Adapting an Evidence-Based Insomnia Practice Guideline for Use in a University Healthcare Setting

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Dedication

This work is dedicated with love to my husband Michael, whose encouragement made it possible. It is not as wonderful as your poetry, but I know you appreciate it anyway. Now there will be more free time for our further adventures!

Abstract

Recent evidence-based practice guidelines (EBPGs) recommend cognitive-behavioral therapy for insomnia (CBT-I) as first-line treatment for adults with chronic insomnia, with pharmacotherapy as a secondary option. Pharmacotherapy is often used in primary care settings, which have limited access to specialty CBT-I services. Proven lower-intensity CBT-I components and delivery modes can be customized for primary care. The purpose of this DNP project was to adapt an insomnia EBPG for use at a university health service with integrated primary care and mental health resources. The integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework guided this project, involving primary care and mental health providers in decision-making about guideline adaptation. A Plan-Do-Study-Act (PDSA) cycle included provider education, guideline tool development, and implementation of CBT-I client education and referral. A pre- and post-survey design used the Organizational Readiness to Change Assessment (ORCA) to assess providers' perspectives on the evidence, context, and facilitation strategies. Aggregate clinical data was used to measure changes in CBT-I referrals and insomnia prescriptions. ORCA responses indicate providers' readiness to implement insomnia EBP change based on the new clinical tools, project context, and facilitation strategies, without a significant change pre- to post-survey. Also, clinical data did not detect a significant change in CBT-I referrals or insomnia prescriptions. Further PDSA cycles are recommended to refine implementation of evidence-based insomnia care, using mixed data collection methods for more detailed evaluation.

Keywords: insomnia, CBT-I, practice guidelines, i-PARIHS, guideline implementation

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Section 1: Introduction to the Problem

Background

Evidence-based treatment for sleep-wake disorders is a complex and burgeoning area of study and practice because of increasing prevalence and new knowledge about these disorders and their treatment. One of many sleep-wake disorders, insomnia occurs when a person has difficulty falling asleep (sleep onset latency) or maintaining sleep (wake after sleep onset), or has poor quality sleep at least three times per week and lasting at least three months, and experiences daytime distress or dysfunction as a result (American Psychiatric Association [APA], 2013). Previously seen as a symptom of another condition, insomnia disorder is now recognized as a separate condition in need of treatment, even when comorbid with another condition such as depression (APA, 2013).

Insomnia increases the risk of work disability, use of sick leave, and a decrease in work performance (Riemann et al., 2015), and is associated with psychiatric disorders, diabetes, and cardiovascular disorders, among other health problems (Winkelman, 2015). Individuals with persistent insomnia have an increased risk of mortality from cardiovascular causes (Parthasarathy et al., 2015). Even in the absence of comorbid health problems insomnia decreases the quality of life, which improves when insomnia is successfully treated (Ishak et al., 2012).

The age-adjusted prevalence of insomnia in a large sample of U.S. adults increased from 17.4% in 2002 to 18.8% in 2012, which is an 8% relative increase (Ford, Cunningham, Giles, & Croft, 2015). Among demographic groups in the study, the largest relative increase in

prevalence, 30.9%, occurred among young adults age 18-24 years (Ford et al., 2015). This higher prevalence is particularly concerning because behavioral health patterns are forming at that age, and early onset of insomnia may result in a larger lifetime burden and negative health effects (Ford et al., 2015). In a large sample of college students, 9.5% met diagnostic criteria for chronic insomnia (Taylor, Bramoweth, Grieser, Tatum, & Roane, 2013). Data from the American College Health Association (2016) student survey during 2015 showed that 23.4% of students at the project site, a university in the southwestern U.S., reported a negative academic impact related to sleep problems, compared to 20% of college students nationally.

Clinical Problem

Treatment of insomnia in primary care settings, where clients with insomnia first present, tends to rely on pharmacotherapy. From 1999 to 2010 there was a 29% increase in the number of outpatient physician visits for insomnia and a 200% increase in the number of visits resulting in a prescription for sleep medication (Ford et al., 2014). However, evidence-based practice guidelines (EBPGs) for treatment of chronic insomnia recommend cognitive-behavioral therapy for insomnia (CBT-I) as a first-line treatment because of its relatively longer-term effectiveness and fewer side effects compared to sleep medications (Qaseem, Kansagara, Forciea, Cooke, & Denberg, 2016; Schutte-Rodin, Broch, Buysse, Dorsey, & Sateia, 2008). CBT-I begins with a thorough assessment of sleep patterns and practices and consists of sleep education, stimulus control to improve sleep practices, sleep restriction to increase sleep efficiency, and cognitive therapy to addresses maladaptive thoughts that perpetuate insomnia (Morin et al., 2016). CBT-I provides clients with behavioral and cognitive tools for eventual self-care of their sleep-wake cycles.

Moderate-quality evidence supports the effectiveness of CBT-I in the general adult population in improving sleep onset latency, wake after sleep onset, sleep efficiency, and sleep quality (Qaseem et al., 2016). Research comparing CBT-I and pharmacotherapy indicate the similar short-term effectiveness of these two modalities and better long-term effectiveness of CBT-I but is limited by small sample sizes and rigid pharmacotherapy protocols that do not reflect the reality of clinical practice (Morin et al., 2016).

Clients' perceptions about insomnia treatment methods influence their help-seeking behaviors, adherence to recommended treatment, and satisfaction with their treatment experiences (Cheung, Bartlett, Armour, & Saini, 2015). Some clients have expressed concern about the potential for side effects or dependence associated with pharmacotherapy (Cheung et al., 2015). Expanding insomnia treatment options to include CBT-I increases the likelihood of treatment acceptability for clients. Unfortunately, CBT-I is not usually available in primary care settings, and there is a national shortage of qualified CBT-I therapists (Manber et al., 2012). Even when CBT-I therapists are readily available, rates of referral for CBT-I may be low because providers lack knowledge about CBT-I and its effectiveness, indicating a need for wider knowledge dissemination about evidence-based insomnia treatment (Conroy & Ebben, 2015).

Sleep researchers have proposed various strategies for disseminating CBT-I more widely to clients with insomnia, including increased CBT-I training of psychotherapists, training non-sleep specialists such as nurse practitioners to provide CBT-I (Fields, Schutte-Rodin, Myers, & Perlis, 2013; Manber et al., 2012), and using less intense CBT-I strategies. Clients can start with self-administered CBT-I via booklet or CD/DVD, and simple behavioral strategies or internet-guided programs, reserving time-intensive, specialized therapy for clients who do not respond to initial treatment (Espie, 2009.) A movement to integrate mental health and primary care services

provides opportunities to make CBT-I available in primary care settings where clients with insomnia usually seek care (Goodie & Hunter, 2014). Investigation of effective CBT-I delivery methods in primary care is ongoing.

In primary care settings clients seeking help for insomnia, or another problem combined with insomnia, often have inadequate knowledge about healthy sleep practices as well as the expectation that the only treatment option is medication (Moloney, Konrad, & Zimmer, 2011). Primary care providers (PCPs) often lack the time and knowledge to educate clients about healthy sleep practices and cognitive-behavioral treatments, and in a well-meaning effort to help, are likely to prescribe sleep medication (Conroy & Ebben, 2015). Clients with persistent insomnia requiring ongoing treatment may come to depend on sleep medication, even when they and their PCPs are concerned about long-term use and dependence. PCPs sometimes provide brief education about sleep practices, also known as sleep hygiene. Sleep hygiene education has been associated with improved sleep, but CBT-I is significantly more effective for treating insomnia disorder (Chung et al., 2017; Morgenthaler et al., 2006).

The PCPs and psychiatric providers at a university health service (Campus Health Services [CHS]) in the southwestern U.S. have expressed interest in learning about effective insomnia treatment. In fall 2015, a local sleep medicine specialist was invited to give an in-service about insomnia treatments to health service providers which included information about CBT-I. However, the providers lack the time and specific skill to provide CBT-I strategies to clients. There is a CBT-I specialist at a local sleep medicine clinic off-campus, but many CHS clients lack the financial and transportation resources to utilize this option. PCPs and psychiatric providers have indicated that they provide sleep hygiene education to clients, but this has limited benefit without additional behavioral strategies. During a 4-month period in fall 2016, CHS

PCPs and psychiatric providers wrote 143 sleep medication prescriptions for clients (L. Reynolds, personal communication, December 7, 2016). Although this number represents just 1.7% of all prescriptions written during the same period, it indicates there may be missed opportunities to provide CBT-I instead of pharmacotherapy. This underutilization is particularly pertinent in a healthcare environment largely serving young adults who can reap lifelong health benefits from this intervention.

Intended Improvement

The intended improvement of the project was to close the gap between insomnia evidence and practice, utilizing primary care and mental health resources so that university health service providers can offer clients CBT-I as an evidence-based treatment option. CHS is an interprofessional setting which includes counseling services. The counseling staff has been developing a behavioral health consultation (BHC) program to increase behavioral treatment resources for clients seen by medical and nursing providers. The counseling director indicated that the BHC program would include insomnia treatment and was interested in collaborative program development (C. O'Saben, personal communication, December 8, 2016). This presented an opportunity for the expansion of evidence-based insomnia treatment in-house.

Adapting an evidence-based insomnia treatment guideline for CHS to include CBT-I strategies was intended to increase accessible treatment options for mutual decision-making based on evidence, provider experience, and client preference. Guidelines are more likely to be used when guideline implementation (GI) tools such as training material, guideline summaries or algorithms, and client information are included (Gagliardi, Brouwers, & Bhattacharyya, 2015). Therefore, the development of useful GI tools would provide essential support for providers' ability to implement CBT-I treatment strategies.

Clinical Question

The CHS providers were considered key to the translation of insomnia research into clinical practice. Thus the clinical question asked: Do primary care and psychiatric providers in a university health service utilize CBT-I treatment options for their clients when given education about insomnia guidelines and CBT-I clinical resources tailored for their practice?

Because of the project's short time frame and focus on guideline implementation, implementation outcomes rather than client outcomes were deemed appropriate for answering the clinical question. Providers' readiness for this practice change and their satisfaction with guideline implementation strategies would increase the likelihood of guideline adoption (Proctor et al., 2011).

Purpose of the Project

The purpose of this DNP project was to adapt insomnia EBPGs for use at a university health service, integrating primary care and mental health resources to include CBT-I as a treatment option. The focus was on practice change by primary care and psychiatric providers while setting the stage for collaboration with counselors as they prepared to offer BHC services.

Section 2: Review of the Literature

The purpose of this literature search was to identify evidence-based treatment options for insomnia disorder which are feasible for healthcare providers serving a university campus community to implement in their daily practice. The objective was 2-fold: 1. Assessing the evidence regarding CBT-I as first-line treatment for insomnia instead of the routine use of pharmacologic treatment or sleep hygiene recommendations would indicate whether practice change was justified. 2. Identifying evidence-based CBT-I strategies suitable for a university

primary care setting that are not resource-intensive and thus are feasible would provide a direction for practice change.

Search Strategy and Process

The search strategy was first to identify and assess studies pertinent to the general topic of evidence-based insomnia treatment, then to narrow the search to the clinical population of concern (Terry, 2015). Databases searched include CINAHL, MEDLINE/PubMed, and PsycINFO. These were selected based on previous experience, textbook suggestions (LoBiondo-Wood & Haber, 2014; Melnyk & Fineout-Overholt, 2015), and the clinical question. CINAHL and PubMed (Medline) provided sources in nursing, medical, and other health professional journals, whereas PsycINFO contained a greater variety of psychological sources related to cognitive behavioral therapy for insomnia.

CINAHL. The search terms *insomnia* AND *cognitive-behavioral therapy*, with the Boolean operator AND, were used for the initial search. Results were filtered for the last five years, English only, age group all adults, and peer reviewed, which yielded 146 articles. An additional filter of research articles was added, reducing the number to 54 articles. Adding filters for outpatient setting and evidence-based practice was too limiting, so these were removed. Titles and when indicated abstracts were reviewed, eliminating articles limited to specific comorbidities such as cancer, or insomnia in older adults. A list of 18 articles was printed for more detailed review.

PubMed (Medline). The search terms noted above were used in PubMed, filtered for the last five years, adults 19-44 and 45-64 years, English only, clinical trial, systematic review, meta-analysis, and practice guideline, which yielded 141 articles. Titles and abstracts were

reviewed to narrow results to eliminate special populations not relevant to the search, and a list of 34 articles was printed for further review.

PsycINFO. The search terms *insomnia* AND *cognitive behavioral therapy* (without the hyphen) were used for this database because of lack of results with the hyphenated term. Filters were the last five years, adults 18 years and older, English only, peer-reviewed, intended audience: all. Filtering intended audience by professional and research was too limiting. This search yielded 212 articles, and after reviewing titles and abstracts, a list of 49 articles was selected for more detailed review.

More specific search terms were also utilized including *CBT-I* (abbreviation of initial search terms), *college students*, *university students*, *stepped care*, *psychological treatment*, and *primary care* which were combined with *insomnia*, but these searches did not provide additional relevant articles initially. However, a recently updated search of PubMed (Medline) using the term *CBT-I* alone yielded one of the keeper studies.

The Cochrane Library was also searched for *insomnia* as well as *cognitive-behavioral therapy* but did not yield relevant results.

The CINAHL search provided two of the keeper studies, PubMed (Medline) provided three keeper studies and one keeper was identified in the PsycINFO search.

Other sources. Five studies had already been identified during the previous year through informal database searches in CINAHL and PubMed (Medline) and other searches. For example, an internet search for insomnia clinical practice guidelines identified information at the American College of Physicians (ACP) website about an insomnia guideline in process. Monitoring this website yielded the ACP insomnia practice guideline upon its release, along with the related comparative effectiveness review and evidence reports.

Selection of Studies

A perusal of the abstracts provided an initial screening of article content for relevance to the clinical question. Some of the articles, such as relevant systematic reviews of CBT-I and the recent evidence-based practice guideline, were appropriate for answering the clinical question. Studies that were included in the retained systematic reviews and meta-analyses were excluded from the keeper list, except for one pertinent study. Further appraisal of other articles for the quality of evidence and pertinence to the clinical question determined their value for inclusion. Resources at the clinical site were also considered. For example, a systematic review of CBT-I delivered by group format was excluded because the clinical site currently lacks the resources to provide group CBT-I.

Studies that were retained fulfill the objectives of providing evidence for CBT-I as a first-line treatment for insomnia instead of routine pharmacologic treatment and identifying feasible evidence-based strategies suitable for a university primary care setting. A systematic review of pharmacologic insomnia treatment (Wilt et al., 2016) was included as the comparison treatment, and also provides useful evidence for clinicians treating insomnia. See Appendix B for the Evaluation Table of Retained Studies.

Review of Retained Studies

An evidence-based clinical guideline for treating insomnia disorder in adults, recently published by the American College of Physicians, forms the basis for identifying key interventions for effective care (Qaseem et al., 2016). The guideline is based on a comparative effectiveness review commissioned by the Agency for Healthcare Quality and Research that evaluated evidence from 169 randomized controlled trials (RCTs) and 12 observational studies of psychological, pharmacologic, and complementary and alternative medicine treatment options

(Brasure et al., 2015). The review was a comprehensive and up-to-date meta-analysis using a sound development strategy. The practice guideline was sponsored by the ACP, a credible organization, was peer-reviewed and is clinically relevant for primary care as well as specialty practice. A weakness of the comparative effectiveness review is that heterogeneous CBT-I interventions limit consistency, but data were pooled only when derived from similar studies. The guideline recommends that 1) all adult patients receive CBT-I for chronic insomnia disorder (strong recommendation, moderate-quality evidence), and 2) when CBT-I unsuccessful, use shared decision-making with patients to decide whether to add medication (weak recommendation, low-quality evidence). There was insufficient evidence to compare insomnia treatments or identify harms. The recommendations call for a change in usual practice in primary care settings and require the development of feasible strategies to make CBT-I more accessible.

Separate evidence reports for the ACP insomnia practice guideline focused on psychological and behavioral insomnia interventions and pharmacologic insomnia interventions, supporting the guideline recommendations (Brasure et al., 2016; Wilt et al., 2016). Both were systematic reviews of RCTs, but the review of pharmacologic treatments also included observational studies and other sources to identify adverse effects (Wilt et al., 2016). Strengths of both reviews include strict inclusion and exclusion criteria and elimination of biased studies. Because of the possible adverse effects of sleep medications, the review of pharmacologic interventions had a six-month study period to assess for harms (Wilt et al., 2016). Weaknesses of the psychological and behavioral interventions review are small sample sizes in single-component behavioral trials, limited ability to pool data because of study heterogeneity, insufficient data on adverse effects and withdrawals, and lack of global outcome reporting (Brasure et al., 2016). Global outcomes included the effects of sleep on daytime functioning such

as fatigue in addition to specific sleep measures such as sleep onset latency. Weaknesses of the pharmacologic interventions review are a large placebo response and lack of global outcome reporting (Wilt et al., 2016). Brasure et al. (2016) found support for the effectiveness of full CBT-I and single-component stimulus control for insomnia disorder when provided by clinicians trained in those therapies, with some evidence of sustained benefit six months after treatment. Regarding the alternative, pharmacologic treatment, Wilt et al. (2016) showed a small beneficial effect of three sleep medications compared to placebo, which must be weighed against possible adverse effects, and no evidence for long-term benefit post-treatment.

A systematic review and meta-analysis of CBT-I published a year before the practice guideline, and related evidence reports also supported CBT-I as a first-line insomnia treatment (Trauer, Qian, Doyle, Rajaratnam, & Cunningham, 2015). The relatively narrow inclusion criteria minimized study heterogeneity and a long follow-up period with multiple measurements allowed assessment of sustained treatment benefits. However, global sleep outcomes were not assessed. The review found that in-person, multiple-component CBT-I with at least three in-person sessions was effective for improving sleep.

Taylor and Pruiksma (2014) investigated the efficacy of CBT-I in psychiatric populations in their systematic review. Insomnia is frequently comorbid with psychiatric diagnoses, so this is a highly significant question. However, the authors searched only two databases, and CBT-I was loosely defined and operationalized. They found that in-person CBT-I improved sleep as well as symptoms of depression and anxiety in the 16 RCTs reviewed.

A meta-analysis of self-help CBT-I RCTs was conducted, using an extensive literature search with self-help CBT-I and clinical improvement criteria clearly defined (Ho et al., 2015). All methodology was explicitly stated in detail in the article. Self-help CBT-I was delivered by

various media including printed, audio-visual, and computer-based. Exclusion of medical and psychiatric comorbidity limits the results' generalizability to real-world primary care populations. Self-help CBT-I improved several sleep measures immediately post-treatment, and at one to three months post-treatment the beneficial effects were maintained (Ho et al., 2015). In RCTs which reinforced self-help CBT-I with telephone consultation by a therapist, they found an even larger effect size. This is useful information to consider when designing insomnia intervention.

In a systematic review and meta-analysis investigated conducted by Seyffert et al. (2016), RCTs of comprehensive internet-delivered CBT-I comprising multiple therapy components and sessions were evaluated. The authors employed an extensive literature search and used within- and between-group comparisons for the final effect. Most of the studies were similar enough for meta-analysis (13 out of 15). The sample was largely middle-aged European adults, although a small proportion were university students. The component trials did not specifically report adverse effects of treatment, which would be useful to report in future studies. There was a clinically meaningful improvement in sleep, with insomnia severity decreasing from moderate severity to sub-threshold according to a validated instrument (Seyffert et al., 2016).

A smartphone app designed to enhance CBT-I was evaluated in a descriptive survey of the mobile app CBT-I Coach (Kuhn et al., 2016). CBT-I Coach was developed to supplement clinician-delivered CBT-I in Veterans Affairs (VA) clinics but is also suitable for civilians. It provides clients with sleep assessment tools and reinforcement of CBT-I strategies, collecting data that can be shared with their clinicians. CBT-I clinicians were surveyed pre- and post-release of the app regarding their perceptions, intention to use (pre-release), and actual uptake of the app (post-release). The surveys were internally consistent and assessed factors related to

diffusion of innovation. However, the pre-release sample (n=138) differed from the post-release sample (n=176) because of clinician turnover, which limits conclusions. Nevertheless, the post-release survey indicated almost half of clinicians with CBT-I clients were using the app and more strongly agreed that it improved homework adherence and client outcomes, compared to clinicians not using the app with CBT-I clients (Kuhn et al., 2016). The authors suggest further study comparing insomnia outcomes in clients using and not using the app.

Because on average the subjects in the preceding insomnia intervention studies are predominantly middle-aged individuals, it is useful to include studies of college students. No systematic reviews of CBT-I with college-aged or predominantly young adult samples were found. A quasi-experimental study tested an e-mail delivered CBT program for sleep health in college students (n=58) (Trockel, Manber, Chang, Thurston, & Tailor, 2011). A comparison group (n=67) received a similar program with different content promoting emotional health and stress-coping strategies. There are several weaknesses of the study. Samples were drawn from a general student population, not limited to those with insomnia. Sample sizes were small, there was no randomization or control, dependent variables were assessed by only one measure each, and there was no long-term follow-up. However, in the group receiving the sleep health program, students with poor sleep at the program's beginning had improved sleep and a relatively high completion rate, suggesting that electronic self-help strategies are a promising strategy for college students (Trockel et al., 2011).

Another study conducted with college students was an RCT designed to pilot test whether CBT-I is an effective treatment for insomnia and daytime functioning in this population (Taylor et al., 2014). In-person, comprehensive CBT-I was provided to a small treatment group in six sessions. Strengths of this study include intervention fidelity, multiple measures of sleep and

daytime functioning, and 3-month follow-up. The sample size was small (n=35), but a power analysis indicated it was adequate, and effect sizes were large. The CBT-I group experienced substantial improvement in sleep measures and decreased general fatigue (Taylor et al., 2014). Although this study was included in previously described systematic reviews (Brasure et al., 2016; Trauer et al., 2015), it is highlighted here because of the specific application to college students.

Literature Synthesis

As a group, the retained studies provide high-level evidence for the use of CBT-I as the first-line treatment for all adults with chronic insomnia disorder. When CBT-I alone is ineffective, selected pharmacotherapeutic agents may provide short-term benefit (Wilt et al., 2016). Seven of the ten articles are systematic reviews or meta-analyses, with one evidence-based practice guideline, providing Level I evidence. A systematic review of CBT-I in psychiatric populations endorses its benefits for clients with comorbid mental health problems (Taylor & Pruiksma, 2014). This is pertinent information for a university health service, where clients with mental health problems are often encountered. Systematic reviews also support the effectiveness of self-help and internet CBT-I delivery, which are feasible options for a primary care college health service. The body of evidence for CBT-I is large, consistent, and of moderate quality (Qaseem, 2016). The selection of keeper studies is consistent with the search for evidence regarding CBT-I and specific implementation strategies.

Where demographic information about samples was stated in the retained studies, the majority of individuals were usually White, female, and middle-aged. The studies conducted with college populations reported younger samples age 18 to 22 years, with 41 to 50% being of non-White race or ethnicity. See Appendix C for the Synthesis Table of Retained Studies.

A literature search to investigate CBT-I yielded several key concepts. There is general agreement that CBT-I is an effective insomnia treatment in the general adult population (Brasure et al., 2016; Qaseem et al., 2016), and that it should be available as the first-line treatment because of its long-term effectiveness (Qaseem et al., 2016). Various modes of CBT-I result in improved sleep measures, including self-help CBT-I via internet-based programs or books, group therapy, brief individual behavioral therapy, and full CBT-I by a sleep specialist (Brasure et al., 2016; Ellis, Cushing, & Germain, 2015; Fernando, Arroll, & Falloon, 2013; Ho et al., 2015; Koffel, E., Koffel, J., & Gehrman, 2015; Qaseem et al., 2016; Seyffert et al., 2016). CBT-I improves sleep in psychiatric populations (Taylor & Pruiksma, 2014) as well as general populations without significant comorbidity. Although CBT-I is considered unlikely to cause harmful effects, one study demonstrated increased daytime somnolence and objectively impaired vigilance with sleep restriction therapy (SRT), a component of CBT-I (Kyle et al., 2014). CBT-I trials have not consistently reported adverse effects or subject withdrawals (Brasure et al., 2016), which is important information for determining relative risks and benefits of treatment.

Because CBT-I is underutilized in primary care settings (Falloon et al., 2015; Fernando et al., 2013), development of stepped care approaches to CBT-I has been advocated to increase access (Espie, 2009; Mack & Rybarczyk, 2011). Stepped care models are intended to provide value-based care through varying care intensity levels, with those not responding to a lower intensity level being stepped up to the next level (Espie, 2009). Stepped care must take into account matching the appropriate level of care to the client's needs, and monitor the client's progress so care level can be intensified if needed. An essential feature of stepped care treatment is that it has a self-correcting mechanism to monitor clients' progress and outcomes so their treatment can be stepped up if improvement is inadequate (Bower & Gilbody, 2005). The first

step for most clients is the least restrictive treatment or that which is convenient and relatively low cost for clients, as well as sparing of healthcare resources to increase availability for those requiring more intense treatment (Bower & Gilbody, 2005).

Proposed models for stepped care insomnia treatment are theoretical and vary from one another, with the first step being either a self-care CBT-I method or guided internet CBT-I (Espie, 2009; Mack & Rybarczyk, 2011; Vincent & Walsh, 2013). Subsequent treatment steps include group CBT-I with a nurse or behavioral therapist, individual CBT-I with a behavioral therapist, and referral to a behavioral sleep specialist as the most intense step. For clients who do not initially respond to CBT-I, treatment at lower steps forms a potentially beneficial basis for more intense work (Espie, Hames, & McKinstry, 2013). Internet programs and mobile apps such as CBT-I Coach used at step one can be integrated into each hierarchical step as well (Espie et al., 2013). The only trial of CBT-I stepped care found, a case series study set in a behavioral medicine sleep clinic, showed that participants more likely to improve with a lower intensity of CBT-I were younger adults, employed, and had less severe insomnia symptoms before treatment (Vincent & Walsh, 2013). Utilization of BHCs for cognitive-behavioral insomnia interventions in primary care settings has demonstrated some early success, although the evidence base is limited (Goodie & Hunter, 2014). In integrated primary care settings, all levels of stepped CBT-I except the most intense specialist level can be recommended or provided in-house (Mack & Rybarczyk, 2011).

Stepped care delivery of CBT-I holds promise for increasing accessibility of this evidence-based insomnia treatment in primary care settings. However, there are insufficient empirical data supporting a specific type and sequence of care levels. Other gaps in the CBT-I literature are comparative effectiveness trials of CBT-I components (Brasure et al., 2016; Harvey

et al., 2014; Qaseem et al., 2016) and comparative effectiveness trials of CBT-I and pharmacotherapy (Qaseem et al., 2016). Short-term, evidence-based pharmacotherapy may be appropriate for certain individuals not responding to CBT-I (Qaseem et al., 2016; Wilt et al., 2016), but evidence for integration of CBT-I and pharmacotherapy is lacking (Sudak, Kloss, & Zamzow, 2014).

A rational system for stepped care delivery of CBT-I can be formulated based on the evidence for individual CBT-I components or modes of delivery, and local treatment resources. Current evidence demonstrates self-care CBT-I is a feasible first step, followed by progressively more intense CBT-I steps such as non-specialist individual therapy or group therapy, culminating in the final step of referral to a behavioral sleep specialist. By developing collaborative practice resources for providers, in conjunction with BHCs, to initiate CBT-I while monitoring client outcomes and stepping them up to the next level of care when needed, customized, evidence-based insomnia treatment can be delivered in a primary care setting.

Theoretical Models

The integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) is the conceptual framework selected to guide this project (Harvey & Kitson, 2015). It emphasizes the participation of stakeholders, teamwork, reflective practice, and the importance of appropriate facilitation. Successful implementation of innovations such as a practice guideline depends on the interrelations among the innovation, the recipients, who are the individuals and teams who decide how to utilize the evidence, and the inner and outer context. Facilitation is the key ingredient for enabling teams to work effectively together toward a common goal (Harvey & Kitson, 2015).

In the i-PARIHS framework, facilitation strategies include planning for implementation using a comprehensive facilitation checklist and Plan-Do-Study-Act cycles which allow fine-tuning methods to achieve incremental improvements. Components of successful implementation include achievement of the agreed-upon implementation goals, uptake and embedding of the innovation in practice, and engagement and motivation of the stakeholders so that they take ownership of the innovation (Harvey & Kitson, 2015).

The i-PARIHS framework suits this project in which insomnia guideline implementation greatly depends on its adaptation to the unique context and recipients of CHS through facilitation activities. Facilitation strategies employed include provider education and translation of the guideline into CBT-I treatment options and the provision of point-of-care GI tools for assessment, treatment, and referral. Provider participation in the decision-making about design and process incorporates recipient-related attributes in i-PARIHS including their values and beliefs, skills and knowledge, time and resources, and professional boundaries (Kitson & Harvey, 2016). Plan-Do-Study-Act cycles are consistent with the long-term insomnia practice change initiated during this project.

Because the project takes place in an interprofessional clinical setting and insomnia treatment spans professions, diverse theoretical perspectives guide the proposed clinical intervention. The theoretical framework includes biological, psychological, and nursing perspectives. The two-process model of sleep regulation is a well-supported biological theory which explains sleep regulation as a balance of homeostatic and circadian processes (Borbely, Daan, Wirz-Justice, & Deboer, 2016). Psychological theory including cognitive, behavioral, and learning theories explain how these biological processes are influenced by cognition and behavior (Garrison & Libby, 2010). In combination, these theories explain some of the underlying constructs

on which CBT-I is based. CBT-I can also be positioned within Orem's self-care deficit nursing theory as a supportive-educative nursing system for clients with insomnia (Denyes, Orem, & SozWiss, 2001; Kurtz & Schmidt, 2016). Individuals with insomnia disorder have a self-care deficit related to negative sleep patterns and an imbalance between rest and activity. They can usually perform self-care but need a supportive-educative nursing system that includes education, guidance, and support in the form of CBT-I (Kurtz & Schmidt, 2016).

The theoretical relationships described above illustrate the holistic nature of insomnia and its treatment, justifying an integrated care approach utilizing primary care and behavioral health resources (Vogel, Kirkpatrick, Collings, Cederna-Meko, & Grey, 2012). Multidisciplinary theories support interprofessional collaboration, an important aspect of organizational context in this project.

Section 3: Project Implementation Plan

Outcomes and Goals

The project goal was to successfully adapt insomnia EBPGs to the CHS setting by increasing providers' knowledge about insomnia treatment and CBT-I, developing a useful GI toolkit, and expanding evidence-based insomnia treatment options available at CHS to include CBT-I. In the i-PARIHS framework, successful implementation of evidence-based practice occurs when there are uptake and embedding of the innovation, recipients are engaged, motivated, and own the innovation, and agreed-upon goals are achieved (Harvey & Kitson, 2015). Because project parameters did not allow guideline implementation to be followed until successful implementation could be fully realized, intermediate implementation outcomes were identified. Implementation outcomes are distinct from and precede service outcomes and client outcomes (Proctor et al., 2011). They reflect stakeholders' perceptions and include acceptability, appropriateness, and feasibility, and adoption (Proctor et al., 2011).

Organizational readiness to change, defined as "psychological, behavioral, and structural preparedness" (Helfrich et al., 2011, p. 2), is another factor influencing implementation success. Organizational readiness to change and acceptability are presumed to be dynamic, changing with experience from pre-implementation through the phases of implementation (Helfrich et al., 2011; Proctor et al., 2011). The project's clinical question links practice change by providers with insomnia education and tailored clinical resources to support CBT-I referral. Because the feasibility of implementing practice guidelines is often not considered during guideline development, it falls to guideline users to adapt recommendations to practice settings (Gagliardi, Marshall, Huckson, James, & Moore, 2015). A participatory approach included providers in decisions about implementation strategies, including the selection of point-of-care GI tools. GI tools were intended to result in increased use of CBT-I for insomnia treatment at CHS.

Population and Setting/Organization

The insomnia project was implemented at the multidisciplinary campus health service (CHS) of a medium-sized public university in the southwestern U.S., a full-service ambulatory care clinic with urgent care, primary care, psychiatric, counseling, and health promotion services. This practice change innovation targeted the fourteen primary care and psychiatric providers, consisting of physicians and nurse practitioners, who provide care to university students and staff. All full-time and part-time providers at CHS who may see clients with insomnia were included. The counselors and other professional staff were not included as recipients in this project because of its limited focus but participated in information exchange and coordination related to implementation activities.

Issues

Resources. Strengths of the setting include administrative and clinical leaders who actively support innovation. Regular team meetings are venues for education and discussion of proposed process and practice changes, and there are audit and feedback processes for assessing practice. One of CHS's strategic priorities is the integration of primary care and behavioral health, which is consistent with the goals of the insomnia project. The engagement and collaboration of nursing, medical, and counseling professionals are contextual strengths for this project, and interprofessional discussions about the project have been helpful. CHS has a shared interprofessional electronic health record (EHR), another asset in which GI tools such as insomnia assessment checklists and client instruction handouts were disseminated to providers.

Barriers. Potential barriers to improving insomnia care at CHS included providers' knowledge deficit regarding evidence-based insomnia treatment, possible confusion about primary care, psychiatric, and behavioral health role boundaries, competing priorities and time constraints, and the lack of GI tools. Frequently, the feasibility of implementing practice guidelines is not considered during development, and it falls to the target users to adapt recommendations to practice settings (Gagliardi, Marshall, et al., 2015), which is a time-consuming undertaking. Different professional worldviews and values can create boundaries and varying expectations about team roles and processes (McNeil, Mitchell, & Parker, 2013), which could impair effective collaboration between counselors and primary care or psychiatric providers. The project facilitator anticipated this possibility and took care to respect professional domains throughout the project.

Ethics. Expansion of insomnia treatment options to include evidence-based CBT-I is consistent with the ethical principles of beneficence, doing good for patients, and

nonmaleficence, not harming patients. The project promoted equitable distribution of practice improvement to all CHS clients by providing information and practice tools to all PCPs and PMHNPs. Maximizing benefits and minimizing risks, including inconvenience and loss of privacy, is essential. Participation by CHS providers was voluntary, and their questionnaire data was kept anonymous and secure. The insomnia project was submitted to the Northern Arizona University (NAU) IRB before implementation, which determined that the insomnia project did not meet the definition of research (see Appendix A).

Costs. The costs incurred by practice improvement projects are usually offset by savings provided by improved quality and increased efficiency (Harris, Roussel, Dearman, & Thomas, 2016). Direct costs include the wages of staff implementing the project, supplies, and other project-specific costs (Moran, Burson, & Conrad, 2017). Meetings of the project team required approximately ten hours of professional staff time. Staff educational activities related to insomnia treatment took approximately two hours per 14 medical and advanced practice nursing staff, occurring during regular staff meetings as part of usual in-service programming. Embedding GI tools in the EHR took IT staff approximately ten hours. Another direct cost was educational insomnia handouts for clients. Indirect costs such as the use of computer equipment, utilities, and office supplies were not calculated, as the project's expenses were incorporated into CHS's usual operating costs.

Implementation Plan

Practice change protocol. The i-PARIHS framework guided the project. Research about insomnia treatment was assessed for relevance to primary care settings and translated into innovative clinical tools and processes with the input of recipients (the providers) and appropriate for the context. A stepped care approach to CBT-I provision fit the usual clinic

operations and integrated care setting. Clients with insomnia would be assessed by their primary care or psychiatric provider to determine whether CBT-I was indicated. If appropriate, the provider would discuss healthy sleep practices and recommend a stepped care CBT-I option, starting with self-help options, then referral to a CHS behavioral health (BH) provider, and finally off-campus to a CBT-I specialist if needed. Availability of the BH program was delayed until after the project time frame, so only the self-help and specialist CBT-I options were available during the project. Clients were to follow up with the provider for reassessment and stepping up to a more intense CBT-I modality if needed. See flow chart in Appendix D.

Facilitating the practice change. The project team included the facilitator (DNP student), faculty mentor, and clinical mentor, as well as informal participants. In the i-PARIHS framework, facilitation emphasizes relationships, shared learning, and shared problem-solving (Harvey & Kitson, 2015). The facilitator is a PMHNP at CHS, thus has inside knowledge of organizational culture, current processes, and personalities (Harvey & Kitson, 2015). The clinical mentor, a family nurse practitioner (FNP) who is the assistant medical director at CHS and leads QI efforts among the medical and advanced practice nursing staff, provided access to organizational leaders and other clinical staff. In her role as a PCP and leader, she provided insight into the challenges of adapting an insomnia practice guideline for use by CHS PCPs. Informal team members included the counseling director and the lead information technology (IT) staff person at CHS.

Insomnia GI tools available from the developer, the American College of Physicians (2016), included a guideline summary for clients and client facts about insomnia diagnosis and treatment. Useful tools for providers such as training materials, a guideline algorithm, guidance for evaluation, or client handouts describing specific treatment strategies (Gagliardi, Brouwers, et al., 2015) were not provided. CHS providers approved the development of GI tools to include an insomnia

guideline summary for providers, an EHR-based template to facilitate client assessment and documentation, and client handouts. All GI tools were available in the EHR so providers could easily access and utilize them during client visits.

An educational presentation about insomnia evidence-based practice, including the effectiveness of CBT-I, and the introduction of the insomnia assessment and referral process with GI tools was conducted for PCPs and PMHNPs at the beginning of the project. Based on their feedback, the tools and process were refined.

Once agreed-upon GI tools and processes were ready, active project implementation took place for three months. During this period the facilitator conducted audit and feedback, solicited provider input, coordinated the practice change with other CHS professional groups, and planned for practice sustainability. The facilitator kept a log of practice change strategies and project milestones to document the guideline implementation process. See Appendix E for a timetable of strategies and milestones.

Evaluation methods/tools. The outcomes to be evaluated included the providers' readiness to change their practice by recommending CBT-I to clients when appropriate, and whether CBT-I referrals increased. Presumably, an increase in CBT-I referrals would be accompanied by a decrease in insomnia prescriptions.

To measure providers' readiness for practice change, all 14 CHS physicians and nurse practitioners were recruited for a purposive sample because of their central role in insomnia guideline implementation. A pre- and post-project survey design was selected, using the Organizational Readiness to Change Assessment (ORCA) (Helfrich, Li, Sharp, & Sales, 2009). The ORCA was developed to operationalize the constructs in an earlier version of the i-PARIHS framework (Helfrich, Li, Sharp, & Sales, 2009), and to measure implementation effectiveness

rather than client outcomes (Helfrich et al., 2011). Administering the ORCA at the beginning of the proposed practice change provided a baseline that identified areas of strength and weakness to be addressed during implementation. Facilitation strategies were designed to increase organizational readiness for change as the project progressed, measured by subsequent ORCA re-administration. An anonymous respondent-generated code was devised to link pre- and post-intervention measures (Haug, Shopshire, Tajima, Gruber, Guydich, 2008).

The ORCA is a 77-item quantitative instrument with three separately scored scales to elicit provider views on the i-PARIHS constructs evidence and innovation, context, and facilitation strategies. Possible Likert-type responses range from *strongly disagree* to *strongly agree* in the evidence and facilitation scales, and from *very infrequently* to *very frequently* in the context scale to measure observed behaviors in the organization. The ORCA evidence scale is designed to be individualized to the specific innovation being implemented. For this project, an evidence scale was given for each of the three GI tools: Insomnia Guideline Summary, EHR Insomnia Sections, and Patient Handouts. As advised by the ORCA developers, the facilitation scale was administered only post-implementation, once providers had an opportunity to experience facilitation strategies (C. D. Helrich, personal communication, March 3, 2017).

The content of ORCA items was based on i-PARIHS constructs and interviews with healthcare staff implementing evidence-based innovations (Helfrich et al., 2009). Content validity is being studied through a Delphi survey of nine experts on readiness to change and 160 volunteers with varying levels of experience in implementation science (C. D. Helfrich, personal communication, March 3, 2017). Factor analysis supports construct validity of ORCA's three constituent scales (Helfrich et al., 2009). Preliminary study indicates ORCA may predict implementation success but is not yet validated for this purpose (Hagedorn & Heideman, 2010;

Helfrich et al., 2011). Cronbach's alpha coefficients for the reliability of evidence, context, and facilitation subscales were 0.74, 0.85, and 0.95 respectively. Although the evidence subscale did not meet the 0.8 threshold, its items were retained because of their high item-rest correlations, another measure of internal consistency, and their conceptual importance within the PARIHS framework (Helfrich et al., 2009). The ORCA's developers recommend cautious interpretation of the evidence subscale and further psychometric testing of the instrument is underway (Helfrich et al., 2009; Helfrich et al., 2011). They permitted its use and adaptation (C. D. Helfrich, personal communication, March 3, 2017). Although the psychometric quality and length of the ORCA are not ideal, there is a scarcity of fully validated and reliable instruments that measure implementation (Lewis et al., 2015), and an advantage to using an instrument congruent with the project's conceptual framework. See Appendix H for the baseline and follow-up ORCA used for this project.

To measure the rate of adoption of practice change, the aggregate number of CBT-I referrals and insomnia prescriptions were to be collected from one of the new GI tools, the EHR insomnia drop-in section. It was designed not only to assist providers in insomnia assessment and treatment but also to capture data about treatment and referrals. Data would be collected from client encounter notes utilizing this EHR tool at the end of the project.

Evaluation and Data Analysis Plan

Data Analysis Techniques

Project implementation began during the summer when some of the providers are not working. All nine providers working during the summer were given the ORCA on a voluntary and anonymous basis in June 2017 (T1) following an educational presentation on the evidence-based practice guideline and CBT-I and discussion about clinical tools they desired. It was not possible to dedicate time for them to complete the ORCA, which takes approximately 15 minutes. Six of the nine providers completed the ORCA. The post-intervention ORCA for this

first provider group was administered in October 2017 (T2). The five providers who were off during summer were given the opportunity to view an audiovisual power point presentation on the guideline and CBT-I resources and to complete the ORCA in September and were given the post- ORCA in January so that the length of their implementation period was equivalent to that of the first group. Two of the five providers in the second group completed the ORCA.

The plan to collect aggregate clinical data from the new EHR insomnia drop-in section was hindered by low utilization of this tool. Instead, only the number of off-campus referrals for CBT-I and the number of insomnia prescriptions could be collected from the EHR, and the number of recommendations for self-help CBT-I was not accessible. Aggregate referrals and insomnia prescriptions during a five-week period in fall 2016 and fall 2017 were compared, as these are equivalent time periods in campus health services. A denominator of unduplicated client visits during those periods was used. Numbers of insomnia diagnoses pre- and post-implementation were collected to describe the extent to which insomnia is recognized by providers in their patients, as part of the project's context.

Data Analysis

The ORCA's Likert response scales provide ordinal data and are described using the median and range (Kim & Mallory, 2017). The first group of linked pre- and post-implementation ORCA questionnaires were analyzed using Wilcoxon's matched-pairs signed-ranks test with JMP statistical software. Wilcoxon's is a nonparametric test for comparing the central tendency of two matched samples (Kim & Mallory, 2017), used when data is non-continuous, or the sample size is very small, and a normal distribution cannot be assumed. In consultation with the NAU Statistical Consulting Lab, the project facilitator first cleaned the data by evaluating and managing missing survey responses and outliers (Kim & Mallory, 2017).

There were many *don't know/not applicable* responses on the pre-project evidence scales, which were treated as missing data and decreased the number of usable pre- and post-project pairs. This reduced the number of matched respondents on the evidence scales from six to three. Accordingly, descriptive statistics about the post-project evidence scales, which were more complete, were calculated to provide additional information. Facilitation scale results, collected post-project only, are also reported using descriptive statistics.

Demographic data about the respondent sample are reported by categorical percentages for informational purposes (see Table 4, Appendix F). The small sample size does not allow for meaningful comparison of responses by demographic category.

The aggregate clinical data collected from the EHR are reported as a rate relative to the number of unduplicated clinic visits during equivalent pre- and post-project time periods and compared by calculating a z-score to determine whether there is a significant difference.

Project Results

Eight of the 14 providers completed both the pre-and post-project ORCA survey. However, one pre- and post-ORCA pair had to be eliminated because of too much missing data, so paired scores were analyzed for a sample of seven or a 50% response rate. Aggregate clinical data is limited by the providers' low utilization of the EHR insomnia drop-in section which was designed to capture information about treatment and referrals.

ORCA Scores

Table 5 shows ORCA scores for each scale (see Appendix G). The difference in scores between T1 and T2 did not reach statistical significance. Responses on the evidence scale indicated agreement that the three clinical tools are useful for improving insomnia care, ranging from *agree* to *strongly agree*. The context scale scores ranged more widely, from the middle

value, *neither frequently nor infrequently,* to *frequently*, reflecting some lower responses on provider time and other resources for implementing change. Facilitation scores ranged from *neither agree nor disagree* to *agree*. Some items on the facilitation scale assess organizational factors not apparent to providers, which may explain lower responses on those items.

Although results did not reach clinical significance, ORCA responses were clinically useful for gaining provider feedback, assessing for potential barriers to practice change, and informing facilitation strategies. At T1 most respondents indicated agreement that the three GI tools (guideline summary, EHR sections, and client handouts) would help them improve insomnia care. Most of the supportive context items were reported to have been observed frequently, with some exceptions: (a) necessary staffing, facilities, or budget for change, (b) leadership regarding improving client education and client participation in treatment, and (c) feedback on performance measures. This information was shared with respondents, and implementation strategies were designed to be sparing of provider time. Project strategies also included client education resources and audit and feedback.

The facilitation subscale was administered at T2 only, once respondents had an opportunity to experience project facilitation strategies. Items with mostly favorable responses included (a) leadership endorsement of the project, (b) effectiveness of the facilitator, (c) implementation plan clarity and staff input, and (d) project communication. Facilitation items with lower scores included (a) project resources, (b) evaluation plans, and (c) tracking progress. These responses indicate areas for improvement in ongoing facilitation strategies.

Aggregate Clinical Data

In-house CBT-I referral was not available in time for this project, so providers utilized patient education, self-help referral resources, and off-campus CBT-I referral. A total of three

patients were referred to the off-campus CBT-I specialist during the project; there were no such referrals during the previous year.

The EHR insomnia sections were used for five client visits. CBT-I was recommended to three of the five clients, and contraindications for CBT-I were listed for the other two.

There was not a significant change in sleep prescriptions during equivalent five-week periods from fall 2016 to fall 2017. There were 42 insomnia prescriptions from 10/3/16 to 11/4/16, a proportion of 0.013 of all unduplicated client appointments for any reason, compared to 47 insomnia prescriptions from 10/2/17 to 11/3/17, a proportion of 0.015. A *z*-score comparing the two proportions is -0.5998, with a *p*-value of 0.5485.

Nor was there a significant change in the number of insomnia diagnoses between fall 2016 and fall 2017. Insomnia was diagnosed in 22 clients from 10/3/16 to 11/4/16, and for 25 clients from 10/2/17 to 11/3/17. The *z*-score comparing the two proportions is -0.487, with a *p*-value of 0.62414.

Discussion, Recommendations, and Conclusions

Discussion of Results

Implementation of evidence-based practice change in primary care is likely to be complex because of factors related to multi-level organizational context, characteristics of health professionals involved, and characteristics of the intervention (Lau et al., 2016). The ORCA survey includes these complex factors, but results must be interpreted with caution because it is partially validated and the evidence scale does not meet reliability standards (Helfrich et al., 2011). Thus, it is possible that ORCA results do not accurately measure CHS organizational readiness for insomnia practice change. An additional limitation is the small sample size and response rate of 50 percent. It is possible that providers who responded were more positively

predisposed to the insomnia project than non-respondents. Missing data on the pre-project evidence scale reduced the pre- and post- comparisons to an *n* of only four.

The lack of significant change in practice indicators may reflect provider factors such as years of practice, perceived lack of time, or competing priorities. Respondent demographics indicate the majority of providers have at least 21 years of practice experience. The recommended practice change for insomnia care involves the new treatment of CBT-I as well as limiting the previously routine practice of prescribing insomnia medication. This change requires unlearning long-held practice patterns in order to incorporate the new information and behaviors, which disturbs providers' status quo equilibrium (Gupta, Boland, & Aron, 2017). It is a trial-and-error process that can take time (Gupta et al., 2017). Counseling clients about sleep health and CBT-I is more time-consuming than writing a prescription, making the practice change more difficult when clients present with multiple problems to be addressed. Providers may lack confidence in their ability to recommend and discuss CBT-I, a psychological treatment which is incongruent with their perceived role and expertise (Lau et al., 2016). It is also possible that this practice change threatens providers' sense of professional autonomy, increasing resistance to change. There may have been other contextual and facilitation factors that impeded practice change, such as adequate staffing or other project resources.

It is also possible that practice change occurred during the project but was not captured by the ORCA or practice measures. During project facilitation activities such as provider meetings and individual discussions, some providers indicated they were using the client handouts for insomnia and CBT-I and found them helpful for discussing non-pharmacologic insomnia treatment. Providers reported mixed views on the EHR insomnia sections: a few who had used the sections gave positive feedback, and others who had not used the sections felt that

would take more time. In general, verbal feedback indicated interest in and movement toward insomnia practice change, but this anecdotal information was not captured by outcome measures.

Finally, practice change takes time. The translation of evidence to change practice is not usually rapid cycle, in contrast with quality improvement projects (Shirey et al., 2011). The ORCA is usually given at baseline and six or nine months, rather than at three months, to allow adequate time for organizational readiness to change to respond to implementation efforts (Helfrich et al., 2011). It is possible that reassessment of insomnia practice change at six to nine months would show significant results.

Implications for Healthcare, Nursing, Advanced Practice Nursing

At the end of the project, the facilitator presented the results to the providers and reviewed insomnia treatment recommendations and the jointly developed GI tools. Implications for ongoing implementation were also discussed, including the recently launched in-house BH provider program. Now the providers can immediately refer clients with insomnia to CHS counselors for discussion of healthy sleep practices and CBT-I strategies, instead of spending time on this themselves or referring to a CBT-I specialist off campus. We discussed a recent case example at CHS in which a PCP referred a client with insomnia to a BH provider as part of the client's visit instead of prescribing insomnia medication. The following week when the client saw a PMHNP she had already incorporated some of the behavioral recommendations and reported improved sleep. This interprofessional collaboration illustrates the benefits of improved work flow making conditions more favorable for practice change (Lau et al., 2016).

The principles of stepped care as applied to insomnia allowed for the introduction of CBT-I into this primary care setting, utilizing client handouts and referral to self-help or guided internet CBT-I resources as a first step, with referral to a CBT-specialist off campus as a step up

for those needing more intense treatment. Now that a middle step, the BH provider program, is readily accessible, providers who may struggle with unlearning the practice of routinely prescribing insomnia medication have an additional referral source. Substituting a warm hand-off to a BH provider for an insomnia prescription gives providers an immediate alternative, a strategy which complements the unlearning process necessary for practice change (Helfrich et al., 2018).

As evidence-based insomnia care that includes CBT-I becomes an interprofessional collaboration at CHS, it promotes the organizational goal of primary care and behavioral health integration. Congruence with organizational systems and an interprofessional approach facilitates practice change (Lau et al., 2016).

The i-PARIHS framework has been useful for guiding project implementation. Attention to the innovation and evidence, recipients, context, and facilitation strategies from the outset enhanced pre-implementation planning. Incremental change allowed participatory refinement of implementation strategies throughout the project. The i-PARIHS framework provides a comprehensive approach to EBPG adaptation which is suitable for tailoring implementation to other practice settings.

Recommendations

Continuation of PDSA cycles to refine provision of evidence-based insomnia care is recommended. Using different measures to study the adoption of CBT-I, such as chart reviews, will yield more accurate and detailed information on which to base refinement of implementation. Adding qualitative measures such as semi-structured interviews with providers or a focus group of providers is also recommended to provide more detail about provider attitudes about the practice change and usefulness of GI tools.

Once CBT-I has been adopted as an evidence-based insomnia treatment option, quality improvement of insomnia care can be implemented. Quality measures for insomnia care include providing evidence-based treatment and assessing the client's sleep quality, daytime functioning, and adverse effects of treatment (Edinger et al., 2015). These quality measures contribute to client outcomes of improved sleep satisfaction and quality and improved daytime functioning (Edinger et al., 2015), which are the ultimate goals of the practice change.

Key Lessons Learned

Data collection methods did not yield as much information as planned. There was a 50% response rate to the ORCA survey. Allowing enough time during the educational presentation for providers to complete the survey may have increased the number of responses. Another option to increase the response rate would be a shorter validated and appropriate survey. Although not available when the insomnia project began, a survey to measure implementation acceptability, appropriateness, and feasibility was recently published and contains just 12 items (Weiner et al., 2017), compared to 77 items on the ORCA. This could be a more pragmatic measure of implementation outcomes for future work.

Because measurement of CBT-I provision and referral was to be collected from one of the new GI tools which was not utilized as much as as anticipated, data on self-help CBT-I recommendations were not available. Only the number of referrals to the off campus CBT-I specialist could be collected, presumably a small proportion of total CBT-I recommendations in the stepped care process. Future data collection methods should not rely on voluntary use of a GI tool.

Conclusions

A GI toolkit for evidence-based insomnia care has been implemented at CHS with providers' input. According to pre- and post-project ORCA results, responding CHS providers agree that all three clinical tools will help improve insomnia assessment and treatment recommendations for their clients. There was not a significant change in providers' opinions during the project. Despite the positive responses to clinical tools, the EHR drop-in section was not utilized for the majority of insomnia-related visits, greatly limiting access to treatment data. The available aggregate data did not detect a significant change in sleep prescriptions or CBT-I referrals. Further PDSA cycles are recommended to refine implementation of evidence-based insomnia care, using mixed data collection methods for more detailed evaluation.

The insomnia project has focused on practice change in CHS primary care and psychiatric providers, setting the stage for collaboration with counseling staff who recently implemented in-house CBT-I services. Although outside the scope of this project, evaluation and refinement of evidence-based insomnia care will continue at CHS.

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Appendix A

To: Maria Denny, MSN
From: NAU IRB Office
Date: June 2, 2017

Project: Adapting an Evidence-Based Insomnia Practice Guideline for Use in a University Healthcare Setting
Project Number: 1079227-1
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).

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Appendix B

Table 1 Evaluation Table of Retained Studies: Cognitive Behavioral Treatment Strategies for Insomnia

Author & Title	Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables Studied	Measurement of Major Variables	Data Analysis	Study Findings	Level & Quality of Evidence Study Strengths & Weaknesses
Qaseem,A., Kansagara, D., Forciea, M. A., Cooke, M., & Denberg, T. D. (2016). Management of chronic insomnia in adults: A clinical practice guideline from the American College of Physicians. Based on: Brasure, M., MacDonald, R., Fuchs, E., Olson, C. M., Carlyle, M. Diem, S.,…Wilt, T. J. (2015).	Not stated	Practice guideline based on an AHRQ comparative effectiveness evidence review of RCTs, SRs, and long-term observational studies. Inclusion criteria: Adults aged 18 and older with chronic insomnia disorder, studies provided at least 4 wks. of follow-up, global or sleep outcomes reported. For observational	128 RCTs & 3 SRs, total 169 RCTs; 12 observational studies to supplement harms data Setting: Outpatient	IVs: Psychological therapies: CBT-I, multi-component behavioral therapy for insomnia, BBT, SC, RS, SRT Pharmacologic therapies CAM: Acupuncture, Chinese herbal medicine DVs: Sleep, daytime functioning, fatigue, mood, QOL, adverse effects of treatment	Sleep questionnaires that include global outcomes (daytime functioning or distress): ISI, PSQI Sleep diary data: SOL, WASO, TST, SE, SQ Functional measures: Beck Depression Inventory, State-Trait Anxiety Inventory, Short-Form Health Survey, WHO QOL, ESS, FSS Reported	Quality assessment of all studies and reviews, exclusion if poor quality. Data extraction and pooling for similar studies. WMDs between groups used to identify likelihood of treatment benefit. Guideline recommen-dations based on GRADE approach.	1) CBT-I delivered by various methods improved remission, treatment response, SOL, WASO, SE, & SQ in general population (moderate-quality evidence). 2) SC improved SOL and TST in general population (low-quality evidence). 3) For older adults, CBT-I improved ISI and PSQI (moderate-quality evidence), and SOL, WASO, and SE (low- to moderate-quality evidence). 4) Various sleep medications improved sleep	Level of evidence: I USPSTF: Database searched, no review found. Strengths: Guideline based on meta-analysis of comprehensive and up-to-date literature review. Weaknesses: Heterogeneous CBT-I interventions limit consistency. Conclusion: Supports CBT-I as first-line insomnia treatment for all adults.

Management of insomnia disorder. Comparative effectiveness review 159.		studies of pharmacologic harm: at least 6 months of f/u, sample at least 100, no major comorbidity, hypnotic reported by class.			adverse effects		measures including SOL, TST, & WASO in general pop. and older adults (low-quality evidence). 5) Insufficient evidence for CAM, pharmacologic therapy with BZDs, or comparative effectiveness of cognitive-behavioral components. 6) Insufficient data to compare insomnia treatments or to identify harms. Guideline recommendations 1) All adult patients receive CBT-I for chronic insomnia disorder (strong rec., moderate-quality evidence). 2) When CBT-I unsuccessful, use shared decision-making with patients to decide whether to add medication (weak rec., low-quality	Clinical significance: Advocates CBT-I as high value care that can be done in primary care setting, but does not offer practical guidance on implementation.

							evidence).	

2) Brasure, M., Fuchs, E., MacDonald, R., Nelson, V. A., Koffel, E., Olson, C. M., …Kane, R. L. (2016). Psychological and behavioral interventions for managing insomnia disorder: An evidence report for a clinical practice guideline by the American College of Physicians.	Not stated, but interventions based on psychologic-al and behavioral theories.	Systematic review Inclusion criteria: RCTs enrolling adults with insomnia d/o, getting at least 4 wks. of psychological and behavioral treatment, reporting global or sleep outcomes, published in English. Exclusion criteria: Pure subgroups of patients with major medical problems or conditions associated with sleep problems.	60 RCTs comparing psychological and behavioral insomnia treatments with inactive controls (sleep hygiene education or waitlist); few trials used sham treatment. Sample predominant-ly female and white, mean age mid-40s in general adult pop. Setting: Outpatient	IVs: CBT-I, BBT, SC, RS, SRT DVs: Sleep, daytime functioning, fatigue, mood, QOL, adverse effects	SOL, WASO, TST, SE, SQ Sleep questionnaires: ISI, PSQI	Quality assessment of all studies and reviews, exclusion if poor quality. Data extraction and pooling for similar studies. RRs, MDs, and WMDs between groups used to identify likelihood of treatment benefit.	1) CBT-I vs. inactive control: improved SOL, WASO, SE, & SQ in CBT-I group 2) BBT vs. inactive control: inconclusive 3) SC vs. inactive control: improved SOL & TST in SC group 4) SR vs. inactive control: inconclusive 5) RS vs. inactive control: inconclusive 6) Some studies demonstrated long-term benefit of CBT-I 6 months post-treatment. 7) Adverse effects not reported, but thought to be low.	Level of evidence: I USPSTF: Database searched, no review found. Strengths: Strict inclusion & exclusion criteria, elimination of biased studies. Weaknesses: Small samples in single-component behavioral trials. Limited ability to pool data because of study heterogeneity. Insufficient data on adverse effects and withdrawals. Studies don't usually report global outcomes. Conclusions: Supports effectiveness of CBT-I and SC for insomnia

								d/o, when performed by clinicians trained in these procedures. Clinical significance: Supports implementing combined cognitive and behavioral therapy or single behavioral treatment SC. Sample older than my clinical pop., and not ethnically diverse.
3) Wilt, T. J., MacDonald, R., Brasure, M., Olson, C. M., Carlyle, M.,...Kane, R. L. (2016). Pharmacologic treatment of insomnia disorder: An evidence report for a clinical practice	Not stated, but interventions based on medical model.	Systematic review. Inclusion criteria for RCTs: Adults with insomnia disorder, followed at least 4 wks., reported global or sleep outcomes. Inclusion	35 RCTs 11 observational studies Sample mostly female, white, and younger than age 50 Setting: Outpatient.	IVs: Non-BZD hypnotics: eszopiclone, zaleplon, zolpidem, zolpidem ER orexin receptor antagonist: suvorexant melatonin melatonin agonist: ramelteon	SOL, WASO, TST, SE, SQ Sleep questionnaire: ISI, PSQI Reported adverse effects	Studies grouped and rated by drug. Results pooled for similar studies. RRs, MDs, and WMDs between groups used to identify likelihood of treatment benefit.	1) Eszoplicone, zolpidem, and suvorexant improved short-term global outcomes (ISI) and sleep variables (SOL, WASO, TST), but effect was small. 2) Evidence for other sleep meds was insufficient or low strength. 3) Insufficient evidence for	Level of evidence: I USPSTF: Database searched, no review found. Strengths: Strict inclusion & exclusion criteria, elimination of biased studies. Six month study period for harms.

guideline by the American College of Physicians.		criteria for observational studies reporting treatment harms: Sample of at least 100 adults with insomnia d/o, without signif. comorbidity, medications FDA-indicated for insomnia, study length at least 6 months, harms reported by drug class. Also reviewed: FDA web sites for sleep meds, FDA product labels, systematic reviews. Exclusion criteria: Studies with high risk of bias.		BZD hypnotics: temazepam, diazepam, flurazepam,chordi-azepoxide AD medication: doxepin DVs: Sleep, daytime functioning, fatigue, mood, QOL, adverse effects of treatment			comparisons. 4) Harms associated with sleep meds are infrequent but potentially serious.	Weaknesses: Global outcome measures not often used. Large placebo response. Conclusion: Small beneficial effect of 3 sleep meds compared to placebo, must be weighed with possible adverse effects. Clinical significance: Provides evidence re: the comparison intervention for insomnia.
4) Trauer, J. M.,	Not stated, but	Meta-analysis	20 RCTs n=1162	IV: CBT-I including	Sleep diary measures	MD to calculate	1) CBT-I using 3 or more therapy	Level of evidence: I

Qian, M. Y., Doyle, J. S., Rajaratnam, S., & Cunnington, D. (2015). Cognitive behavioral therapy for chronic insomnia: A systematic review and meta-analysis.	interventions based on psychologic-al and behavioral theories.	Inclusion criteria: RCTs enrolling adults with insomnia d/o age 18 and older, receiving CBT-I (at least 2 components) in at least 2 sessions. Controls could be sham therapy, waiting list, no treatment, SL, or information provision. Exclusion criteria: RCTs with comorbid conditions listed as necessary inclusion criteria.	Sample 64% female, mean age 56 yo Setting not reported	at least 2 components (all studies had at least 3 components) DV: Sleep	including SOL, WASO, TST, and SE. Measured immediately after treatment (17 RCTs), early f/u (4 wks. to <6 months---5 RCTs), and late f/u (6 to 12 months---4 RCTs).	effect size. Statistical significance $p < .05$ Stata 13.0 and R 3.1.3 used.	components improved SOL, WASO, and SE at clinically meaningful levels, with gains maintained at early and late f/u. 2) Minimal improvement in TST likely treatment-related because of decreased time in bed to improve SE, and may increase over longer f/u. 3) Analysis and results limited to in-person and multiple-session CBT-I 4) No harms reported.	USPSTF: Database searched, no review found. Strengths: Narrow inclusion criteria minimized heterogeneity. Long f/u period with multiple measures. Weaknesses: Did not assess global sleep outcomes. Conclusion: CBT-I highly effective for noncomorbid insomnia d/o in adults, with long-term benefit. Supports use as first-line treatment. Clinical significance: Supports in-person CBT-I at least 3 in-person contacts, which

								may not be feasible for all insomnia d/o patients in primary care settings. Study sample generally older than clinical pop.
5) Taylor, D. J., & Pruiksma, K. E. (2014). Cognitive and behavioural therapy for insomnia (CBT-I) in psychiatric populations: A systematic review.	Not stated, but interventions based on psychologic-al and behavioral theories.	Systematic review Inclusion criteria: RCTs of in-person CBT-I treatment in psychiatric samples or insomnia samples reporting psychiatric as well as sleep outcomes Exclusion criteria: RCTs with primarily medical comorbidity, those not reporting data using sleep diary, validated sx questionnaire, or weekly	16 RCTs n=571 Mean ages ranged from 20-70, but largely middle-aged. Comorbid d/o's: Depression, PTSD, alcohol dependence, hypnotic dependence, other/mixed psychiatric d/o's.	IV: CBT-I with various components: SC, SR, CT, RS, given in 2-10 sessions (*m*=6) DV: Sleep, psychiatric symptoms, hypnotic use	SE, Insomnia Symptom Scale, Depression Symptom Scale, PTSD Symptom Scale, Anxiety Symptom Scale	Effect size weighted according to study sample size.	1) Insomnia: sleep improved, medium to large ES. 2) Depression sx decreased: small to medium ES. 3) Anxiety: No RCTs for CBT-I in comorbid insomnia and anxiety d/o; no significant improvement in anxiety sx with CBT-I. 4) PTSD: Sleep improved but unclear whether r/t CBT-I or other PTSD tx. 5) Alcohol dependence: Improved SE in small samples. 6) Hypnotic dependence: improved SE but not significant, small decrease in	Level of evidence: I USPSTF: Database searched, no review found. Strengths: Studied CBT-I for insomnia comorbid with a range of psychiatric problems or sx. Weaknesses: Only 2 databases searched. CBT-I loosely defined and operationalized Conclusion: In-person CBT-I improves sleep in people with comorbid insomnia and

		hypnotic use					hypnotic use.	psychiatric d/o's, and sx of depression and anxiety in those with primary insomnia. Clinical significance: Studies limited to in-person CBT-I. Supports beneficial effects on sleep and sx of depression and anxiety in comorbid insomnia and psychiatric d/o.
6) Ho, F. Y., Chung, K., Yeung, W., Ng, T. H., Swan, K., Yung, K., Cheng, S. K. (2015). Self-help cognitive-behavioral therapy for insomnia: A meta-analysis	Not stated, but interventions based on psychologic-al and behavioral theories.	Meta-analysis Inclusion criteria: RCTs of self-help CBT-I for primary insomnia, c/t wait list control, routine care, no tx, placebo control, or therapist-administered CBT-I.	20 RCTs n=2411 74.2% female *m*=49.3 yo	IV: Self-help CBT-I DV: Sleep Secondary outcomes: Sx of anxiety and depression, daytime functioning, QOL, dysfunctional beliefs about insomnia	SOL, WASO, and SE, derived from sleep diaries; ISI Measured immediately post-tx in 19 studies, short-term f/u in 16 studies	RevMan 5.1, random effects models used. Clinical significance of CBT-I defined as proportion of those achieving: SOL < 30 min. or WASO < 30 min., SE at least 85%, or	1) Self-help CBT-I improved SE, SOL, and WASO at immediate post-tx, medium to large effect. Had small to medium effect on reducing sx of depression and anxiety, and dysfunctional beliefs about insomnia. 2) At 1-3 months	Level of evidence: I USPSTF: Database searched, no review found. Strengths: Extensive literature search. Self-help CBT-I and clinical improvement criteria clearly

of randomized controlled trials.		English language. Not restricted to particular self-help delivery model. Exclusion criteria: Self-help CBT-I combined with pharmaco-therapy or other psychological tx. Most studies excluded participants with comorbid medical, psychiatric, or other sleep problems.				ISI score < 8 at immediate post-tx ES assessed with Hedge's g and RR	post-tx, beneficial effects on SE and ISI were maintained. 3) Larger effect size for self-help CBT-I with telephone consultation. 4) No significant difference in effect size for use of audiovisual materials. 5) Drop-out rate relatively low at 14%, similar to therapy-administered CBT-I.	defined. All methodology explicitly stated in detail. Weaknesses: Elimination of medical and psychiatric comorbidity limits generalizability to real-world primary care populations. Conclusion: Provides evidence for use of self-help CBT-I as a first step in insomnia stepped care tx, when not feasible to provide in-person CBT-I to all. Clinical significance: Supports use of self-help CBT-I for primary insomnia using various media including print (booklet)

								audio, video, internet. Adding telephone consultation may increase effectiveness.
7) Seyffert, M., Lagisetty, P., Landgraf, J., Chopra, V. Pfeiffer, P. N., Conte, M. L., Rogers, M. A. (2016). Internet-delivered cognitive behavioral therapy to treat insomnia: A systematic review and meta-analysis.	Not stated, but interventions based on psychologic-al and behavioral theories.	Systematic review and meta-analysis Inclusion criteria: RCTs of internet delivery of comprehen-sive CBT-I Exclusion criteria: Studies using abbreviated or modified version of CBT-I, children < 16 yo, or targeting specific patient groups.	15 RCTs n=2392 13 RCTs included in meta-analysis Sample largely middle-aged, majority women. Setting: mostly community residents, minority of university students, teachers	IV: Internet-delivered CBT-I given in 6 weekly sessions (8 trials), 8 sessions (3 trials), 5 sessions (2 trials), or 9 sessions (2 trials) DVs: Sleep Severity of depression or anxiety	Primary: SE, severity of insomnia (ISI) Secondary: TST, SOL, WASO, time in bed, SQ, number of awakenings, CES-D	Both a within-person comparison (before-after), and between-group. Mean differences in improve-ment calculated using Hartung-Knapp-Sidik-Jonkman method for random effects meta-analysis.	1) Improved SE, TST, SOL, WASO, ISI, and CES-D with internet CBT-I vs. wait list. Improved ISI clinically meaningful, moving insomnia from moderate severity to sub-threshold level. 2) Maintenance or further improvement in SE and ISI at long-term f/u 4 to 48 weeks post-tx. 3) Equivalent benefits with internet and in-person CBT-I in 2 trials. 4) Improved sleep when weekly e-mails supplemented internet CBT-I in 1 trial.	Level of evidence: I USPSTF: Database searched, no review found. Strengths: Extensive literature search; no significant effect modification by age or gender; use of within- and between-group comparisons for final effect. Weaknesses: Most of the studies conducted in Europe, and with middle-aged adults. Adverse effects not mentioned in the trials.

								Conclusion: Supports use of internet-delivered CBT-I as alternative to in-person tx, potentially increasing the accessibility of CBT-I. Clinical Significance: Internet-delivered CBT-I may appeal to younger college-aged population. Al-though most of sample was middle-aged, lack of a significant age effect indicates potential benefits in my clinical pop.
8) Kuhn, E., Weiss, B. J., Taylor, K. L., Hoffman, J. E., Ramsey, K. M., Manber, R.,…Trockel, M. (2016).	Diffusion of Innovations Theory	Descriptive survey study Inclusion criteria: All VA-trained CBT-I clinicians Surveys pre- and post-	Pre-release survey: n=138, a 37.7% response rate 87.7% smart-phone owners 42.8% early adopters (using app for other tx)	Clinicians' perceptions of CBT-I Coach app and intention to use, after reading a description of app (pre-release) Uptake of the app (post-release)	Pre-release: Original survey of demographics, 10 items re: likelihood of app to enhance CBT-I, 17 items re: app's relative advantage,	PAWS Statistics 21 Frequency, mean, and SD used for summary outcomes. Independent samples *t*-tests. Multiple	1) Pre-release, clinicians reported app moderately to very likely to improve care, provide advantage over current practice, be compatible with practice	Level of evidence: VI USPSTF: Database searched, no review found. Strengths: Internal consistency of

CBT-I Coach: A description and clinical perceptions of a mobile app for cognitive behavioral therapy for insomnia.		release of CBT-I Coach mobile app All CBT-I clinicians were sent e-mail with hyperlink to survey, with f/u e-mail one week later to those not responding	*m*=47.73 yo 93.5% psych-ologist or social worker Post-release survey: n=176, a 28.7% response rate (more trained clinicians at that time) Demographic info not collected post-release		compatibility, and complexity, 2 items re:intention to use. Post-release: Original survey of actual use of app with insomnia pts. and extent of improvement in homework adherence and pt. outcomes attributable to app. 7-point Likert-type scale used for both.	regression analysis.	style, and not too complicated to use. They endorsed strong intention to use app. 2) Smartphone owners and early adopters of app for pt. care had more favorable perceptions. 3) Post-release, 44.9% clinicians with current CBT-I pts. reported using the app with an average of 54.9% of caseload. 4) Clinicians using app reported stronger agreement that it improved homework adherence and pt. outcomes c/t clinicians not using app.	survey; assessment of factors r/t diffusion of innovation. Weaknesses: Different samples pre- and post-release limit conclusions. Conclusion: Trained CBT-I clinicians using CBT-I Coach see this app as potentially improving tx. Further study needed to determine comparative benefits with CBT-I not using this app. Clinical significance: CBT-I Coach adds a potentially useful tool for clinicians providing CBT-I, especially those working with a younger

								college-age population using smart mobile devices.
9) Trockel, M., Manber, R., Chang, V., Thurston, A., & Tailor, C. B. (2011). An e-mail delivered CBT for sleep-health program for college students: Effects on sleep quality and depression symptoms.	Not stated, but interventions based on psychologic-al and behavioral theories.	Quasi-experimental Inclusion criteria: All college freshmen in 2 first-year student dorms invited into a health promotion program. One dorm designated for Refresh program, to promote sleep health. Other dorm designated for Breathe, to promote emotional health and coping with stress.	Refresh: n=58 (70% of invitees) 17% attrition Breathe: n=67 (41% of invitees) 21% attrition 18-22 yo 48.8% female 50% White, 14% Latino, 11% Asian American, rest declined to answer or very small number of single race/ethnicity Baseline and post-intervention online surveys e-mailed, with up to 3 reminders	IVs: Refresh, 2 tracks assigned according to baseline sleep quality, with attenuated version for those without sleep difficulty Breathe, single track for all Both delivered in 8 weekly sessions via e-mail with attached PDF files DVs: Sleep quality Depressive sx	PSQI CES-D Both administered to Refresh and Breathe groups.	*t*-tests for independent samples for between-group differences in score changes Cohen's *d* effect size for within-group score changes	1) Refresh group members with poor sleep had greater sleep improvement than Breathe group members with poor sleep. 2) Refresh members with poor sleep also had greater improvement in depressive sx than Breathe members with poor sleep. 3) No benefits observed for Refresh members without sleep difficulty at baseline. 4) No significant difference in baseline score or gender for those not completing study.	Level of evidence: III USPSTF: Database searched, no review found. Strengths: High completion rate for Refresh members with poor sleep. Weaknesses: Small sample size; no randomization or control; general sample, not limited to insomnia disorder; Breathe group had higher average baseline depressive sx; DVs each assessed by

			Setting: College students living on campus.					only one self-reported measure; no long-term f/u. Conclusion: Electronic self-help well-received by this sample, especially those in the Refresh group with poor sleep at baseline. Further study using experimental design is recommended. Clinical significance: In a general college student population, electronic delivery of self-help for poor sleep shows promise.
10) Taylor, D. J., Zimmerman, M. R., Gardner, C. E., Williams, J. M., Grieser, E. A., Tatum, J. I.,…Ruggero,	Cognitive and behavioral models	Pilot RCT Inclusion criteria: Volunteers from a gener-al college stu-dent popula-tion at least 18 yo meeting	n=34 *m*=19.71 yo 58.8% female 59% White, 21% Latino, 12% Black, 6% Asian/Pa-cific Islander, 3% multi-racial	IV: 6 sessions of comprehensive CBT-I vs. wait-list control DV: Sleep	Primary: SE Secondary: SOL, WASO, number of awakenings, time in bed after final awakening, TST	Cohen's *d* for effect size	1) Tx group had 16% improve-ment in SE, 68% improvement in SOL, 81% improvement in WASO, 64% improvement in number of awakenings, 34%	Level of evidence: II USPSTF: Database searched, no review found. Strengths: Intervention

C. (2014). A pilot randomized controlled trial of the effects of cognitive-behavioral therapy for insomnia on sleep and daytime functioning in college students.		insomnia dx criteria. Exclusion criteria: Taking prescription medication for insomnia or other psychiatric condition, sx suggestive of another sleep disorder, or psychiatric condition associated with sleep disturbances.	Setting: College campus, outpatient				improvement in SQ; large effect sizes. 2) Compared to wait-list control, significantly more CBT-I participants responded to tx and remitted. 3) Post-tx improvement was durable at 3-month f/u.	fidelity; multiple measures of DV; 3-month f/u Weaknesses: Small sample (but adequate per power analysis); lack of comorbidity limits generalizability Conclusion: College students benefit from CBT-I similar to general population. Clinical significance: Supports use of CBT-I for college students.

AD=antidepressant; **AHRQ**=Agency for Healthcare Research & Quality; **BBT**= brief behavioral therapy; **BZD**=benzodiazepine; **CAM**=complementary and alternative medicine; **CBT-I**=cognitive-behavioral therapy for insomnia; **CES-D**=Center for Epidemiologic Studies Depression Scale; **CG**=control group; **DV**=dependent variable; **ESS**=Epworth Sleepiness Scale; **ER**=extended release; **ES**=effect size; **FSS**=Fatigue Severity Scale; **ISI**=Insomnia Severity Index; **IV**=independent variable; **MD**=mean difference; **PSQI**=Pittsburgh Sleep Quality Index; **QOL**=quality of life
RCT=randomized controlled trial; **RR**=risk ratio; **RS**=relaxation strategies; **SC**=stimulus control; **SE**=sleep efficiency; **SOL**=sleep onset latency; **SQ**=sleep quality; **SR**=systematic review; **SRT**=sleep restriction therapy; **sx**=symptoms; **TST**=total sleep time; **tx**=treatment; **WASO**=wake time after sleep onset; **WHO**=World Health Organization; **WMD**=weighted mean difference

Appendix C

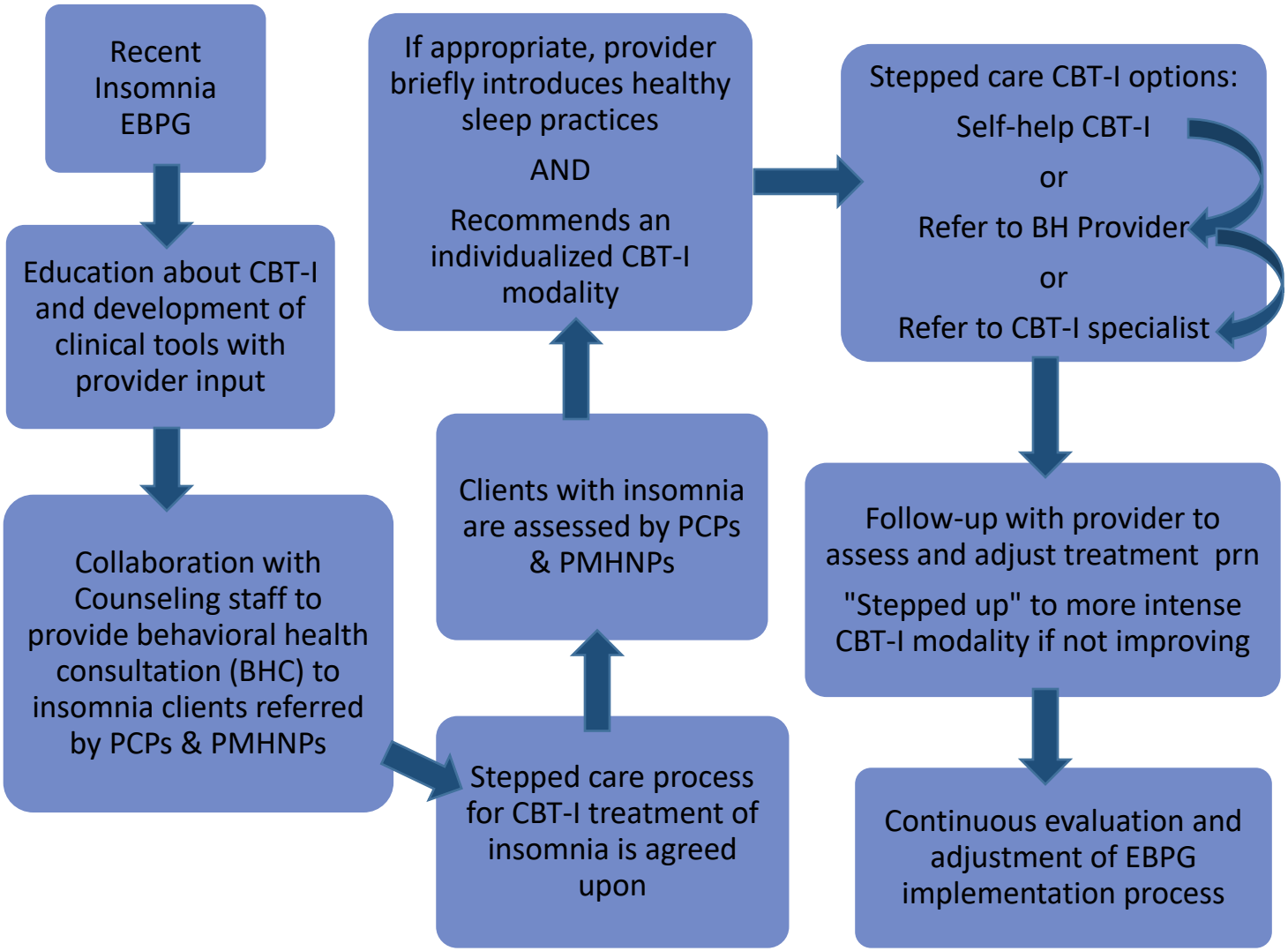
Table 2 Synthesis Table of Retained Studies: Cognitive Behavioral Treatment Strategies for Insomnia

	Primary Author and Publication Year									
	Qaseem et al. (2016)	Brasure et al. (2016)	Wilt et al. (2016)	Trauer et al. (2015)	Taylor & Pruiksma (2014)	Ho et al. (2014)	Seyffert et al. (2016)	Kuhn et al. (2016)	Trockel et al. (2011)	Taylor, Zimmerman et al. (2014)
Study Design	EBPG	SR	SR of RCTs	MA	SR	MA	SR & MA	Descriptive survey	Quasi-experimental	Pilot RCT
Number	NS	60 RCTs	35 RCTs & 11 observ. studies	20 RCTs n=1162	16 RCTs n=571	20 RCTs n=2411	15 RCTs n=2392	1st survey: n=138 2nd: n=176	n=125	n=34
Age in years	Adults 18+	*m* mid-40s	Most < 50	*m*=56	Most middle-aged	*m*=49.3	Most middle-aged	1st: *m*=47.73 2nd: not obs.	18-22	*m*=19.71
Race/ethnicity & Gender	NS	Most white, F	Most white, F	Race NS, 64% F	Race NS; RCTs 10-90% F	Race NS; 74.2% F	Race NS (European); Most F	NS	50% W, 14% L, 11% AA, rest ?; 48.8% F	59% W, 21% L, 12% B, 6% AA; 58.8% F
Setting	Outpatient	Outpatient	Outpatient	NS	NS	NS	Community residents, minority university	VA outpatient	College students living on campus	College campus outpatient
Discipline	NS	NS	NS	NS	NS	Self-help	NS	93% psychol-ogists or SWs	Self-help	Doctoral psychology students
Intervention	Various modes of CBT-I; sleep Rxs	Various modes of CBT-I	Sleep Rxs	CBT-I with multiple components	Various modes of CBT-I	Self-help CBT-I, various modes	Internet-delivered CBT-I	Mobile app to support CBT-I (CBT-I Coach)	Sleep health promotion program by e-mail	CBT-I with multiple components
Major Pertinent Finding	CBT-I is 1st line tx for chronic insomnia in all adults	Multiple component CBT-I ↑ global sleep outcomes, LT benefits	Eszoplicone, zolpidem, & suvorexant ↑ global sleep outcomes, weigh benefit with harms	Multiple component CBT-I ↑ global sleep outcomes, LT benefit	CBT-I ↑ sleep & sx of depression in samples with psychiatric comorbidity	Self-help CBT-I ↑ sleep, LT benefit; larger effect with telephone consult	Internet-delivered CBT-I ↑ global sleep outcomes, LT benefit	CBT-I Coach is potentially useful tool for therapists & their cts.; further study needed	E-mail delivery of self-help sleep promo. ↑ sleep (in grp. w/o insomnia dx)	CBT-I ↑ sleep in college students, similar to general pop., LT benefit

↑=improved or increased; **AA**=Asian American; **B**=Black; **CBT-I**=cognitive-behavioral therapy for insomnia; **EBPG**=evidence-based practice guideline; **F**=female; **L**=Latino; **LT**=long-term; **MA**=meta-analysis; **NS**=not stated; **RCT**=randomized controlled trial; **Rx**=medication; **SR**=systematic review; **ST**=short-term; **SW**= social worker; **sx**=symptoms; **tx**=treatment; **W**=White

Appendix D

Flow Chart: Implementation Process in Plan-Do-Study-Act (PDSA) Cycles



Appendix E

Table 3. Project Facilitation Strategies Employed in Relation to Measurement Time Points

Period	Facilitation Stage (i-PARIHS)	Details of Strategies
	Clarify and engage:	
October 2015 – February 2016	Problem identification	Gap between insomnia EBPG guidelines and local practice is identified by facilitator and discussed with CHS medical director as focus of DNP project.
September – December 2016	Identify and engage stakeholders	Identification of clinical mentor/organizational partner for insomnia project, CHS assistant medical director, a FNP Meeting with CHS PCPs and PMHNPs about potential insomnia project results in preliminary buy-in and suggested tools to support implementation. Meeting with CHS counseling services (CS) director yields agreement to coordinate the insomnia project with the CS incipient behavioral health consultant (BHC) program.
	Assess and measure:	
October – December 2016	Evaluate evidence, recipients, and context	Literature search and review of insomnia treatment and CBT-I implementation strategies are completed.
February – May 2017		Preliminary project plan is developed, based on evidence, stated opinions of CHS staff, and contextual opportunities and challenges.
June 2017		ORCA survey is administered to CHS PCPs and PMHNPs for first time (T1).
	Action and implementation:	
May – July 2017	Plan-Do-Study-Act	Guideline implementation (GI) tools are developed and revised based on feedback from PCPs and PMHNPs and ORCA responses, and in cooperation with information technology (IT) staff.
June 2017		Educational presentation to PCPs and PMHNPs on insomnia EBPG, CBT-I, and implementation strategies
July – October		GI tools are ready and implementation of practice change to include

2017 August 2017		CBT-I as an insomnia treatment option is underway. Ongoing coordination of PCP/PMHNP practice change with CS and nursing staff. Off-campus CBT-I specialist is contacted for coordination of referrals. PCPs who were off for the summer are given educational materials and narrated powerpoint on insomnia EBPG, CBT-I, and implementation strategies. (Their ORCA T1 takes place in September.) Meeting with all PCPs and PMHNPs to elicit their initial experiences with insomnia practice change and give feedback about aggregate data. Suggestions made for minor revisions are then implemented.
	Review and share:	
October 2017 October 2017 – February 2018 January 2018	Re-audit Reflect and discuss results with stakeholders Plan next steps for sustainability	ORCA questionnaire is re-administered to PCPs and PMHNPs (T2). Aggregate data collected to compare with pre-project data. Meetings are held with clinical mentor and then PCPs and PMHNPs to review project accomplishments, share ORCA results and aggregate data, and elicit suggestions for sustaining the use of CBT-I. CBT-I training is provided to CS counselors. BHC program begins, which includes in-house CBT-I services by counselors.

Appendix F

Table 4

Individual Characteristics as a Percentage of the Sample

Characteristic	Providers (*n*=6 out of 7, one chose not to provide demographics)
Profession	
Nurse Practitioner	66.66
Physician	33.33
Years of Practice	
11-15	16.66
16-20	16.66
21-25	50
26-30	16.66
Age in Years	
25-34	16.66
35-44	16.66
45-54	50
55-64	16.66
Race/Ethnicity	
Asian/White	16.66
White	83.33
Gender	
Female	83.33
Male	16.66

Appendix G

Table 5

Organizational Readiness to Change Assessment (ORCA) Scores for Scales at the Two Measurement Time Points

Scale	Time 1 median (range)	Time 2 median (range)	
Evidence for Insomnia Guideline Summary	4.125 (4-4.75)*	4.34 (4-4.84)	*P=0.62**
Evidence for EHR Insomnia Sections	4 (4-4.75)*	4.33 (4-4.75)	*P=0.5**
Evidence for Patient Handouts	4.335 (4-4.75)*	4.75 (4-5)	*P=0.12**
Context	4.09 (3.96-4.24)	4.04 (3.78-4.17)	*P=0.78*
Facilitation	not given	3.88 (3.68-4.52)	

**n*=4 because of missing data; otherwise *n*=7

Appendix H

Organizational Readiness to Change Assessment: Baseline

***Coded ID*_____ *Date*_____**

We need your help assessing your and your colleagues' readiness to implement 3 new tools for managing patients below and ask you to provide your opinions. In the Context section that follows we ask some questions about features of the health center. Please consider each question carefully and circle the answer that best reflects your opinion.

IA. Assessment of Insomnia Guideline Summary

Tool Description: The Insomnia Guideline Summary is being designed for use by CHS providers to facilitate evidence-based assessment and treatment decisions for patients c/o sleep-wake problems.

Outcome Statement: The EHR Guideline Summary will improve providers' ability to assess sleep-wake complaints and make evidence-based insomnia treatment recommendations, including CBT-I when appropriate.

In my opinion, within 1 year the Insomnia Guideline Summary will help improve insomnia assessment and treatment recommendations.

strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
1	2	3	4	5	99

Respected clinical experts in my institution feel using the Insomnia Guideline Summary will help improve insomnia assessment and treatment recommendations.

strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know / not applicable
1	2	3	4	5	99

The changes to improve insomnia assessment and treatment from using the Insomnia Guideline Summary:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
are supported by clinical experience with your CHS patients	1	2	3	4	5	99
are supported by clinical experience with patients in other health care systems	1	2	3	4	5	99
conform to the opinions of clinical experts in this setting	1	2	3	4	5	99

The changes to insomnia assessment and treatment from using the Insomnia Guideline Summary:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
a) have been well-accepted by CHS patients in a pilot study *(hint: this is not applicable)	1	2	3	4	5	99*
b) are consistent with clinical practices that have been accepted by your CHS patients	1	2	3	4	5	99
c) take into consideration the needs and preferences of your CHS patients	1	2	3	4	5	99
d) appear to have more advantages than disadvantages for your CHS patients	1	2	3	4	5	99

IB. Assessment of EHR Insomnia Section(s)

Tool Description: The EHR insomnia section is being designed for use by CHS providers to facilitate evidence-based assessment, treatment recommendations and documentation for patients c/o sleep-wake problems.

Outcome Statement: The EHR insomnia section will improve providers' ability to assess sleep-wake complaints, make evidence-based insomnia treatment recommendations, and document insomnia care.

In my opinion, within 1 year the EHR insomnia section will help improve insomnia assessment, treatment, and documentation.

strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
1	2	3	4	5	99

Respected clinical experts in my institution feel using the EHR insomnia section will help improve insomnia assessment, treatment, and documentation.

strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know / not applicable
1	2	3	4	5	99

The changes to improve insomnia assessment, treatment, and documentation from using the EHR insomnia section:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
are supported by clinical experience with your CHS patients	1	2	3	4	5	99
are supported by clinical experience with patients in other health care systems	1	2	3	4	5	99
conform to the opinions of clinical experts in this setting	1	2	3	4	5	99

The changes to insomnia assessment, treatment, and documentation from using the EHR insomnia section:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
e) have been well-accepted by CHS patients in a pilot study *(hint: this is not applicable)	1	2	3	4	5	99*
f) are consistent with clinical practices that have been accepted by your CHS patients	1	2	3	4	5	99
g) take into consideration the needs and preferences of your CHS patients	1	2	3	4	5	99
h) appear to have more advantages than disadvantages for your CHS patients	1	2	3	4	5	99

IC. Assessment of Patient Handouts: Healthy Sleep Practices & Stimulus Control

Tool Description: The patient handouts on Healthy Sleep Practices and Stimulus Control are being designed to enhance patient education about sleep practices and behavioral sleep strategies by CHS providers.

Outcome Statement: The patient handouts will improve providers' ability to educate patients about healthy sleep practices and behavioral sleep strategies, and provide resources for CBT-I.

In my opinion, within 1 year using these handouts will improve patient education about healthy sleep practices and behavioral sleep strategies.

strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know / not applicable
1	2	3	4	5	99

Respected clinical experts in my institution feel using these patient handouts will improve patient education about healthy sleep practices and behavioral sleep strategies.

strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know / not applicable
1	2	3	4	5	99

The changes to improve patient education about healthy sleep practices and behavioral sleep strategies:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
are supported by clinical experience with your CHS patients	1	2	3	4	5	99
are supported by clinical experience with patients in other health care systems	1	2	3	4	5	99
conform to the opinions of clinical experts in this setting	1	2	3	4	5	99

The changes to improve patient education about healthy sleep practices and behavioral sleep strategies:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
i) have been well-accepted by your CHS patients in a pilot study *(hint: this is not applicable)	1	2	3	4	5	99*
j) are consistent with clinical practices that have been accepted by your CHS patients	1	2	3	4	5	99
k) take into consideration the needs and preferences of your CHS patients	1	2	3	4	5	99
l) appear to have more advantages than disadvantages for your CHS patients	1	2	3	4	5	99

II. Context Assessment

For each of the following statements, please indicate how frequently you have observed the following sets of behaviors, from 1 (very infrequently) to 5 (very frequently).

In the past year, how frequently have you seen senior leadership/clinical management in your clinic:

	very infrequently	infrequently	neither frequently nor infrequently	frequently	very frequently	don't know/ not applicable
a) reward clinical innovation and creativity to improve patient care	1	2	3	4	5	99
b) solicit opinions of clinical staff regarding decisions about patient care	1	2	3	4	5	99
c) seek ways to improve patient education and increase patient participation in treatment	1	2	3	4	5	99

In the past year, how frequently have you observed staff members in your clinic:

	very infrequently	infrequently	neither frequently nor infrequently	frequently	very frequently	don't know/ not applicable
a) exhibit a sense of personal responsibility for improving patient care and outcomes	1	2	3	4	5	99
b) cooperate to maintain and improve effectiveness of patient care	1	2	3	4	5	99
c) demonstrate willingness to innovate and/or experiment to improve clinical procedures	1	2	3	4	5	99
d) respond receptively to change in clinical processes	1	2	3	4	5	99

In the past year, how frequently have you observed senior leadership/clinical management in your clinic:

	very infrequently	infrequently	neither frequently nor infrequently	frequently	very frequently	don't know/ not applicable
a) provide effective management for continuous improvement of patient care	1	2	3	4	5	99
b) clearly define areas of responsibility and authority for clinical managers and staff	1	2	3	4	5	99
c) promote team building to solve clinical care problems	1	2	3	4	5	99
d) promote communication among clinical services and units	1	2	3	4	5	99

In the past year, how frequently have you observed senior leadership/clinical management in your organization:	very infrequently	infrequently	neither frequently nor infrequently	frequently	very frequently	don't know/ not applicable
a) provide staff with information on your clinic's performance measures and guidelines	1	2	3	4	5	99
b) establish clear goals for patient care processes and outcomes	1	2	3	4	5	99
c) provide staff members with feedback/data on effects of clinical decisions	1	2	3	4	5	99
d) hold staff members accountable for achieving results	1	2	3	4	5	99

In the past year, how frequently have you observed opinion leaders in your clinic:	very infrequently	infrequently	neither frequently nor infrequently	frequently	very frequently	don't know/ not applicable
a) express belief that the current practice patterns can be improved	1	2	3	4	5	99
b) encourage and support changes in practice patterns to improve patient care	1	2	3	4	5	99
c) demonstrate willingness to try new clinical protocols	1	2	3	4	5	99
d) work cooperatively with senior leadership/clinical management to make appropriate changes	1	2	3	4	5	99

In the past year, when there has been agreement that change needs to happen, how frequently have you or your colleagues:	very infrequently	infrequently	neither frequently nor infrequently	frequently	very frequently	don't know/ not applicable
a) had the necessary support in terms of budget or financial resources	1	2	3	4	5	99
b) had the necessary support in terms of training	1	2	3	4	5	99
c) had the necessary support in terms of facilities	1	2	3	4	5	99
d) had the necessary support in terms of staffing	1	2	3	4	5	99

Demographic Information—Skip any you prefer not to answer.

Profession—Please circle one:

Physician Advanced Practice Nurse Other (please specify)_____

Years of Professional Practice—Please circle one range (APNs, include pre-APN nursing):

1-5 6-10 11-15 16-20

21-25 26-30 31-35 36-40

41-45 46-50

Age—Please circle one range:

18-24 years old 25-34 years old 35-44 years old

45-54 years old 55-64 years old 65-74 years old

75 years or older

Race/ethnicity—Please circle all that apply:

American Indian or Alaska Native Asian

Black or African American Hispanic, Latino, or Spanish Origin

Native Hawaiian or Other Pacific Islander White

Other (please specify) _____

Gender identity—Please circle one:

Female Male Other (please specify)_____

Thank you for your assistance in completing this survey!

The Organizational Readiness to Change Assessment (ORCA) was developed by the Ischemic Heart Disease Quality Enhancement Research Initiative of the Veterans Health Administration. For more information contact Christian Helfrich, christian.helfrich@va.gov or 206-277-1655.

Organizational Readiness to Change Assessment: Follow-Up

***Coded ID*_____ *Date*_____**

We need your help assessing your and your colleagues' readiness to implement 3 new tools for managing patients below and ask you to provide your opinions. In the Context section that follows we ask some questions about features of the health center. Please consider each question carefully and circle the answer that best reflects your opinion.

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In my opinion, within 1 year the Insomnia Guideline Summary will help improve insomnia assessment and treatment recommendations.

strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
1	2	3	4	5	99

Respected clinical experts in my institution feel using the Insomnia Guideline Summary will help improve insomnia assessment and treatment recommendations.

strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know / not applicable
1	2	3	4	5	99

The changes to improve insomnia assessment and treatment from using the Insomnia Guideline Summary:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
are supported by clinical experience with your CHS patients	1	2	3	4	5	99
are supported by clinical experience with patients in other health care systems	1	2	3	4	5	99
conform to the opinions of clinical experts in this setting	1	2	3	4	5	99

The changes to insomnia assessment and treatment from using the Insomnia Guideline Summary:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
m) are consistent with clinical practices that have been accepted by your CHS patients	1	2	3	4	5	99
n) take into consideration the needs and preferences of your CHS patients	1	2	3	4	5	99
o) appear to have more advantages than disadvantages for your CHS patients	1	2	3	4	5	99

IB. Assessment of EHR Insomnia Section(s)

Tool Description: The EHR insomnia section is being designed for use by CHS providers to facilitate evidence-based assessment, treatment recommendations and documentation for patients c/o sleep-wake problems.

Outcome Statement: The EHR insomnia section will improve providers' ability to assess sleep-wake complaints, make evidence-based insomnia treatment recommendations, and document insomnia care.

In my opinion, within 1 year the EHR insomnia section will help improve insomnia assessment, treatment, and documentation.

strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
1	2	3	4	5	99

Respected clinical experts in my institution feel using the EHR insomnia section will help improve insomnia assessment, treatment, and documentation.

strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know / not applicable
1	2	3	4	5	99

The changes to improve insomnia assessment, treatment, and documentation from using the EHR insomnia section:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
are supported by clinical experience with your CHS patients	1	2	3	4	5	99
are supported by clinical experience with patients in other health care systems	1	2	3	4	5	99
conform to the opinions of clinical experts in this setting	1	2	3	4	5	99

The changes to insomnia assessment, treatment, and documentation from using the EHR insomnia section:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
p) are consistent with clinical practices that have been accepted by your CHS patients	1	2	3	4	5	99
q) take into consideration the needs and preferences of your CHS patients	1	2	3	4	5	99
r) appear to have more advantages than disadvantages for your CHS patients	1	2	3	4	5	99

IC. Assessment of Patient Handouts: Healthy Sleep Practices & Stimulus Control

Tool Description: The patient handouts on Healthy Sleep Practices and Stimulus Control are being designed to enhance patient education about sleep practices and behavioral sleep strategies by CHS providers.

Outcome Statement: The patient handouts will improve providers' ability to educate patients about healthy sleep practices and behavioral sleep strategies, and provide resources for CBT-I.

In my opinion, within 1 year using these handouts will improve patient education about healthy sleep practices and behavioral sleep strategies.

strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know / not applicable
1	2	3	4	5	99

Respected clinical experts in my institution feel using these patient handouts will improve patient education about healthy sleep practices and behavioral sleep strategies.

strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know / not applicable
1	2	3	4	5	99

The changes to improve patient education about healthy sleep practices and behavioral sleep strategies:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
are supported by clinical experience with your CHS patients	1	2	3	4	5	99
are supported by clinical experience with patients in other health care systems	1	2	3	4	5	99
conform to the opinions of clinical experts in this setting	1	2	3	4	5	99

The changes to improve patient education about healthy sleep practices and behavioral sleep strategies:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	don't know/ not applicable
s) are consistent with clinical practices that have been accepted by your CHS patients	1	2	3	4	5	99
t) take into consideration the needs and preferences of your CHS patients	1	2	3	4	5	99
u) appear to have more advantages than disadvantages for your CHS patients	1	2	3	4	5	99

II. Context Assessment

For each of the following statements, please indicate how frequently you have observed the following sets of behaviors, from 1 (very infrequently) to 5 (very frequently).

In the past year, how frequently have you seen senior leadership/clinical management in your clinic:	very infrequently	infrequently	neither frequently nor infrequently	frequently	very frequently	don't know/ not applicable
d) reward clinical innovation and creativity to improve patient care	1	2	3	4	5	99
e) solicit opinions of clinical staff regarding decisions about patient care	1	2	3	4	5	99
f) seek ways to improve patient education and increase patient participation in treatment	1	2	3	4	5	99

In the past year, how frequently have you observed staff members in your clinic:	very infrequently	infrequently	neither frequently nor infrequently	frequently	very frequently	don't know/ not applicable
e) exhibit a sense of personal responsibility for improving patient care and outcomes	1	2	3	4	5	99
f) cooperate to maintain and improve effectiveness of patient care	1	2	3	4	5	99
g) demonstrate willingness to innovate and/or experiment to improve clinical procedures	1	2	3	4	5	99
h) respond receptively to change in clinical processes	1	2	3	4	5	99

In the past year, how frequently have you observed senior leadership/clinical management in your clinic:	very infrequently	infrequently	neither frequently nor infrequently	frequently	very frequently	don't know/ not applicable
e) provide effective management for continuous improvement of patient care	1	2	3	4	5	99
f) clearly define areas of responsibility and authority for clinical managers and staff	1	2	3	4	5	99
g) promote team building to solve clinical care problems	1	2	3	4	5	99
h) promote communication among clinical services and units	1	2	3	4	5	99

In the past year, how frequently have you observed senior leadership/clinical management in your organization:	very infrequently	infrequently	neither frequently nor infrequently	frequently	very frequently	don't know/ not applicable
a) provide staff with information on your clinic's performance measures and guidelines	1	2	3	4	5	99
b) establish clear goals for patient care processes and outcomes	1	2	3	4	5	99
c) provide staff members with feedback/data on effects of clinical decisions	1	2	3	4	5	99
d) hold staff members accountable for achieving results	1	2	3	4	5	99

In the past year, how frequently have you observed opinion leaders in your clinic:	very infrequently	infrequently	neither frequently nor infrequently	frequently	very frequently	don't know/ not applicable
e) express belief that the current practice patterns can be improved	1	2	3	4	5	99
f) encourage and support changes in practice patterns to improve patient care	1	2	3	4	5	99
g) demonstrate willingness to try new clinical protocols	1	2	3	4	5	99
h) work cooperatively with senior leadership/clinical management to make appropriate changes	1	2	3	4	5	99

In the past year, when there has been agreement that change needs to happen, how frequently have you or your colleagues:	very infrequently	infrequently	neither frequently nor infrequently	frequently	very frequently	don't know/ not applicable
e) had the necessary support in terms of budget or financial resources	1	2	3	4	5	99
f) had the necessary support in terms of training	1	2	3	4	5	99
g) had the necessary support in terms of facilities	1	2	3	4	5	99
h) had the necessary support in terms of staffing	1	2	3	4	5	99

III. Facilitation Assessment:

For each of the following statements, please rate the strength of your agreement with the statement, from 1 (strongly disagree) to 5 (strongly agree).

For this project, senior leadership/clinical management have:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	Don't know/ Not Applicable
a) endorsed a project that is appropriate and feasible	1	2	3	4	5	99
b) endorsed clear goals for improvement in patient care	1	2	3	4	5	99
c) endorsed the project schedule and deliverables	1	2	3	4	5	99
d) designated a clinical champion for the project (Maria Denny)	1	2	3	4	5	99

The project clinical champion (Maria Denny):	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	Don't know/ Not Applicable
a) accepts responsibility for the success of this project	1	2	3	4	5	99
b) has the authority to carry out the implementation	1	2	3	4	5	99
c) is considered a clinical opinion leader	1	2	3	4	5	99
d) works well with the intervention team and providers	1	2	3	4	5	99

Senior leadership/clinical management/staff opinion leaders:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	Don't know/ Not Applicable
a) agree on the goals for this intervention	1	2	3	4	5	99
b) are informed and involved in the intervention	1	2	3	4	5	99
c) agree on adequate resources to accomplish the intervention	1	2	3	4	5	99
d) set a high priority on the success of the intervention	1	2	3	4	5	99

The implementation team members (the primary care providers & PMHNPs):	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	Don't know/ Not Applicable
a) share responsibility for the success of this project	1	2	3	4	5	99
b) have clearly defined roles and responsibilities	1	2	3	4	5	99
c) can accomplish intervention tasks within their regular work load	1	2	3	4	5	99
d) have staff support and other resources required for the project	1	2	3	4	5	99

The implementation plan for this intervention:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	Don't know/ Not Applicable
a) identifies specific roles and responsibilities	1	2	3	4	5	99
b) clearly describes tasks and timelines	1	2	3	4	5	99
c) includes appropriate provider/patient education	1	2	3	4	5	99
d) acknowledges staff input and opinions	1	2	3	4	5	99

Communication is maintained through:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	Don't know/ Not Applicable
a) regular contact with the project champion and team members	1	2	3	4	5	99
b) involvement of quality management staff in project planning and implementation	1	2	3	4	5	99
c) regular feedback to clinical management on progress of project activities and resource needs	1	2	3	4	5	99
d) regular feedback to clinicians on effects of practice changes on patient care/outcomes	1	2	3	4	5	99

Progress of the project will be measured by:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	Don't know/ Not Applicable
a) collecting feedback from patients regarding proposed/implemented changes	1	2	3	4	5	99
b) collecting feedback from staff regarding proposed/implemented changes	1	2	3	4	5	99
c) developing and distributing regular performance measures to clinical staff	1	2	3	4	5	99
d) providing a forum for presentation/discussion of results and implications for continued improvements	1	2	3	4	5	99

The following are available to make the selected plan work:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	Don't know/ Not Applicable
a) staff incentives	1	2	3	4	5	99
b) equipment and materials	1	2	3	4	5	99
c) patient awareness/need	1	2	3	4	5	99
d) provider buy-in	1	2	3	4	5	99
e) intervention team	1	2	3	4	5	99
f) evaluation protocol	1	2	3	4	5	99

Plans for evaluation and improvement of this intervention include:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree	Don't know/ Not Applicable
a) periodic outcome measurement	1	2	3	4	5	99
b) staff participation/satisfaction survey	1	2	3	4	5	99
c) patient satisfaction survey	1	2	3	4	5	99
d) dissemination plan for performance measures	1	2	3	4	5	99
e) review of results by clinical leadership	1	2	3	4	5	99

Demographic Information—Skip any you prefer not to answer.

Profession—Please circle one:

Physician Advanced Practice Nurse Other (please specify)_____

Years of Professional Practice—Please circle one range (APNs, include pre-APN nursing):

1-5 6-10 11-15 16-20

21-25 26-30 31-35 36-40

41-45 46-50

Age—Please circle one range:

18-24 years old 25-34 years old 35-44 years old

45-54 years old 55-64 years old 65-74 years old

75 years or older

Race/ethnicity—Please circle all that apply:

American Indian or Alaska Native Asian

Black or African American Hispanic, Latino, or Spanish Origin

Native Hawaiian or Other Pacific Islander White

Other (please specify) _____

Gender identity—Please circle one:

Female Male Other (please specify)_____

Thank you for your assistance in completing this survey!

The Organizational Readiness to Change Assessment (ORCA) was developed by the Ischemic Heart Disease Quality Enhancement Research Initiative of the Veterans Health Administration. For more information contact Christian Helfrich, christian.helfrich@va.gov or 206-277-1655.