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MESSIAH UNIVERSITY

SCHOOL OF GRADUATE STUDIES

DOCTOR OF NURSING PRACTICE (DNP) PROGRAM

Family Nurse Practitioner Track

A DNP PROJECT

Sleep Quality Screening in Primary Care Patients with Chronic Pain

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DNP PROJECT TEAM MEMBERS: Kristen Slabaugh, Kimberly Fenstermacher, Nancy Woods, Louann Zinsmeister

DATE: August 2020

MESSIAH UNIVERSITY

SCHOOL OF GRADUATE STUDIES

Sleep Quality Screening in Primary Care Patients with Chronic Pain

A Project Presented to the Faculty of the Department of Nursing

Messiah University

In partial fulfillment of the requirements

For the Degree of Doctor of Nursing Practice

Family Nurse Practitioner Track

By

Nicholas Montgomery, BSN, RN

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Sleep Quality Screening in Primary Care Patients with Chronic Pain

Submitted in Partial Fulfillment of the Requirements

for the Degree of Doctor of Nursing Practice at Messiah University

By

Nicholas D. Montgomery

July, 2020

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Abstract

Background: Many patients receive treatment for chronic pain from a primary care provider. There is a known relationship between sleep and pain perception, making sleep an important factor to assess in patients with chronic pain. Unlike in specialist pain management settings, sleep is not routinely assessed in the primary care setting, resulting in missed treatment opportunities and suboptimal chronic pain management. **Objective:** To assess the sleep quality of patients with chronic pain in the primary care setting through the use of the Pittsburgh Sleep Quality Index (PSQI) questionnaire during the patient intake process. **Methods:** Patients meeting inclusion criteria received a PSQI while waiting to see a provider at chronic care visits. The primary care provider was alerted to the result, and patients who were identified as having poor sleep quality scoring > 5 on the PSQI had the opportunity to receive further assessment and treatment from the provider. **Results:** Sample data scores revealed 77.7% (n = 7) of patients with chronic pain had global PSQI greater than 5, which is indicative of impaired sleep quality (M = 13, SD = 5.24). All patients (n = 9) received educational handouts from their providers concerning sleep hygiene. The number of patients with an insomnia diagnosis (n = 7) and the number of patients receiving prescribed medication for insomnia (n = 2) did not change after the screening implementation. **Conclusion:** Implementation of a sleep assessment tool such as the PSQI did not support the increased identification of an insomnia diagnosis or increased management of insomnia with medication in the primary care setting.

Keywords: Sleep quality, sleep assessment, chronic pain

Title of Project

The title of this project is Sleep Quality Screening in Primary Care Patients with Chronic Pain.

Background

Chronic pain and sleep have an intricate, bidirectional relationship with pain decreasing the quality of sleep, and poor sleep quality being known to exacerbate pain (Abbasi, Kazemifar, Fatorechi, & Yazdi, 2018). According to the 2016 National Health Interview Survey, greater than 50 million adults in the United States suffer from chronic pain (Dahlhamer et al., 2018). Among people with sleep difficulties who suffer from chronic pain, more than four out of ten stated that poor sleep quality interfered with their work (Appold, 2015). At the individual level, poor sleep quality adversely affects activity performance, mood, pain experience, and overall quality of life. Patients with insomnia reported experiencing spontaneous pain on twice as many days as healthy controls during at-home actigraphy recording (Haack et al., 2012). Management of patients with chronic pain is challenging and time-consuming. Over 90% of prescribers stated that assessing medical comorbidities such as sleep was extremely important in this population however, 66% admitted being unable to refer to guidelines for therapy (Provenzano, Kamal, & Giannetti, 2018).

Problem Statement

Primary care providers (PCP) are regularly responsible for treating and managing chronic pain in adults, but without the specialized knowledge of those practicing in the pain management discipline (Provenzano et al., 2018). For patients with chronic pain managed at the primary care level, sleep assessments are not routinely integrated into primary care visits. The question this project seeks to answer is, in adults ages 18 and older diagnosed with chronic pain who present to primary care offices for chronic care visits, does routine screening for sleep quality with the

Pittsburgh Sleep Quality Index (PSQI) increase the identification of a diagnosis of insomnia and management with medication in a single sample of patients after screening was implemented as compared to before screening was implemented?

Needs Assessment

In the past, practitioners were encouraged to treat pain and sleep as unidirectional, with the notion that decreased pain would improve sleep quality. Finan, Goodin, and Smith (2013) have suggested a multidirectional relationship between sleep and pain such that impaired sleep heightens a patient's pain perception leading to a cyclical effect of fatigue and pain. Recognizing and treating sleep has been shown to improve the quality of sleep and improve pain severity in patients with chronic pain (Finan et al., 2013).

The quality improvement project site is a Federally Qualified Health Center (FQHC), which provides care to a rural 1,017 square mile area bordering Maryland in south-central Pennsylvania. During the 60-day implementation period, both offices combined conducted approximately 3,000 patient visits for a variety of primary care needs. The project site serves patients with chronic pain. Best practices for pain management in this population are important, as public programs absorb financial repercussions of excessive visits and a greater need for medications through the use of 340b pharmacy programs, Medicare, and Medicaid (Chang, Bynum, & Lurie, 2019). The project site is well-suited for the implementation of this quality improvement project as there are few primary care providers in the area, and the nearest specialty pain management practice is located 45 minutes away. Other strengths include the use of a robust electronic medical records system that facilitates easy review by the doctor of nursing practice (DNP) student of documentation as well as an internal culture among providers of employing multimodal pain relief for chronic pain management.

The project site's existing internal structure supports the integration of sleep assessments to be easily integrated into chronic care visits for patients with chronic pain. There are already policies and procedures in place for the management of chronic pain, such as routine urine drug screening and random medication counts performed by the nursing staff for those taking opioid medication. The practice does not routinely assess patients with chronic pain for sleep quality and chronic pain is not always well managed. A meta-analysis by Mathias, Cant, and Burke (2018) suggested that the prevalence of poor sleep quality in patients with chronic pain is 72%; however, few patients with chronic pain at the project site had documentation addressing sleep quality in the medical record. A weakness of the project site is the risk for variability between the two office locations for data collection. With multiple offices comprised of different providers and support staff, the potential exists for the sleep assessment to be conducted inconsistently between the two offices. See Appendix A for a complete SWOT analysis.

Aims, Objectives, Purpose Statement

The aim of this project was to improve the identification of a diagnosis of insomnia and management of insomnia with medication among patients with a history of chronic pain in the primary care setting through the use of a validated self-assessment sleep questionnaire. In support of this aim, three objectives were created: (a) at least 75% of patients with a history of chronic pain who present for a chronic care visit will be screened for sleep quality within a 2-month time period using the PSQI; (b) during this 2-month screening period, all patients with newly demonstrated poor sleep quality based on positive results from the PSQI will have his/her provider for that visit alerted to this finding; and (c) providers alerted to a patient with a positive PSQI will provide an intervention to a minimum of 90% of patients identified during the 2-month investigation. The purpose of this quality improvement project was to introduce a

standardized sleep assessment tool into the primary care setting to screen patients with chronic pain for the presence of untreated poor sleep quality.

Review of Literature

A search of the literature from CINAHL, PsycINFO, and PubMed was performed in May 2019 to March 2020 for articles containing the keywords sleep quality, quality of sleep, or sleep problem and pain management, pain relief, pain control, or pain reduction. The MeSH search terms sleep and pain management were used to search the PubMed database. After removing duplicates and screening articles published in English, 23 relevant articles were reviewed (see Appendix B), and the Johns Hopkins Evidence-Based Model was used to appraise the literature (Dang & Dearholt, 2018). The available evidence was primarily level III of A or B quality consisting of two systematic reviews, a meta-analysis, a review of literature, a randomized controlled trial, several quasi-experimental studies, and numerous descriptive studies on pain and sleep.

Sleep disorders encompass a broad range of impairment related to a patient's ability to achieve the necessary sleep required to function effectively (Schutte-Rodin, Broch, Buysse, Dorsey, & Sateia, 2008). Insomnia, the most common sleep disorder, is defined as trouble initiating or maintaining sleep, which is associated with negative daytime consequences and is not attributable to environmental circumstances, including a lack of opportunity to sleep (Sateia, 2014). Another important component of sleep as it relates to pain is sleep latency, the time it takes to fall asleep following bedtime (Sateia, Buysse, Krystal, Neubauer, & Heald, 2017).

Patients with chronic pain are at greater risk for poor sleep quality due to taking opioids, which have the potential to alter sleep regulation and are independently associated with poor sleep quality and insomnia (Els et al., 2017). Of the multiple dimensions to sleep quality, sleep

latency and restlessness may have a stronger relation to pain perception than total sleep duration (Song et al., 2018). Sleep duration and latency are associated with decreased pain thresholds (Edwards, Almeida, Klick, Haythornthwaite, & Smith, 2008; Haack et al., 2012; Mathias, Cant, & Burke, 2018). Improvements in fatigue and sleep were significantly associated with the reduction of pain intensity (Vega et al., 2019). Improvements have occurred in sleep latency following a single brief educational intervention focusing on strategies to improve sleep hygiene (Berry et al., 2015; Vega et al., 2019).

The American Academy of Sleep Medicine (AASM) recommends the assessment of patients with symptoms of insomnia and recommends treatment when insomnia has "a significant negative impact on the patient's sleep quality, health, comorbid conditions, or daytime function" (Schutte-Rodin et al., 2008, p. 487). In the outpatient setting, assessment is most practically accomplished through the use of self-reported questionnaires that screen for sleep disorders, the oldest and most studied questionnaire being the PSQI (Klingman, Jungquist, & Perlis, 2017). The PSQI provides a meaningful breakdown of a patient's sleep quality into multiple dimensions of sleep, which provides an advantage over other well-established sleep assessment instruments that only provide a single summation of a patient's responses (Klingman et al., 2017). See Appendix C for a comprehensive review of literature evidence matrix.

Theoretical Model

The theory of unpleasant symptoms (see Appendix D) seeks to explain how a physiologic pathology can trigger a psychological response that in turn can heighten the perception of the initial symptom, in addition to creating a new independent symptom (Lenz, Pugh, Milligan, Gift, & Suppe, 1997). It explains symptom clusters in terms of three factors: the actual symptoms, factors that influence the symptoms, and the performance outcomes for the patient (Lenz et al.,

1997). Consequently, pain and sleep may not be unidimensional symptoms in the chronic pain population, and the assessment and treatment need to be comprehensive to treat both conditions effectively.

Translation Model

The Ottawa Model of Research Use (see Appendix E) was selected to guide the translation of evidence. It describes the overall translation process beginning with assessing barriers and supports, monitoring the adoption process of the intervention, and assessing the results of the project (Graham & Logan, 2004). The useful aspect of this model is the inclusion of supportive steps in the process map, such as analyzing the attributes of the innovation, the attitudes of adopters of the intervention, and the response of the practice environment. Specific to this project, the DNP student gave careful attention to the ongoing monitoring of the implementation as it was influenced by uncontrolled events and perceived barriers as reported by staff. As part of the continuous process evaluation, it was important to acknowledge how these factors informed the outcomes of the implementation and use this insight when evaluating the outcomes of the project, such as a smaller than expected sample size. The model was particularly useful in the context of adapting the implementation during the 2019 novel coronavirus pandemic, which led to remote oversight of the implementation rather than the intended direct on-site supervision originally planned.

Methodology

The quality improvement project involved a single sample of primary care patients with a history of documented chronic pain as determined by a retrospective chart review. Patients who presented for chronic care visits with a history of chronic pain as determined by a documented international classification of diseases (ICD-10) code indicating chronic pain were identified by

the nursing support staff when escorting patients to an exam room. Eligibility was not dependent on current opioid usage. Patients who met the inclusion criteria were provided informed consent (Appendix F) and a PSQI questionnaire to complete while waiting to see the provider before the appointment in a private exam room.

Participants

The patients of the healthcare center with a history of chronic pain must have been 18 years of age or older and could read and write in English to participate in this project. Exclusion criteria included being actively seen by a pain management specialist and being unable to provide informed legal consent. On average, 30 patients per month are treated for chronic pain by each PCP in western Pennsylvania, therefore 60 patients were projected to be included in this project assuming a 50% participation rate of the patients seeing each of the four full-time providers (Provenzano et al., 2018).

Setting

The setting for this project was a small two-location, rural FQHC. The facility avoids the use of controlled substances to treat pain whenever possible. The office consists of multiple providers. On any given day, there are two providers with their own medical assistants at each site. A medical assistant or licensed practical nurse facilitates patient intake. The main office location consists of eight exam rooms and a procedure room. There is ample space in a large shared provider office for providers, students, and the project leader. The second office location offers similar accommodations.

Tools

The PSQI (see Appendix G) was chosen as a standardized instrument to measure the quality of patient sleep (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). A self-reporting

sleep questionnaire requiring less than 10 minutes to complete, the PSQI measures sleep across seven domains: (a) subjective sleep quality; (b) sleep latency; (c) sleep duration; (d) habitual sleep efficiency; (e) sleep disturbances; (f) use of sleep medication; and (g) daytime dysfunction in the month preceding the time of assessment (Buysse et al., 1989). Each sleep domain is scored 0-3, and a global sleep quality score out of a possible total of 21 is calculated as the sum of the seven dimensions of the assessment tool (Mollayeva et al., 2016). Global PSQI values greater than five are indicative of poor sleep quality. This tool has demonstrated reliability (Cronbach's $\alpha = 0.83$), and construct validity has been supported through the use of the PSQI in subjects with varying known sleep disorders consistently yielding $p < 0.001$ (Buysse et al., 1989). Written permission (see Appendix H) to use the PSQI in this project was granted by Dr. Daniel Buysse and The University of Pittsburgh in July 2019.

Intervention

The nursing support staff identified the patient as having chronic pain by reviewing patient charts for ICD coding supporting a chronic pain diagnosis. Patients who met the inclusion criteria were provided the opportunity to complete the PSQI during the check-in process. Nursing support staff scored the PSQI and alerted the provider if poor sleep quality was indicated by scores greater than five before the patient saw the provider. After reviewing the results of the PSQI, the provider was encouraged to make appropriate evidence-based recommendations unless otherwise indicated, which included assigning a formal diagnosis of insomnia, the distribution of printed educational material concerning sleep hygiene (see Appendix I), or medication management. Providers were free to use their knowledge of the patient and professional discretion when pursuing evidence-based interventions with the patient;

however, only interventions categorized into areas of diagnosis, patient education, or medication management were considered for the scope of this project.

The DNP student serving as the project leader assisted the support staff and providers with questions and logistic concerns. Before the implementation of the project, several meetings were held with staff from both offices. Evidence in the literature was shared indicating the role of sleep in patients with chronic pain. Data were reviewed with staff highlighting the high prevalence of poor sleep quality in the local region. The PSQI was discussed, samples distributed, and scoring reviewed.

Each provider received a binder detailing the interpretation of the PSQI scoring for each dimension of sleep. A systematic review published by the AASM about treatment practices and recommendations was provided in addition to highlighted national and statewide prevalence data for sleep disorders and data on frequently occurring comorbid conditions found within the population by the Centers for Disease Control and Prevention (CDC). Recommendations from the CDC for identifying and treating common sleep disorders such as insomnia, REM sleep behavior disorder, shift work sleep disorder, and an introduction to brief behavioral treatment for insomnia (BBTI) were given to the providers. Intervention fidelity was planned to occur as part of a weekly review of patients seen to audit for missed opportunities for screening, lack of communication of the results to the provider, and the frequency in which the providers took action based on the results from the PSQI. See Appendix J for a process map.

Data Collection

Data collection was comprised of an analysis of completed PSQI forms and retrospective reviews of the electronic medical record. The post-implementation phase included data extraction for use in descriptive statistics and univariate analysis. Data analyzed included the

total number of (a) patients who completed the PSQI, (b) patients who screened positive for poor sleep per the PSQI, (c) breakdown of sleep dimension scores on the PSQI, and (d) patients who received follow-up from their provider related to the PSQI results. Demographic data were also collected including age, gender, past medical history of a sleep disorder, history of sleep disorder treatment with medication, and comorbid conditions.

Cost Analysis

A comprehensive budget (see Appendix K) listed donated expenses for consideration of the costs of labor involved for use in future implementations. The project's total estimated cost was $9,180.00, all of which was donated on behalf of the facility or the DNP student. The relative costs are offset by reducing visits and healthcare utilization. Insurance programs save money as a result of fewer claims, patients save money with fewer expenses for those with cost-sharing insurance plans, and the facility receives financial incentives tied to improved outcomes. In addition to reducing acute visits to the PCP, a reduction of hospitalizations and emergency department visits result in fewer follow-up appointments and aid in long-term sustainability from a cost perspective.

Timeline

A GANTT chart (see Appendix L) was created to guide the timeline for this project. Pre-implementation tasks include the project proposal, implementation site board approval, Institutional Review Board (IRB) approval, and preparation of materials for the implementation phase. Pre-implementation was completed in February 2020. The implementation phase included meetings with staff in addition to the implementation of the PSQI in March 2020. The implementation continued through May 2020, at which point the post-implementation phase began with data extraction, statistical analyses, presentation of the results to the facility, and the

creation and submission of the final manuscript. The post-implementation phase concluded in July 2020.

Ethics and Human Subject Protection

Formal support was obtained from the Hyndman Area Health Center leadership, and final research protocol approval was deferred to the IRB at Messiah University. Approval from the Messiah University IRB was obtained prior to initiating the quality improvement project. All participants were protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which provides privacy protections for the patients' health information (Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 2013). Additionally, the DNP student and practice staff who conducted this project carefully followed the established guidelines and regulations to ensure all protections were afforded to patients in the primary care office. All information collected as part of evaluating the impact of this project were aggregate data from the project participants and did not include any patient identifiers.

The risks to patients participating in this project were no different from the risks of patients who did not complete the PSQI survey instrument, which is the current standard of care. Participant confidentiality was assured by coding the participants using individual identification numbers. The list of participants was kept secured in double-locked, tamper-proof containers at each practice location, only accessible to the DNP student. Electronic files were password-protected to prevent access by unauthorized users, and only the DNP student had access to the passwords.

Results

Analysis and Evaluation

Quantitative data analysis was performed using IBM SPSS version 26.0. Descriptive statistics were reviewed for patient demographics, including age, gender, past medical history, global PSQI scores, as well as the seven individual dimensions of sleep quality measured by the PSQI. To evaluate the differences between demographics and the results of the PSQI, chi-square and Fisher's exact test of independence were conducted. Because the outcome data consisted of paired samples, a McNemar's test was used to ascertain whether a significant change had occurred in insomnia diagnosis or treatment with medications before the sleep assessment was conducted (as determined through historical chart review) as compared to after the patient completed the sleep assessment and met with the provider.

Nine patients were included in this quality improvement project aged 42-90 ($M = 57.11$, $SD = 14.28$), the majority of which were female (55.6%, $n = 5$). As indicated by ICD coding, 77.8% ($n = 7$) of patients had a documented history of a sleep disorder in the medical record. The sample population had a significant number of comorbidities with the most common being obesity (88.9%, $n = 8$), coronary heart disease (66.7%, $n = 6$), and depression (55.6%, $n = 5$). See Appendix M for a complete listing of highlighted comorbidities within the sample. An analysis of individual participant demographic variables found that female participants were significantly more likely to report taking sleep medication three or more times a week on the PSQI as compared to male participants ($\chi 2\ (1) = 5.760$, $p = .048$, Fisher's exact test). There were no other statistically significant relationships found between the demographic variables of age, gender, or past medical history and the results of the PSQI.

An analysis of the sample data scores revealed 77.7% (n = 7) of patients with chronic pain had global PSQI greater than five, which is indicative of impaired sleep quality (M = 13, SD = 5.24). See Appendix N for a detailed description of the PSQI score results by sleep dimension. All patients (n = 9) received educational handouts from their providers concerning sleep hygiene. The number of patients with an insomnia diagnosis (n = 7) and the number of patients receiving prescribed medication for insomnia (n = 2) did not change after the screening was implemented. The McNemar's test determined that there was not a statistically significant difference in the identification of a diagnosis of insomnia or the management of insomnia with medications before and after the screening was implemented, p = 1.00.

Discussion

The data highlight the significant prevalence of poor sleep quality in this sample of patients with chronic pain. The high occurrence of poor sleep quality among patients with chronic pain in this sample is consistent with previously published literature, which found that patients with chronic pain are more than twice as likely to have poor sleep quality as compared to healthy patients (Call-Schmidt & Richardson, 2003). Of the 77.8% of patients with a documented diagnosis of poor sleep quality, only two patients had documentation in the medical record of treatment with medication. No new medication regimens were initiated as a result of this intervention. While all patients in the sample population (n = 9) received printed educational materials about sleep hygiene, no new diagnoses of insomnia were noted in the medical record following the implementation of the sleep quality assessment. In short, the implementation of the PSQI did not increase the identification of a diagnosis of insomnia or increase the management of insomnia with medication in this sample. This highlights that assessment alone,

even with well-designed tools such as the PSQI, does not yield statistically or clinically significant outcomes.

In the context of the pre-intervention objectives, the aims of this project were only partially met. All patient results (positive or negative) from the PSQI were communicated to the provider. While all patients in the sample received educational materials exceeding the 90% or greater original objective, there was no effect on the identification or management with medication. Chronic care visits conducted using telehealth systems resulted in a decreased number of eligible patients available to participate in this project in relation to the total number of documented chronic care visits during the implementation period. Strategies to sustain the project going forward include discussing with providers ways to offer the PSQI to patients virtually in the case of future social distancing and stay-at-home orders impacting the ability of patients to safely present to the office in person. Barriers experienced by the providers that may have prevented the application of the PSQI results to identification and management of poor sleep quality must also be explored prior to continued use.

Sleep assessments such as the PSQI are not frequently a part of chronic care visits in many primary care offices. Barriers to implementation and interpretation of the assessment results include time constraints not present in specialty offices such as decreased appointment times and providers needing to actively managing multiple comorbidities in addition to chronic pain. Primary care providers also have fewer specialized resources and education to prepare them to provide evidence-based recommendations and treatment modalities. Any of these barriers alone may account for the effect size of zero for the implementation of the PSQI in this setting. Future research may discover other barriers to identifying insomnia and managing symptoms with medication that are unique to the rural primary care setting.

An unexpected finding from the review of completed PSQI was the report of 44.4% (n = 4) of patients taking medications for sleep three or more times each week despite only 22.2% (n = 2) patients having documented medications indicated for sleep in the medical record. This knowledge should prompt providers to clarify what medications (over the counter or prescription) the patient may be taking for insomnia. From a safety perspective, patients may be taking medications that are contraindicated or taking medication inappropriately for sleep that has been prescribed for another purpose altogether. It is important to note that all four patients who indicated they took medication for sleep three or more times a week were female. This complements the statistically significant relationship found between the use of sleep medication and gender, the only demographic variable that showed a statistically significant relationship with results from the PSQI.

There are limitations to this project. COVID-19 played a significant role in the execution of the implementation of sleep quality assessments. Statewide restrictions of non-essential travel and business prevented many patients from attending chronic care appointments. Of those patients with chronic pain who did need to have chronic care appointments, telephone and virtual appointments were conducted for some in light of social distancing recommendations. These patient appointments did not follow the usual intake process and resulted in a missed opportunity for assessment with the PSQI. The project's small sample size is underpowered thus increasing the risk of a Type II error; nonsignificant findings must be viewed with caution. The findings may not accurately capture a true representation of the rural primary care practice's population of patients with chronic pain. Another limitation in the implementation of this project is the homogenous racial and ethnic makeup of the patient population. The local population is

predominately lower to middle-class Caucasians of European descent, which may reduce generalizability to other more diverse populations of patients with chronic pain.

For future research, an investigation into patient reports of using unreported medication for sleep-related purposes may provide insight into the lack of documentation in the medical record of sleep medication despite patients with chronic pain citing frequent use according to the PSQI in this sample. In addition, a nonequivalent groups pre-post study design to ascertain the impact of including the PSQI assessment tool into care would provide valuable insight into eliminating any potential confounding variables. As a future a priori analysis, control and intervention groups of 237 participants each would provide an adequate sample size when considering a projected 10% loss of participation rate given 80% power, an alpha of .05, and a small to medium effect size. Although this may present practical difficulties in recruiting a large number of participants with chronic pain in a rural primary care setting, future research is needed to demonstrate clinical significance and provide high-level evidence to support using a standardized sleep assessment tool such as the PSQI in this population.

Conclusion

Sleep and pain are interrelated. For patients with chronic pain, optimizing sleep quality is the responsibility of many primary care providers managing this population of patients not only to improve sleep quality, but also to complement pain management. As a standard of practice, sleep is not routinely assessed at chronic care visits in the primary care setting. Data from this project suggest that implementation of a sleep assessment tool such as the PSQI does not increase the identification of an insomnia diagnosis or increase the management of insomnia with medication in the rural primary care setting.

The results from this project support the role of advanced practice nursing by introducing data on the use of evidence-based sleep assessment tools in the rural primary care setting. For providers seeking to optimize pain management strategies, the use of standardized sleep assessment tools such as the PSQI in primary care is valuable despite the nonsignificant findings from this project. Results from this project do raise important questions about the role gender plays in the use of sleep medication, the undocumented use of sleep medication in the population of patients with chronic pain, and the unique barriers to addressing poor sleep quality in the primary care setting. Future research is needed to inform care and improve this important dimension of chronic pain management in rural primary care settings.

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Appendices

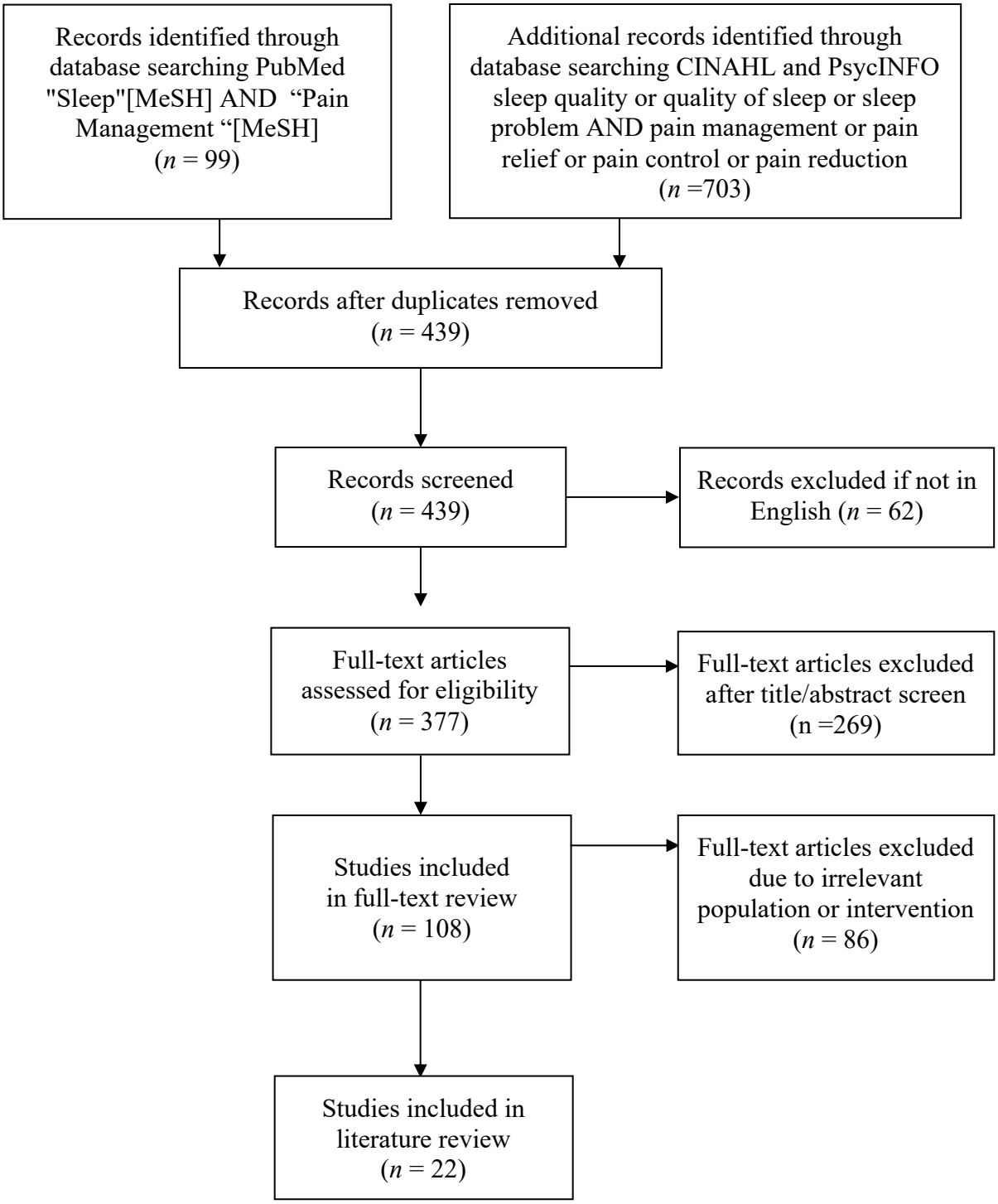
Appendix A:

SWOT Analysis of Proposed Project Site

Strengths	Opportunities
• Supportive organizational culture • Strong dedication to community-centered needs and care • Available and accessible workplace • Medical Director dedicated to minimizing the use of controlled substance pain medication whenever possible • Current EHR facilitates easy verification of chronic pain history	• Being the only healthcare facility in the immediate area attracts a broad population including those with chronic pain • No Pennsylvania-based pain management specialist within 45-minute drive
Weaknesses	**Threats**
• Inconsistency among staff rooming patients • Lack of consistent wireless internet access for electronic data collection • Multiple providers and support staff across two physical locations may lead to inconsistencies in data collection	• External environment accustomed to opioid use as the norm for chronic pain treatment • Difficulty in accessing external treatment records and history from other providers • Stigma associated with chronic pain

Appendix B

PRISMA Diagram



Appendix C:

Literature Review Table

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
1	Afolalu, Sleep Medicine Reviews, 2017	Systematic review with meta-analysis of RCTs, quasi-experimental, and descriptive studies. To evaluate the effect of sleep changes (simulating sleep deterioration, sleep stability, and sleep improvement) on subsequent pain-related outcomes in the general population.	Review of 16 longitudinal studies involving 61,000 participants across 10 countries.	Sleep deterioration has a negative effect on pain-related health outcomes. There was insufficient evidence to suggest a clear positive effect of sleep improvement on pain. Poor sleep at baseline is a risk factor for developing a future pain condition. Changes in sleep are prospectively associated with the experience of pain, suggesting a potential causal association.	Very small (3) number of studies included in the meta-analysis. Lack of uniformity in how the quality of sleep was assessed across the 16 studies reviewed.	III	B
2	Alkkan Melikoglu, Eurasian Journal of Medicine, 2017	Original correlational research study. To evaluate the quality of sleep in patients with neuropathic pain and to investigate the association	70 patients with neuropathic pain (18-64 years old) and 30 age- and sex-matched controls were included in the study. No further description of the same	Neuropathic pain duration, and pain intensity were factors related to having poor quality of sleep in patients with neuropathic pain. While comparing Pittsburgh Sleep Quality scores, patients with	The authors did not report the results of any power analysis or impact that a smaller sample size would have on the generalizability of their findings. A disproportionate number of females vs.	III	B

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
		between possible quality of sleep impairment and neuropathic pain characteristics.	selection was described.	neuropathic pain had statistically significant lower quality of sleep latency, duration, efficiency, disturbance, and daytime dysfunction as compared to the control group. 80% of patients with neuropathic pain and 37% of controls were classified as having poor sleep quality.	males represented in the recruited sample. No discussion of sample selection methods.		
3	Berry, Rehabilitation Psychology, 2015	Randomized controlled trial. To determine whether a brief education session that incorporates sleep hygiene and cognitive-behavioral strategies would help to improve the sleep of individuals with chronic pain.	A convenience sample of 85 adults (18-80 years old) was recruited from those attending a tertiary pain center in Alberta, Canada, who had experienced chronic pain for a minimum of six months. Participants were randomly assigned to either a control group or a group receiving a brief cognitive-behavioral educational	Disabled patients with diagnosed chronic pain and co-occurring disorders of anxiety, depression, and/or a diagnosed sleep disorder experienced measurable improvements in sleep latency following a brief one-on-one educational session about sleep hygiene. While sleep latency improved, other dimensions of sleep remained unchanged following the cognitive-behavioral session.	The study did not exclude participants on the basis of anxiety, depression, or other mental illness, any of which could have skewed results and are all highly present in this convenience sample of patients. It is unclear why additional patients were excluded from the study in the final step shown in Figure 2.	I	A

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
			session about sleep.				
4	Call-Schmidt, Pain Management Nursing, 2003	Descriptive, quantitative research study. The aim of the descriptive study was to determine the prevalence of sleep disturbance in adults with chronic pain, and how this prevalence compares with healthy and insomniac adults. Also, the authors sought to examine the relationship between sleep disturbance and chronic pain.	A convenience sample of 99 patients at an interdisciplinary pain clinic, which required at least monthly visits with patients presenting with chronic pain. All patients in the study had chronic pain (>12 weeks, average length of time with pain = 8.17 years). Patients with a history of CVA, cerebral neurological deficit, or history of OSA were excluded from participation.	Participants' sleep patterns exhibited frequent fragmentation, longer sleep latency, and decreased overall quality of sleep as compared to data from healthy patients without chronic pain. Sleep disturbance was positively correlated with the participants' pain intensity scores as follows: r = .46 between pain intensity and Mid-sleep awakening (MSA), r = .33 between pain intensity and Wake after sleep onset (WASO), r = 0.35 between pain intensity and Movement during sleep (MDS), r = 0.44 between pain intensity and Quality of disturbance (QD), r =.30 between pain intensity and Sleep latency (SL), and r = 0.41 between pain intensity and Total sleep time (TST). Although 70% of participants were on	Quality of sleep was based upon subjective reports from patients. Secondary data on "normal healthy" population used as a comparison is unidentified and unpublished, making it difficult to validate. Inadequate sample size to truly measure the effect of confounders such as gender and medication use in a generalizable way to the greater population.	III	B

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				opioid medication, sleep deprivation was still a problem. Sleep of men was more fragmented than that of women. The average sleep disturbance scores were consistently twice as high in the chronic pain population as compared with the healthy adult population with the exception of Wake After Sleep Onset. As the sample age increased, soundness of sleep increased.			
5	Edwards, Pain, 2008	Descriptive (cross-sectional) quantitative research study. To quantify the relationship between nightly sleep duration and next-day pain report.	The sample was derived from the National Study of Daily Experiences (NSDE), a sub-study within the Midlife in the United States Survey of 1031 participants. A mean reported age of 47 years old, 90% were Caucasian, and 81% were married.	Individuals sleeping for less than 6 hours, or for 9 hours or more, reported more frequent pain complaints the following day. Sleeping for three hours or less was associated with an 81% increase in pain frequency relative to sleeping 6-9 hours. Sleep disturbance, manifested as either reduced or increased	The assessment of sleep in this study was based solely on a single item question-self reported total sleep time, which was subjective and only measured one dimension of sleep. Does not differentiate between acute and chronic pain. The questions asked on the telephone survey state, “daily pain” which	III	A

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				sleep duration, may serve as a marker identifying individuals at elevated risk for poor pain-related outcomes.	may or may not be indicative of chronic pain. There is no data on the length of time patients have suffered from pain.		
6	Els, Cochrane Database of Systematic Reviews, 2017	Systematic review of 16 previously published Cochrane reviews including 61 RCT and quasi-experimental studies. To provide an overview of the occurrence and nature of adverse events associated with opioid use in the treatment of chronic non cancer pain in adults.	Review of research included 61 unique studies with more than 18,000 participants related to opioid medications and their side effects.	Opioids have the potential to alter sleep regulation, and are associated with poor sleep quality and insomnia.	Serious harm event reporting in the articles reviewed was not performed including sleep apnea or sleep-disordered breathing. Several of the studies included had a high attrition rate which raises questions about whether the results of those studies accurately captured the effect in the sample population that can be generalized to the general population.	II	A
7	Finan, The Journal of Pain, 2013	Review of Literature To summarize recent literature whether pain and sleep are reciprocally or unidirectionally related and what mechanisms	Experimental studies retrieved from PubMed and Google Scholar published 2006-2013	Data support a reciprocal relationship between sleep disturbance and clinical pain reports. Insomnia symptoms significantly increase the risk of developing future chronic pain disorders in previously pain-free individuals.	Lack of transparency in disclosing criteria for article inclusion and exclusion. Articles were chosen based upon relevance based upon the author's own judgement alone for addressing the questions of directionality	V	B

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
		account for the associations between sleep and pain.		Existing pain is not a strong predictor of new incident cases of insomnia.	and mechanisms of the association of sleep and pain.		
8	Frange, Climacteric, 2017	Observational quantitative research study. To investigate whether insomnia influences aspects of pain in postmenopausal women and to evaluate the objective sleep pattern of insomniacs with pain.	A convenience sample of 57 postmenopausal women at the Universidade Federal de Sao Paulo's women's outpatient clinic were included in this study.	The interference aspects of pain were statistically higher in the group of women with insomnia as compared to the control group without insomnia ($p = .02$ between sample groups). Postmenopausal women with insomnia perceive pain differently, independent of its intensity.	Study does not consider and attempt to address comorbidities present within the sample population beyond sleep apnea.	III	B
9	Haack, European Journal of Pain, 2012	Original quasi-experimental study. To assess the role of chronic sleep disturbances in pain processing.	Seventeen participants with primary insomnia and seventeen age and sex matched healthy controls with subjectively reported good quantity/quality of sleep were included in this study. Participants were recruited for by means of public advertisements at or around	Primary insomnia subjects reported experiencing spontaneous pain on twice as many days as healthy controls during at-home actigraphy recording. During laboratory testing, primary insomnia subjects had lower pain thresholds than healthy controls. Pain-inhibitory circuits in patients with insomnia may be in a state of	Possibility may exist for sensitization during laboratory pain threshold testing. Younger age of participants may not be generalizable to overall population of varying ages. Participants were recruited based on his/her subjective perception of sleep habits which may differ from actual quality of sleep,	III	A

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
			Boston area colleges.	constant activation to compensate for ongoing subclinical pain which ultimately may result in a ceiling effect of the pain-inhibitory phenomenon.	especially in the college-aged population which is known to have non-standard sleep patterns.		
10	Irwin, Sleep, 2012	A quasi-experimental quantitative research study. To examine the effect of sleep loss during part of the night on daytime mood symptoms and pain perceptions in patients with rheumatoid arthritis.	27 individuals with RA and 27 healthy control subjects were recruited through newspaper advertisements in the area immediately surrounding the UCLA General Clinical Research Center. Participants were 18 years of age and older must have been clinically stable on a DMARD for 3 months or longer and not have any significant comorbidities. The purpose of the study was blinded to the participants	Pain severity immediately after partial sleep deprivation was significantly greater than all other time points in patients with RA-related joint pain. Sleep loss activated RA-related joint pain as indicated by increases in the number of painful joints and the severity of associated joint pain. Partial sleep deprivation resulted in a slight increase in self-reported pain among health control subjects.	The sample population was composed mainly of female subjects and as such may not be generalizable to male patients. Due to the limited power of the study, it cannot be possible to account for differences in baseline sleep quality and baseline pain reports between individual subjects.	II	B

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
11	Kundermann, Pain Research and Management, 2004	Review of Literature including articles from RCTs, quasi experimental, and non-experimental research. To summarize the available literature on the mechanism of poor sleep interfering with pain processing	A total of seven studies met the inclusion criteria for human experiments on the effects of sleep deprivation on pain	The available evidence indicates that sleep deprivation does produce hyperalgesic changes in healthy subjects. Nociceptive thresholds decreased after poor sleep interference and subsequently increased after recovery of REM sleep. Sleep deprivation is known to produce additional effects like sleepiness, increased fatigue, negative mood or cognitive dysfunctions, which might cause or mimic a modulation of pain processing. An ongoing cycle might arise starting either with disturbed sleep or with pain in which the two components stabilize or even augment each other to potentiate a pain response or sleep impairment.	Several reviewed research articles were based upon animal trials which may not be transferrable to humans. The majority of studies reviewed on the relationship between sleep and pain were not based on an experimental design, but relied on correlation only. Four of the studies included in this review were comprised of mostly male participants or the sample population was entirely male which raises the question of the appropriateness of the relationships found for females.	V	B
12	Kuralay, International Journal of Caring Sciences, 2018	Original descriptive, non-experimental research study.	A convenience sample of 90 patients with knee osteoarthritis who came to the	A significant positive relationship ($r = 0.303$; $p = 0.004$) was found between the sleep quality of patients with knee	The presence of confounding factors as a yes/no choice limits the value in how they can be applied to pain,	III	B

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
		To assess the quality of sleep and other factors affecting pain in patients who have knee osteoarthritis.	Physical Therapy and Rehabilitation outpatient clinic of a hospital in Ordu, Turkey.	osteoarthritis and pain scores. A significant negative relationship r = (-0. 387; p = 0.000) was found between the self-rated physical health and sleep quality scores.	cold sensitivity, and sleep thus presenting a threat to transferability. Categorizing comorbidities would hold more significance to the data. No discussion within the article of limitations.		
13	Mathias, Sleep Medicine, 2018	Meta-Analysis of 22 case controlled and 15 prevalence studies. To examine the prevalence of measured sleep impairment findings from studies that used objective polysomnography in people with chronic pain.	37 case controlled polysomnography studies and studies that reported the prevalence of diagnosed sleep disorders found in PubMed, PsychInfo, and Embase were reviewed. The studies included persons 16 years or age and older with chronic pain.	Objective polysomnography supported previously subjective reports that individuals who suffer from chronic pain experience significant sleep disturbances. Of the sleep disturbance recorded both sleep initiation and maintenance was worse in patients with chronic pain. The pooled prevalence of sleep disorders in chronic pain was 44%, with insomnia, restless leg syndrome, and obstructive sleep apnea being the most common diagnoses.	The prevalence studies included did not report the duration of the sleep disorders or when they were diagnosed in relation to the chronic pain making causal assumptions impossible to assume between sleep quality and the presence of chronic pain.	III	A
14	McCracken, Pain Research and Management, 2002	Original descriptive	Participants comprised 287	Correlation analyses showed that greater sleep	Study participants were seeking	III	B

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
		quantitative research study. To investigate the role of disturbed sleep in the daily functioning of persons with chronic pain.	patients seeking treatment for chronic pain at a university pain clinic. The average age was 46.7 years old. 75.6% reported to be Caucasian, 20.7% reported African American heritage, with the remainder of Hispanic and Asian ancestry.	disturbance was associated with greater pain (r = .26), disability (r = .49), depression (r = .41), physical symptoms (r = .34), and less daily uptime (r = -.27). Regression analyses showed that sleep disturbance predicted disability, daily uptime and physical symptoms independent of pain or depression.	treatment because previous treatments, including medications, were ineffective or unsatisfying potentially skewing the findings to demonstrate a stronger correlation between pain and sleep as compared to a sample more representative of the overall chronic pain population. This potentially weakens the study's external validity and generalizability to the greater chronic pain patient population as a whole.		
15	Robertson, Anaesthesia, 2016	Original quasi-experimental research study. To assess rest-activity timing and physiological sleep in a population of patients with chronic pain.	Thirty-one participants (10 healthy controls, 21 patients with chronic back pain: 6 on non-opioid medication; 15 on opioid medication) ages 18-65 years old were assessed using actigraphy, polysomnography, and questionnaires	Patients with chronic pain subjectively reported significant sleep and wake disturbances as shown by decreased overall sleep quality, increased symptoms of insomnia, and increased fatigue, increased time in bed, and taking longer to get to sleep as compared to healthy controls. Chronic pain can be	The small sample size does not hold enough power to be generalizable to the general population. The age range 18-65 may introduce a confounding factor, rate of metabolism and elimination of opioids, that was not addressed by this study. Actigraphy's utility is limited as it cannot	III	A

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
			to assess pain and sleep quality.	associated with significant disruption in brain activity which is not improved by, and may even be exacerbated by patients taking opioid medication.	distinguish between motionless wakefulness (ie-sedation from opioid medication) and true sleep.		
16	Sezgin, Journal of Back & Musculoskeletal Rehabilitation, 2015	Original cross-sectional descriptive study. To investigate sleep quality in patients with chronic low back pain and its relationship with pain, functional status, and health-related quality of life.	Two hundred patients (100 male and 100 female) admitted to an outpatient clinic at Mersin University Medical Faculty of Physical Therapy and Rehabilitation diagnosed with chronic low back pain were included in this study as well as 200 (100 male and 100 female) pain-free healthy controls.	The sleep quality of patients with chronic low back pain was worse compared to the healthy controls, and there was a positive relationship between the sleep quality with pain and functional status. Also, the poor sleep quality had negative effect on the physical component of quality of life. There was a statistically significant difference in quality of sleep between the genders. Women had decreased overall quality of sleep, worse sleep latency, sleep disturbance, increased use of sleep medications, and daytime dysfunction scores as compared to their male counterparts who also had chronic low back pain.	Patients with a disclosed history of depression were excluded from the study potentially yielding incomplete results without this comorbid condition which frequently is cited as impacting sleep and pain perception. Quality of sleep was measured subjectively without actigraphy or polysomnography. The control group was comprised of friends, hospital staff, and relatives which, although convenient, may introduce bias into the study results.	III	B

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
17	Song, Osteoarthritis & Cartilage, 2018	Descriptive quantitative research study. To examine the potential benefits in relation to pain from trading time in one type of wake or sleep behavior for another.	A stratified random sample of 185 Osteoarthritis Initiative participants from the Physical Activity and Sleep Monitoring Pilot Study from four study sites: Baltimore, MD; Columbus, OH; Pittsburgh, PA; and Pawtucket, RI.	Time spent performing moderate physical activity in lieu of sleep was associated with lower odds of pain in participants who did not report restless sleep. This relationship was not seen in participants who reported restless sleep activity. Sleep duration alone may not accurately reflect sleep quality. Restlessness may have a stronger relation to pain than sleep duration.	Causation cannot be inferred from these observational data. The participants in the Osteoarthritis Initiative all reside in the northeast geographic region which may influence the type of moderate physical activity in which they chose to participate. Patients in other regions may not choose equivalent activities which may impact results.	III	B
18	Taylor-Gjevre, Musculoskeletal Care, 2011	Descriptive quantitative research study To assess components of sleep quality and self-identified contributors to sleep fragmentation in rheumatoid and osteo arthritis patient populations.	The study population included 145 rheumatoid arthritis and 78 osteoarthritis patients from a Canadian single-site university-based rheumatology practice over a 12-month. 4% were previously diagnosed with insomnia.	A high prevalence of abnormal sleep quality (63.7%) in both rheumatoid and osteoarthritis patient populations was observed despite reporting no known sleep disorder. The most common abnormality was sleep fragmentation, with an increased sleep disturbance score. No significant differences between groups were observed in any of the sleep disturbance scores.	Data for this study was entirely derived from self-administered questionnaires completed in the clinic. Due to the nature of the study being conducted over a 12-month period, seasonal changes in the environment which have been known to effect the perceived severity of arthritis may have impacted patient pain and likely sleep perception at	III	B

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				Many arthritis patients will have sleep abnormalities without clear evidence of a primary sleep disorder.	various points more than others.		
19	Vega, Pain Practice, 2019	Original quasi-experimental research study. To evaluate the role that changes in sleep quality and fatigue might have on the benefits of an interdisciplinary chronic pain treatment plan.	A convenience sample of 125 adult patients with chronic pain being treated in an outpatient interdisciplinary pain treatment program in Halifax, Canada.	Treatment improvements in fatigue and sleep, were significantly associated with the reduction of pain intensity. 36% of participants reported significant improvements in pain intensity supporting sleep interventions, such as teaching sleep hygiene techniques or cognitive behavioral therapy for insomnia as potential pain treatments in and of themselves.	Sleep and pain medication intake were not assessed making it possible that changes in these medications also had effects on sleep changes. As a correlational study, absolute causation cannot be determined even though it is longitudinal. The authors mention that patients may have been receiving multiple sleep related treatments at the same time however did not disclose or did not inquire as to what treatments these were. It is difficult to know which sleep related intervention is responsible for changes in sleep quality.	II	B

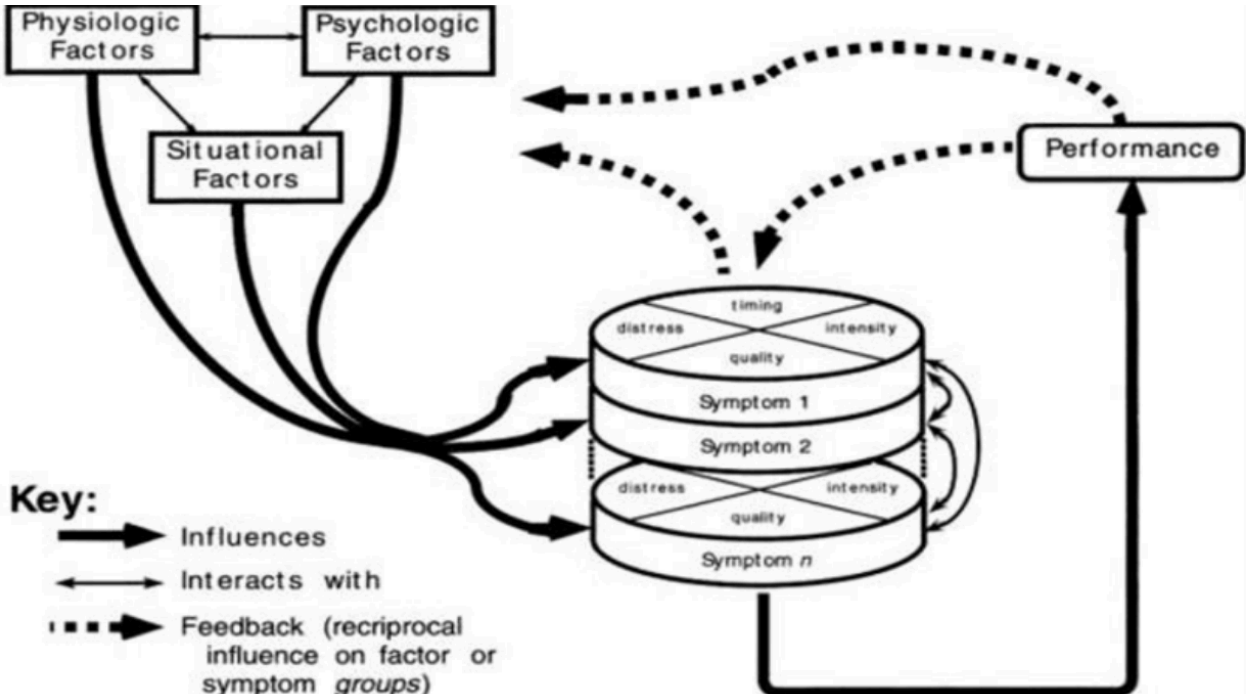
Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
20	Van de Water, Manual Therapy, 2011	Descriptive quantitative research study. To investigate differences in subjectively and objectively measured sleep patterns of people with chronic low back pain, and compare this to age- and gender matched controls.	A convenience sample of 16 people with chronic low back pain was recruited from the waiting list of the outpatient physiotherapy department of Beaumont Hospital 16 control participants without report of low back pain were recruited by poster and email advertisements through the University College of Dublin	The chronic low back pain group had significantly higher scores on both subjective sleep quality instruments (PSQI and ISI) when compared to the control group. The chronic low back pain group had significantly longer sleep onset latency as compared to the control group without any difference in actigraphy data to indicate a change in sleep pattern. There was a significant negative correlation between the PSQI total sleep time and Oswestry Disability Index disability score ($r = -0.628$; $p = 0.021$).	Attrition in this study was high due to noncompliance with participation in actigraphy and keeping sleep diaries. This lowered the power of this study. The chronic low back pain group had a higher BMI than the control group potentially predisposing them to greater sleep impairment and OSA.	III	A
21	Vleeshouwers, BMC Musculoskeletal Disorders, 2019	Descriptive quantitative research study. The secondary purpose of this study was to explore possible mediation of psychosocial work factors	Data collected on 6277 adults who took part in, “The new workplace: Work, health, and participation in the new work life” study conducted by the Norwegian National Institute	The psychosocial dimension “coworker support” showed a significant relationship ($p = 0.028$), with the number of musculoskeletal pain sites. There was a positive association with “coworker support” and sleep initiation but no	While the study used evidence supported survey questions for measuring psychosocial work factors, only two questions related to sleep quality and initiation were asked of participants to assess sleep. The use	III	B

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
		impacting musculoskeletal pain through addressing sleep problems.	of Occupational Health. The subset of adults from the original study was selected based on reporting both sleep disturbance and musculoskeletal pain.	association with sleep disturbance. Sleep may be a mediating factor in the relationship between pain and work-related psychosocial stressors.	of a full sleep assessment tool would have strengthened the inference of sleep as a mediating factor for psychosocial work factors. The survey instrument made it impossible to investigate reverse causality effects of sleep and pain on each workers' self-reported work environment.		
22	Wong, Journal of Psychomatic Research, 2012	Cross-sectional descriptive research study. To estimate the co-occurrence of chronic pain, insomnia, and fatigue in terms of prevalence and associated factors in the general adult population of Hong Kong.	5001 adults aged ≥18 years drawn from the Hong Kong general population were contacted randomly by telephone and completed a survey over the phone.	The observed prevalence of reporting all three chronic symptoms (pain, fatigue, insomnia) was 6%. Women had a higher odds of reporting all three symptoms. Co-morbid chronic pain/sleep disturbances were the most prevalent comorbidity at 15%.	The response rate to the telephone surveys was 58%, potentially excluding the representation of a significant portion of the population reducing generalizability. The working male population was less likely to be available to answer the phone during the interview calls leading to underrepresentation of this demographic in the study results.	III	B

* From: Dang, D., & Dearholt, S. L. (2018). *Johns Hopkins evidence-based practice: Model and guidelines* (3rd ed.). Indianapolis, IN: Sigma Theta Tau.

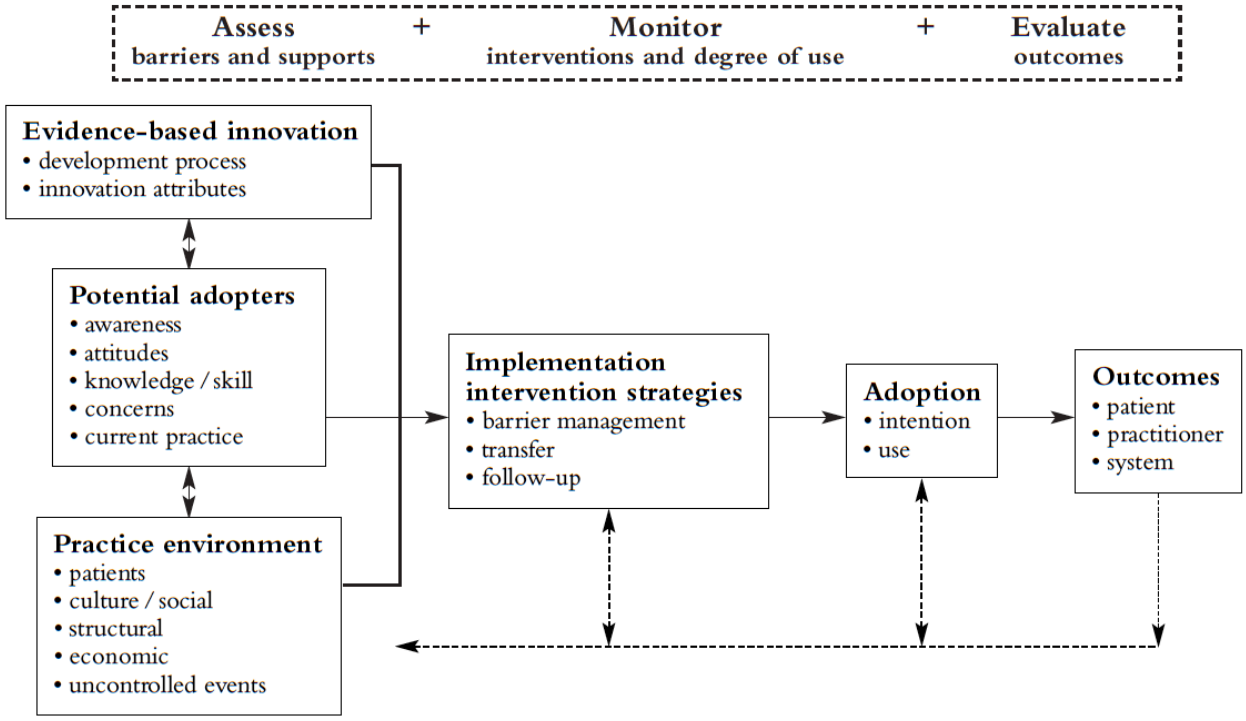
Appendix D:

The Theory of Unpleasant Symptoms (Lenz, Pugh, Milligan, Gift, & Suppe, 1997)



Appendix E:

Ottawa Model of Research Use (Graham & Logan, 2004)



Appendix F

Informed Consent/Information Script

Informed Consent Form
Messiah College

Title of Project:	Screening for Sleep Quality in Patients Presenting to a Primary Care Office with Chronic Pain: A Quality Improvement Project
Principal Investigator:	Nicholas Montgomery, BSN, RN 949 Cedar Hollow Rd. Hollidaysburg, PA 16648 nm1278@messiah.edu 814.571.0982
Advisor:	Kristen L. Slabaugh, DNP, CRNP, FNP-C, CNE Associate Professor of Nursing, Clinical Track Coordinator of DNP/FNP Program Messiah College One College Ave, Suite 3031 Mechanicsburg, PA 17055 717.796.1800 x6560 kslabaugh@messiah.edu

1. **Purpose of the Study:** The purpose of this research is to give patients who experience chronic pain the opportunity to take a brief (5-10 minute) survey about sleep. The results will be shared with your provider and may suggest that you have "good" or "poor" sleep quality. You or your provider may then have the opportunity to discuss your results during your visit.

2. **Procedures to be followed:** You will be asked to complete a brief 10-question sleep survey asking questions about your sleep habits. Staff will collect the completed sleep survey, tally the results, and share them with your provider. You and your provider may then discuss the results and he/she may make specific recommendations to you based on his/her opinion and established professional guidelines.

3. **Discomforts and Risks:** There are no risks in participating in this research beyond those experienced in everyday life. Some of the questions are personal and might cause discomfort.

4. **Benefits:** The benefits to you include being afforded an opportunity to discuss your sleep habits with your provider and may reveal new recommendations to improve your sleep quality and quality of life.

   The benefits to society include indirect cost savings as a result of improved care resulting in decreased utilization of healthcare resources and increases in productivity on a population-wide basis.

5. **Duration/Time:** The initial time to complete the sleep survey is expected to take 5-10 minutes of your time. Any results from the sleep survey that you discuss with your provider at this and future appointments is in addition to that time.

6. **Statement of Confidentiality:** Your participation in this research is confidential. The data will be stored and secured at Hyndman Area Health Center in a locked and password-protected file. Messiah College's Institutional Review Board for the Protection of Human Subjects, and the Department of Health and Human Services' Office for Human Research Protections may review records related to this research study. In the event of a publication or presentation resulting from the research, no personally identifiable information will be shared.

7. **Right to Ask Questions:** Please contact the principal researcher, Nicholas Montgomery at 814.571.0982, or the research advisor, Kristen Slabaugh at 717.796.1800 x6560, with questions, complaints, or concerns about this research. You can also call this number if you feel this study has harmed you. Questions about your rights as a research participant may be directed to Messiah College's Office of the Provost at 717.766.2511 x5375. You may also call this number if you cannot reach the research team or wish to talk to someone else.

8. **Voluntary Participation:** Your decision to be in this research is voluntary. You can stop at any time. You do not have to answer any questions you do not want to answer. Refusal to take part in or withdrawing from this study will involve no penalty or loss of benefits you would receive otherwise.

You must be 18 years of age or older to consent to take part in this research study. If you agree to take part in this research study and the information outlined above, please sign your name and indicate the date below.

You will be given a copy of this consent form for your records.

_____
Printed Name

_____ _____
Participant Signature Date

The informed consent procedure has been followed.

_____ _____
Person Obtaining Consent (Investigator) Date

Appendix G:

Pittsburgh Sleep Quality Index (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989)

Page 1 of 4

Patient Name _____ DOB _____ Date _____

PITTSBURGH SLEEP QUALITY INDEX

INSTRUCTIONS:
The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night?

   BED TIME _____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

   NUMBER OF MINUTES _____

3. During the past month, what time have you usually gotten up in the morning?

   GETTING UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)

   HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you . . .

a) Cannot get to sleep within 30 minutes

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

b) Wake up in the middle of the night or early morning

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

c) Have to get up to use the bathroom

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

Page 2 of 4

d) Cannot breathe comfortably

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

e) Cough or snore loudly

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

f) Feel too cold

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

g) Feel too hot

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

h) Had bad dreams

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

i) Have pain

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

j) Other reason(s), please describe_____

_____

How often during the past month have you had trouble sleeping because of this?

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

6. During the past month, how would you rate your sleep quality overall?

Very good _____

Fairly good _____

Fairly bad _____

Very bad _____

7. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all _____

Only a very slight problem _____

Somewhat of a problem _____

A very big problem _____

10. Do you have a bed partner or room mate?

No bed partner or room mate _____

Partner/room mate in other room _____

Partner in same room, but not same bed _____

Partner in same bed _____

If you have a room mate or bed partner, ask him/her how often in the past month you have had . . .

a) Loud snoring

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

b) Long pauses between breaths while asleep

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

c) Legs twitching or jerking while you sleep

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

d) Episodes of disorientation or confusion during sleep

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

e) Other restlessness while you sleep; please describe_____

_____

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

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Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: Psychiatry Research, 28:193-213, 1989.

Appendix H

Permission for Use of PSQI

Request to use the Pittsburgh Sleep Quality Index (PSQI)

Gasiorowski, Mary <GasiorowskiMJ@upmc.edu>
Wed 7/31/2019 5:28 PM
To: Montgomery, Nick <nm1278@messiah.edu>

CAUTION: This email originated outside of Messiah University

Sent on behalf of Dr. Buysse

Dear Nicholas,

You have my permission to use the PSQI for your research study. You can find the instrument, scoring instructions, the original article, links to available translations, and other useful information at www.sleep.pitt.edu under the Research/Instruments tab. Please ensure that the PSQI is accurately reproduced in any on-line version (including copyright information). We request that you do cite the 1989 paper in any publications that result.

Note that Question 10 is not used in scoring the PSQI. This question is for informational purposes only, and may be omitted during data collection per requirements of the particular study.

This copyright in this form is owned by the University of Pittsburgh and may be reprinted without charge only for non-commercial research and educational purposes. You may not make changes or modifications of this form without prior written permission from the University of Pittsburgh. If you would like to use this instrument for commercial purposes or for commercially sponsored research, please contact the Office of Technology Management at the University of Pittsburgh at 412-648-2206 for licensing information.

Good luck with your research.

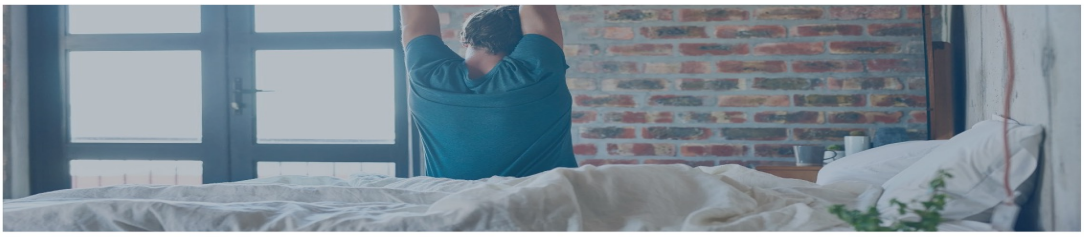
Sincerely,

Daniel J. Buysse, M.D.
Professor of Psychiatry and Clinical and Translational Science
University of Pittsburgh School of Medicine
E-1123 WPIC
3811 O'Hara St.
Pittsburgh, PA 15213
T: (412) 246-6413

Appendix I

Educational Handout for Provider Distribution to Patients

CDC's National Center for Chronic Disease Prevention and Health Promotion



Do You Get Enough Sleep?

1 in 3
Adults don't get enough sleep.

Adults need 7+ hours of sleep a night.

7
OR MORE

Lack of sleep is linked to several chronic diseases and conditions, including:

TYPE 2 DIABETES

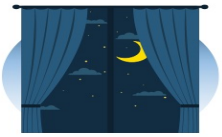
HEART DISEASE

OBESITY

DEPRESSION

Tips for Good Sleep

Go to bed and get up at the same time each day, including weekends.



Keep the bedroom quiet, dark, and a comfortable temperature.

Remove electronic devices from the bedroom.

Avoid large meals, caffeine, and alcohol before bedtime.

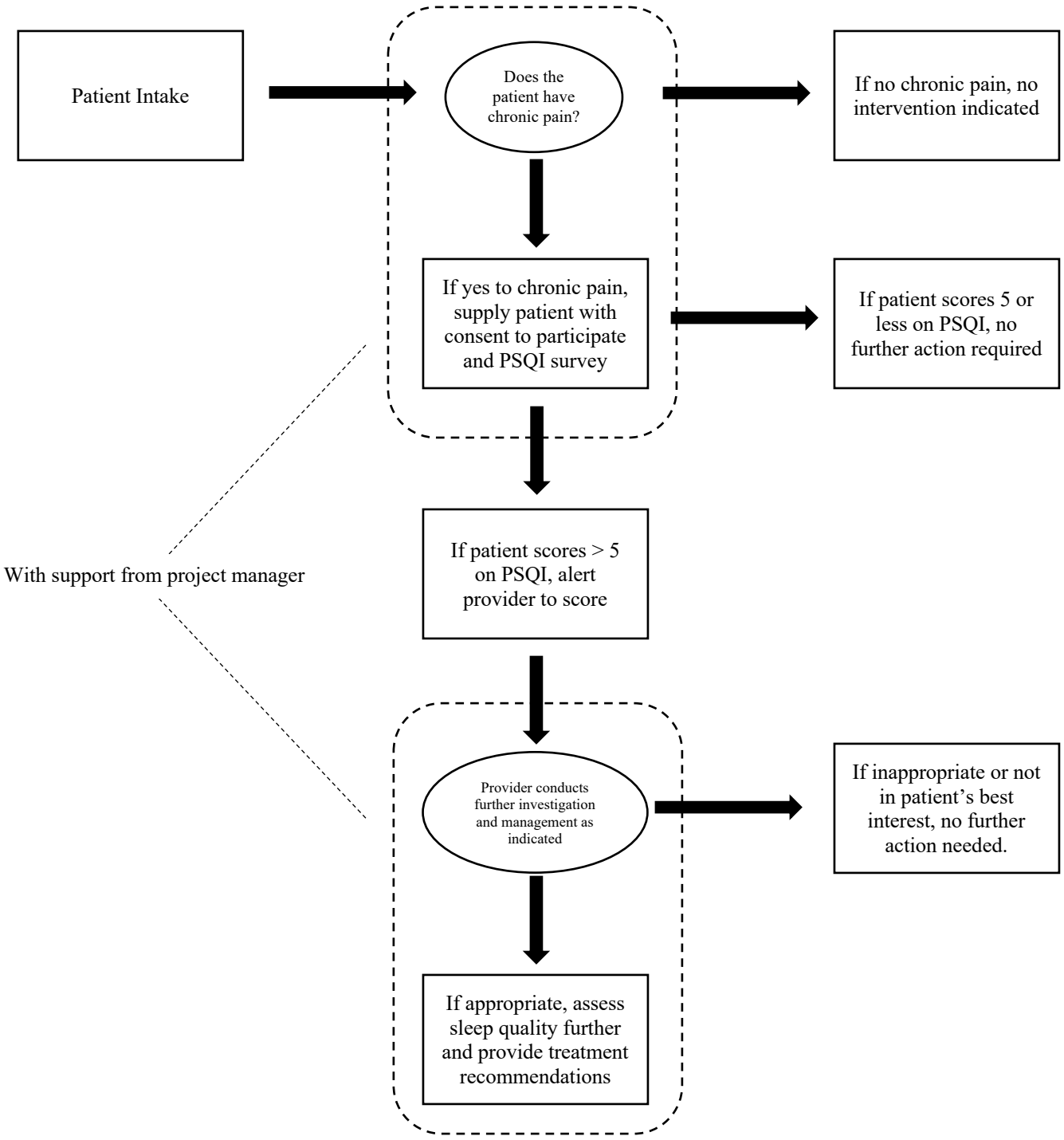
Be active during the day to help you fall asleep at night.

Learn more about good sleep habits at www.cdc.gov/sleep.

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion
@CDCChronic | www.cdc.gov/chronicdisease

Appendix J

Process Map



Appendix K

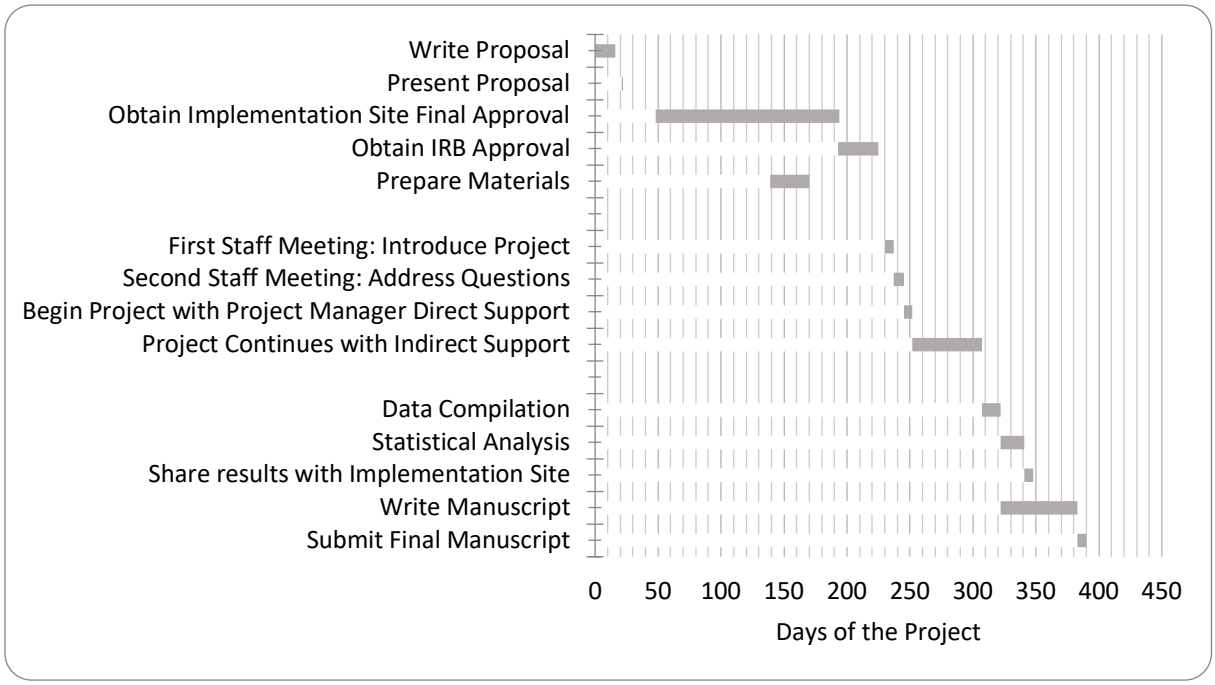
DNP Project Budget

Project Expenses		
Salaries/Wages		
		Total
Practitioners	472.00/month	1416.00*
Support Staff	63.00/month	189.00*
Project Manager	2475.00/month	7425.00*
Total Salary Costs		9030.00*
Startup Costs		
		Total
Copies	25.00/month	75.00*
Provider Handouts	60.00	60.00*
Total Startup Costs		135.00*
Capital Costs		
Physical Supplies	5.00/month	15.00*
Total Capital Costs		15.00*
Operational Costs		
		Total
Electricity/Utilities	0.00/month	0.00
Physical Workspace	0.00/month	0.00
Total Operational Costs		0.00
Total Project Expenses		**9180.00**
Project Revenue		
Revenue Generation		0.00
Total Project Revenue		0.00
Project Benefit/Loss		
Total Revenue		0.00
Less Expenses		9180.00
Total Program Benefit/Loss		**-9180.00***

*Donated by DNP student and/or implementation facility

Appendix L:

GANTT Chart



TASK NAME	START DATE	END DATE	START ON DAY	DURATION (WORK DAYS)
Pre-Implementation				
Write Proposal	7/15	7/30	0	16
Present Proposal	8/5	8/5	21	1
Obtain Implementation Site Final Approval	9/1	1/24	48	146
Obtain IRB Approval	1/24	2/24	193	32
Prepare Materials	12/1	12/31	139	31
Implementation				
First Staff Meeting: Introduce Project	3/1	3/7	230	7
Second Staff Meeting: Address Questions	3/8	3/15	237	8
Begin Project with Project Manager Direct Support	3/16	3/22	245	7
Project Continues with Indirect Support	3/23	5/16	252	55
Post-Implementation				
Data Compilation	5/17	5/31	307	15
Statistical Analysis	6/1	6/19	322	19
Share results with Implementation Site	6/20	6/26	341	7
Write Manuscript	6/1	7/31	322	61
Submit Final Manuscript	8/1	8/7	383	7

Appendix M

Sample Comorbidities

Condition	**Frequency**
Myocardial Infarction	11.10% (n = 1)
Coronary Heart Disease	66.70% (n = 6)
Stroke	0% (n = 0)
Asthma	22.20% (n = 2)
Chronic Obstructive Pulmonary Disease	44.40% (n = 4)
Arthritis	44.40% (n = 4)
Depression	55.60% (n = 5)
Diabetes	33.30% (n = 3)
Obesity	88.90% (n = 8)

Appendix N

Summary of PSQI Scores by Sleep Dimension

Sleep Dimension	**Possible Score**	**Mean (SD)**
Subjective Sleep Quality	0-3	2.22 (.83)
Sleep Latency	0-3	2.11 (1.05)
Sleep Duration	0-3	1.89 (1.45)
Sleep Efficiency	0-3	1.78 (1.48)
Sleep Disturbance	0-3	2.11 (.33)
Sleep Medication	0-3	1.33 (1.58)
Daytime Disturbance	0-3	1.56 (1.01)
Global PSQI Score	0-21	13.00 (5.24)