete on a weekly basis. The activities will be time-matched to the CBT modules in study arm two, with three hours of educational content weekly being provided to participants. These healthy life practice educational modules are devised by this researcher and includes pre-recorded materials that participants in study arm one can watch on-demand. A list of the modules with recommended viewing order will be provided to participants that includes: Insomnia, Grief, Positivity, Healthy Eating, Exercise, and Resilience. Pre- and post-measures to be administered via REDcap at baseline and end of week 8.

Study arm two. The participants in this arm will use the online CBT-I program, SHUTi. This includes video presentations and materials that participants will watch weekly. It is expected that they will spend three hours weekly on this educational material. Once they obtain the login and password information in the welcome email, they will be expected to complete a short interactive tutorial that will ‘unlock’ the remainder of SHUTi program that consists of 6 modules. They will be completed as follows: Get Ready, Sleep Window, Behaviors, Thoughts, Education, and Looking Ahead. Each module will be assigned to a specific week, i.e., Get Ready for Week 1, Sleep Window for Week 2, and so on. Additionally, this group will be expected to log information about their sleep into the online sleep diary.

Retention. To increase retention, weekly emails from the PI will be sent to the participants in both groups. These emails will indicate the week of the study that the

participant has reached. Each of these weekly emails will remind the participant what they should be doing (i.e., Module 2 on Sleep Window). They will also contain the PI's contact information, with words of encouragement to seek assistance for any technical issue or questions that arise. By keeping in close communication with the participant, this will help to 1) clarify procedures for that week and 2) keep them on track. Participants will also receive a $200 gift certificate when they complete the study. Information to obtain this gift certificate will be sent via email as soon as they complete the questionnaires at the end of week 8. A "Thank You" for your participation email will be sent to participants at that time (see Appendix K).

Intervention fidelity. A manual will be used by the PI to ensure that the same procedures are being administered to each study arm. Email scripts for each of the study arms will be included in the manual. A checklist and notes will be kept on a prescriptive document (Microsoft Excel spreadsheet) that will be saved on the UMMS server by the PI. This will permit the PI to monitor (on a weekly basis) that the participant is receiving their prescribed material during the study (per study arm designation; Santacroce, Maccarelli & Grey, 2004). Intervention fidelity will be measured using the checklists (see Appendix I) for each participant that are saved to UMMS server. The measurement of intervention dose is completed automatically for the online SHUTi program for study arm two by looking at the login frequency and length for each participant. The time that participants are working on learning activities within SHUTi is tracked daily. This data will be exported by the PI at the conclusion of the program; however, it will also be reviewed weekly by the PI to ensure participants have logged into the module assigned to that week. If they have not, the PI will contact them via

email – see Appendix N. Treatment receipt will be measured using the Receipt of SHUTi content measure (see Appendix I). For study arm one, intervention fidelity will be measured using a questionnaire that is completed at week 8 (see Appendix J). Additionally, they will be asked as part of the SHUTi program, to verify that they have implemented the prior week's learning into their sleep routines, which will be available to the PI. Participants in both arms will respond to whether they shared information about what they did in their arm of the study because it is possible that participants might be from the same bereavement group (see Appendix L). Two members of any given bereavement group might be in different arms of this current study. In order to measure potential for crossover, it is necessary this question is asked. This will be administered at week 8.

Data collection. Data collection (Appendices B–D) will be conducted using REDCap 7.0, a web application used to help researchers to collect and manage data (UMassMEdIT, 2017). All of the survey measures will be administered at baseline and week 8. The participant will receive an email with a link to these surveys (listed in Table 1). The REDCap survey results will be captured in a central database. The data can be extracted and downloaded from REDCap to SPSS 24.0.

Measures

There are a number of study measures that will be used to capture data from the participants. The first is the Screening Tool that will assess inclusion and exclusion criteria (see Appendix E). Those who do not meet the inclusion and exclusion criteria will not be assigned to a study arm. Should they be part of the study, the measures assigned to all study arms includes: 1) Demographics, Appendix A; 2) World Health

Organization Quality of Life Abbreviated (WHO-QOL BREF), Appendix B; 3) Insomnia Severity Index (ISI), Appendix C; and 4) Depression Anxiety Stress Scale Short Form (DASS-21), Appendix D. The total estimated time required to complete the measures at baseline and end of week 8 is 40 minutes.

The WHO-QOL BREF is a 26-item measure that captures information about the domains of physical health, psychological health, social relationships, and environment. It is used to capture data about those domains of quality of life that are not otherwise measured in the DASS. Its Cronbach's alpha is 0.7 and the Tucker-Lewis Index is 0.919 (Cheung, Yeo, Chong, Khoo, & Wee, 2017). Each question within the survey is assigned to one of the domains. The responses each have five options assigned scores of 1–5. They are reverse coded, and the domains tallied.

The ISI is a seven-item measure that captures data regarding sleep behaviors of insomnia. The concurrent criterion validity has demonstrated a strong score of .76–.92, and the test-retest reliability of the measure have been found to be .62–.74 (Synder, Cai, DeMuro, Morrison & Ball, 2018). The survey questions each have five responses that are assigned points 0–4. The values of the response are added together and correspond with ranges signifying severity levels.

Finally, the DASS Short Form is a 21-item measure that looks at depressive, anxiety, and stress symptoms that the participant has within the past week. It will capture these mental health symptoms to see if there is improvement from pre- to post-CBT-I intervention. The reliability estimates for the DASS subscales are: anxiety (alpha = .897), depression (alpha = .947), and stress (alpha = .933), with the total score reliability being .966 (Crawford & Henry, 2003). The convergent validity for depression

was .78 and anxiety was .72. The response options are assigned points as follows: 0, did not apply to me at all; 1, applied to me to some degree, or some of the time; 2, applied to me a considerable degree, or a good part of the time; and 3, applied to me very much, or most of the time. Each question is assigned to one of the dimensions: depression, anxiety or stress. The scores are added and corresponded with a specific level in three dimensions including normal, mild, moderate, severe, and extremely severe.

Data management. Data will be secured on an encrypted, password protected server at UMMS. The database will be maintained by the PI for this study. It will be monitored frequently by the PI throughout the duration of the research study to ensure that there are no technical issues with gathering and capturing the data from participant's surveys at baseline and week 8. All other data will be captured by direct entry into REDcap by the study participants. Any technical issues with the management of the data from measures will be promptly addressed so that they can be resolved in a timely manner. The PI and the dissertation committee chair and biostatistician will be the only people permitted to access the data for this study. The database will be password protected.

Data analysis. The data will be reviewed and cleaned by the PI by reviewing the secured databases on the UMMS network and checked by the biostatistician. The planned data analysis (see Table 6) will occur using SPSS 24.0. All analyses run by the PI will be checked and verified by the biostatistician. Demographics will be analyzed using descriptive statistics to examine race, ethnicity, age, and gender of the two study arms. Reliability analyses for the multi-item scales (WHO-QOL BREF, ISI, and DASS-

21) will be conducted. Intervention fidelity data will be analyzed using descriptive descriptives that captures average time spent on each module in study arm one and two and reporting of the rates of implementation of SHUTi modules into real-life in study arm two.

Table 6.

Planned data analysis for each study aim

	Aim 1	**Aim 2**	**Aim 3**
Demographics Tool using Descriptive Statistics including Retention Rate		X	
WHO-QOL BREF using 2-Sample Paired t-test to compare the within participant changes; ANOVA for change over time between groups	X		
ISI using 2-Sample Paired t-test to compare the within participant changes; ANOVA for change over time between groups	X		
DASS-21 using Paired Comparisons t-Test (within groups); ANOVA (between groups)	X		
Intervention Fidelity Data in SHUTi and Appendix L using Descriptive Statistics including Average Module Time and Implementation Rate	X	X	X

Note. Data are assumed to be normally distributed.

If data are not normally distributed, nonparametric tests will be performed. For example, a Wilcoxan test will be performed for the WHO-QOL, ISI, and DASS-21 within groups and a Kruskal-Wallis test between groups.

Human Subjects Issues

The PI is a certified nurse practitioner who specializes in mental health. She has four years working with adults with serious mental illness. The participants will provide informed consent before any study procedures begin. The consent form will outline their rights including the right to withhold information as well as withdrawal from the study at any time. For both study arms, any questions that participants have about the learning activities or the study itself will be answered by the PI. The PI is a psychiatric mental health nurse practitioner (PMHNP) who has completed the advanced course in CBT-I, received supervision under a licensed psychiatrist, and has experience delivering CBT-I with a number of patients. The PI will seek consultation by a psychologist, who delivers CBT-I to a number of patients in his practice, throughout the duration of the study.

The participants will be adults who have recently experienced loss of a loved one. They are at risk for experiencing hopelessness and helplessness; thus, they might present as a safety risk to themselves or others at any point during the study. If the PI is concerned about a safety risk, the participant will be contacted immediately by phone by the PI for further assessment. The participant will also be assessed if depression scores on the DASS-21 at baseline and week 8 questionnaires reveal a score of 21 and greater which is indicative of severe and extremely severe depression. The following questions will be asked of the participant: 1) “Are you having thoughts to harm yourself or others?” and 2) “Do you have intent or a plan to harm yourself or others?” If the participant

responds yes to any of these questions, the local emergency services (EMS) will be contacted for a wellness check at the participant's home. EMS will determine if a higher level of care is appropriate at that time. A psychiatric contact hotline (available 24/7) will also be provided to participants at the beginning of the study should they feel that they need additional support during their time in the study. For this feasibility study, we will exclude patients with severe mental illness by asking them if they have received mental health treatment or taken psychiatric medications in the past (or currently) including antipsychotics, mood stabilizers, and substance use replacement therapies. The PI will follow up with the participant to determine eligibility, i.e., major mental health diagnoses like schizophrenia, bipolar disorder, personality disorders, and current substance use disorders will be excluded.

The privacy of the participants will be maintained throughout the study by assigning them with a unique ID number so that identifying information is not used on the REDcap database. In any dissemination of the findings, no identifying information will be shared except in the context of group demographics.

Potential Challenges

There are anticipated challenges with this study. One challenge is recruitment of eligible participants. There are a number of inclusion criteria that need to be met that might be particularly difficult for this age group. Access to technology and competence with technology for adults aged 55 and older might pose difficulties. Not everyone has access to the Internet at home or at a friend's/family member's home. Even if a computer with a camera and an Internet connection is in place, knowing how to use it appropriately on their own can be a barrier to their participation in the study. Another

challenge, which is also a limitation to the study, is that the inclusion criteria will limit those who are from socioeconomically diverse backgrounds. Computer literacy, English comprehension, and internet access make it so that those from higher SES groups may be more likely to participate in this study. These challenges have been considered for this feasibility study. It is this PI's plan to address these exclusion factors (and increase inclusion) in a future study with larger grant funding. Lastly, SHUTi is a program that has not yet been tested in an older adult population that is older than 55 years old (www.myshuti.com). As part of SHUTi, the participants will also not be required to complete sleep diaries. This is usually part of in-person CBT-I, which involves discussion of sleep diaries with the therapist or therapy group; however, this study will not involve data collection or analysis of sleep diaries. There is also the potential for the participants to share information about the interventions during the study (those in different arms), which has been accounted for in the informational sheet to participants as well as the survey question in Appendix L.

Conclusion

There is an unmet need in society to address insomnia in older adults during bereavement. It is costing hospitals, insurance companies, taxpayers, employees, and patients tremendous amounts of money to repair the damage resulting (fully or in part) from lack of restorative sleep (Kaplan, 2007). Disability and chronic diseases are not well-managed when sleep is poor. Furthermore, the number of falls and consequent injuries in patients rise when their sleep is compromised. Not only are balance and perceptual cues altered by insomnia, but the current intervention of prescribing psychopharmacological medications creates yet more problems, particularly in older

adults. These medications, like sedative hypnotics and benzodiazepines, are dangerous for this population because of their potential side effects, such as dizziness, weakness, and unsteady gait.

Unfortunately, many older adults experience sleep disturbances during bereavement. The treatment of sleep disturbances in this population can be problematic because of limited access to non-pharmacologic interventions. CBT-I has been proposed as a cost effective non-pharmacological treatment for sleep disturbances in bereavement. An online based CBT-I program has the potential to reach a large audience in isolated regions without access to trained sleep behaviorist clinicians. Frontline clinicians, such as nurses, are in an ideal position to make use of sleep research to help the bereaved population and improve patient outcomes.

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Executive Summary

The following changes were made in the execution of the study:

1. The compensation for participant involvement in this study increased from 100 dollars to 200 dollars to adequately compensate subjects for the minimum 18 hours required to participate in the intervention.
2. Access to the online CBT-I program, SHUTI, was given to the attention control group following the completion of the study. Six participants chose this option.
    a. The Pear Therapeutics, Inc. company provided 15 additional licenses to the non-experimental group at the close of the study.
3. The intervention fidelity questions were not initially included in the final REDCAP survey. They were missed in error; thus, the researcher emailed out the questions in a second REDCAP survey for them to complete a few days after the first-round of questions were sent via email.

PowerPoint


FEASIBILITY OF AN ONLINE
COGNITIVE BEHAVIORAL THERAPY
PROGRAM TO IMPROVE INSOMNIA, MOOD, AND
QUALITY OF LIFE IN BEREAVED ADULTS AGES 55 AND
OLDER.
Graduate School of Nursing, University of Massachusetts at Worcester
In partial fulfilment of the requirements for the degree of Doctor of Philosophy For
Cassandra Godzik, PMHNP-BC, MSN
Spring 2020

INTRODUCTION

- Loss of sleep has negative consequences on mood and physiological health (Carroll et al., 2015; Harvey et al., 2018).
- Insomnia includes: difficulty falling asleep, multiple nighttime awakenings, and early morning awakening (Simpson, Allegra, Ezeamama, Elkins, & Miles, 2014).
- Common after loss of loved one, with it documented to last up to five years following start of bereavement (Jonasson et al., 2009).

PURPOSE

The purpose of the current study was to examine the feasibility of an online CBT-I protocol in bereaved older adults (ages 55 and older) suffering from insomnia.

RESEARCH AIM 1

Describe the time to recruitment, rate of retention, acceptability and barriers associated with the use of an online CBT-I sleep program among bereaved adults ages 55 and older.

RESEARCH AIMS 2

Explore the preliminary efficacy of an **online** CBT-I sleep program including its feasibility **[nursing therapeutics]** on insomnia, cessation of sleep medication, neuropsychological changes including mood and anxiety, and quality of life **[personal conditions]** in bereaved adults **[change trigger]** ages 55 and older.

RESEARCH AIMS 3

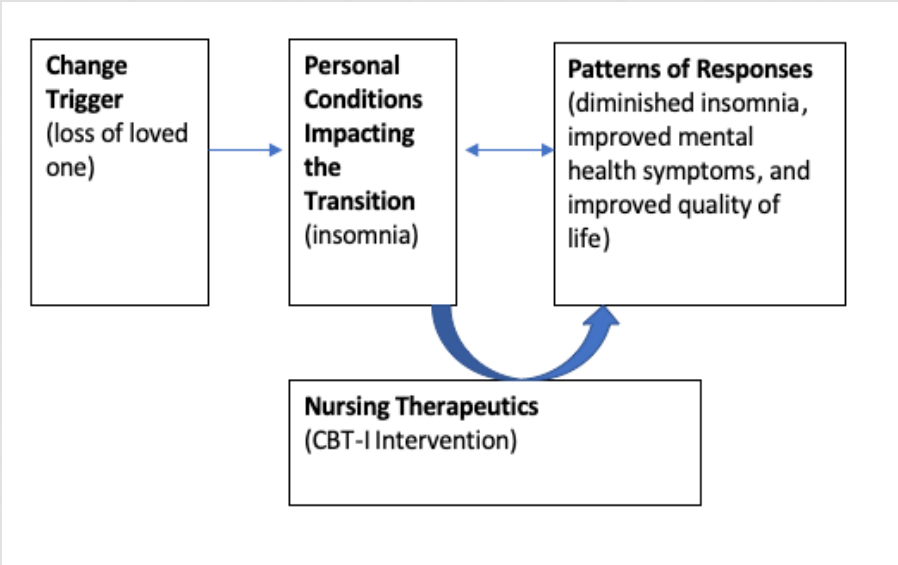
- Describe the treatment fidelity associated with an online CBT-I sleep program.

BACKGROUND

- Pharmacologic
  - 1/3 of older adults in the U.S. use medications to induce/prolong sleep (Maust, et al., 2019)
- Non-pharmacologic
  - Biofeedback, Mindfulness, and Tai Chi (Frame & Alexander, 2013; Hubbling, Reilley-Spong, Kreitzer, & Gross, 2014; and Irwin et al., 2015)
- Cognitive Behavioral Therapy for Insomnia (CBT-I)
  - Many studies for in-person CBT-I (Kanady et al., 2018; Trockel, Karlin, Taylor, Brown and Manber, 2015); however, little to examine online CBT-I in older adults

FRAMEWORK

The transitions theory proposed by Afaf Meleis (2010) was used to guide this study.



INCLUSION AND EXCLUSION CRITERIA

Inclusion	Exclusion
Aged 55 or older	Current experience of suicidal/homicidal ideation or intent to harm self or others
Speak and write in English – SHUTi is currently only available in English	Previous mental health treatment or current (past) taking of antipsychotic medications, mood stabilizers, or substance use replacement therapy medications. Diagnosis from a healthcare provider or therapist of serious mental illness, i.e. bipolar disorder, schizophrenia or schizoaffective disorder, current substance use disorder or alcohol use disorder, or personality disorders.
At least one loved one who passed away within the past 5 years	Inpatient psychiatric hospitalization within the 12 months
Currently experiencing symptoms of insomnia	
Wants to improve insomnia symptoms	
Access to a computer for at least 3 hours weekly for 8 weeks	
Ability (physical and mental) to use a computer mouse, keyboard, and audio	
Reliable internet access	
Working email address to receive study materials	

METHODS

This study was a randomized controlled trial design. Subjects were randomized 1:1 to:

- Arm 1 — attention control
- Arm 2 — online SHUTi CBT-I program

Study procedures took place in the participants' homes or friend/familys' homes for both study arms.

Recruitment involved online social media bereavement groups and hospice & palliative care email listservs.

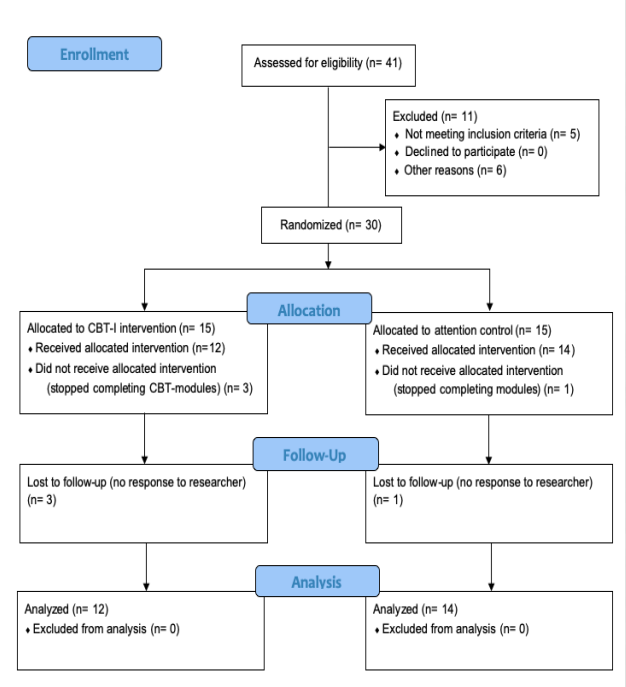
DESCRIPTION OF TWO ARMS

Arm 1 Modules (Attention Control)	Arm 2 Modules (CBT-I - Experimental)
Insomnia	Get Ready
Grief	Sleep Window
Positivity	Behaviors
Healthy Eating	Thoughts
Exercise	Education
Resilience	Looking Ahead

MEASURES AND ANALYSIS

	Aim 1	Aim 2	Aim 3
Demographics Tool using Descriptive Statistics including Retention Rate	X		
ISI - insomnia: 2-samples t-test for baseline measures; paired t-test for within participant change from baseline to week 8		X	
WHO-QOL BREF: 2-samples t-test for baseline measures; paired t-test for within participant change from baseline to week 8		X	
DASS-21: 2-samples t-test for baseline measures; paired t-test for within participant change from baseline to week 8		X	
Sleep Medications: 2-samples t-test for baseline measures; paired t-test for within participant change from baseline to week 8		X	
Intervention Fidelity Data: Descriptive Statistics that including Average Module Time and Implementation Rate			X

RESULTS


Enrollment
Assessed for eligibility (n= 41)
Excluded (n= 11)
Not meeting inclusion criteria (n= 5)
Declined to participate (n= 0)
Other reasons (n= 6)
Randomized (n= 30)
Allocation
Allocated to CBT-I intervention (n= 15)
Received allocated intervention (n=12)
Did not receive allocated intervention (stopped completing CBT-modules) (n= 3)
Allocated to attention control (n= 15)
Received allocated intervention (n= 14)
Did not receive allocated intervention (stopped completing modules) (n= 1)
Follow-Up
Lost to follow-up (no response to researcher) (n= 3)
Lost to follow-up (no response to researcher) (n= 1)
Analysis
Analyzed (n= 12)
Excluded from analysis (n= 0)
Analyzed (n= 14)
Excluded from analysis (n= 0)

RESULTS - AIM 1

- Results demonstrated feasibility:
  - 30 eligible participants (5 weeks), high retention rate (87%), retention highest for control group (93%) compared to CBT-I (80%).
- The social media bereavement group yielded the greatest number of participants.
- There were several barriers:
  - CBT-I - (1) tracking sleep diaries, (2) technological difficulty, and (3) guidelines too rigid.
  - Control - (1) repetitive material, (2) irrelevant content, and (3) audio challenges with videos.

RESULTS - AIM 2

Within-Person Means[b]

Item	CBT-I Mean +/- SD	*t*	df	Level of Signifi-cance	Control Mean +/- SD	*t*	df	Level of Significance
ISI: insomnia	5.83 +/- 4.28	4.72	11	0.00	3.71 +/- 5.61	2.50	13	0.03
DASS-21								
Depression	0.92 +/- 0.67	4.80	11	0.00	0.50 +/- 2.71	0.70	13	0.50
Anxiety	0.42 +/- 2.84	0.51	11	0.62	0.60 +/- 1.50	1.42	13	0.20
WHO QOL-BREF								
Physical	-10.42 +/- 9.70	-3.73	11	0.00	-11.00 +/- 12.20	-3.40	13	0.00
Psychological	-4.20 +/- 5.90	-2.50	11	0.03	-4.46 +/- 10.90	-1.53	13	0.20
Social	-13.20 +/- 27.90	-1.64	11	0.13	-6.00 +/- 11.50	-1.93	13	0.08
Environmental	-2.34 +/- 9.24	-0.88	11	0.40	2.90 +/- 7.40	1.46	13	0.20
Sleep Medications	0.11 +/- 0.60	0.56	8	0.60	0.07 +/- 0.61	0.43	13	0.70

[b] Paired Sample *t*-test.

RESULTS - AIM 3

- 100% of the subjects completing the week 8 survey reported completing all assigned learning modules.
- Attrition:
  - 3 participants in CBT-I group: 1, 4, & 5.
  - 1 participant in control group; indeterminate which week they dropped the study.
- Shared content with others enrolled/not enrolled in the study:
  - 45.5% of the CBT-I group
  - 54.5% of the control group

DISCUSSION

- This study showed that an online CBT-I program is feasible.
  - Interest in learning coping skills to manage insomnia in older adults; consistent with the literature (Cahn et al., 2005; Culver et al., 2019; and Gebara et al., 2019).
  - Convenience sampling like that seen in other studies (Fernandez-Mendoza et al., 2012; Lin et al., 2016; and Maloney et al., 2019).
  - Quick recruitment experienced.
- High retention rate in participants completing the study.
  - Other studies have found similar retention rates: 90.9% (Gebara et al., 2019), 83-96% (Sadler et al., 2018), and 85% (Javaheri et al., 2019).

DISCUSSION CONTINUED

- Online CBT-I program was effective in improving insomnia, depression, and physical and psychological functioning for older adults in bereavement. Control group showed similar improvements in insomnia and physical functioning only.
  - Online programs that educate participants about sleep and ways to improve it can lead to positive outcomes in terms of reduction in insomnia and quality of life.

LIMITATIONS

- High contamination within the study.
  - Recruitment from bereavement support groups, which increased the likelihood that they would share information with each other.
- Small, heterogenous sample size that is educated and Caucasian.
- Compensation for the participants was a significant challenge to the researcher.
  - 1/3 participants contacted researcher about gift card: (1) unable to access the monies, (2) confusion about how to use the card in brick-and-mortar stores, and (3) dislike of wanting to purchase items online.
  - Monetary incentives has been shown to improve study completion rates (Singer et al., 2017).

CONCLUSIONS

Unmet need in society for addressing insomnia (Mahowald, 2007) especially in the bereaved.

Limited access to non-pharmacologic interventions – online CBT-I can be part of the solution.

Older adults' use of online CBT-I is feasible and accepted.

CBT-I improved symptoms of insomnia, depression, and quality of life.

Acknowledgements

We want to acknowledge Pear Therapeutics(c) for providing the licenses for use of the SHUTi program.

We also want to acknowledge Nurses Educational Funds, Inc. for their financial support through way of grant.

Dissertation Committee

Chair: Carol Bova, PhD, ANP

Sybil Crawford, PhD

Elizabeth T. Ryan, PhD

Others

- Diane Quinn
- Jen, Jenn, Jo, Meg, Penni, Rosemarie, Deb, and Patty (my PhD cohort)
- My Family and Friends for their support throughout this journey!

Dissemination Plan

The dissertation study was submitted on April 10, 2020 to the *Geriatric Nursing* journal.

Appendices

Appendix A. Demographics

1. What is your current age in years?
2. What is your sex?
    a. Female
    b. Male
    c. other
    d. Prefer not to say
    e. Are you of Hispanic, Latino, or Spanish origin?
    f. Yes
    g. No
3. How would you describe yourself (select all that apply)?
        a. American Indian or Alaska Native
        b. Asian
        c. Black of African American
        d. Native Hawaiian or Other Pacific Islanders
        e. White
4. What is your marital status?
        a. Single (never married)
        b. Married, or in a domestic partnership
        c. Widowed
        d. Divorced
        e. Separated
5. What is the highest degree or level of school you have completed?
        a. Less than a high school diploma
        b. High school degree or equivalent
        c. Some college, no degree
        d. Associate degree
        e. Bachelor's degree
        f. Master's degree
        g. Professional degree (e.g., MD, DDS, CVM)
        h. Doctorate (e.g., PhD, EdD)
6. What is your current employment status?
        a. Employed
        b. Unemployed
        c. Student
        d. Retired
        e. Homemaker
        f. Self-employed
        g. Unable to work
7. Which loss(es) did you experience within the past 5 years? *(select all that apply)*
        a. Spouse/partner
        b. Child
        c. Grandchild

d. Sibling
e. Parent
f. Close friend
g. Other [please specify]

8. What caused your loved one's death? List all that apply **[free text].**

9. Approximately how many months has it been since the death of your loved one? _____ **months**

10. Do you have a history of insomnia that occurred prior to the death of your loved one? [**Circle Yes/No]**

11. Are you taking any of the following medications at bedtime and/or for inducing sleep**? [select all that apply]**

Alprazolam (Xanax)
Ambien (zolpidem)
Ativan (lorazepam)
Belsomra (suvorexant)
Benadryl (diphenhydramine)
Dalmane (flurazepam)
Deesyrel (trazodone)
Halcion (triazolam)
Hydroxyzine (Vistaril)
Klonopin (clonazepam)
Lunesta (eszopiclone)
Melatonin
Mirtazepine (Remeron)
Prosom (estazolam)
Restoril (temazepam)
Seroquel (quetiapine)
Silenor (doxepin)
Sonata (zalplon)
Valium (diazepam)
Other – please specify **[free text]**

12. Please list all the names of your medications that you are currently prescribed by a healthcare provider **[free text].**
13. Are you participating in any other sleep treatments at this time? **[Circle Yes/No]**
14. If yes to Question 14, what sleep treatments are you participating in? List all that apply. **[free text].**

Appendix B: World Health Organization Quality of Life Abbreviated **(**WHOQOL-BREF)

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Appendix C. Insomnia Severity Index (ISI)

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Appendix D. Depression Anxiety Stress Scale **Short Form 21 (**DASS)

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Appendix E. Screening Phone Call

Thank you for your interest in this study. I have a few questions to ask you in order to determine your eligibility. To begin:

Where did you hear about this study?

Thank you for sharing this information with me. Please respond yes or no to the following questions:

1. Are you 55 years of age or older?
2. Are you able to speak, write, and read in English?
3. Do you have a loved one who passed away within the past 5 years?
4. Are you currently experiencing symptoms of insomnia?
5. Do you want to improve your symptoms of insomnia?
6. Do you have access to a computer in a quiet location with internet connect for at least 3 hours each week?
7. Are you able to use a keyboard, computer mouse, and listen to computer audio?
8. Do you have a personal working email address?

If no to any of these questions, the potential participant is not eligible.

9. Are you currently experiencing suicidal or homicidal thoughts or have a plan to harm yourself or others?
10. Have you taken, in the past or currently, psychiatric medications that include antipsychotics, mood stabilizers or substance use replacement therapies?
11. Have you been hospitalized to treat a mental health problem within the past 12 months?
12. Have you ever been diagnosed with bipolar disorder, schizophrenia or schizoaffective disorder, or personality disorder?
13. Are you currently dealing with a substance use disorder or alcohol use disorder?

If yes to any of these questions, the potential participant is not eligible.

Based on your responses, you are eligible [not eligible] to participate in this study.

I am now going to discuss some information about the study in order to obtain your informed consent to participate in this research study. I will send you this information by email after we are done. **[I will have a discussion with the potential study participant including reading the consent fact**

sheet that was approved by the IRB and answering any questions that the participant has].

Do you have any other questions about this study? **Yes/No**
Are you interested in continuing with the study? **Yes/No**
Do I have your verbal informed consent to participate in this study? **Yes/No**

Thank you.

What is your full name? **[OBTAIN NAME]**
What is your personal email address that I can send the Welcome Materials to? **[OBTAIN EMAIL ADDRESS]**

I thank you for your time. You will receive an email within the next 72 hours to get started. Please don't hesitate to reach out with questions. I am available during the day, 7 days weekly from 8am to 9pm eastern standard time. I can help troubleshoot any issues you might run into when you are completing the activities in this study. You will receive my contact information in this introduction email.

Appendix F. Welcome Emails

Study Arm One

Welcome to Week 1 of this research study. You will receive weekly email reminders directly to your email outlining what is expected for you to complete that week.

1) To begin, please complete surveys within REDcap. Click **[here]** to access.

2) There are six learning modules on **healthy living** that you will be accessing at the drop-box link below. You will complete one module each week for the next six weeks. Click **[here]** to access the learning module material for Week 1 entitled **[Name of Drop-Box Activity here].**

Remember, each week's activity is expected to take approximately three hours to complete.

If you have questions about the learning activities this week or experience technical difficulties with any of the materials, please contact Primary Investigator, Cassandra Godzik's email address at cassandra.godzik@umassmed.edu. You can also reach me by calling 802-558-3439. I am available during the day, 7 days weekly from 8am to 9pm eastern standard time. I can help troubleshoot any issues you might run into when you are completing the activities in this study. You will receive an email and/or phone response within 24 hours of your inquiry.

Thank you,
Cassandra Godzik, MSN, PMHNP-BC
University of Massachusetts at Worcester Graduate School of Nursing

Study Arm Two
Welcome to Week 1 of this research study. You will receive weekly email reminders directly to your email outlining what is expected for you to complete that week.

1) To begin, please complete surveys within REDcap. Click **[here]** to access.

2) Lastly, there are six learning modules on **improving your sleep** that you will be accessing weekly using the online SHUTi program. You will now complete the module entitled "Get Ready" during Week 1. To access your account, please see website URL and login information here: **[INCLUDE LOGIN INFORMATION TO SHUTi]**

Remember, each week's activity is expected to take approximately three hours to complete.

If you have questions about the learning activities this week or experience technical difficulties with any of the materials, please contact Primary Investigator, Cassandra Godzik's email address at cassandra.godzik@umassmed.edu. You can also reach me by calling 802-558-3439. I am available during the day, 7 days weekly from 8am to 9pm eastern standard time. I can help troubleshoot any issues you might run into when you are completing the activities in this study. You will receive an email and/or phone response within 24 hours of your inquiry.

Thank you,
Cassandra Godzik, MSN, PMHNP-BC
University of Massachusetts at Worcester Graduate School of Nursing

Appendix G. Weekly Reminder Emails

This email template will be used for both study arms **[arms one and two]** and have the correct week's information listed within it. It will be sent after the "Welcome to the Study" email for week 1, and then subsequently weekly after that.

Weeks 2-6
Thank you for you continued participation in this research study. You have completed the [Module Name]. Today, you will begin [Module Name] and have seven (7) days to complete it. Remember, the estimated time to complete each module is three (3) hours.

If you have questions about the learning activities this week or experience technical difficulties with any of the materials, please contact Primary Investigator, Cassandra Godzik's email address at cassandra.godzik@umassmed.edu. You can also reach me by calling 802-558-3439. I am available during the day, 7 days weekly from 8am to 9pm eastern standard time. I can help troubleshoot any issues you might run into when you are completing the activities in this study. You will receive an email and/or phone response within 24 hours of your inquiry.

Thank you,
Cassandra Godzik, MSN, PMHNP-BC
University of Massachusetts at Worcester Graduate School of Nursing

Appendix H. Week 7 Email

Both Study Arms
Welcome to the end of Week 7 of this research study. You have completed all of the learning modules for this program - congratulations! You will receive the final survey in 1 week. It is important that you complete these final surveys so we can evaluate how helpful this program has been for you personally. You will receive a $100 gift card upon completion of the final surveys.

If you have questions about the learning activities this week or experience technical difficulties with any of the materials, please contact Primary Investigator, Cassandra Godzik's email address at cassandra.godzik@umassmed.edu. You can also reach me by calling 802-558-3439. I am available during the day, 7 days weekly from 8am to 9pm eastern standard time. I can help troubleshoot any issues you might run into when you are completing the activities in this study. You will receive an email and/or phone response within 24 hours of your inquiry.

Thank you for your time and participation in this study.

Sincerely,
Cassandra Godzik, MSN, PMHNP-BC
University of Massachusetts at Worcester Graduate School of Nursing

Appendix I. Week 8 Email

Both Study Arms
Welcome to Week 8 of this research study. Once you complete the surveys in the link below, you will receive an email with the steps about how to claim your $200 gift certificate.

1) To begin, please complete surveys within REDcap. Click **[here]** to access.

If you have questions about REDcap or experience technical difficulties with any of the questions, please contact Primary Investigator, Cassandra Godzik's email address at cassandra.godzik@umassmed.edu. You can also reach me by calling 802-558-3439. I am available during the day, 7 days weekly from 8am to 9pm eastern standard time. I can help troubleshoot any issues you might run into when you are completing the activities in this study. You will receive an email and/or phone response within 24 hours of your inquiry.

Thank you,
Cassandra Godzik, MSN, PMHNP-BC
University of Massachusetts at Worcester Graduate School of Nursing

Appendix J. Intervention Fidelity Checklist

Procedure	**Received On**
Baseline - Participant receives informed consent document to their personal email.	
Week 1 email sent - • Initial login information for drop-box or SHUTi are sent via email • Appendices A-D • Review the log in the programs to determine if participants logged into the system to complete the assigned module. Send reminder (see Appendix N) if they have not.	
Week 2 email sent - • Appendix G • Review the log in the programs to determine if participants logged into the system to complete the assigned module. Send reminder (see Appendix N) if they have not.	
Week 3 email sent - • Appendix G • Review the log in the programs to determine if participants logged into the system to complete the assigned module. Send reminder (see Appendix N) if they have not.	

Week 4 email sent - • Appendix G • Review the log in the programs to determine if participants logged into the system to complete the assigned module. Send reminder (see Appendix N) if they have not.	
Week 5 email sent - • Appendix G • Review the log in the programs to determine if participants logged into the system to complete the assigned module. Send reminder (see Appendix N) if they have not.	
Week 6 email sent - • Appendix G • Review the log in the programs to determine if participants logged into the system to complete the assigned module. Send reminder (see Appendix N) if they have not.	
Week 7 email sent - • Appendix H • Review the log in the programs to determine if participants logged into the system to complete the assigned module. Send reminder (see Appendix N) if they have not.	
Week 8 email re-surveys sent - • Appendices B-D, M • Appendix J for Study Arm 1	
Completion Email Sent to Participants Thanking Them with Gift Card Information Once They Have Completed Their Surveys - • Appendix K and P	

Appendix K. Intervention Receipt Measure

1. Did you complete all of the learning activities in this program? **Yes or No**
    a. Check-off the activities that you DID complete:
        i. Module 1
        ii. Module 2
        iii. Module 3

iv. Module 4
v. Module 5
vi. Module 6
vii. Pre-Study Questionnaires
viii. Post-Study Questionnaires

2. How much time did you spend on the computer to complete the learning modules?
    i. Less than 3 hours per week
    ii. About 3 hours per week
    iii. More than 3 hours per week

Appendix L. Thank You Letter

Study Arm One

Thank you so much for being part of this research study. I want to inform you that you have received the non-sleep program during this study. If you would like to access the modules from the SHUTi company, please let me know by emailing me back. I will then be able to provide you with complete access, free of charge, to 8-weeks of the CBT-I SHUTi program

Please find your gift certificate for completing the study here **[insert link to gift certificate].**

If you have questions or experience technical difficulties with this process to obtain compensation or have general questions or comments about your experience in this study, please contact Primary Investigator, Cassandra Godzik's email address at cassandra.godzik@umassmed.edu. You will receive an email response with further information within 24 hours.

Once again, thank you for your time and participation in this study.

Sincerely,
Cassandra Godzik, MSN, PMHNP-BC
University of Massachusetts at Worcester Graduate School of Nursing

Study Arm Two

Thank you so much for being part of this research study.

Please find your gift certificate for completing the study here **[insert link to gift certificate].**

If you have questions or experience technical difficulties with this process to obtain compensation or have general questions or comments about your experience in this study, please contact Primary Investigator, Cassandra

Godzik's email address at cassandra.godzik@umassmed.edu. You will receive an email response with further information within 24 hours.

Once again, thank you for your time and participation in this study.

Sincerely,
Cassandra Godzik, MSN, PMHNP-BC
University of Massachusetts at Worcester Graduate School of Nursing

Appendix M. Final Survey Questions at End of Week 8 (for both groups)

1. Did you discuss with anyone the type of information you learned in the modules, specifically to those who were also participating in the same study? **[Circle Yes/No].**
2. During this study, did you **begin** taking any of the following medications at bedtime and/or for inducing sleep? **[select all that apply]**
   - Alprazolam (Xanax)
   - Ambien (zolpidem)
   - Ativan (lorazepam)
   - Belsomra (suvorexant)
   - Benadryl (diphenhydramine)
   - Dalmane (flurazepam)
   - Deesyrel (trazodone)
   - Halcion (triazolam)
   - Hydroxyzine (Vistaril)
   - Klonopin (clonazepam)
   - Lunesta (eszopiclone)
   - Melatonin
   - Mirtazepine (Remeron)
   - Prosom (estazolam)
   - Restoril (temazepam)
   - Seroquel (quetiapine)
   - Silenor (doxepin)
   - Sonata (zalplon)
   - Valium (diazepam)
   - Other – please specify **[free text]**
3. During this study, did you **begin** taking any other medications prescribed by a healthcare provider? (Yes/No)
4. If yes – please specify: **[free text].**
5. During this study, did you participate in any other sleep treatments outside of this study? **[Circle Yes/No].**
6. If yes to Question 16, what sleep treatments are you participating in? List all that apply. **[free text].**
7. What challenges did you experience when completing the study? **[free text]**
8. What recommendations do you have to improve the program you participated in? **[free text]**

Appendix N. Reminder for Non-opening of Modules (for both groups)

Participants will receive this email if, upon review, the PI does not see that the participant has logged into the SHUTi or the health education programs.

> Hello, you are receiving this email because it appears that you have not yet opened or completed the **[insert module name]** for **[insert week number].** I would appreciate it if you could complete this as soon as possible in order to progress to the next learning module.
>
> If you are no longer interested in participating in this study, please respond to this email with the following information:
> - For what reason(s) are you stopping this study? **[free text]**
> - Did you discuss with anyone the type of information you learned in the modules, specifically to those who were also participating in the same study? **Circle: Yes or No**
> - What challenges did you experience when completing the study? **[free text]**
> - What recommendations do you have to improve the program you participated in? **[free text]**
>
> Once again, thank you for your time and participation in this study.
>
> Sincerely,
> Cassandra Godzik, MSN, PMHNP-BC
> University of Massachusetts at Worcester Graduate School of Nursing

Appendix O. Recorded Message at the Phone Number Listed on Informational Materials

> Hello, you have reached Cassandra Godzik. If you are calling about the sleep study, please leave your name and number, and I will get back to you as soon as possible. Thank you.

Appendix P. Additional Resources for Participants to Continue Addressing Their Insomnia

> Hello,
>
> **This is an email I referred to regarding additional resources for improving sleep.**
>
> Thank you for participating in this study. Below are some additional resources to help you if you want to continue to work on your insomnia. You may want to

consult your primary health care provider about identifying a cognitive behavioral therapy specialist in your area.

You can search for CBT-I trained therapists in your area by going to the following website:

CLICK HERE —> https://cbti.directory

If you enjoy technology, phone apps and computer apps might be a good choice for you (of course, after consulting with your HCP first. Here are some great options:

CLICK HERE —-> https://mobile.va.gov/app/cbt-i-coach

CLICK HERE —-> https://www.sleepio.com/cbt-for-insomnia/

You might also consider subscribing to sleep websites for the latest on sleep health and research by going to:

CLICK HERE —> https://www.sleepfoundation.org/articles/choosing-cbt-insomnia-specialist

The resources described above might require payment or proof of health care insurance, so it is recommended that you consult your primary care provider and read the terms and conditions carefully.

Thank you for your time and participation in this study.

Sincerely,
Cassandra Godzik, MSN, PMHNP-BC
University of Massachusetts at Worcester Graduate School of Nursing