Promoting Sleep Quality in Chronic Pain Patients

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Abstract

Objective: Chronic low back pain in adults is a global health and economic problem. Many with back pain experience compromised sleep. While Cognitive Behavioral Therapy (CBT) is a gold standard in improving sleep among individuals with pain, this approach requires trained staff. The sleep hygiene education and meditation techniques, components of CBT, were utilized in patients with chronic low back pain to improve sleep quality.

Methods: Twenty patients with chronic back pain volunteered to receive sleep hygiene education and meditation videos to practice for 12 weeks and participate in 4-weekly phone calls. Participants were assessed at baseline and post-treatment with the Pittsburgh Sleep Quality Index (PSQI). Participants were patients at a local pain clinic with chronic low back pain without untreated mental illness, sleep apnea, or restless leg syndrome. Informed consent was obtained from participants, along with demographic data. Participants received a brochure with education information to engage daily for 12 weeks. Participants were then contacted weekly by phone to review the learned information.

Results: 13 participants completed the post-intervention questionnaire (35 % attrition rate). Mean age was 55.15 yrs. and most were female (n=11). Paired t-test demonstrated that change in pre and post PSQI score, and Medication Use did not show statistical significance (p=0.372; p=0.502). However, Subjective Sleep Quality had clinical significance (p=.022) suggesting individuals thought their sleep have improved.

Discussion: Sleep hygiene education and meditation techniques is an approach for individuals considering non-invasive and cost-effective approach to improve sleep.

Keywords: sleep hygiene education, sleep quality, chronic low back pain

Improving Chronic Back Pain and Sleep Quality

Obtaining adequate sleep every night is essential for every individual's optimal health as it can affect hormone levels, mood, and even weight. Characterized by an inability to initiate or maintain sleep, insomnia is a common sleep disorder that affects many people and is associated with the development of chronic diseases such as diabetes, cardiovascular disease, and depression (Centers for Disease Control and Prevention [CDC], 2014; CDC, 2018). Insomnia is a substantial burden for the healthcare system affecting nearly 25% of the general population with an annual cost over $100 billion (Koffel et al., 2018).

Consequently, various organizations strive to raise public awareness of insomnia and continue to develop evidence-based policies (American Academy of Sleep Medicine [AASM], 2020; CDC, 2017). However, management of insomnia among people who have existing co-morbidities such as chronic pain is challenging as sleep has a bidirectional relationship with pain; pain interferes with sleep, and lack of sleep can cause pain (Marshanasky et al., 2018). Utilization of appropriate instruments and comprehensive assessment can help restore sleep among chronic pain patients (Marshanasky et al., 2018; Martel et al, 2018).

Background and Significance

Insomnia has high associated costs; individuals with insomnia are more likely to use sick leave and seek medical care (Dopheide, 2020). Loss of productivity can be disabling for many individuals, especially for individuals in school or work. Along with the high prevalence of insomnia, low back pain is a costly problem that affects up to 80% of adults at some point in their life (Hajihasani et al., 2019). Individuals with chronic pain are more susceptible to disrupted sleep. Delayed treatment and poor management can lead to various consequences, including increased healthcare costs and adverse effects such as anxiety or depression. Among

those who received treatment, many remained symptomatic despite using a benzodiazepine, a medication with adverse effects when administered long-term (Sato et al., 2019).

Clinicians often address the severity of low back pain by prescribing medications like non-steroid anti-inflammatory drugs (NSAIDs), muscle relaxants, and narcotics to help alleviate pain (Zgierska et al., 2016). Such an approach complicates care for individuals who take medications to improve their sleep. Long-term use of opioids and muscle relaxants can be a double-edged sword with adverse effects such as drowsiness, sleepiness, respiratory depression, and even death (Marshansky et al., 2018; Tang et al., 2019). Despite the various risk of drug-drug interactions and adverse effects, individuals can become reluctant to explore different avenues, especially non-pharmacological approaches, to reduce pain.

Internal Evidence

A pain clinic located in the Southwestern United States provides a continuum of care for individuals who have chronic back pain, neuropathy, or have undergone an operation for their chronic pain. Out of 638 patients seen by two providers at the clinic in January 2021, 451 patients had a low back pain diagnosis (L. Baker, personal communication, February 10, 2021). The two most common causes of low back pain were lumbar degenerative disc disease and lumbar spondylosis.

In addition to inadequate pain control, a well identified problem at the pain clinic is the prevalence of compromised sleep quality. The current approach to poor sleep in an individual is sleep hygiene counseling and education based on individual needs (L. Baker, personal communication, February 10, 2021). While sleep disturbance is recognized in this patient population, the exact prevalence and extent of the insomnia are unclear as the pain clinic primarily focuses on pain assessment and management. Currently, the reported barrier to

managing sleep quality includes a lack of appropriate instruments, time, and management plans to provide comprehensive sleep management. Therefore, intervention is warranted to minimize the adverse effects of additional medication and provide safe and effective education.

This inquiry has led to the following clinically relevant PICOT question, "Among adults with chronic low back pain (P), does cognitive behavioral therapy (I), compared to medication alone (C), improve sleep quality (O) over a 12-week period (T)?"

Search Strategy

To answer the clinical question, an extensive search was completed through the Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, and PsychINFO databases. Keywords for the search included: *insomnia, sleep disorder, cognitive behavioral therapy, cognitive therapy, intervention, chronic pain, pain,* and *back pain.* All search limits were set to include publication within the last 5 years and English language.

A total of 57 articles were selected for further review. The publications were reviewed thoroughly for inclusion and exclusion criteria. Inclusion criteria were studies that studied adult participants and utilized CBT or behavioral change treatment as an intervention. Additionally, the intervention must have targeted chronic pain, sleep disorder, or both. Studies from various countries, settings, and treatment delivery methods were considered. Exclusion criteria were studies that only investigated adolescents or pediatric populations and articles that propose trials but have not completed participant recruitment. Studies that examined other medical conditions other than chronic pain and sleep disorder were also excluded. After careful review through rapid critical appraisal (RCA), 10 studies were chosen for the literature review. Of these, nine publications were randomized controlled trials (RCT) and one cohort study (see Appendix A, Table 1).

Critical Appraisal & Synthesis of Evidence

The RCA process developed by Melnyk and Fineout-Overholt (2019) was utilized to evaluate the quality of the 10 articles selected for this literature review. Most of the studies were high level evidence, including 9 RCTs and one cohort study (see Appendix A, Table 2). All studies received funding; however, only two studies recognized potential researcher bias. Two studies had large sample sizes and the rest had small sample sizes. However, small sample size was acceptable given the strict inclusion criteria. The intervention period ranged from 4 weeks to 12 weeks. However, follow-up data were collected both post-treatment and several weeks after intervention completion in most studies. Follow-up data allowed to determine the long-term effects of the intervention. The sample characteristics were relatively comparable among ten studies. The majority of participants in nine studies were middle-aged females, and one study primarily focused on females. All studies were conducted in outpatient settings.

The location of the study conducted varied widely. Three out of 10 studies were conducted in the USA, while the rest were in various countries, including Sweden, Norway, Japan, and the United Kingdom. Such heterogeneity provided insight into the effectiveness of cognitive-behavioral education in other cultures. Regardless of the country, all studies produced positive outcomes in the participants.

There is compelling evidence to suggest that CBT focusing on pain is effective in producing better sleep quality and even improved mood (Blake et al., 2015; Espie et al., 2019; Sato et al., 2019). The benefits of improved sleep among individuals who have chronic pain are numerous. Enabling individuals to recognize their current health behaviors and promote positive lifestyle changes could reduce medication use; improve anxiety, depression, and sleep characteristics.

AASM (2020) also recognizes Cognitive Behavioral Therapy (CBT) as first-line approach to improve sleep quality. CBT is a psychotherapy that entails behavioral, cognitive, and educational components (Edinger et al., 2021; Espie et al., 2019). It is an engaging therapy that challenges individuals to recognize the negative thoughts and beliefs towards their health condition (Hanscom et al., 2015). The primary difference between CBT and traditional clinician-guided education is that CBT is patient-centered. Such an approach helps change individuals' perspectives towards a problem, identify barriers, and make positive changes. When an individual voluntarily makes the change, its effect lasts longer (Blom et al., 2016).

However, CBT is a rigorous therapy that requires an experienced clinician. The evidence suggests that the core components of CBT, sleep hygiene, dysfunctional thought, and relaxational technique, produce positive outcomes such as improved mood (Blake et al., 2015; Espie et al., 2019; Sato et al., 2019). Sleep hygiene education and meditation techniques are less labor-intensive strategies to improve sleep. According to Zengin and Aylaz (2019), sleep hygiene education helped increase sleep quality and decreased fatigue among individuals receiving chemotherapy. Sleep hygiene education and relaxation exercises have also improved sleep among postmenopausal women who are suffering from insomnia (Duman & Timur Taşhan, 2018). Given the bidirectional relationship between chronic pain and sleep, individuals with chronic pain can benefit from cost-effective education to improve sleep quality and potentially decrease the need for additional medication. This inquiry has led to the following evaluation questions, "Among adults with chronic low back pain, does CBT-based education improve sleep quality over 12 weeks?"

Theoretical Framework and Implementation Framework

The Cognitive Model (CM) was chosen as the conceptual framework for this project for its applicability (see Appendix B, Figure 1). Aaron Beck first formulated the CM over 45 years ago, and CM-based psychotherapies are often utilized synonymously to CBT (Knapp & Beck, 2008). Early in Beck's CM journey, he identified the Cognitive Triad, which consists of three elements of the belief system: negative representations of the self, the personal world, and the future (see Appendix B, Figure 2). These three factors influence each other and form either a positive or negative outlook in an individual. Such a discovery prompted researchers to develop therapies and theoretical frameworks that promote positive thoughts and behaviors. According to Beck Institute (n.d.), the CM consists of these six key elements: situation, automatic thought and images, reactions, emotion, physical, and physiological (see Appendix B, Figure 1). The CM gives insight into how one's perceptions or spontaneous thoughts about the environment or situation can influence emotional, physical, and psychological reactions. All six elements continuously interact with one another. This interactive model explains why an individual in physical pain can develop negative thoughts about the situation and respond with negative emotions and behaviors. The goal of CBT is to help the individual recognize this cognitive process and thereby promote positive responses. Therefore, utilizing the core aspect of CBT may positively impact individuals' health outcomes

The Model for Change to Evidence-Based Practice (Rosswurm & Larrabee, 1999) is appropriate for this project in developing and implementing an intervention. This model is a frequently utilized framework for quality improvement projects as it provides a systematic guidance for change in practice (see Appendix B, Figure 3). It involves six steps that generally progress successively; however, the researcher can revise the prior steps at any point if needed (Rosswurm & Larrabee, 1999).

The initial step of the framework helped identify the need for change. The fieldwork helped identify problems, gaps, and issues in the current practice. The next step involved assessing the problems to current practice, potential intervention, and the benefit of the change. Next, the writer completed literature synthesized for its quality. Then, the writer further defined the proposed change and designed the implementation and study. The writer encountered the barrier that CBT requires a trained and qualified clinician, and the intervention was re-considered. The writer reexamined the current literature and evidence-based practice, and intervention was re-considered. When planning was complete, the execution of the study began, and the writer evaluated the result to determine whether to reject or adopt the practice change. These steps were appropriate to yield a high-quality improvement project and allow future studies with necessary modifications. Therefore, this theoretical model worked seamlessly in developing a plan for patients with chronic pain who also experience s poor sleep quality.

Methods

Privacy and Confidentiality

The project approval was received from the Arizona State University's Institutional Review Board in September 2021. The participants were recruited through project flyers which provided details about the expectation of the project, eligibility, and contact information of the project lead. Willing individuals signed the informed consent after receiving further information about the background, significance, intervention, screening tool, and the risk and benefit of the project. The privacy of the participants was protected by including no identifiable patient information. All documents were linked to the last four digits of the patient's phone number to allow for paired analysis at the completion of the project. The collected data were kept on a password-protected electronic device that is only accessible by the project lead. The data was managed and stored

until the study was completed and published.

Inclusive and Exclusive Criteria

Inclusive criteria were existing patients at the pain clinic aged 18 or older. Individuals diagnosed with chronic low back pain, lumbar degenerative disc disease, or lumbar spondylosis were eligible to participate. An in-person encounter for the initial assessment was necessary. Individuals who scheduled a telemedicine encounter were excluded. In addition, individuals with an unmanaged mental disorder or untreated obstructed sleep apnea and restless leg syndrome were excluded. Such parameters were necessary to exclude health conditions that can contribute to compromised sleep.

Project Procedure

Participants were invited to engage in daily sleep hygiene practices and meditation activities for 12 weeks to improve sleep quality. Sleep quality was assessed utilizing the Pittsburg Sleep Quality Index (PSQI) at the beginning of the project and 12 weeks after the initial encounter. In addition to the screening tool, demographic data and their contact information was collected to perform weekly follow-up phone calls for the next four weeks. Completing the PSQI and filling out the initial information took about 10 minutes. Completing the PSQI and filling out the initial information took about 10 minutes. After this, participants were provided with a sleep hygiene education brochure with recommended activities to help improve their sleep to practice daily. Participants received face-to-face education regarding these instructions and had an opportunity to ask questions. The education included the significance of sleep among individuals with chronic pain, sleep hygiene education recommendations, and links to meditation videos.

After the initial encounter, participants were contacted by phone weekly for four weeks to review any questions or concerns and to assess their ability to engage in the provided activities. Participants were encouraged to review the sleep education brochure during this time. Each phone call lasted between 5 to 10 minutes. Participants had the right not to answer any question and to stop participation at any time. Participants were expected to return to the clinic after 12 weeks to complete another PSQI questionnaire. This visit was coordinated with a regular follow-up visit to the clinic. However, if participant was unable to return in-person, the project lead read all the instructions and questions on the PSQI questionnaire for the participant to answer.

Data Collection and Outcome Measurement

The measurable outcome was improved sleep quality through behavioral changes. This links to the CM framework that positive thought yields desired behaviors. Demographic information collected was participant's age, gender, primary diagnoses, and status of mental disorder, if applicable. The PSQI questionnaire result assessed baseline sleep quality. Then, at the end of the project, a repeat PSQI questionnaire result evaluated the efficacy of sleep education. The PSQI is a tool that is easy to use and understand, measures sleep quality, and distinguishes good and poor sleepers (Buysse et al., 1989). The PSQI comprises seven components: *Subjective Sleep Quality, Sleep Latency, Sleep Duration, Habitual Sleep Efficacy, Sleep Disturbances, Use of Sleep Medication, Daytime Dysfunction*. The score ranges from 0-to 3 for each component, with a total possible score of 21. A score of 5 or more indicated poor sleep quality (Buysse et al.,1989). According to Buysse et al. (1989), the global PSQI tool demonstrated a sensitivity of 89.6% and specificity of 86.5% in identifying good and poor sleepers.

Budget and Funding

The total expense for this project was $375 (see Appendix A, table 3). Expense items include stationeries, brochures, survey print-out, gas for transportation, and intellectus software. No funding was received for the project.

Results

A total of 20 individuals volunteered to participate in the project; 13 participants completed the post-intervention survey. The attrition rate was 35%. The mean age of participants who completed the project was 55.15 years. Out of 13 participants, 84.62% (n=11) were female participants and 84.62% (n=11) were Caucasians. Such an outcome is consistent with the literature where most participants were female with a mean age of 47.95 yrs. (Blake et al., 2015; Burke et al., 2019; Espie et al., 2019; Lami et al., 2018; McCrae at el., 2019; Nordin et al., 2016; Sato et al., 2019; Smitherman et al.2016; Vedaa et al., 2020; Zgierska et al., 2016).

The data analysis with paired t-tests and descriptive statistics showed a slight reduction in total PSQI score, indicating improvement but without statistical significance (p=.372). Similarly, The *Use of Sleep Medication* component also had some improvement but without statistical significance (p=.502). The result had good internal reliability with Cronbach's alpha coefficient of .87.

While the overall PSQI score did not have statistical significance, the *Subjective Sleep Quality* component indicated clinical significance (p=.022) with Cronbach's alpha coefficient of .90, indicating excellent internal reliability. Before the intervention, the mean PSQI score was 1.62 with the Standard Deviation (SD) of 0.77. After the intervention, the mean PSQI was 1.27 with an SD of 0.83. Many participants also commented that they were sleeping better during the subsequent visit to complete the questionnaire. Such findings indicate that participants believed

they were sleeping better than they did. This positive shift in their belief can improve their sleep habits with continuous education.

Discussion

Overall, sleep hygiene education and meditation techniques did not have statistical significance to the overall sleep quality index score. However, there was clinical significance. Participants considered they were sleeping better than before the study. For patients who have back pain and are willing to explore a non-invasive approach, the project intervention provides cost-effect methods to encourage a suitable environment for sleep. If utilized accordingly, improved sleep quality through the non-invasive way can reduce the need for providers to prescribe additional medication with undesirable side effects or dependence. Reducing the need for hypnotics or pain medication can prevent medical treatment related to medication-related complications.

The feasibility and sustainability of the project intervention rely on patients, healthcare providers, medical directors, and staff caring for the patients. In a busy clinic, additional education or screening tools can be unfavorable. Hence, healthcare staff perspective assessment and buy-in are necessary to deliver appropriate educational material. Implementing another screening tool at the clinic is challenging as individuals complete several screening tools at each visit. However, continuous use of the brochure is feasible as it provides standardized education without requiring skilled staff.

Additional study is necessary to provide an innovative approach to improving sleep quality among individuals with chronic pain. Limitations and barriers encountered identified are external factors that could contribute to poor sleep quality. Participants verbalized traveling, holiday gatherings, and moving were barriers to practicing sleep hygiene education and

meditation techniques. In addition, when arranging follow-up questionnaires during their existing provider visit, some individuals canceled or rescheduled their appointment. Missed appointments resulted in a loss in follow-up by the project investigator.

Previous literature has demonstrated insignificant findings to determine the effectiveness of sleep hygiene education and medication techniques among individuals with insomnia or other comorbidities. The project finding aligns with other existing studies and their limitations. Despite various limitations and barriers, additional investigation is warranted. Individuals at the pain clinic recognize the importance of obtaining adequate sleep and its benefit to overall health quality. Future studies can investigate more interactive education and individualized approach.

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Appendix A

Evaluation and Synthesis Table

Table 1

Quantitative Evaluation Table

Citation	Theory/ Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	LOE; Decision for practice/ application to practice
Blake et al. (2015) The impact of a cognitive behavioral pain management program on sleep in patients with chronic pain: Results of a pilot study. **Funding:** Brona M. Fullen received a non-restricted educational grant from Pfizer	CM, inferred	**Design:** Non-RCT/ cohort study **Purpose**: To determine the impact of a CBT-pain management program on sleep in patients with chronic pain **Sampling:** Purposive	N=46 CG: n=22 IG: n=24 **Demographic:** M age (IG=47.7; CG=46.8), number of years with pain (IG=6.9; CG= 7.9; p-value=0.80), smoking, employment status. Daily NSAID use (IG n = 8, CG n = 0) **Setting:** Outpatient	**IV:** CBT **DV1:** Sleep quality **DV2:** Mood **DV3:** Physical function **Definition:** Multidisciplinary approach (daily physiotherapy, gym-based sessions, hydrotherapy pool); 3 days a week for 6 hours for 4	PSQI, Simmond's functional tests, HADS, WASO Actigraphy	All data coded Pearson's correlation coefficients ANOVA models	Δ 2 months **DV1**: P = 0.04 **DV2:** P<0.05	**LOE:** level 3 **Strength:** PSQI has sensitivity:98.7 & specificity: 84.4; Actigraphy is cost-effective & easy; CBT help with anxiety and depression. **Weakness**: small sample size, low statistical power. Follow up limited to 2 months. More IG utilized

Key: **ANCOVA** – Analysis of covariance; **ANOVA** – Analysis of variance; **BPI** – brief pain inventory; **CBT** – Cognitive behavioral therapy; **CM** – Cognitive model; **CSQ** – coping strategies questionnaire; **CG** – control group; **DCBT**—digital cognitive behavioral therapy; **DV**—dependent variable; **ESS** – Epworth sleepiness scale; **f** – female; **FAM** – Fear Avoidance Model; **FM** – fibromyalgia; **GAD** – Generalized anxiety disorder scale; **GSII** – Glasgow Sleep Impact Index; **HADS** – Hospital anxiety and depression scale; **ICM** – Integrated care model; **IG** – intervention group; **ITT** – intention-to-treat analysis; **IV** – independent variable; **LOE** – level of evidence; **LBP** – low back pain; **LT** – Learning theory; **M** – mean; **N** – number of participants in study; **n** – number of participants in subset; **NSAID**– Nonsteroidal anti-inflammatory drug; **PHQ-9** – patient health questionnaire-depression scale; **PSQI** – Pittsburgh Sleep Quality Index**; QOL –** quality of life scale; **RCT –** randomized control trial; **SES** – self efficacy scale; **SCT** – Self-care Theory; **UC** – usual care; **VAS** – visual analog scale; **WASO** – wake after sleep onset; **y**– year; Δ – pretest to posttest change for intervention group; **&** – and

Citation	Theory/ Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	LOE; Decision for practice/ application to practice
Healthcare Ireland **Country:** United Kingdom **Bias:** No			**Exclusion:** Declined to participate **Attrition:** 2.17%	weeks with post-program review at 2 and 6 months.				NSAID at baseline **Feasibility:** Test is easily duplicated for future study with larger participants. Clinician can encourage CBT for other health conditions.
Espie et al. (2019) Effect of digital cognitive behavioral therapy for insomnia on health, psychological well-being, and sleep-Related quality of life: A randomized clinical trial **Funding:**	CM, inferred	**Design:** RCT **Purpose**: To determine the impact of a DCBT- insomnia management program on sleep in patients with chronic pain compared to sleep hygiene education. **Sampling:** Convenience	N=1711 CG: n= 853 IG: n=858 **Demographic:** f= 77.7%, M age 48, White (91.1%) **Setting:** outpatient **Exclusion:** life expectancy of less than 6 months, currently receive psychological treatment for	**IV:** DCBT **DV1**: Sleep Quality **DV2:** Physical Function **DV3:** Mood **Definition:** IG: DCBT delivered via Sleepio program and mobile app;	PROMIS, GSII, PHQ-9, GAD	Linear mixed-effects model	Δ 8 weeks & 24 weeks **DV1:** P = <0.001 (IG) **DV3:** P= <0.001 GAD P<0.001 PHQ-9	**LOE:** level 2 **Strength:** Large sample size; easily deliverable intervention; included individuals who take medications for sleep problems or for other physical and mental problem.

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Big Health Ltd; Supported by multiple research centers **Country:** United Kingdom **Bias**: Dr.Espie is a cofounder, chief medical officer, shareholder. Receive salary from Big Health Ltd and is a developer.			insomnia or were expecting treatment within 6 months, who reported suicidal thoughts **Attrition:** 47%	CG: access to website and downloadable booklet; Recommend bed routines and use of alcohol and caffeine				**Weakness**: single-blinded RCT; convenience sampling; white females; questionnaires; high attrition rate; single-blinded RCT **Feasibility:** Clinician can encourage DCBT for other health conditions. Highly motivated patient can benefit from the treatment. DCBT; cost effective.
McCrae et al. (2019) Cognitive behavioral	CM, inferred	**Design:** RCT **Purpose:** To examine the effects of	N=113 CG: n=37 IG-Insomnia: n=39 IG-Pain: n=37	**IV:** CBT **DV1:** Sleep **DV2:** Pain Intensity	WASO, Sleep Efficacy, Sleep Quality, Sleep Onset Latency	ANOVA	Δ 6 months **DV1:** IG-	**LOE:** level 2 **Strength:** Cost-effective and easy to

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treatments for insomnia and pain in adults with comorbid chronic insomnia and fibromyalgia: clinical outcomes from the SPIN randomized controlled trial **Funding:** Funded by the National Institute of Arthritis and Musculoskeletal and Skin Diseases **Country:** USA **Bias:** none		cognitive behavioral treatments for insomnia and pain in patients with comorbid fibromyalgia and insomnia. **Sampling:** Purposive sampling	**Demographic:** mean age: 53 f: (IG-Insomnia & CG: 100%; IG-Pain: 91.89%) **Setting:** outpatient **Exclusion:** <11 tender points, other sleep disorder, medical and psychiatric condition **Attrition:** 34.51%	**DV3:** Mood **Definition:** IG: 8 audiotaped sessions, 50 minutes each IG-Insomnia: - Sleep education - Sleep hygiene and stimulus control - Relaxation - Cognitive therapy IG-Pain: - Pain education - Progressive muscle relaxation - Autogenic relaxation - Visual imaginary - Cognitive therapy - Review skills	VAS Beck Depression Inventory Actigraphy Ambulatory polysomnography	Power analysis	Insomnia P = .02 IG-Pain P= .06 **DV2:** morning pain P = 0.06 **DV3:** P>0.08	use; excluded individuals with other sleep disorder **Weakness**: Participants were compensated; excluded individuals with medical and psychiatric condition; female; self-report questionnaires **Feasibility:** CBT can be beneficial for both pain and insomnia; modifiable for individual's health condition.

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Sato et al. (2019) Effectiveness of Internet-delivered computerized cognitive behavioral therapy for patients with insomnia who remain symptomatic following pharmacotherapy: Randomized controlled exploratory trial **Funding:** Supported by Grant-in-Aid for Scientific Research from the Japan Society for the	CM, inferred	**Design:** RCT **Purpose:** examine the effectiveness of our DCBT program as an adjunct to UC in patients with insomnia who remain symptomatic following hypnotics **Sampling:** Purposive	N= 23 CG (UC): n=12 IG (UC+DCBT): n=11 **Demographic:** M age= 50; nonsmoker. PSQI>5.5 after use of hypnotics (100%) **Setting:** outpatient **Exclusion:** Severe anxiety and depression, psychosis, organic mental disorder, or current high risk of suicide, substance abuse, or dependence	**IV:** DCBT **DV1:** Sleep characteristics **DV2:** quality of life **DV3:** mood **Definition:** UC-pharmacotherapy & received email magazines with general information about insomnia and hypnotics 4 times over a 6-week period. CG received UC and 5 weekly face-to-face CBT for insomnia	Self-rated questionnaire (PSQI, HADS, QOL)	Fisher exact test ANCOVA	Δ 6 weeks: **DV1:** IG: P<0.001 Δ12 weeks: **DV2:** P<0.01 **DV3:** HADS (IG) p<0.01	**LOE:** level 2 **Strength:** No adverse effect of DCBT; cost-effective; studies individual who takes benzodiazepines; no changes of sleep medication during the study; participants were blinded **Weakness:** small sample size; short follow up; subjective data; assessors not blinded

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Promotion of Science **Country:** Japan **Bias:** none			within the 12 months before enrollment, antisocial personality disorder, or unstable medical condition **Attrition:** 4.34%					**Feasibility:** Clinician can encourage DCBT for other health conditions. DCBT has no adverse effects.
Nordin et al. (2016) Effects of the web behavior change program for activity and multimodal pain rehabilitation: Randomized controlled trial **Funding:** Financed by the REHSAM research project, a cooperation	CM, inferred	**Design:** RCT **Purpose:** To evaluate the effects of multimodal pain rehabilitation in combination with the DCBT compared with MMR alone among persons with persistent musculoskeletal pain in primary health care	N=109 CG (UC): n=49 IG (UC & DCBT): n= 60 **Demographic:** M age=43; f=85% Pain duration (CG= 78 months; IG=79months) **Setting:** outpatient **Exclusion:**	**IV:** DCBT **DV1:** Pain intensity **DV2:** self-efficacy **DV3**: coping strategies **Definition:** UC= patient-centered biopsychosocial treatments with at least three health care professionals; 2	Questionnaire (VAS, SES, CSQ)	Independent-samples t test, Mann-Whitney U test, chi-square test ANOVA	**DV1& DV2** P=0.002 Δ12 weeks **DV3:** P=0.003 *other finding: Satisfaction Δ 4 months: P<.001	**LOE:** level 2 **Strength:** longer pain duration and higher level of pain **Weakness:** No significance found between groups; bias in sampling method; Questionnaire; control group also received

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between the Swedish Social Insurance Agency, the Ministry of Health and Social Affairs, the Swedish Association of Local Authorities and Regions. **Country:** Sweden **Bias:** none		**Sampling:** purposive	Reduced Cognitive ability, current alcohol or drug abuse, need other medical care, pregnancy **Attrition:**9.17 %	to 3 times a week for 8 weeks DCBT: 8 self-guided modules				patient-centered treatment provided by healthcare professionals. **Feasibility:** utilize cost-effective intervention for chronic pain patients (>5 years), increase adherence and patient satisfaction. make them feel more in control with their health.
Zgierska et al., (2016) Mindfulness meditation and cognitive behavioral	ICM CM, inferred	**Design:** RCT **Purpose:** To assess benefits of mindfulness meditation and CBT for opioid-	N=35 CG (UC only): n=14 IG (UC+CBT): n=21 **Demographic:**	**IV:** CBT **DV1:** pain intensity **DV2:** physical function	BPI, Oswestry Disability Index, Biomarkers, Opioid dose, Thermal	linear mixed model ITT Wilcoxon tests	**DV1:** Δ 8 & 26 weeks: P = 0.045 thermal stimuli P < 0.05	**LOE:** level 2 **Strength:** RCT study; no participants withdrew from

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therapy intervention reduces pain severity and sensitivity in opioid-treated chronic low back pain: Pilot findings from a randomized controlled trial **Funding:** Funds from the University of Wisconsin-Madison; Clinical and Translational Science Award, National Institutes of Health & National Institute on Alcohol Abuse and Alcoholism **Country:** USA **Bias:** none		treated chronic low back pain **Sampling:** Purposive	M age= 51.8; white f=80% **Setting:** outpatient **Exclusion:** No daily opioid use: prior experience with mindfulness meditation training, inability to consent for or reliably participate in study activities; diagnoses of borderline personality, bipolar, or delusional disorders; or current pregnancy **Attrition:** 0%	**DV3:** Medication use **Definition:** UC= opioid management by regular clinician; pharmacotherapy, safety, treatment progress monitoring, specialty care; physical therapy, complementary therapies for pain and/or mental health IG= UC and 2 hours per week manualized training, mindful meditation at least 6 days/week for at	Sensory Analyzer		**DV2:** P=0.434 **DV3:** P=0.654	the study; included more than self-questionnaire; involved individuals with severe chronic opioids use in large dosage **Weakness:** small sample size; participants received a financial renumeration upon completion; individuals can decline to participate; no significant benefit found in biomarkers; non-blinding **Feasibility:** High retention

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				least 30 minutes/day				rate indicates this is feasible intervention for patients in clinic who are motivated. Can offer to individuals who are opioid dependent
Smitherman et al. (2016) Randomized controlled pilot trial of behavioral insomnia treatment for chronic migraine with comorbid insomnia **Funding:** Dr. Smitherman received fund from Migraine Research	LT; CM, inferred	**Design:** single blinded RCT **Purpose:** To pilot-test the efficacy of a brief behavioral insomnia intervention for adults with chronic migraine and comorbid insomnia **Sampling:** Purposive	N=32 (1 dropout after baseline assessment) CG=15 IG=16 **Demographic:** M age = 30.8 years; f=90.3%; white=80.6% No significant difference in M age, gender, race, disability, depression anxiety. **Setting:** outpatient **Exclusion:**	IV: CBT **DV1:** Headache frequency **DV2:** Sleep efficacy **DV3:** Mood **Definition:** IG= daily practice of 5 instructions (stimulus control and sleep restriction) with rationale, treatment provided by	Actigraphy Sleep diary Structured Interviews Self-Questionnaire (Migraine Disability Assessment Questionnaire, Headache Impact Test, PHQ-9, ESS, PSQI, GAD)	ITT Generalized linear models	**DV1:** Headache frequency P=0.028 OR=0.40 Cl=95% **DV2:** P=0.001 **DV3:** No significant difference between group	**LOE:** level 2 **Strength:** No adverse effects reported; both groups yielded reduction in headache frequency; high adherence; objective monitoring through actigraphy; included difference race

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Foundation; Dr. Houle receives unrestricted grant funding from Merck, Inc **Country:** USA **Bias:** none			secondary headache disorder, pregnancy or breastfeeding, untreated sleep apnea; alcohol, substance abuse or dependence; active bipolar disorder, psychiatric hospitalization within the last year, recent changes in preventive pharmacotherapy **Attrition:**21.87 %	three graduate-level therapist, acupressure training, range of motion exercises.				**Weakness:** small sample size; high attrition rate; short study (6-week follow up), study lack details in intervention (time, duration, accessibility) **Feasibility:** Useful to address sleep and other comorbidities. Effective in different race and gender.
Burke et al. (2019) An internet-delivered cognitive behavioural therapy pain	SCT; Holistic Framework	**Design:** RCT **Purpose:** To test the efficacy of Spinal Cord Injury Pain Ireland (SPIRE)	N=69 CG= 34 IG=35 **Demographic:** M age= 51; f=25%, M post-injury time= 16	**IV: CBT** **DV1:** Quality of life **DV2**: Pain **DV3:** Mood **DV4:** Sleep quality	PSQI, BPI, QOL, HADS	linear mixed models Cohen's d Chi-square	Δ 3 months **DV1:** P> 0.16 **DV2:** P=0.15 **DV3:**	**LOE: level 2** **Strength:** included individuals who reported

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management programme for spinal cord injury pain: A randomized controlled trial. **Funding:** Supported by The Irish Society of Chartered Physiotherapists Eastern Branch Research Bursary 2016 and the Health Informatics Society of Ireland Research Bursary 2016. **Country:** Ireland **Bias:** none		pain management programme, an internet-delivered CBT for spinal cord injury pain **Sampling:** purposive	y; analgesic in last 6 months (61%) **Setting:** outpatient **Exclusion:** Mental health issues requiring active psychiatric management, previous completed a CBT, confounding co-morbidities (cancer, substance misuse **Attrition:** 26%	**Definition:** CBT= six modules delivered weekly, physiotherapist engagement and feedback, live webinar, written educational information		Spearman's rank correlation coefficient	HADS-anxiety: P=0.12 HADS-Depression P=0.16	poor computer skills; national database utilized. **Weakness:** low recruitment rate; high attrition rate; low rate of intervention completion; non-blinded RCT; participants underwent other concurrent treatment; participants pre-selected during sampling process. **Feasibility:** Clinician can

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								encourage CBT among highly motivated participants.
Vedaa et al. (2020) Effects of digital cognitive behavioural therapy for insomnia on insomnia severity: a large-scale randomised controlled trial. **Funding:** Norwegian Research Council; Liaison Committee for Education, Research and Innovation in Central Norway	CM, inferred	**Design:** RCT **Purpose:** To investigate the effect of a fully automated DCBT programme on insomnia severity, sleep–wake patterns, sleep medication use, and daytime impairment **Sampling:** purposive	N=1721 CG: n=853 IG: n=868 **Demographic:** M age =45 years, female (68%), sleep problem >6 years (66%) **Setting:** outpatient **Exclusion:** ESS >10; self-reported regular snoring and breathing problems with difficulties staying awake during the day; medical comorbidities (epilepsy,	**IV:** DCBT **DV:** insomnia severity **DV2:** Medication Use **DV3:** Mood **Definition:** IG=Six fully automated and interactive online sessions designed to be completed within a 9-week intervention period	Sleep diary (onset, wake time, early morning awakening, total sleep time, sleep efficiency) Insomnia Severity Index, Bergen Insomnia Scale HADS	Cohen's d latent growth models	Δ 9 weeks: **DV1:** p<0·001 **DV2:** p<0.001 OR=0.49 Cl=95% **DV3:** P<0.001	**LOE: level 2** **Strength:** intervention is cost effective as it is fully automated; does not require participant and assessor interaction; first large RCT conducted in non-English speaking country; no adverse effects **Weakness:** female predominance; only 65%

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Citation	Theory/ Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	LOE; Decision for practice/ application to practice
Country: Norway **Bias:** Two authors report financial or business interests in BeHealth Solutions and Pear Therapeutics, two companies that develop and disseminate digital therapeutics			bipolar disorder, schizophrenia or psychotic disorders, or recent cardiac surgery); night-time shift workers Attrition: 35.03%					completed questionnaire at 9-week follow up; over 5000 individuals were initially screened; only self-report data utilized **Feasibility:** DCBT can be a cost effective and low-intensity modality to help improve sleep in short period of time.

Key: **ANCOVA** – Analysis of covariance; **ANOVA** – Analysis of variance; **BPI** – brief pain inventory; **CBT** – Cognitive behavioral therapy; **CM** – Cognitive model; **CSQ** – coping strategies questionnaire; **CG** – control group; **DCBT**—digital cognitive behavioral therapy; **DV**—dependent variable; **ESS** – Epworth sleepiness scale; **f** – female; **FAM** – Fear Avoidance Model; **FM** – fibromyalgia; **GAD** – Generalized anxiety disorder scale; **GSII** – Glasgow Sleep Impact Index; **HADS** – Hospital anxiety and depression scale; **ICM** – Integrated care model; **IG** – intervention group; **ITT** – intention-to-treat analysis; **IV** – independent variable; **LOE** – level of evidence; **LBP** – low back pain; **LT** – Learning theory; **M** – mean; **N** – number of participants in study; **n** – number of participants in subset; **NSAID**– Nonsteroidal anti-inflammatory drug; **PHQ-9** – patient health questionnaire-depression scale; **PSQI** – Pittsburgh Sleep Quality Index**; QOL –** quality of life scale; **RCT –** randomized control trial; **SES** – self efficacy scale; **SCT** – Self-care Theory; **UC** – usual care; **VAS** – visual analog scale; **WASO** – wake after sleep onset; **y**– year; Δ – pretest to posttest change for intervention group; **&** – and

Citation	Theory/ Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	LOE; Decision for practice/ application to practice
Lami et al. (2018) Efficacy of combined cognitive-behavioral therapy for insomnia and pain in patients with fibromyalgia: A randomized controlled trial **Funding:** Financially supported by the Spanish Ministry of Science and Innovation and Spanish Ministry of Economy and Competitiveness **Country:** Spain	Fear-avoidance model CM, inferred	**Design:** RCT **Purpose:** To identify the clinical benefits of CBT for management of insomnia and pain compared with the usual psychological treatment focused on pain and the usual medical care regarding sleep quality, pain and other troubling symptoms in fibromyalgia women **Sampling:** convenience	N= 126 CG (UC): n= 42 IG1 (CBT-pain: n=42 IG2 (CBT-insomnia & pain): n=42 **Demographic:** M age=50.19; female (100%) **Setting:** outpatient **Exclusion:** concomitant medical conditions (inflammatory rheumatic disease, cancer, recent surgery); pregnancy; mental disorders with severe symptoms (suicide ideation, schizophrenia, personality	**IV:** CBT **DV1:** sleep quality **DV2**: self-efficacy **D3: use of medication** **D4:** **Definition:** CBT=90-minutes group sessions weekly for 9 weeks CBT-pain: based on Fear-Avoidance Model of Chronic Pain CBT- insomnia & pain involves CBT-pain and training in cognitive, affective, and behavioral skills for better	Semi-structured interview Sleep diary PSQI SES	ANOVA ANCOVA Kruskal-Wallis test Chi-square test Cohen's d	**CBT-insomnia &pain** Δ post-treatment: total sleep quality, using sleep medication $p<0.01$ Δ 3 months: $p>0.05$ *other finding No significant improvement on anxiety and depression in three groups	**LOE:** level 2 **Strength:** explored hybrid therapy; compared three modalities; only those completed treatment was included in analysis **Weakness:** All participants were female; high attrition rate; treatment only demonstrated short-term benefits; participants had fibromyalgia diagnosis rather than generalized chronic pain;

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Citation	Theory/ Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	LOE; Decision for practice/ application to practice
Bias: none			disorder); other organic sleep disorder; severe dependence of hypnotic drugs; irregularities in circadian rhythms at the time of the study **Attrition:** 42.86%	management of sleep problems				require trained psychologist. **Feasibility:** Can be useful hybrid approach to patients with chronic pain who have comorbid sleep disorders. CBT is modifiable for individual's needs.

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Table 2

Synthesis Table

Study characteristic	Blake et al.	Burke et al.	Espie et al.	Lami et al.	McCrae et al.	Nordin et al.	Sato et al.	Smitherman et al.	Vedaa et al.	Zgierska et al.
Year	2015	2019	2019	2018	2019	2016	2019	2016	2020	2016
RCT		•	•	•	•	•	•	•	•	•
Cohort Study	•									
# of subjects	46	69	1771	126	113	99	23	31	1721	35
Theory Model										
CM	•	inferred	•	inferred	•	•	•	inferred	•	inferred
FAM				•						
ICM										•
LT								•		
SCT		•								
Intervention Length	4 weeks	12 weeks	8 weeks	9 weeks	8 weeks	8 weeks	6 weeks	4 weeks	9 weeks	8 weeks
Measurement Tools	Actigraphy, PSQI, HADS, WASO, QOL,	BPI, HADS, PSQI, QOL,	PROMIS, GSII, PHQ-9, GAD	PSQI, SES, SCL	Actigraphy, Sleep Efficiency, VAS	VAS, SES, CSQ	PSQI, HADS, QOL	Actigraphy, PSQI, PHQ-9, GAD	Insomnia Severity Index, Bergen Insomnia Scale, HADS	BPI, Biomarkers, Thermal sensory analyzer
Setting										
outpatient	•	•	•	•	•	•	•	•	•	•
Country										

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USA					•			•		•
Other	UK	Ireland	UK	Spain		Sweden	Japan		Norway	
Demographic										
Mean age (y)	47.7	51	48	50.19	53	43	50	30.8	45	51.8
%f	58.7%	25%	77.7%	100%	97%	84.8%	78%	90.3%	68%	80%
Condition										
Pain	•	•		•	•	•		•		•
Type of Pain	General	Spinal cord		FM	FM	General		Migraine		LBP
Insomnia			•	•	•		•	•	•	
Independent Variable										
CBT sessions	•			•	•			•		•
DCBT sessions		•	•			•	•		•	
Dependent Variable										
Sleep quality	•	•	•	•	•		•	•	•	
Pain intensity		•		•	•	•				•
Self-efficacy				•		•		•		
Medication use				•					•	•
Physical Function			•	•				•		•
Mood	•	•	•	•	•		•	•	•	•
QOL	•	•					•			
Findings										
Improved Sleep Quality	•		•	•	•		•	•		
Improved Pain Intensity						•		•		•
Improved Mood	•		•				•		•	

Key: **ANCOVA** – Analysis of covariance; **ANOVA** – Analysis of variance; **BPI** – brief pain inventory; **CBT** – Cognitive behavioral therapy; **CM** – Cognitive model; **CSQ** – coping strategies questionnaire; **CG** – control group; **DCBT**—digital cognitive behavioral therapy; **DV**—dependent variable; **ESS** – Epworth sleepiness scale; **f** – female; **FAM** – Fear Avoidance Model; **FM** – fibromyalgia; **GAD** – Generalized anxiety disorder scale; **GSII** – Glasgow Sleep Impact Index; **HADS** – Hospital anxiety and depression scale; **ICM** – Integrated care model; **IG** – intervention group; **ITT** – intention-to-treat analysis; **IV** – independent variable; **LOE** – level of evidence; **LBP** – low back pain; **LT** – Learning theory; **M** – mean; **N** – number of participants in study; **n** – number of participants in subset; **NSAID**– Nonsteroidal anti-inflammatory drug; **PHQ-9** – patient health questionnaire-depression scale; **PSQI** – Pittsburgh Sleep Quality Index**; QOL –** quality of life scale; **RCT –** randomized control trial; **SES** – self efficacy scale; **SCT** – Self-care Theory; **UC** – usual care; **VAS** – visual analog scale; **WASO** – wake after sleep onset; **y**– year; Δ – pretest to posttest change for intervention group; **&** – and

Reduced Medication Use				•					•	
Improved QOL							•			

Key: **ANCOVA** – Analysis of covariance; **ANOVA** – Analysis of variance; **BPI** – brief pain inventory; **CBT** – Cognitive behavioral therapy; **CM** – Cognitive model; **CSQ** – coping strategies questionnaire; **CG** – control group; **DCBT**—digital cognitive behavioral therapy; **DV**—dependent variable; **ESS** – Epworth sleepiness scale; **f** – female; **FAM** – Fear Avoidance Model; **FM** – fibromyalgia; **GAD** – Generalized anxiety disorder scale; **GSII** – Glasgow Sleep Impact Index; **HADS** – Hospital anxiety and depression scale; **ICM** – Integrated care model; **IG** – intervention group; **ITT** – intention-to-treat analysis; **IV** – independent variable; **LOE** – level of evidence; **LBP** – low back pain; **LT** – Learning theory; **M** – mean; **N** – number of participants in study; **n** – number of participants in subset; **NSAID**– Nonsteroidal anti-inflammatory drug; **PHQ-9** – patient health questionnaire-depression scale; **PSQI** – Pittsburgh Sleep Quality Index**; QOL –** quality of life scale; **RCT –** randomized control trial; **SES** – self efficacy scale; **SCT** – Self-care Theory; **UC** – usual care; **VAS** – visual analog scale; **WASO** – wake after sleep onset; **y**– year; Δ – pretest to posttest change for intervention group; **&** – and

Table 3

Budget and Funding

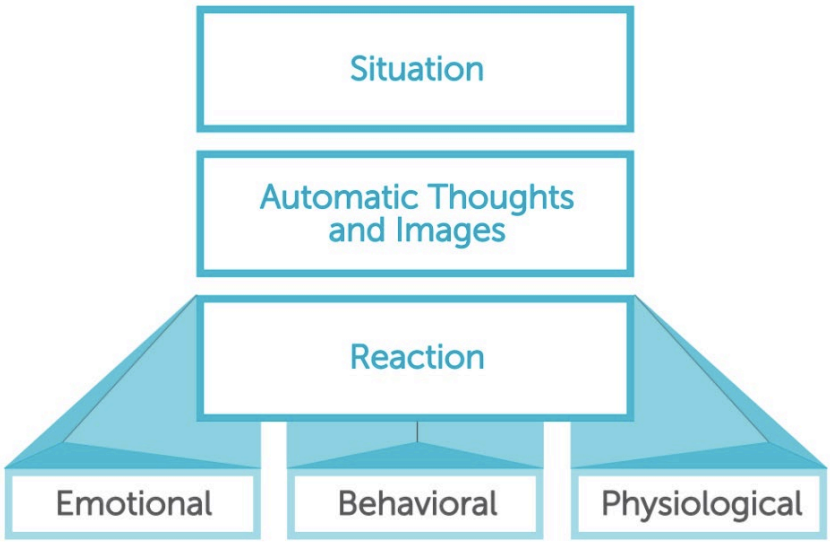
EXPENSE ITEMS	AMOUNT
Equipment	$30
Survey Print-Out	$50
Utensils	$10
Brochure (color printing)	$13
Delivery: Gas	$120
Evaluation: Intellectus Software	$150
TOTAL EXPENSE	$373
TOTAL FUNDING	$0

Appendix B

Models and Framework

Figure 1

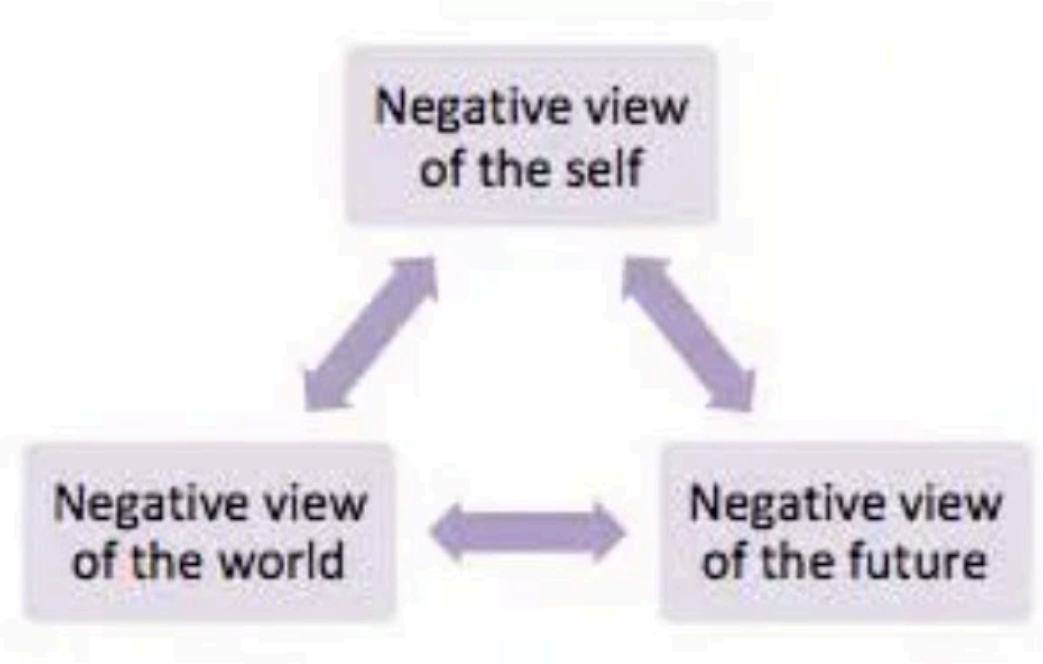
Cognitive Model



Beck Institute (n.d.).

Figure 2

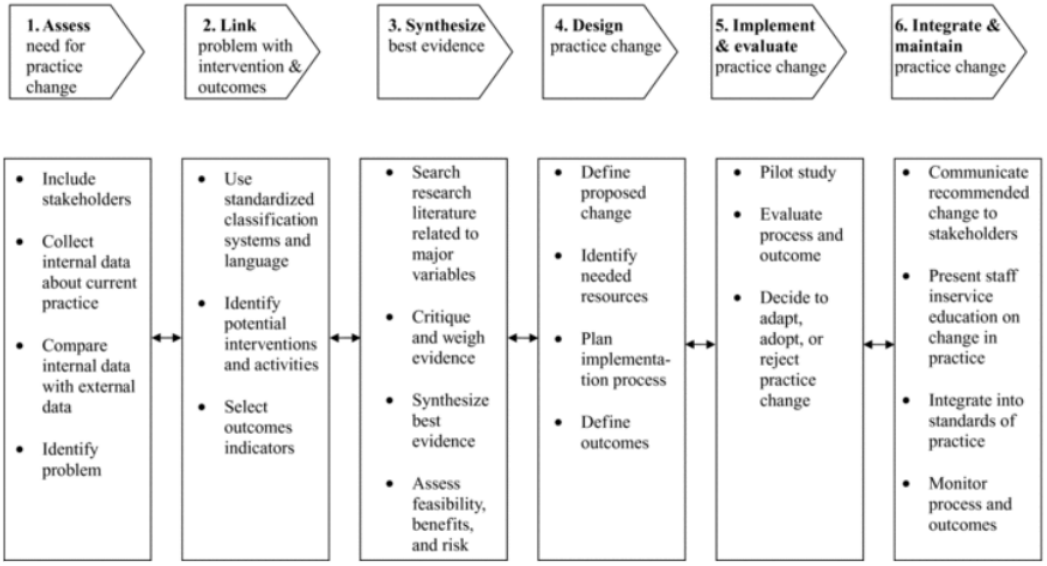
Cognitive Triad



McLeod (2019).

Figure 3

Rosswurm and Larrabee's Model for evidence-based practice



Rosswurm & Larrabee (1999).