# Implementing Evidence to Improve Chronic Insomnia Treatment for Older Adults in Primary Care: A Quality Improvement Project

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May 5, 2019

Acknowledgments

All praises to the Almighty God for providing me with the strength and determination to complete this project. The work would not have been possible without the help of the Almighty God. He has been the light of this project.

I am grateful to all the professors at Northern Arizona University who have been supportive of this project and who worked actively to provide me with the guidance to complete this health care improvement project. I would especially like to thank Dr. Katherine Watkins, the program coordinator for your countless encouragements and for believing in me. Dr. Laura Marie Karnitschnig for your endless patience and calm mentorship throughout this process. I thank you for answering all my text messages and phone calls during my most difficult times.

To my clinic mentors Dr. Alvarado, sleep specialist, and Susan Peppers, I thank you for being part of my academic journey.

Nobody has been more important to me in the pursuit of this project than my family and friends. I want to thank my mother, Haja Titi Kamara and Haja Neneh Isatou Jallow for the endless prayers and support. To my children, Mohamed, Mamie, and Baboucarr for your understandings and supportive attitudes. I dedicate this degree to you three angels. To Carla Lockhart, you have been a true friend throughout this project. We shared tears, laughter, and more. Dr. Greta Brown, you have been the best big sister that one could ask for. I thank you for your supporting me and for being a role model. Words can express my love for you. I thank you. Dr. Cherno Bah, you have been a great mentor, thank you for inspiring me. Mansata Bayang, thank you for the cooking and your daily encouragement, especially during the most challenging times. Uncle Brian, for your continuous support and encouragement.

Abstract

*Background:* Chronic insomnia (CI) affects over 50% of American adults 65 years and older. The most currently used treatment approach for this problem is inconsistent with the most up-to-date evidence-based clinical guidelines and research. Despite the apparent benefits of cognitive-behavioral therapy for insomnia (CBTI) as an effective tool for the treatment of CI in adults, pharmacologic treatment remains the standard care for CI in the primary care setting. This health care improvement project aimed to improve the application of evidence for CI treatment by increasing the clinic providers' awareness of CBTI as first-line treatment for CI. *Methods*: The Plan Do Study Act method of quality improvement was used for this project. A retrospective chart review of patient medical records was conducted to evaluate trends in provider treatment approaches (CBTI and pharmacologic) at baseline and over a six-week period after the intervention. Pre-and post-intervention surveys measured provider knowledge and opinions about CBTI. *Intervention*: A one-hour interactive educational intervention session was provided to a convenience sample of eight primary care providers focusing on CBTI as first-line treatment of CI in adults. *Results*: Six-weeks following the educational session intervention, referral rate increased from 15% at baseline to 26% six-weeks post-intervention while pharmacologic prescription rates remained consistent at about 70% between baseline and post-intervention. While these average figures suggested that the intervention was successful with the increasing use of CBTI among the providers, examination of trends in prescribing over the pre- and post-intervention demonstrated that changes in prescribing patterns peaked three weeks post-intervention, but then began to return to original rates. By week six, any advances made in lowering pharmacological prescribing were no longer evident. All eight providers report that educational intervention improved their knowledge of the clinical guidelines. *Conclusions*: An

educational session on CBTI as a first-line of treatment for CI to providers in a primary care setting appeared to have an impact on increasing CBTI rate, but did not decrease the rate of pharmacological prescription rates. However, a trend analysis suggests that trends in change peaked three-weeks post-intervention and began to return to baseline values. These findings are consistent with literature about resistance to practice and organization change, and highlight the importance of "refreezing" as part of the theoretical framework. While these findings are encouraging, additional options need to be considered for assuring a sustainable change in this particular clinical environment.

*Keywords*: Chronic insomnia, educational intervention, cognitive behavioral therapy, older adults, clinical guidelines, pharmacological, guideline implementation.

Implementing Evidence to Improve Chronic Insomnia Treatment for Older Adults in Primary Care: A Quality Improvement Project

Chronic insomnia (CI) is a significant health problem among adults 65 years and older, affecting millions globally. Epidemiological data has found that over 50% of non-institutionalized persons aged 65 years and older report experiencing some form of chronic disruption of sleep (Wickwire, Shaya, & Scharf, 2015). The American Academy of Sleep Medicine (AASM) (2017) defines CI as a subjective perception of a person's inability to fall asleep, stay asleep, or feel satisfied with the quality and duration of sleep. Multiple factors contribute to the development of CI in older adults. If the condition remains untreated, the health and well-being of older adults may be compromised. Compared to people without sleep difficulties, people with CI suffer from numerous insomnia-related neurologic, heart, and metabolic health disorders (Centers for Disease Control and Prevention, 2015; Manjavong, Limpawattana, Mairiang, & Anutrakulchai, 2016). Furthermore, lack of sleep reduces the quality of life of older adults (Komada et al., 2012) while increasing the risk of depression, anxiety, and other psychiatric disorders (Spira et al., 2014). Health economists estimate that the direct and indirect health care spending for CI surpassed $100 billion in the United States (US) alone (Wickwire et al., 2015).

## Problem Description

The issue of using evidence-based research and clinical guidelines in primary care are lacking although most patients with CI initially consult their primary health care providers for treatment. Primary care providers favor the use of pharmacologic therapy to treat CI, prescribing medications such as the benzodiazepines, sedative-hypnotics, antidepressants, and over-the-counter (OTC) sleep aids. These medications have been found to have several adverse effects

when used long-term in older adult populations (Matheson & Hainer, 2017). The side effects and toxicity of benzodiazepines and the so-called “Z-drugs” can result in increased morbidity and mortality for some people, especially older adults (Morin et al., 2016). Insomniacs consider pharmacologic therapy as a “quick fix” that best fits their demanding schedules although concerns about dependency and other potential side effects of pharmacologic treatment are often expressed (Epstein, Babcock-Parziale, Haynes, & Herbs, 2012). Therefore, the use of pharmacologic therapy to treat CI in older adults may be detrimental.

With millions of people suffering from CI globally, primary care providers must rely on and integrate the most up-to-date evidence to inform their decision-making when managing CI. The American Geriatrics Society (2015) has been a steward of safe practice for older adults and recommends against the use of sedative-hypnotics or benzodiazepines in older adults. Likewise, the US Foods and Drug Administration (FDA) has not yet approved the efficacy and safety of some of the drugs used to treat CI. Thus, the clinical question addressed in this project was: In primary care providers treating older adults ages 65-100 years with CI (P), does an interactive educational intervention to enhance provider awareness about the clinical guidelines to manage CI (I) compare to no intervention (C) improve application of evidence-based practice by increasing the number of referrals to cognitive-behavioral therapy for insomnia (CBTI) and decreasing the amount of medication in the older adult population (O)?

## Available Knowledge

An exhaustive literature search was conducted to identify current evidence-based treatment strategies recommended for older adults with CI. Databases used to conduct this search include the Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, the Cochrane library, and Google Scholar. These electronic databases were utilized in this literature

search because of their significant distribution, acceptance as recognized sources of reliable information, and are frequently cited as sources for nursing literature (LoBiondo & Haber 2013; Melnyk & Fineout-Overholt, 2015).

**Electronic Searches**

The literature search in CINAHL included keywords *insomnia* AND *intervention*. This search identified 1,054 articles which were then filtered for articles published within the previous five years, related to individuals 65 years of age and older and written in the English language only, yielding 135 articles. An additional filter limiting search results to "peer-reviewed" and "research articles" resulted in 93 articles. After filtering the remaining 93 articles for "outpatient setting," "evidence-based practice," and special interest ("geriatric"), the search became too limited as no results were found so, these search criteria were removed. The titles and abstracts were screened for consideration. Excluded articles focused on comorbidities such as cancer, Parkinson's disease, or insomnia in adults younger than 60 years old. Ten articles from CINAHL search were retrieved in full text for further reading and consideration.

In PubMed, the search term was *insomnia*, filtered for articles published between 2012 to 2018, age 65 and older, and written in the English language only. This search identified 279 articles. Additional limiters included *clinical trial, meta-analysis, randomized-controlled trial (RCT)*, and *systematic review* did not change the generated 279 articles. The titles and abstracts were examined for relevance. Eight of the articles retrieved from PubMed were duplicates of those found in CINAHL. Therefore, those articles were not printed for consideration.

Additional searches were completed through the Cochrane Library and Google Scholar. In Cochrane Library, the searched term was *insomnia* AND *older adults*, filtered for review, which yielded six articles. Two articles were relevant to the treatment of CI in older adults,

however, one was published beyond the timeframe and therefore was excluded. Articles were also considered using Google Scholar. A reference list of previously published articles and studies were hand-searched. Titles of articles selected based on the quality of their content were searched on Google Scholar, which yielded five articles. These searches in the Cochrane Library and Google Scholar yielded two relevant articles for the treatment of CI in older adults.

**Included Studies**

Titles and abstracts of all articles were examined to determine whether the articles applied to the clinical question. Through a critical appraisal of the evidence using the Johns Hopkins Research Evidence Appraisal Tool, some studies were excluded from consideration. These included articles were deemed as poor in quality based on the methodology, bias, or a format that is not relevant to primary care settings.

Of the ten studies retained, six were randomized controlled trials (RCT), one was a quasi-experimental study, and three were systematic reviews of the commonly accepted interventions that improve sleep in older adults with CI. These ten studies provided current best practice strategies intended to improve sleep in older adults are listed on an evidence-based table (see Appendix A for evidence table). In addition to these articles, two clinical guidelines in the management of CI in adults were also reviewed.

This literature search provided ample evidence of strategies that may improve sleep in older adults. Five studies addressed the use of cognitive-behavioral therapy (CBTI) to treat the psychological dysfunctional attitudes and behaviors associated with insomnia (Morin et al., 2016). One study used an online CBTI delivered via an automated media-rich web application (Espie et al., 2012) and two used a self-help CBTI modality (Morgan, Gregory, Tomeny, David, & Gascoigne, 2012; Tamura & Tanaka, 2017). One study evaluated CBTI use in adults with

occult sleep-disordered breathing (Fung et al., 2016) and the other study tested the efficacy of CBTI on 519 Veterans (Alessi et al., 2016). The remaining studies include assessments of alternative therapies including music (Jespersen, Koenig, Jennum, & Vuust, 2015; Wang, Chair, Wong, & Li, 2016), herbal medicine (Leach & Page, 2016), yoga (Afonso et al., 2012), and melatonin (Auld, Maschauer, Morrison, Skene, & Riha, 2016).

Similarly, two clinical guidelines from the ACP and AASM recommend that adults with CI receive CBTI as the initial treatment approach (Qaseem, Kansagara, Forciea, Cooke, & Denberg, 2016; Sateia, Buysse, Krystal, Neubauer, & Heald, 2017). These guidelines outline recommendations on the most effective, efficient, and safe interventions to treat adults who meet the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) definition of CI (Qaseem et al., 2016; Sateia et al., 2017).

In their comprehensive systematic review of 169 RCTs and 12 observational studies of psychological, pharmacologic, and complementary alternative medicine therapy options for adults 18 years and older, Qaseem et al. (2016) provided moderate quality evidence that concluded that CBTI was the preferred first-line treatment for adults with CI because of its relatively long-term benefits and fewer side effects. The second recommendation states that when CBTI alone is unsuccessful, clinicians should discuss the benefits, harms, and costs involved with adding a short-term pharmacologic treatment (weak recommendation, low-quality evidence) (Qaseem et al., 2016).

Sateia et al. (2017) revised the 2008 AASM clinical guideline for the evaluation and management of CI in adults. The report used findings from existing evidenced-based insomnia practice parameters as well as a consensus recommendation from broadly constituted experts in the field of sleep (Sateia et al., 2017). The experts concluded that primary care providers should

consider psychological and behavioral therapies as a first-line treatment for insomnia in all adults (Sateia et al., 2017).

**Synthesis**

The use of CBTI to treat CI in adults provides a longer-lasting effect than the use of pharmacologic therapy to treat CI in adults, but there are several barriers to the use of CBTI in the primary care setting. This comprehensive search of the literature revealed that five current relevant studies and two clinical guidelines agree that use of CBTI is safe, effective, and yields long-term benefits for the treatment of CI in older adults (Alessi et al., 2016; Espie et al., 2012; Fung et al., 2016; Morgan et al., 2012; Tamura & Tanaka, 2017; Qaseem et al., 2016; Sateia et al., 2017). CBTI delivered in a range of formats (booklet, CD/DVD, internet, group, and individual sessions), are highly effective in improving subjective and objective reports of sleep disturbances. Although CBTI has been found to significantly impact outcomes as measured by the Pittsburg Sleep Quality Index and Insomnia Severity Index, the utilization and referral to CBTI continue to be underutilized by primary care providers. The use of CBTI requires highly specialized training and is conducted in one-hour sessions for 12-20 weeks (Blane, Williams, Morrison, Wilson, & Mercer, 2013). Barriers to the use of CBTI in primary health care settings therefore include time constraints, lack of education and training, and clinician beliefs about effectiveness of CBTI (Blane et al., 2013; Koffel, Bramoweth, & Ulmer, 2017; Mignogna et al., 2018; Possemato, 2011; Passemato, Johnson, Wray, Webster, & Stecker, 2018).

In addition, adherence to clinical guidelines also results in discrepancies in the treatment of CI in primary care settings. Scholars have stated that despite the apparent benefit of clinical guidelines to ease decision-making in clinical practice, guidelines are often not applied, resulting in suboptimal care (Fischer Lange, Klose, Greiner, & Kraemer, 2016). Several reasons for

provider non-adherence to clinical guidelines were grouped into three internal factors including (1) Lack of awareness and familiarity with the guidelines, (2) Disagreement with the recommendations, and (3) Self-efficacy (Fischer et al., 2016). Furthermore, adherence to guidelines is also affected by externally driven factors such as complexity, layout, accessibility, and applicability to organizational practices (Fischer et al., 2016). Available literature demonstrated significant evidence on the effectiveness of CBTI in the treatment of CI. However, a host of barriers to referring patients for CBTI for the management of CI were also identified (Cheung et al., 2014). The initial treatment for CI in the primary care setting is more often pharmacologic therapies in spite of evidence-based research suggesting non-pharmacological therapies. The gap between evidence-based research and clinical practice has remained a challenge not only for chronic insomnia but for improving population health in general.

## Rationale

Johnson's (1980) behavioral systems and Kurt Lewin's change model were used to developed a theoretical understanding on which this health care improvement project was based. Johnson's behavioral systems model was used to address the contrasting perspectives that exist between the health care provider treating CI and the patients seeking care for CI. Johnson's behavioral systems model emphasizes that internal or external stimuli create disturbances in equilibrium (Clayton State University, 2019). The basis of nursing care should emphasize plans to reduce stressful stimuli and help individuals prevent or recover from illness or injury. Generally, nursing care should be holistic, focusing on the patient as in individual, and not on the specific disease entity. This health care improvement project considers that several factors contribute to the development of CI in older adults. Health care providers are encouraged to incorporate the range of options to help the patient return to a state of equilibrium, improve well-

being, and quality of life and to reduce health care cost associated with the adverse effect of CI and pharmacologic use.

Creating change within an organization is challenging to accomplish. For example, Schwartz, Bouckenooghe, and Vakola (2018) warn that most organizational change projects fail within a short period after implementation. Therefore, it is crucial for change leaders to identify an appropriate change model to provide a framework that guides and supports the implementation and evaluation of the change (Mitchell, 2013). In addition to Johnson's behavioral system model, Kurt Lewin's change model was used to guide the implementation of this project (see Appendix B for framework). This model was chosen because the model is seen as the pioneer of implementing and sustaining a change within an organization (Mitchell, 2013). Lewin's change model has a three-step approach to achieving and managing change, which is unfreezing, changing, and refreezing (Cummings, Bridgman, & Brown, 2016).

The three-stage process was used to persuade the involved stakeholders to adapt to this health care improvement project. The first step, known as the "unfreezing" stage involves disrupting the status quo to allow change to occur. Kurt Lewin states that the unfreezing stage focuses on the idea of human behavior is held by driving and restraining forces defined as "quasi-stationary equilibria" (Schein, 1996, p. 59). For a change to occur at micro-, meso-, or macro-levels, the process needs to be altered under complex psychological conditions (Schein, 1996). The 'unfreezing" stage involved the processes of "(1) disconfirmation of the relevancy of the status quo, (2) induction of guilt or survival anxiety, and (3) creating psychological safety" (Schein, 1996 p. 60). In this first stage, a gap between research and clinical practice in the treatment of CI in older adults was recognized to disrupt the current CI treatment approaches and implementing a change that is sustainable. After disrupting the status quo, it is crucial to move to

the “changing” stage. In this stage, sufficient psychological safety should be promised, and change-related anxiety should be minimized (Schein, 1996). This stage involves the actual change occurring. Time and effective communication are the two essential keys for a successful transition to happen. During the change stage, some of the clinic providers were concerned about how this change will affect their practice. Resistance to change is a normal reaction for most humans. Questions and discussions were encouraged throughout the implementation of this health care improvement project to minimize anxiety levels. The final step or the “refreezing” stage involves anchoring the new change into the organizational culture, and the implementer should make sure that others are using the new change at all time (Cummings et al., 2016).

## Specific Aims

The primary purpose of this health care improvement project was to improve the application of evidence for the treatment of CI in older adults. The specific aim was to determine if an interactive educational intervention with the clinic providers focusing on the ACP and AASM clinical recommendations for CI will impact the number of referrals to a sleep specialist and pharmacologic use in the primary care clinic in Sun City West, AZ.

Project aims and objectives were aligned with the health care organization’s proposed system initiative for the treatment and management of insomnia. The system initiative has been approved and is entering the design phase (D. K. Kukafka, personal communication, July 16, 2018). The initiatives' goal is to ensure that primary care providers and ambulatory behavioral health providers use non-pharmacologic/behavioral measures as a first-line treatment and pharmacologic therapy as an alternate option (D. K. Kukafka, personal communication, July 16, 2018). The proposed treatment goal is to expand the availability of CBTI specialist and other resources to people with CI. Treatment modalities will include self-help CBTI resources and

telemedicine-based delivery of insomnia therapy as an additional option. Together, these two goals support an effective treatment plan for older adults with CI.

## Methods

### Context

The primary care setting serves as the first point of contact for most patients with CI (American Academy of Family Physicians, 2019). The health care improvement project was implemented at a large primary care/internal medicine clinic in Sun City, Arizona. The clinic is among the many health centers within a large integrated health system in the area that is committed to providing comprehensive health care for all ages but primarily serves adults 65 years and older. Three family nurse practitioners (FNPs) and seven physicians currently serve over 7,500 older adult patients per month (B. M. Muriith, personal communication, July 20, 2018) with a significant number of these patients presenting to the clinic with complaints consistent with CI. The commonly prescribed medications used to treat CI in this primary care clinic include Trazodone, Zolpidem, Temazepam, Melatonin, Alprazolam, and Mirtazapine. Other clinic staff includes one practice manager, two practice supervisors, ten medical assistants, and several front office personnel. This facility also maintains a sleep center with one sleep specialist who treats a variety of sleep conditions, including CI. Because this setting provides care to adults 65 years and older primarily and the availability of a collaborating sleep specialist in the same building, made this primary care clinic an ideal setting for this health care improvement project.

Eight clinic providers participated in this project. The project participants include two full-time family nurse practitioners (FNPs), two medical doctors (MDs), and four doctors of osteopathic medicine (DOs) who saw patients at the clinic during the intervention period of October 2, 2017 through November 30, 2018. A convenience sampling procedure was used to

select clinic providers. This type of nonrandom sampling approach is best suited for this health care improvement project because the participants are easily accessible to the DNP student and this sampling approach is likely to save time and effort compared to other methods (Kim & Mallory, 2017). Inclusion criteria required that the respondent was a current provider of primary health service during the intervention period and they were willing to participate. Providers who were not seeing patients during the project dates, sleep specialists, and non-primary care practice staff did not meet inclusion criteria.

## Intervention

The primary educational intervention objectives were to improve provider knowledge of the ACP and AASM clinical guideline recommendations focusing on CBTI treatment and to encourage prescription-free treatment for CI in older adults (see Appendices C and D for guidelines). The literature supports CBTI as a treatment that yields robust and lasting benefits for adults with CI (Alessi et al., 2016; Espie et al., 2012; Fung et al., 2016; Morgan et al., 2012; Qaseem et al., 2016; Sateia et al., 2017; Tamura & Tanaka, 2012). An email invitation was sent to all staff who met the inclusion criteria. Information regarding the context of the project, purpose of the educational intervention, scheduled activities, date, time, and location of the session, and their right to accept or refuse the invitation were sent to potential participants. The PowerPoint presentation was published on YouTube to allow the clinic providers to review the information session without restriction. The teaching method used has been proven to have some effect on maintaining provider adherence to clinical guidelines and sustainability (Kovacs et al., 2017).

The educational session was held during staff lunchtime from 12:00 to 1:00 PM in an unoccupied conference room. The clinic providers were provided with paper and laminated

copies of the two current clinical guidelines and the PowerPoint presentation (see Appendix E for presentation). The session opened with an introduction to the DNP student, school, work title, an overview of the project purpose. The session was followed by a PowerPoint presentation addressing "chronic insomnia" background, problem statement, and current medications used to treat insomnia, and a special message from the American Geriatric Society on benzodiazepine and hypnotic use in older adults. Questions and discussions were encouraged throughout the presentation and attention was given to each of the additional educational materials provided in each of the folders. The presentation was completed in 20-minutes and the remainder of the hour was focused on a vigorous discussion among the attendees. After the presentation, the group spent approximately 40-minutes discussing the recommended clinical guidelines focusing on CBTI as first-line treatment for CI and barriers to CBTI referral in primary care. Questions and concerns regarding referral rates of patients with CI to a sleep specialist and utilization of online CBTI to treat patients were addressed. To determine the population impact, chart review was completed on patients diagnosed with CI (the International Classification of Diseases [ICD-10] codes G47.00, F51.09, F51.02, or F51.04) for the six weeks before and after exposure to the educational intervention. After the completion of the six-week intervention period, a post-implementation chart review was conducted to collect data on the project outcomes.

## Study of Intervention

The Plan-Do-Study-Act (PDSA) cycle was the approach used to assess the contextual elements that contributed to the success of this process improvement intervention. The PDSA model is a widely employed model that tests interventions using a small-scale, iterative approach to allow rapid assessment of whether the intervention will be successful or not (Agency for Healthcare Research and Quality [AHRQ], 2015; Institute for Healthcare Improvement [IHI],

2019). Specific goals for the success of this practice change focused on improving the clinic providers' knowledge base on the two clinical guideline recommendations focusing on CBTI as first-line treatment for CI in older adults.

The PDSA model helped test the change process during the planning, implementation, and evaluation phases of change. The objective of the first PDSA cycle was to test the feasibility of referring patients with CI to a CBTI specialist within the healthcare organization. The early cycle testing was conducted on two clinic providers. The plan was to refer every patient with CI seeking treatment in the clinic to a CBTI specialist. After one week of this trial, the electronic records of patients diagnosed with 'insomnia' or 'chronic insomnia (ICD-10 codes G47.00, F51.09, F51.02, or F51.04) were studied to assess whether referrals were being made. Verbal feedback was obtained from the clinic providers regarding the provider's attitude towards referring patients to CBTI, which suggested that the current awareness of CBTI use within the organization was one of several critical barriers to CBTI utilization in primary care. Feedback from this cycle revealed several vital clues as to why patients were not referred to CBTI. The barriers identified for providers to refer patients to CBTI was because of a lack of awareness about local CBTI services, concerns about insurance issues, and patient reluctance to use CBTI.

To measure provider knowledge, survey questionnaires were utilized. A pre-intervention survey (see Appendix F for the survey) was conducted to measure all provider's awareness and perceived barriers to prescribing CBTI as a primary treatment for CI in the primary care setting. The survey questionnaires were distributed to each clinic provider to answer at their leisure. The results revealed that 37% of the clinic providers were unfamiliar with the 2016 ACP and 2017 AASM guidelines. The responses also suggested that there is a lot of patient reluctance towards CBTI and that patients tend to prefer pharmacologic treatment. Identifying and addressing these

barriers is important because potential solutions may increase the number of CBTI services utilized by patients with CI.

The second PDSA cycle, therefore, addressed some of the reported barriers by (1) involving administration and the medical director for sleep to assist in hiring a CBTI specialist for patients with CI, and (2) creating a collaborative effort with the sleep specialist who uses an on-line CBTI modality to treat patients. There are a limited number of CBTI specialists available in the geographic area, and the available specialist does not accept Medicare insurance. After two weeks, the two clinic providers' electronic records were reviewed again for the second cycle of the PDSA, which concluded that two patients were diagnosed with CI. One clinic provider referred a patient to the sleep clinic, while another clinic provider treated a patient pharmacologically. The second cycle concluded that there was a 50% chance that the clinic providers would refer patients with CI to a collaborating sleep specialist, suggesting that this form of intervention would likely be sustained in the clinic.

## Measures

The project utilized two sources of measurements to determine project effectiveness. A categorical response to a series of pre-and-post survey questions were used to assessed practitioner knowledge at baseline and three-month follow-up. Practitioner survey responses were recorded as dichotomous (Y/N), categorical, and open-ended (see Appendix G for the survey). Medical record information included DSM-5/ICD-10 diagnosis of chronic insomnia, pharmacological treatment (Y/N), and CBT referral (Y/N). The effectiveness of the intervention was assessed by conducting a retrospective chart review using Cerner Millennium electronic medical record (EMR) six weeks before the intervention (baseline) and 6-weeks after the educational session intervention. Data extracted from the EMR were restricted to patients with a

DSM-5/ICD-10 diagnosis of chronic insomnia (Y/N), Pharmacological (Y/N) and CBT referral (Y/N) treatment prescribed. These data were recorded in the provider electronic notes of each patient encounter. Secondary data collection from retrospective chart reviews is considered a readily available and reliable source of diagnostic, treatment, and outcome data (Weiskopf & Weng, 2013).

In order to evaluate the project's population impact, a total of 604 electronic records of patients diagnosed (DSM-5/ICD-10) with CI were reviewed as part of the analysis. Among the 604 patient records, a total of 137 records included a treatment plan for CI. Patients with a primary diagnosis of insomnia because of a neurologic, psychiatric, or physical condition were excluded from the record review. Treatments prescribed were calculated for a six-weeks pre-intervention average and each of six-weeks post-intervention. This calculation allowed for an examination of time-sensitive changes in prescribing behavior after clinicians were exposed to the educational intervention. Trends were used to identify the change in the rate of referrals to behavioral specialist versus pharmacologic therapy.

## Analysis

All surveys and electronic data were collected, entered and managed with Microsoft Excel. Medical record data were and transferred to SPSS for analysis. This method allowed for summarizing descriptive (frequencies, percents), and trends. Graphics were created in Excel for the visual illustration of findings.

## Ethical Considerations

Ethical concerns associated with the planning, implementation, and evaluation of this health care improvement project were minimal. The Northern Arizona University Institutional Review Board determined that the project was "not research" and therefore did not require

oversight by the NAU IRB (see Appendix H for IRB letter). The healthcare organization's Research Determination Committee also approved the implementation of this project (see Appendix I for approval letter). Individual provider's verbal consent was obtained to participate in this health care improvement project. The DNP student assured that all responses were confidential and that all data would be analyzed only in the aggregate so that linking answers to any individual would not be possible. All data were stored and managed in a password secured single user computer, accessible only to the DNP student.

## Results

The educational intervention was presented to a group of eight family medicine and internal medicine clinic providers. The providers were six physicians and two nurse practitioners (see Table1). The clinic providers were asked about their familiarity with the treatment guidelines both pre- and post-exposure to the educational session. Practitioners were asked to report if they had ever heard of ACP or AASM guidelines to therapy recommendations for the management of CI. Before the educational intervention, five out of the eight clinic providers had heard of the guidelines. At six-weeks post-intervention all eight practitioners reported familiarity with the guidelines. At baseline seven of the respondents reported the guidelines could be useful for improving health outcomes. This figure increased to eight at six-weeks follow-up (see Figure 1).

Survey responses indicated that the educational intervention was beneficial to the clinic providers. All of the eight practitioners reported that the educational intervention increased their awareness of CBT as a first-line for treatment for older patients (see Figure 2). All the practitioners reported that the training increased the likelihood that the clinic providers would refer to a sleep specialist while seven of the clinic providers said that the training decreased the

likelihood that the practitioners would prescribe pharmaceuticals as the first-line of treatment for CI (see Figure 3).

A chart review was completed to determine the population impact of the intervention. A total of 604 electronic charts of patients who experienced CI were reviewed over 12-weeks. The majority of the patients evaluated were female 78.9% (n=477) and ranged in age between 65 year and 98 years with the age groups well distributed at 65-69 years 20.4% (n=123), 70-74 years 24.7% (n=249), 75-79 years 19.7% (n=119), 80-86 years 18.5% (n=112), and over 85 years of age 16.7% (n=101). The charts suggested that 367 patients were reported as having CI before the intervention and 237 patients six-weeks after the educational intervention. It was noted that 23% (n=137) of the patients diagnosed with CI were prescribed a treatment plan, reflecting 15.5% and 2.7% for pharmacological and CBT respectively at baseline. After the intervention, 17% of the entire patient group with CI received pharmaceutical treatment and 6% were referred to sleep specialist. These cumulative figures suggest that the proportion of patients prescribed pharmaceuticals remained about equal after the intervention, while the proportion of the patient population referred to CBT more than doubled (see Figure 4).

Of particular interest was examining the trend in which prescribing behaviors among the 137 patients receiving some type of treatment plan had changed over the 12-weeks baseline and post-intervention period. Patterns in practitioner prescription behaviors suggested that at baseline the majority (71%) of the patients who were treated for CI were prescribed a pharmacologic therapy, while only 15% were referred to a sleep specialist. The rates of pharmacologic treatment decreased between weeks one and five post-intervention, while the rates in CBTI also appeared to increase over the same five-week period. The lowest rate of pharmacologic use (63%) and the highest percentage of referring patients to CBTI (38%) occurred on week three. After this period,

prescribing pharmacological therapy treatment began to rise again, while referring patients to CBTI also began to decline, at 83% and 15% for pharmacologic and behavioral treatment referrals respectively (see Figures 5 and 6). This trend indicated there may be barriers to the sustainability of this project.

## Discussion

The purpose of this health care improvement project is to implement evidence-based practice for the treatment of CI in older adults in the primary care setting. Before the implementation of this process improvement project, clinicians practicing at this primary care setting commonly treated patients with CI with pharmacologic therapies. Referring patients to CBTI was completed at low rates, despite recommendations by the 2016 ACP or the 2017 AASM guideline to use CBTI as the first-line of treatment. The project intervention involved a one-hour presentation and discussion regarding CBTI as an effort to increase awareness of this method as a first-line treatment.

The outcome data of this process improvement project demonstrated that the primary care providers who took part in the education intervention reported an increased awareness of the ACP and AASM clinical guidelines for the management of CI in adults. Also, participants reported that exposure to the interactive education intervention impacted the likelihood that they would consider increasing referrals to a sleep specialist and decreasing prescribing pharmacologic therapy.

The project had some strengths such as that the project used a combination of participant response data and medical record data to address a public health problem that affects a significant number of adults 65 years and older. Primary care practitioners are the medium between the patients and the health care system, so choosing this setting and a sample of N=8 practitioners provided a good population and setting on which to base this project. The project

sample comprised of eight primary care providers, which is larger than the usual five or fewer clinic providers in the majority of clinic sites (Petterson, McNellis, Klink, Meyers, & Bazemore, 2018), making it possible to be spread to another context.

## Interpretation

An analysis of trend data based on a chart review of patients seen before (baseline) and practitioners attended the educational workshop, suggested that the number of patients prescribed pharmacologic treatment was nearly five times higher than CBTI for the treatment for CI. The proportion of patients receiving pharmacological treatment dipped to the lowest rates three-weeks after exposure to the intervention with rates remaining stable and even reaching higher levels by the end of week six. While pharmacologic therapy continued to be preferred, a "quick fix," easily accessible, and convenient, it is, however, worth noting that prescribing of more toxic medications like Zolpidem and benzodiazepines declined while medicines with fewer side effects such as trazodone and melatonin increased. By comparison, the rate of referring patients to CBTI nearly doubled by week three but began to decrease at week four, returning to baseline figures by the end of week six.

A number of possible factors could account for this downwards trend in referral rates. The analysis concluded that changing attitudes, behaviors, and practice patterns of health care providers is relatively difficult to achieve over a short period. These findings are consistent with the literature addressing resistance to practice and organizational change (Burnes, 2015; McKay, Kuntz, & Naswall, 2013). Schwartz et al. (2018) also argued that it is not uncommon for most organizational change to fail within a short period. Kurt Lewin's change model which was used to guide this project has three phases for change. It appears that the "refreezing" stage of Lewin's model defines is the most difficult to achieve although the need for change has been perceived

and accepted as needed. Moving toward the new, desired level of behavior, and solidifying that new practice as the norm creates the most challenging stage of change to achieve.

After this health care improvement intervention, the percentage of the clinic provider familiarity with the two clinical guidelines to manage CI significantly improved, resulting in nearly twice the number of referrals to a sleep specialist between pre- and post-intervention. While these findings suggested that the intervention was successful, pharmacologic use among the clinic providers remained high.

A surprising finding was that the clinic providers who took part in this project stopped the initiation of new pharmacological therapies after the intervention session, but almost all continued their current treatment plans. However, the use of medications like Zolpidem and benzodiazepines were discontinued, and most patients were switched to medications like trazodone and melatonin. It is worth noting that the providers were aware of the possible consequences of these medications before initiating therapy. Perhaps, patient reluctance to do CBTI and patient perceptions of pharmacologic therapy as a “quick fix,” easily accessible, and is a convenience for their daily life may have contributed to the high amounts of pharmacologic use. Epstein et al. (2012) conducted a qualitative study on Iraq veterans to evaluate patients’ preference and acceptability of various treatment options for CI. The results concluded that a large number of insomniacs who visit their primary care providers preferred pharmacologic therapy to improve sleep (Epstein et al., 2012). This request and demand from patients may be due, at least in part, to the overwhelming use of pharmacologic therapy in the treatment of CI in primary care. One of the few generally accepted facts in primary care is that promoting patient satisfaction is a driving force of how patients are treated.

## Limitations

The project had some important limitations. First, the survey tools used for this health improvement project were original and lacked the validation of a standardized instrument. Second, the retrospective chart review was based on data from Cerner EMR system, which is structured on clinical notes. It has been well established that note taking is not always consistent between practitioners (Weiskopf & Weng, 2013). Third, a degree of bias could have occurred because clinical providers are aware of the implementation of this project, and may have increased the referral to a sleep specialist and decreased pharmaceutical treatment of patients during the early post-implementation period. This form of bias may have functioned as a confounder in the increase in CBTI referral and decrease in pharmacologic therapy in the first three weeks. Fourth, the project was conducted during a six-week timeframe, which is considered a short time to assess for any process improvement results, and fifth, although not a focus of this project, variation was noted in prescribing CBTI versus prescription drugs according to the professional orientation of the clinic providers (MD, DO, FNP). Data outcomes suggested that NPs experienced the largest percentage of increase (+7%) in prescribing CBTI, followed by MDs (+2%), but decreased among DOs (-1%). Further study of the reasons for the variation of CBTI between the professions is warranted.

## Conclusion

The overarching objective for this health care improvement project was to close the existing gap between evidence-based recommendations and clinical practice in the treatment of CI in primary care. The goal was to improve patient care by addressing providers' knowledge about the recommendations from research and two clinical guidelines focusing on CBTI as first-line treatment in adults with CI who sought care at a large primary care setting in Sun City, AZ.

A one-hour intervention session via PowerPoint presentation was provided to a group of primary care providers. After a six-week retrospective chart review, there was a significant change in the perception of CBTI utilization and pharmacologic use in the primary care setting. The overall CBTI referral rates for treatment of CI increased significantly between pre- and week three of the post-intervention period. The overall rate of pharmacologic used appeared to stay constant. Although the period used to view trends in treatments was fixed over a short period, outcomes seem to suggest that the intervention was successful with increasing CBTI and decreasing pharmacological treatment although those changes were not sustained. It is critical to recognize that long-term or "permanent" change may be difficult to maintain. Nonetheless, evidence provided by this project suggests that there is potential for creating an environment of sustainable change. In as much, it is critical that the appropriate theoretical framework and approaches be used to guide the planning so sustainability of challenging current practices can be exchanged for best practices (evidence-based care). Falling back on traditional ways of treating CI will be a waste of resources and can increase resistance to later process improvement initiatives (Hovlid, Bukwe, Haug, Aslaksen, & von Plessen, 2012).

These findings have implications for patients with CI and for primary care practitioners. Given the rapid increase in numbers of individuals age 65 years and older, the prevalence of CI and CI-related conditions may increase in the coming years. Making appropriate assessments and implementing safe and effective treatment for insomnia will improve health outcomes for this growing population. Furthermore, the US health care system is shifting from care relying on opinions of health care providers to an evidence-based practice system. This paradigm shift suggests that clinical decisions cannot rely on the opinion of a medical specialist or health

professionals, but rather depend on the critical appraisal of scientific evidence available when serving the patient population.

CBTI as a treatment modality is recommended as first-line treatment for CI in adults given its long-term effectiveness and lower risk of side effects compared to pharmacological approaches. Future projects are recommended to test the sustainability of this health care improvement project. Although the project demonstrated that the educational intervention was effective with increasing recommendations of CBTI to patients with CI, increases in CBTI trends appeared to be short-lived during a six-week timeframe. Finally, further study on the adoption of CBTI recommendations between clinical professional groups is warranted.

## Funding

No external funding sources to support this health care improvement project.

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Tables

**Table 1.**
*Demographic Description of Practitioners (N=8)*

| | N | Percent |
|---|---|---|
| **Gender** | | |
| Male | 2 | 25 |
| Female | 6 | 75 |
| **Age** | | |
| Under 40 | 1 | 88 |
| Over 40 | **7** | 12 |
| **Practitioner** | | |
| Physician | 6 | 75 |
| Nurse Practitioner | 2 | 25 |

**Table 2.**
*Demographic Description of Patients (N=604)*

| | N | Percent |
|---|---|---|
| **Gender** | | |
| Male | 127 | 21.1 |
| Female | 477 | 78.9 |
| **Age** | | |
| 65-69 | 123 | 20.4 |
| 70-74 | 149 | 24.7 |
| 75-79 | 119 | 19.7 |
| 80-85 | 112 | 18.5 |
| Over 85 | 101 | 16.7 |

Figure 1

Familiarity with guidelines pre- and post-intervention

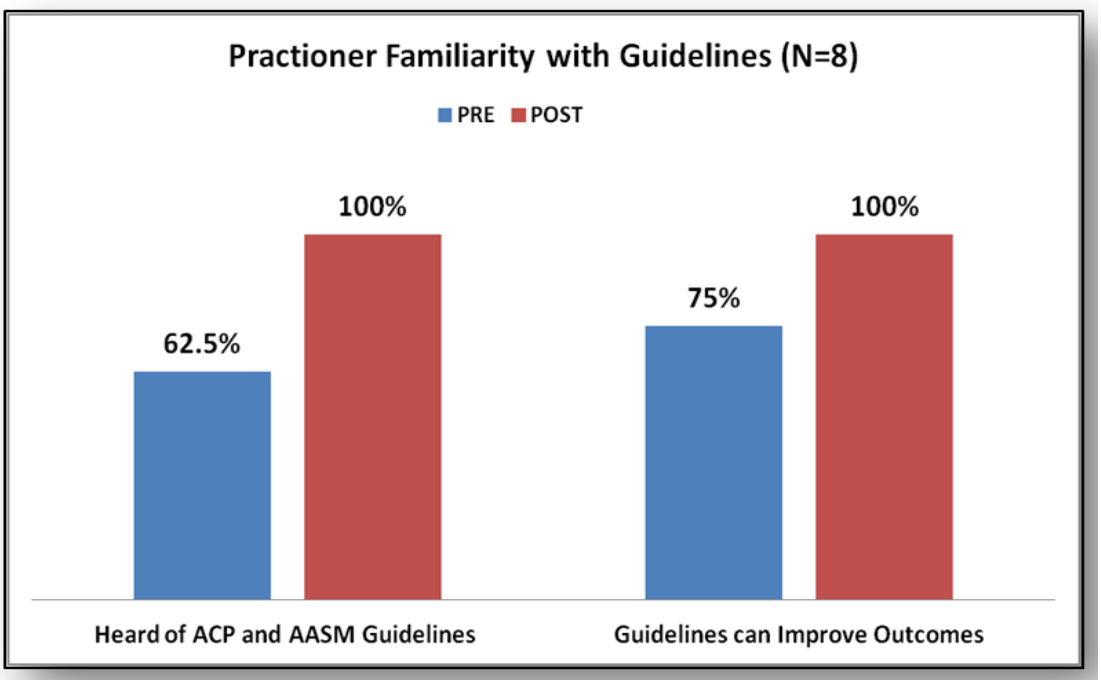


Figure 2

Awareness of CBT pre and post educational intervention

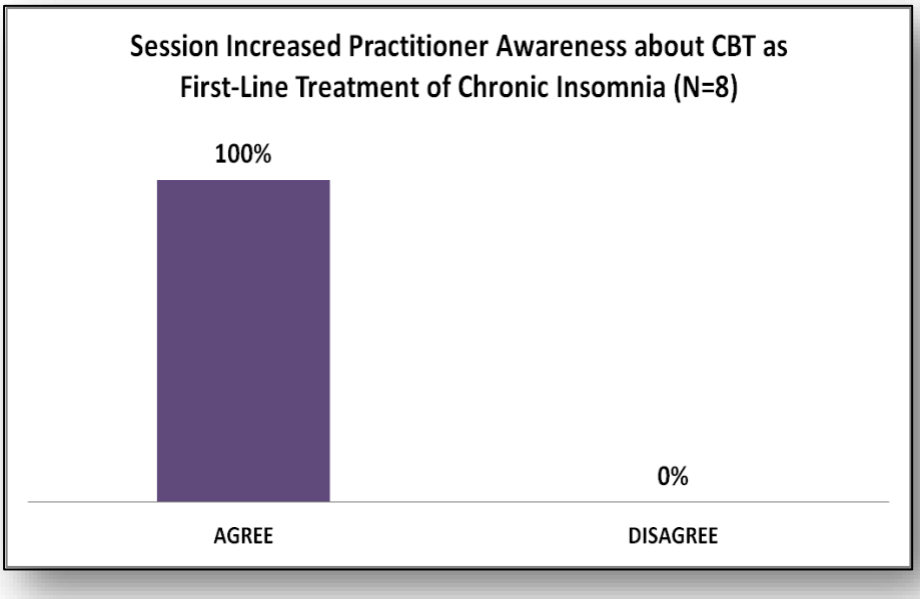


Figure 3

Treatment Perceptions Pre and Post intervention

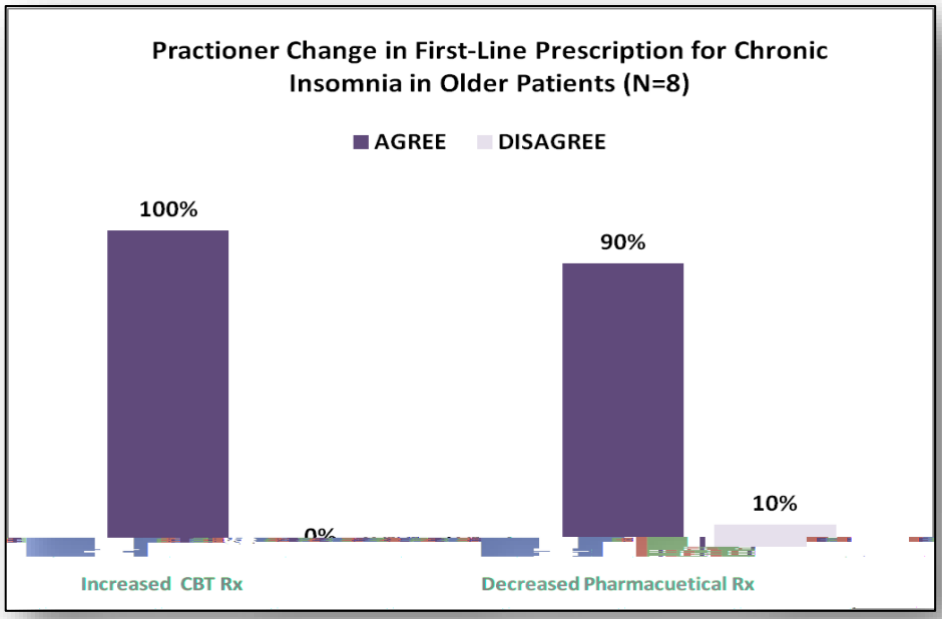


Figure 4

Prescribing Rx and CBT to All Patients with CI Pre and Post Intervention

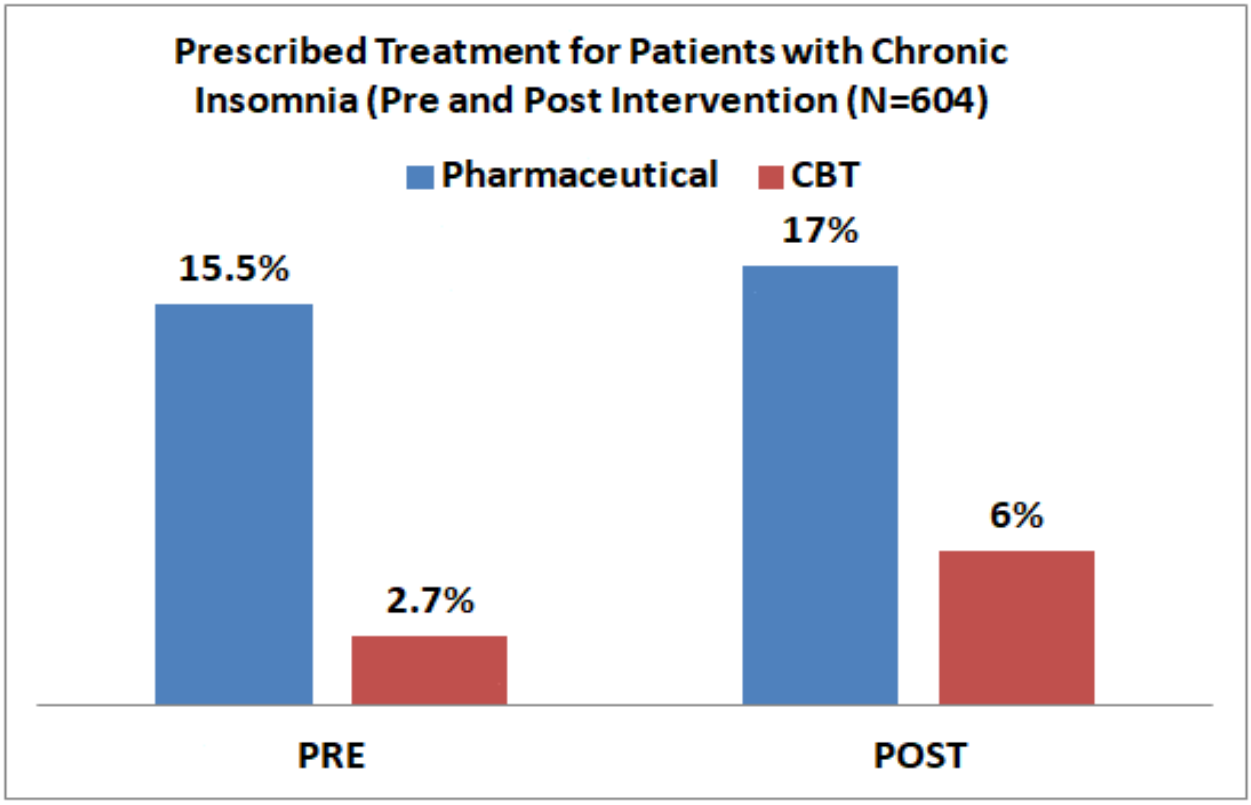


Figure 5

Trend in Prescribing Rx and CBT at Baseline and 6 weeks Post Intervention

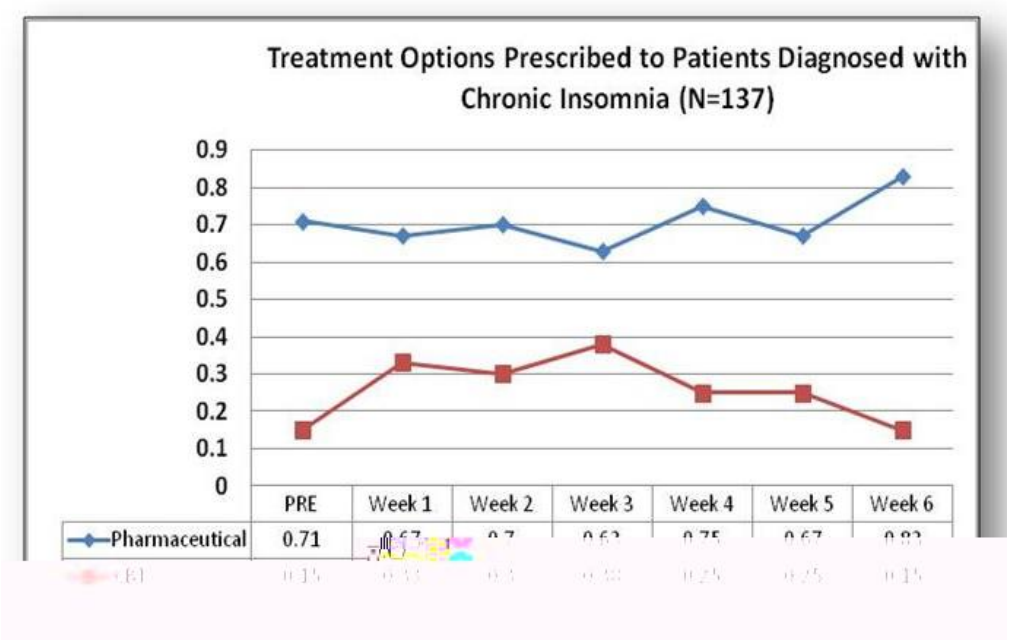
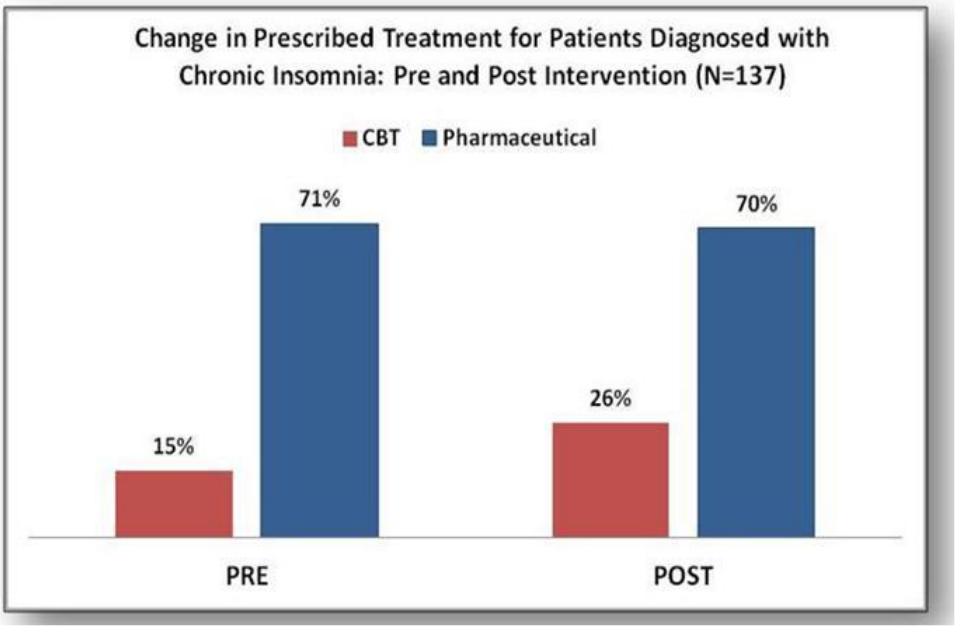


Figure 6

Cumulative change in method used to Treat Chronic Insomnia: Pre and Post Intervention



# Appendix A

## Evidence Table

| Author/Title/Date | Topic/Focus/ Question | Conceptual Framework | Design/Method | Setting/Sample | Major Variables | Measurement/Data Analysis | Study Findings | Level & quality of Evidence/Strength/Weakness/Conclusion |
|---|---|---|---|---|---|---|---|---|
| Espie, C. A., Kyle, S. D., Williams, C., Ong, J. C., Douglas, N. J., Hames, P., Brown, &J. S. (2012)<br><br>A randomized, placebo-controlled trial of online cognitive behavioral therapy for chronic insomnia disorder delivered via an automated media-rich web application. | "Is CBT for chronic insomnia disorder - delivered via an automated, media-rich web application - superior to a credible placebo intervention, as well as to a treatment as usual condition, in improving nighttime sleep and associated daytime functioning? Are these effects durable and clinically important?" | N/A | Randomized, placebo-controlled trial comprising CBT, imagery relief therapy (IRT: placebo), treatment as usual (TAU) | Online community of participants in the UK<br><br>N=156<br>Mean age =49 (18-79)<br>G= F 120<br>CBT n=53,40F<br>IRT n=52,42F<br>TAU n=51,38F<br>Homogeneous sample<br>Employ=2/3<br>Socioec st=less deprived<br>Health=average<br>30% on meds for physical health<br>10% on med for mental health<br>1 in 5 on prescribed sleep aid<br>40% on OTC sleep aid | IV= 6 weekly sessions of CBT - delivered by an automated virtual therapist<br>IRT - delivered by an automated therapist<br>TAU - Real world practice protocol<br><br>DV= Sleep onset latency (SOL, min), difficulty maintaining sleep (wake time after sleep onset {WASO, min}, total time in bed (TIB), sleep efficiency (SE), total | Pre-post-follow-up questionnaires<br><br>effect size in % (Cohen)<br><br>ANOVA<br><br>P < 0.05 | **Variable SE**<br>CBT - 19.5% increase from 15.3 to 23.7, 95% CI<br>IRT - 5.7% increase (95% CI, 2.79 to 8.52<br>TAU 6.4% increase (95% CL, 2.88 to 9.86<br>At follow-up - 20% improvement in CBT group (15.7 to 23.6) compared to IRT 7% (4.53 to 10.1) and TAU 9% (4.89to 13.7<br>Conclusion: CBT yield superior outcome relative to IRT (d=1.00) and TAU (d=0.69).<br>Reduction in SOL and WASO 26 and 28 min respiration at post treatment and follow up. IRT was 20 min & 10 min for TAU.<br>At both time point for WASO, CBT exhibited a large ES relative to TAU and a moderate to large ES related to IRT.<br>**For SOL**=large effect in favor of CBT relative to IRT and modest ES relative to TAU.<br>TWT down by 75 min following CBT, | **Level of Evidence:**<br>Level II<br><br>USPSTF grading schema: Grade B, Good quality<br><br>**Strength:**<br>findings are consistent with other research<br>The use of advanced technology to collect data which enhanced fidelity<br>large sample size which makes it generable to my patient population<br>No contact between the participants and researchers<br><br>**Limitations:**<br>participants were recruited by online survey and may represent a cohort unusually interested in addressing sleep problems<br>Limited generalizability of the study findings<br>Short follow-up period of 8 weeks- it usually takes 6-12 months with some showing durability up to 2 years |

| Author/Title/Date | Topic/Focus/ Question | Conceptual Framework | Design/Method | Setting/Sample | Major Variables | Measurement/Data Analysis | Study Findings | Level & quality of Evidence/Strength/Weakness/Conclusion |
|---|---|---|---|---|---|---|---|---|
| | | | | | sleep time (TST, h) and sleep quality | | exhibiting large ES compared with IRT or TAU.<br>At post-treatment, TST increased by ~40 min in CBT and TAU compared with 20 min in IRT.<br>At follow-up - TST increased by 70 min in the CBT group compared with 28 and 47 min in IRT and TAU resp.<br>Self-reported sleep quality also increased to a greater extent in CBT than in either IRT or TAU.<br>Global sleep-wake function as well as daytime functioning, performance, and social functioning improved in the CBT group | **Conclusion:** CBT delivered using an online media-rich web application with automated support and a community forum appears effective in improving the sleep and associated daytime functioning of adults with insomnia. Further studies with patient with active comorbidities and with respect to objective sleep outcomes using polysomnography<br><br>Clinical Significance:<br>This study looked at the effectiveness of CBTI in adults, which helps answer my clinical question. Its strong fidelity and validity makes this study generalizable to my patients. |

| Author/Title/Date | Topic/Focus/ Question | Conceptual Framework | Design/Method | Setting/Sample | Major Variables | Measurement/Data Analysis | Study Findings | Level & quality of Evidence/Strength/Weakness/Conclusion |
|---|---|---|---|---|---|---|---|---|
| Tamura & Tanaka (2017) Effects of sleep management with self-help treatment for the Japanese elderly with chronic insomnia: a quasi-experimental study | "To determine whether sleep management with self-help treatment is more effective in improving insomnia, compared to a waiting-list control. | | Quasi-experimental study | Public health center in Kure city in Hiroshima Perfecture, Japan.<br><br>N=51<br>Age=60 year and older<br>intervention group=28<br>control=23 (23 needed to identify a change | The effect of self-help treatment on chronic insomnia.<br><br>IV=stepped-care model<br>DV=insomnia severity. | Pre-post Student's t test<br>Linear mixed model analyses<br>Spear-man.<br><br>5-point Likert scale<br>ISI-J, PSQI-J, JESS, eight-item Short-Form Health Survey of the Medical Outcomes Study (SF-8) | Participants in the treatment group exhibited significant improvements in their insomnia severity, sleep disturbance, daytime sleepiness, and mental QOL, whereas the wait-list control group did not. Participants were also observed to improve significantly in the treatment group, which support the researchers hypothesis that suggest that sleep management with self-help treatment showed greater efficacy at post-treatment than seen in the waiting-list group. | Level of Evidence: Level II<br><br>USPSTF grading schema: Grade B, Good quality<br><br>Strength:<br>findings are consistent with other research<br>The use of advanced technology to collect data which enhanced credibility.<br><br>Limitation -small sample size<br>Limited generalizability due to Japanese participants. |
| Fung, C.H., Martin, J. L., Josephson, K., Fiorentino, L., Dzierzewski, J. M., Jouldjian, S. … Alessi, C. (2016).<br><br>Efficacy of cognitive | "To determine whether CBTI results differ based upon SDB status. Hypothesized that, at 6-months follow-up, | None | A larger randomized controlled trial | VA Greater Los Angeles Healthcare System between August 2009 and June 2011. N=134Mean Age=72.2Gender=n=130 (97%)Race=105(78.4%)=white60 | IV=Individual CBTI, group CBTI, and sleep education - baseline, post-treatment, 6 months follow-up, | Descriptive statistics.<br>ANOVA model.<br>Bonferroni-adjusted alpha level of | Participants with mild SDB who received CBTI shows significant improvements in sleep onset latency and PSQI total score, but shows no significant improvements in wake after sleep onset, total wake time at night, diary-measured sleep | Level of Evidence: Level II<br><br>USPSTF grading schema: Grade B, Good quality<br><br>Strength:<br>findings are consistent with other research<br>Intervention was |

| Author/Title/Date | Topic/Focus/ Question | Conceptual Framework | Design/Method | Setting/Sample | Major Variables | Measurement/Data Analysis | Study Findings | Level & quality of Evidence/Strength/Weakness/Conclusion |
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| behavioral therapy for insomnia in older adults with occult sleep-disordered breathing. | the presence of untreated mild SDB would not limit the improvements in sleep efficiency, sleep onset latency, wake after sleep onset, total wake time, or Pittsburgh Sleep Quality Index (PSQI) total score among older adults randomized to CBTI versus a sleep education control condition. And that CBTI would decrease the number of patients with mild SDB who meet CMS indications for SDB therapy. | | | has some college degree+ chronic insomnia disorder, no h/o of OSA, MMSE>24, no serious mental or physical health issues, AHI<15. Participants randomized to 3 groups (individual CBTI, group CBTI, or sleep education control condition). | and 12 months follow up of CBTI<br><br>DV = Sleep efficiency, sleep onset latency, wake after sleep onset, total wake time, or Pittsburgh Sleep Quality Index (PSQI). | 0.0083 Pearson correlation coefficients. Fisher's Exact test. Instruments - Unattended in-home sleep study, Sleep diaries, Actigraphy, PHQ-9, PSQI, ISI, and ESS. | efficiency, or actigraphy-measured sleep efficiency. | provided by a health educators who were supervised by a sleep psychologist during the research.<br>The use of multiple instruments to enhance fidelity<br>large sample size.<br><br>Limitation:<br>Primarily whites males<br>The used of unattended in-home sleep study instrument to measure participants' AHI.<br><br>Conclusion: Patients with insomnia and mild SDB are likely to see improvements in their sleep when treated with CBTI.<br><br>Sig to practice: Most patients in my clinic setting will benefit from this study most of them are also affected by SBD. |

| Author/Title/Date | Topic/Focus/ Question | Conceptual Framework | Design/Method | Setting/Sample | Major Variables | Measurement/Data Analysis | Study Findings | Level & quality of Evidence/Strength/Weakness/Conclusion |
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| Wang, Q., Chair, S. Y., Wong, E. M. L, and Li, X (2016).<br><br>The effects of music intervention on sleep quality in community-dwelling elderly. | To examine the effects of music intervention on sleep quality among Chinese community-dwelling elderly over a 3-month period. | | Two-armed randomized controlled trial.<br><br>Participants randomized to the music and control group n=32 each. | Four urban community in Xi'an, China. N=64, mean age=69.38 Inclusive criteria=60+yo, poor sleep quality (PSQI >7), able to communicate in Chinese. No cognitive disabilities, no h/o ETOH/drug, no impaired hearing abilities, no h/o musician or previously received music intervention. | IV=3-month music therapy DV= sleep quality (PSQI) | An intention-to-treat analysis was used in the data analysis. Skewness and kurtosis stats was used to test normality of each variable. Independent t-test and chi-square to test homogeneity. Two-way RM-ANOVa test the effects of music. Eta square | The intervention group demonstrated continuous improvements in sleep quality, with the global PSQI score of 9.28 at 1-month f/u, 8.28 at 2-month f/u, and 7.28 at 3-month f/u. | Level of Evidence: Level II<br><br>USPSTF grading schema: Grade B, Good quality<br><br>Strength:<br>The researchers developed 169 pieces of music by a an expert team. The researchers involved a psychiatric physician with expertise in sleep d/os and a gerontologist were included in the expert team. |
| Morgan, K., Gregory, P., Tomeny, M., D | To evaluate the effectivenes | NONE | A pragmatic two-arm | 193 self-referred adults aged 55-87yo with | IV - 6 self-help booklet, | | In the self-help group, sleep outcomes showed significant | Strength - strict inclusion and exclusion criteria. Elimination of bias. Study |

| Author/Title/Date | Topic/Focus/ Question | Conceptual Framework | Design/Method | Setting/Sample | Major Variables | Measurement/Data Analysis | Study Findings | Level & quality of Evidence/Strength/Weakness/Conclusion |
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| Clin, P., David, B. M., & Gascoign, C. (2012).<br><br>Self-help treatment for insomnia symptoms associated with chronic conditions in older adults: A randomized Controlled Trial | s of a self-help cognitive behavioral intervention in improving sleep quality in older adults reporting insomnia symptoms associated with chronic disease. | | randomized controlled trial comparing supported self-help with treatment as usual (TAU) with assessment at baseline, after treatment and at 3 month and 6 months. | insomnia.<br><br>Setting - Primary Care | designed as a structured psychoeducational program, low-cost telephone helpline available M-F from 2-4pm and 6-8 pm staffed by trained advisers DV- global score from PSQI, ISI, subjective estimated sleep efficiency, and Fatigue Severity Scale (FSS). BDI, Epworth Sleepiness Scale (ESS), and pain severity from the Brief Pain Inventory (BPI) were also assessed. | | improvements after treatment. Participants in the self-help intervention group reported significant PSQI and sleep efficiency, significant less insomnia severity index and significant lower odds of consuming sleep medication. | is applicable to primary care<br><br>Limitation - Small sample size. Insufficient data on adverse effects and withdrawals. |

| Author/Title/Date | Topic/Focus/ Question | Conceptual Framework | Design/Method | Setting/Sample | Major Variables | Measurement/Data Analysis | Study Findings | Level & quality of Evidence/Strength/Weakness/Conclusion |
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| Jerpersen, K. V., Koenig, J. Jennum, P., & Vuust, P. (2015)<br><br>Music for insomnia in adults. | to assess the effects of listening to music on insomnia in adults and to assess the influence of specific variables that may moderate the effects | There were no obvious health belief models | Systemic review of RCTs and quasi randomized controlled trials. | 6 studies compromising a total of 314 participants. | Independent variable is the music therapy for sleep. The dependent variables is sleep quality and length of time it takes to fall asleep, the amount of actual sleep someone gets, and the number of times people wake-up. | Moderate quality | The findings suggest that listening to music can improve sleep quality. One study reported data on other aspects of sleep, including the length of time it takes to fall asleep, and the number of times people wake up. This study found no evidence to suggest that listening to music benefits these outcomes. None of the studies reported any negative side effects caused by listening to music. | Study strength adequate sample size, they independently screened and reported bias throughout the article. They assessed for homogeneity through the use of mean difference in Chi test.<br>Limitations the research did not use objective measures of sleep such as somnography and actigraphy. The use of moderate quality RCTs and quasi-experimental studies. |
| Auld, F. et al. (2016)<br>Evidence for the efficacy of melatonin in the treatment of primary adult sleep disorders. | To study the effects to assess the evidenced-base for the therapeutic effect of exogenesis melatonin in treating primary sleep disorders in older adults. | No health belief model discussed | Meta-analysis of published, peer-reviewed RTC's on the use of exogenesis melatonin to treat primary sleep disorders | The were no restriction in sample size of adults >18 years old with established primary sleep disorder. | Melatonin effects on sleep. | The measurement used to assess was the polysomnography test. | The study findings were that melatonin has a role in the treatment of some primary sleep disorders namely the delayed sleep phase syndrome (DSPS), non-24-hour sleep-wake disorder, and people who are blind. And, there is evidence of melatonin is beneficial in patients REM behavior disorder but more research is requested. | They searched 1950 to 2014' which gives and unlimited sample size. Weaknesses are the time frame was too large and no select sample size. |

| Author/Title/Date | Topic/Focus/ Question | Conceptual Framework | Design/Method | Setting/Sample | Major Variables | Measurement/Data Analysis | Study Findings | Level & quality of Evidence/Strength/Weakness/Conclusion |
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| Leach, M. J., & Page, A.T. (2014). Herbal medicine for insomnia: A systemic review and meta-analysis. | The study focus is to evaluate the safety and efficacy of herbal medicine for the management of insomnia | No health belief model discussed | systemic review of RCTs. They did 14 RCT's involving 1602 participants. | The sample size included 1602 participates. The studies were conducted 8 different countries including 4 in Germany, 3 in US, 2 in Iran, 1 in Australia, Mexico, Brazil, China, and Norway. | The use of herbal medication such as Velarium, Chamomile, Cava, Wuing and there effects on sleep. The dependent variable is sleep parameters and incidence and type of adverse effects, also daytime functioning, sleep score, and quality of life. | The measurement PSQI, random effect model and review manager 5.1 software and funnel plots were used to assess for potential existence of small study bias. They used standard square test and significance level of alpha pi =1 | The study findings suggest that there is insufficient evidence to conclude that herbal medicine, specifically Valerian, Chamomile, Kava, and Wuling are any benefit to adults suffering from insomnia. But many of the trials were of poor or uncertain methodological quality with unclear bias. | The studies limitations were the search strategy was comprehensive, and it was discussed that pertinent unpublished reports or studies published in languages other than English could have been missed, unintendedly. Thus language and publication bias cannot be excluded.<br><br>Strengths include - comprehensive meta-analysis using sound strategies.<br>Comprehensive assessment and elimination of biased studies<br>Heterogeneity was thoroughly assessed using appropriate assessment tools and statistics.<br>Seep outcomes are assessed. |

| Author/Title/Date | Topic/Focus/ Question | Conceptual Framework | Design/Method | Setting/Sample | Major Variables | Measurement/Data Analysis | Study Findings | Level & quality of Evidence/Strength/Weakness/Conclusion |
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| Afonso, R. F. et al., (2012).<br><br>Yoga decreases insomnia in postmenopausal women: a randomized clinical trial. | The aim of this study is to evaluate the effectiveness of yoga practice on the physical and mental health and climacteric symptoms of postmenopausal women with a diagnosis of insomnia. | Not mentioned | RCT | Postmenopausal, literate women between 50 and 65 years with insomnia dx by DSM4. Had amenorrhea >1yr, FSH level>30, BMI<30. Recruited via local newspaper and outpatient service at the Universidade Federal de Sao Paulo-Escola Paulista de Medicina. Exclusive criteria- uncontrolled illnesses such as SAH DM, cancer; use of psychotropic drugs, AHI>15; participate in psychological treatment of menopausal. 44 women, study took 4 months | IV=ISI, Beck Anxiety Inventory (BAI), BDI, the Kupperman Menopausal Index (KMI), Limpp's Inventory of Stress Symptoms for Adults (ISSL). DV-1 hour of yoga session by a teacher per week (technique- yoga, Sana and some Tibetan) and passive stretching by a PT. Participants were evaluated using questionnaires from the above tools and polysomnography. | SPSS version 17 statistical program was used for data analyses. Means and SDs were used to characterized the groups. A general linear model of repeat measures used to investigate the effects on the scores of the questionnaires, | | |

| Author/Title/Date | Topic/Focus/ Question | Conceptual Framework | Design/Method | Setting/Sample | Major Variables | Measurement/Data Analysis | Study Findings | Level & quality of Evidence/Strength/Weakness/Conclusion |
|---|---|---|---|---|---|---|---|---|
| Alessi, c., Martin, J. L., Fiorentino, L., Fung, C.H., Dzierzewski, J.M., Rodriguez Tapia, J. C., Song, Y, Josephson K., Jouldjian, S., & Michelle, M.N. (2016). Cognitive behavioral therapy for insomnia in older veterans using nonclinical sleep coaches: Randomized-Controlled Trial. | To test a new cognitive behavioral therapy for insomnia (CBT-I) program designed for used by nonclinicians . | None | RCT. | Department of Veterans Affairs healthcare system: community-dwelling veterans aged 60 and older who met diagnostic criteria for insomnia of 3 months duration or longer. 1:1:1N=519. 106 received = 52 group, 54 individual Predominantly non-Hispanic male, age 72.2. Reported an average of 6 commodities. Intervention Nonclinician "sleep coach' delivered a 5-session CBTI program including stimulus control, sleep restriction, sleep hygiene, and individual cognitive therapy, with weekly telephone behavioral sleep medicine supervision. Control received 5 sessions of | IV = CBT-I DV = self-reported (7 day sleep diary), sleep onset latency (SOL), wake after sleep onset, total wake time, and sleep efficiency. PSQI, objective sleep efficiency (7-day wrist actigraphy) were measured at baseline, posttreatment, 6 months, and 12 month f/u. ISI, PHQ-9, Medical Outcomes Study 12-item Short-Form Survey version (SF-12v2) | | Intervention subjects had greater improvement than controls between the baseline and posttreatment assessments, at baseline, at 6-month, and at 12 month. Improvement in SOL, TWT, SE, PSQI, and ISI. No significant differences in SE, PHQ-9, and SF-12v2. Conclusion - Manual-based CBT-I delivered by nonclinician sleep coaches improves sleep in older adults with chronic insomnia. | Strength - Study was a blinded randomized reducing bias. Data was collected by nonmember of the research team, constancy was achieved maintain fidelity. Long-term follow up - 6 months and 12 months<br><br>Weakness - Veterans were targeted for the study selection affecting external validity. Mostly white male, which pose a problem for generalizability Participants were predominantly white male. Study uses old diagnostic criteria to define insomnia |

| Author/Title/Date | Topic/Focus/ Question | Conceptual Framework | Design/Method | Setting/Sample | Major Variables | Measurement/Data Analysis | Study Findings | Level & quality of Evidence/Strength/Weakness/Conclusion |
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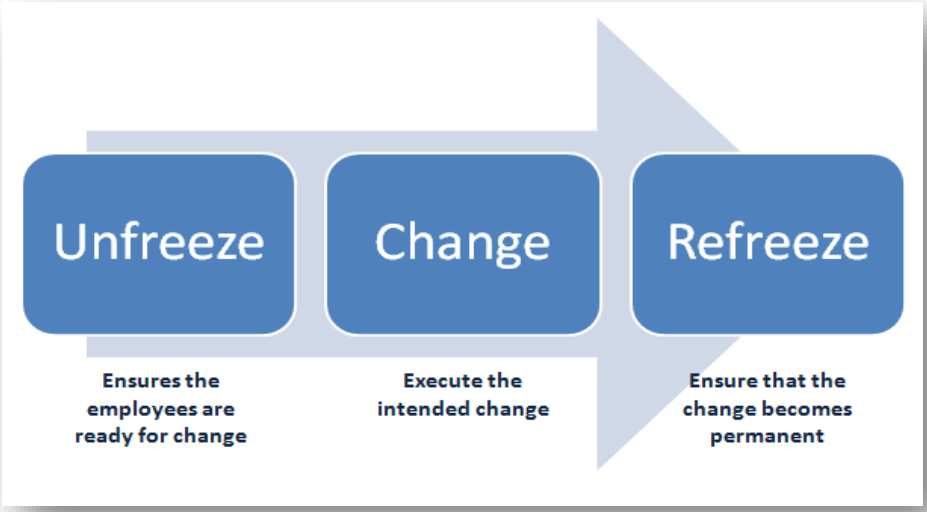
| | | | | general sleep education | | | | |

| Author/Title/Date | Topic/Focus/ Question | Conceptual Framework | Design/Method | Setting/Sample | Major Variables | Measurement/Data Analysis | Study Findings | Level & quality of Evidence/Strength/Weakness/Conclusion |
|---|---|---|---|---|---|---|---|---|
| Zhang, J. X., Liu, X.H., Zhao, D., Shan, M. S., Zhang, X. L., Kong, X. M, & Cui, H. (2015).<br><br>Mindfulness-based stress reduction for chronic insomnia in adults older than 75 years: a randomized, controlled, single-blind clinical trial. | To assess the effectiveness of mindfulness-based stress reduction (MBSR) for chronic insomnia and depressive or anxiety symptoms of older adults aged 75 years and over. | None. | Randomized, controlled, single-blind clinical trial. | Participants are 60 adults aged 75+ with chronic insomnia N=60 Race - Chinese Participants were assigned to 8weeks MBSR group or wait list control group. | PSQI, self-rating anxiety scale (SAS), GDS were taken at baseline and post treatment | Data was analyzed using SPSS 16.0. A repeat analysis of variance was used to detect changes across assessments. Data analyses were performed based on the intent-to-treat (ITT principle. Alpha criterion was set at P<.05. Cohen's d to calculate effect size | There was significant time x group interaction for the PSQI score (P=.006), the MBSR group has d a decrease in the PSQI global score, while the control did not. Among the PSQI components, there was a sig time x group interaction for daytime dysfunction. Cohen's d of the MBR group was .76, while Cohen's d of group was -.04. There was no significant time x group interaction for the SAS score whole for the GDS there was a significant time x group interaction.<br><br>Conclusion - The study demonstrated that the MBSR program could be a beneficial treatment for chronic insomnia in older adults aged 75 years and older. | Strength - Data collector was blinded to the study.<br><br>Weakness - Study is the only known study to test MBSR on chronic insomnia in adults older than 75 year Participants were Chinese which limit generalization.<br>No objective measures such as polysomnography to assessment findings, sleep assessment was primarily assessed by subjective reports.<br>Small sample size.<br>No follow up on participants after the study to assess retention of MBSR. |

Appendix B

Kurt Lewin's Change Theory



Appendix C

ACP Summary Guideline

| Disease | Disease/Condition |
|---|---|
| Target Audience | **Internists, family physicians, other clinicians** |
| Intervention Evaluated | **Adults with insomnia disorder** |
| Outcomes Evaluated | **Psychological:** CBT-I, BBT, multicomponent behavioral therapy, sleep restriction, stimulus control, relaxation therapy<br><br>**Pharmacologic:** benzodiazepines (triazolam, estazolam, temazepam, flurazepam, quazepam), nonbenzodiazepines (eszopiclone, zaleplon, zolpidem, suvorexant, melatonin, ramelteon, antidepressants)<br><br>Complementary and alternative treatments: acupuncture, Chinese herbal medicine |
| Benefits | **Older Adults**<br><br>**Psychological**<br><br>CBT-I: improved PSQI (3.0 points) and ISI (3.6 points) scores, SOL (8.2 min), WASO (37.6 min), sleep efficiency Multicomponent behavioral therapy/BBT: improved SOL (10.4 min), WASO (14.9 min), sleep efficiency, sleep quality<br><br>Stimulus control: improved TST (40.4 min)<br><br>Pharmacologic Eszopiclone: improved remission, ISI score (2.3 points), TST (30.0 min), WASO (21.6 min) Zolpidem: improved SOL (18.3 min) Ramelteon: improved SOL (10.1 min) Doxepin: improved ISI score (1.7 points), SOL (14.7 min), TST (23.9 min), WASO (17.0 min)<br><br>Complementary and alternative Insufficient evidence |
| Harms | **Psychological**: sparsely reported but likely small because of noninvasive nature of therapy<br><br>**Pharmacologic:** sparsely reported overall from the included RCTs<br><br>**Benzodiazepines**<br><br>Daytime drowsiness, dizziness or lightheadedness, dementia Increased risk for falls, hip fractures, and mobility problems in |

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| | older adults Temazepam associated with an increase in incident cancer cases<br><br>**Nonbenzodiazepines**<br>Eszopiclone: somnolence, unpleasant taste, myalgia, memory impairment, psychiatric-related adverse effects, depression, anxiety, accidental injury<br><br>Zaleplon: pain, somnolence or dizziness, gastrointestinal events, arrhythmia, hallucinations<br><br>Zolpidem: anxiety, somnolence, mood alterations, hallucinations, depression, psychiatric-related adverse events, memory and driving impairment, risk for fractures or major head injury or fracture requiring hospitalization, increase in incident cancer cases<br><br>Suvorexant: somnolence; cognitive and behavioral changes, such as amnesia, anxiety, hallucinations, and other neuropsychiatric symptoms; complex behaviors, such as “sleep-driving”; worsening of depression, including suicidal thinking in persons with depression; daytime impairments; sleep paralysis; hypnagogic/hypnopompic hallucinations<br><br>Ramelteon: dizziness; somnolence (similar to placebo); fatigue; headache; unpleasant taste; nausea; new cognitive or behavioral abnormalities; complex behaviors, such as “sleep-driving”; exacerbation of depression and suicidal ideation in primarily depressed patients<br><br>Doxepin: sedation, fatigue, weakness, lethargy, dry mouth, constipation, blurred vision, headache Infrequent but serious adverse events, such as fractures and dementia, have been reported for hypnotic drugs in observational studies. FDA label warnings include daytime impairment, “sleep driving,” behavioral abnormalities, and worsening depression in depressed patients. Complementary and alternative treatments: none reported |
| Recommendations | **Recommendation**<br><br>1: ACP recommends that all adult patients receive cognitive behavioral therapy for insomnia (CBT-I) as the initial treatment for chronic insomnia disorder. (Grade: strong recommendation, moderate-quality evidence) Recommendation<br><br>2: ACP recommends that clinicians use a shared decision-making approach, including a discussion of the benefits, harms, and costs of short-term use of medications, to decide whether to add |

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| | pharmacological therapy in adults with chronic insomnia disorder in whom cognitive behavioral therapy for insomnia (CBT-I) alone was unsuccessful. (Grade: weak recommendation, low-quality evidence) |
| Full Report | This is a partial report. Please refer to the copy of the full report provided in your folder. |

Appendix D

AASM Summary Guideline

***American Academy of Sleep Medicine Clinical Guideline for the Evaluation and Management Chronic Insomnia***

| Evaluation | Psychological and Behavioral Therapy | Pharmacological Therapy |
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| Insomnia is primarily diagnosed by clinical evaluation through a thorough sleep history and detailed medical, sub- stance, and psychiatric history. **(Standard)**<br><br>The sleep history should cover specific insomnia complaints, pre-sleep conditions, sleep-wake patterns, other sleep-related symptoms, and daytime consequences. **(Consensus)**<br><br>The history helps to establish the type and evolution of insomnia, perpetuating factors, and identification of comorbid medical, substance, and/or psychiatric conditions. **(Consensus)**<br><br>Additional assessment instruments that may aid in the baseline evaluation and outcomes follow-up of patients with chronic insomnia include measures of subjective sleep quality, psychological assessment scales, daytime function, quality of life, and dysfunctional beliefs and attitudes. **(Consensus)**<br><br>Physical and mental status examination may provide important information regarding comorbid conditions and differential diagnosis. **(Standard)** | Psychological and behavioral interventions are effective and recommended in the treatment of chronic primary and comorbid (secondary) insomnia. **(Standard)**<br><br>These treatments are effective for adults of all ages, including older adults, and chronic hypnotic users. **(Standard)**<br><br>These treatments should be utilized as an initial intervention when appropriate and when conditions permit. **(Consensus)**<br><br>Initial approaches to treatment should include at least one behavioral intervention such as *stimulus control therapy or relaxation therapy, or the combination of cognitive therapy, stimulus control therapy, sleep restriction therapy with or without relaxation therapy*—otherwise known as cognitive behavioral therapy for insomnia (CBT-I). **(Standard)**<br><br>Multicomponent therapy (without cognitive therapy) is effective and recommended | Short-term hypnotic treatment should be supplemented with behavioral and cognitive therapies when possible. **(Consensus)**<br><br>When pharmacotherapy is utilized, the choice of a specific pharmacological agent within a class, should be directed by: (1) symptom pattern; (2) treatment goals; (3) past treatment responses; (4) patient preference; (5) cost; (6) avail- ability of other treatments; (7) comorbid conditions; (8) contraindications; (9) concurrent medication interactions; and (10) side effects. **(Consensus)**<br><br>For patients with primary insomnia (psychophysiologic, idiopathic or paradoxical ICSD-2 subtypes), when pharmacologic treatment is utilized alone or in combination therapy, the recommended general sequence of medication trials is: Short-intermediate acting benzodiazepine receptor agonists (BZD or |

Polysomnography and daytime multiple sleep latency testing (MSLT) are not indicated in the routine evaluation of chronic insomnia, including insomnia due to psychiatric or neuropsychiatric disorders. **(Standard)**

Polysomnography and daytime multiple sleep latency testing (MSLT) are not indicated in the routine evaluation of chronic insomnia, including insomnia due to psychiatric or neuropsychiatric disorders. **(Standard)**

Polysomnography is indicated when there is reason- able clinical suspicion of breathing (sleep apnea) or movement disorders, when initial diagnosis is uncertain, treatment fails (behavioral or pharmacologic), or precipitous arousals occur with violent or injurious behavior. **(Guideline)**

Actigraphy is indicated as a method to characterize circadian rhythm patterns or sleep disturbances in individuals with insomnia, including insomnia associated with depression. **(Option)**

Other laboratory testing (e.g., blood, radiographic) is not indicated for the routine evaluation of chronic insomnia unless there is suspicion for comorbid disorders. **(Consensus)**

therapy in the treatment of chronic insomnia. **(Guideline).**

Other common therapies include *sleep restriction*, *paradoxical intention*, and *biofeedback therapy*. **(Guideline)**

Although all patients with chronic insomnia should adhere to rules of good *sleep hygiene*, there is insufficient evidence to indicate that sleep hygiene alone is effective in the treatment of chronic insomnia. It should be used in combination with other therapies. **(Consensus)**

When an initial psychological/ behavioral treatment has been ineffective, other psychological/ behavioral therapies, combination CBT-I therapies, combined treatments (see below), or occult comorbid disorders may next be considered. **(Consensus)**

**Combined Treatments:**

The use of combined therapy (CBT-I plus medication) should be directed by (1) symptom pattern; (2) treatment goals; (3) past treatment responses; (4) patient preference; (5) cost; (6) availability of other treatments; (7) comorbid

newer BzRAs) or ramelteon: examples of these medications include zolpidem, eszopiclone, zaleplon, and temazepam. **(Consensus).** Alternate short-intermediate acting BzRAs or ramelteon if the initial agent has been unsuccessful. Sedating antidepressants, especially when used in conjunction with treating comorbid depression/anxiety: examples of these include trazodone, amitriptyline, doxepin, and mirtazapine. Combined BzRA or ramelteon and sedating antidepressant. Other sedating agents: examples include anti-epilepsy medications (gabapentin, tiagabine) and atypical antipsychotics (quetiapine and olanzapine). These medications may only be suitable for patients with comorbid insomnia who may benefit from the primary action of these drugs as well as from the sedating effect.

Over-the-counter antihistamine or antihistamine/analgesic type drugs (OTC “sleep aids”) as well as herbal and nutritional substances (e.g., valerian and melatonin) are not recommended in the treatment of chronic insomnia due to the relative

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| | conditions; (8) contraindications; (9) concurrent medication interactions; and (10) side effects. **(Consensus)**<br><br>Combined therapy shows no consistent advantage or disadvantage over CBT-I alone. Comparisons to long-term pharmacotherapy alone are not available. **(Consensus)** | lack of efficacy and safety data. **(Consensus)**<br><br>The following guidelines apply to prescription of all medications for management of chronic insomnia: **(Consensus)**<br><br>Pharmacological treatment should be accompanied by patient education regarding: (1) treatment goals and expectations; (2) safety concerns; (3) potential side effects and drug interactions; (4) other treatment modalities (cognitive and behavioral treatments); (5) potential for dosage escalation; (6) rebound insomnia.<br><br>Patients should be followed on a regular basis, every few weeks in the initial period of treatment when possible, to assess for effectiveness, possible side effects, and the need for ongoing medication.<br><br>Efforts should be made to employ the lowest effective maintenance dosage of medication and to taper medication when conditions allow.<br><br>Medication tapering and discontinuation are facilitated by CBT-I.<br><br>Chronic hypnotic medication may be indicated for long-term use |

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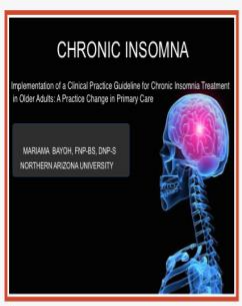
| | in those with severe or refractory insomnia or chronic comorbid illness. Whenever possible, patients should receive an adequate trial of cognitive behavioral treatment during long-term pharmacotherapy.<br><br>Long-term prescribing should be accompanied by consistent follow-up, ongoing assessment of effectiveness, monitoring for adverse effects, and evaluation for new onset or exacerbation of existing comorbid disorders<br><br>➢ Long-term administration may be nightly, intermit- tent (e.g., three nights per week), or as needed. |

# Appendix E

## PowerPoint Presentation

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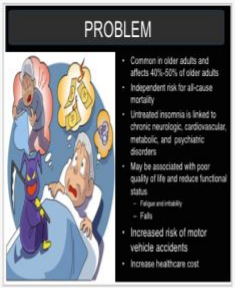


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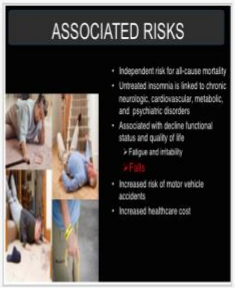


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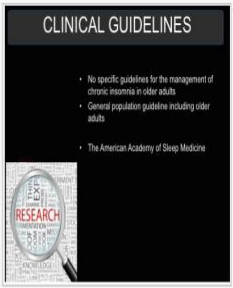


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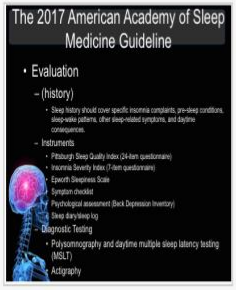


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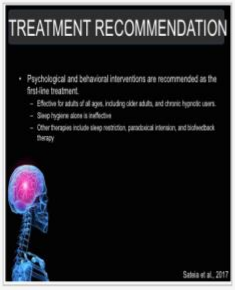


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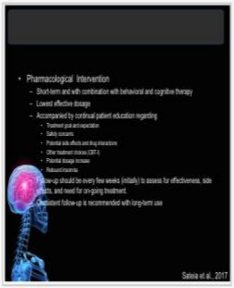


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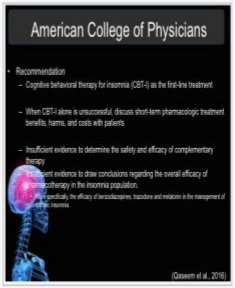


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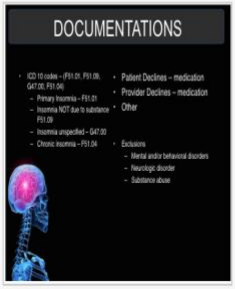


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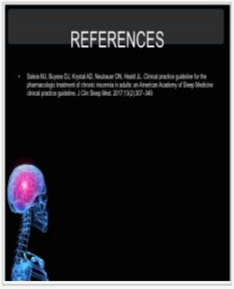


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Appendix F

Pre-intervention Survey

As part of a quality improvement project, you will participate in a 60 minute educational and discussion session to enhance your knowledge regarding the use of CBT for treating chronic insomnia (CI) in older patients. Before the session, please complete this short survey regarding your level of awareness and perceptions of barriers to using CBT as a first line of treatment.

I thank you for taking the time to complete this short survey.

- Mariama Bayoh, FNP-BC
Doctor of Nursing Practice Candidate
Northern Arizona University

1. Have you heard of the 2016 American College of Physician (ACP) guidelines or the 2017 American Academy of Sleep Medicine (AASM) guidelines on chronic insomnia treatment in adults?

   ☐ YES
   ☐ NO

2. Do you believe the guidelines can improve patient care outcomes?

   ☐ YES
   ☐ NO

3. Name the **two most pressing barriers** you have encountered in treating chronic insomnia in older adults.

1. _____
2. _____

4. Would you be willing to support the implementation of an evidence-based insomnia treatment in older adults in this primary care/internal medicine clinic?

   ☐ YES
   ☐ NO

5. Please offer any **feedback** or **thoughts** you may have about treating older patients with CI.

_____
_____
_____

Appendix G

Post-Intervention Survey

As part of a quality improvement project, on October 18, 2018, you participated in a 60 minute educational and discussion session to enhance your knowledge regarding the use of CBT as a first line of treatment for chronic insomnia (CI) in older patients. Before the session, you completed a short survey to measure your baseline level of awareness and perceptions regarding barriers to using CBT. You are being asked to complete a short follow-up survey to explore changes in perceptions and practices that may have occurred in the three months after participating in the training.

Again, I thank you for taking the time to complete this short survey.

- Mariama Bayoh, FNP-BC
Doctor of Nursing Practice Candidate
Northern Arizona University

1. Have you heard of the 2016 American College of Physician (ACP) guideline or the 2017 American Academy of Sleep Medicine (AASM) guideline on chronic insomnia treatment in adults?

   ☐ YES
   ☐ NO

2. Do you believe the guidelines can improve patient care outcomes?

   ☐ YES
   ☐ NO

3. Name the **two most pressing barriers** you have encountered in treating chronic insomnia in older adults.

   _____

   _____

4. The information session you attended increased your **awareness** about using CBT as a first line of treatment of CI for the elder patients.

   ☐ Strongly Agree
   ☐ Somewhat Agree
   ☐ Somewhat Disagree
   ☐ Strongly Disagree

5. The information session you attended **increased** the likelihood of **prescribing CBT** as a first-line of treatment of CI for older patients with CI.

☐ Strongly Agree
☐ Somewhat Agree
☐ Somewhat Disagree
☐ Strongly Disagree

6. The information session you attended lead you to **decrease** the amount or strength of pharmaceutical **medications you prescribe** to your older patients with CI.

☐ Strongly Agree
☐ Somewhat Agree
☐ Somewhat Disagree
☐ Strongly Disagree

7. Can you offer any **feedback** on how the information session may have changed your practice patterns when treating older patients with CI?

_____

_____

_____

_____

_____

# Appendix H

## Northern Arizona University Approval Letter

NORTHERN ARIZONA UNIVERSITY | Office of Regulatory Compliance

Institutional Review Board
Human Research Subjects Protection Program

805 S Beaver St
Building 22, Room 215
PO Box: 4062
Flagstaff AZ 86011
928-523-9551
http://nau.edu/Research/Compliance/Human-Subjects/Welcome

| | |
|---|---|
| **To:** | Mariama Bayoh, FNP/MSN, DNP Student |
| **From:** | NAU IRB Office |
| **Date:** | July 27, 2018 |
| **Project:** | Implementing an evidence-based clinical guideline to treat insomnia in older adults in a primary care clinic. |
| **Project Number:** | 1253713-1 |
| **Submission:** | New Project |
| **Review Level:** | Administrative Review |
| **Action:** | NOT RESEARCH |
| **Project Status:** | Not Research |

The project listed above does not require oversight by the Northern Arizona University Institutional Review Board because the project does not meet the definition of 'research' and/or 'human subject'.

- **Not Research as defined by 45 CFR 46.102(d):** As presented, the activities described above do not meet the definition of research as cited in the regulations issued by the U.S. Department of Health and Human Services which state that "research means a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge".
- **Not Human Subjects Research as defined by 45 CFR 46.102(f):** As presented, the activities described above do not meet the definition of research involving human subjects as cited in the regulations issued by the U.S. Department of Health and Human Services which state that "human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information".

Note: Modifications to projects not requiring human subjects review that change the nature of the project should be submitted to the Human Research Protection Program (HRPP) for a new determination (e.g. addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the research question). Please contact the HRPP to consult on whether the proposed changes need further review.

Northern Arizona University maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #0000357).

Appendix I

Health Institution Approval Letter

Banner Research

Date: September 27, 2018

To: Mariama Bayoh, BSN, MSN/FNP, DNP-Student

RE: *Banner Health Approval for Project*

Project Title: Implementation of an Evidence-Based Clinical Practice Guideline for Chronic Insomnia Treatment in Older Adults: A Practice Change in Primary Care.

Banner Research Determination Committee: Project #18-016, Not Research

Dear Ms. Bayoh,

Thank you for the time and effort you and your staff have put forth on submitting the above named project. This serves as the official notification that your project application was approved. You may now begin your project.

This project has received all of the following required approvals to begin your project:

- NAU IRB review and approval
- Letter of support, Director of Professional Practice
- Banner Research Determination Application Process and Data Collection
- Banner Research Determination Committee review and approval

We value your efforts to work with us to ensure quality conduct of your project and protection of patients. If you have any questions please do not hesitate to contact me. We are interested in your findings and look forward to results of your project which will further support our mission of "making health care easier so life can be better".

Please retain this letter for your records.

Sincerely,

Karen Johnson, PhD, RN
Research Director, Nursing