

Chronic Non-Malignant Pain and Cognitive Behavioral Therapy

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## Abstract

For patients who experience chronic non-malignant pain, opioid prescriptions have been steadily increasing despite questionable efficacy, safety concerns, and economic implications. Some types of pain are clearly identified and treated effectively while others persist and cause not just unwanted physiological changes, but psychological and cognitive effects as well. Positive and negative correlations have been seen in cognitive behavioral therapy and its effects on outpatient adjunct treatments in patients with chronic non-malignant pain. To ease the burden in economic crisis and humanitarian suffering it is important for the community to approach the problem in a multidisciplinary way. Alternative treatments from costly procedures should be considered such as counseling, self-care facilitation, and other forms of cognitive behavioral therapy that can help improve quality of life (Institute of Medicine, n.d.). This project addressed the current community need in managing patients with chronic non-malignant pain and maladaptive thinking or behaviors at the AdventHealth University Hope Clinic. A qualitative study was performed by interviewing key players and identifying barriers and facilitators to determine the feasibility of developing cognitive behavioral therapy as an adjunct treatment for patients within the AdventHealth University Hope Clinic with chronic non-malignant pain. In conclusion, a CBT program is feasible within the AdventHealth Hope Clinic based on the resources currently available as well as the facilitators identified during our qualitative analysis. However, barriers that were identified should be addressed, facilitators pursued, and a pilot study should be performed.

*Keywords:* chronic non-malignant pain, cognitive behavioral therapy, opioid use, feasibility study

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### Chronic Non-Malignant Pain and Non-Pharmacological Management

It is estimated that 116 million Americans suffer from chronic non-malignant pain (CNMP) and the use of opioids among them have been steadily increasing despite questionable efficacy, safety concerns, and economic implications (Lipman & Webster, 2015). The astonishing increase of opioid prescriptions for CNMP treatment has contributed to the US opioid epidemic, leading to opioid-related overdose deaths and opioid use disorders (Bonnie, Schumacher, Clark, & Kesselheim, 2019). The United Nations on Drugs and Crime (UNODC) reported that 29.5 million of the global adult population used prescriptions inappropriately, suffered from drug use disorders, and dependence (United Nations on Drugs and Crime, 2017). The use of opioids was found to be most detrimental with 70 percent leading to negative health implications (United Nations on Drugs and Crime, 2017). Strikingly, more than 130 people die daily after opioid overdose (National Institute on Drug Abuse, 2019). The current opioid epidemic is costing the United States 78.5 billion dollars a year from treatment costs and loss of productivity (Lipman & Webster, 2015). The Centers for Disease Control (CDC) suggests clinicians consider multimodal treatments for chronic pain management because opioids present serious risk of overdose, drug use disorders, and death (Dowell, Haegerich, Chou, 2016). Access to multimodal treatment modalities, particularly for those that are underserved or uninsured is abbreviated, calling for innovative thinking to meet the needs of this unique patient population.

The AdventHealth University Hope Clinic provides occupational therapy to the underserved and uninsured members of the community. An assessment of need regarding the prevalence of CNMP and its treatment modalities was undertaken in 2016. The assessment identified a 51.51% prevalence of CNMP with Norco comprising 14.7% of the 34 total

medications used to treat their chronic pain (Snell, Hughes, Fore, Lukman & Morgan, 2019). Individuals most likely to experience CNMP within the clinic included: (a) females, (b) African Americans, (c) Hispanic/ Latin descent, and (d) individuals with a cerebral vascular accident (CVA) (Snell, Hughes, Fore, Lukman & Morgan, 2019). With the understanding that chronic pain is a multidimensional (biological, psychological, social) subjective disease it requires comprehensive treatment with an interdisciplinary approach (Dysvik, Kvaloy, & Furnes, 2014). Certified Registered Nurse Anesthetists (CRNAs) are highly skilled professionals and receive extensive training in pain management (American Association of Nurse Anesthetists, 2014). CRNAs are able to utilize a variety of therapeutic, physiological, pharmacological, interventional, and psychological modalities to treat and manage chronic pain (AANA, 2014). This scholarly project outlines a plan to provide individualized supportive care that focuses on self-management skills to a cohort of individuals who are resource poor.

### **PICO Questions**

Two questions, posed in PICO format, have been utilized in formulating a systematic review of literature. The first question addresses the clinical problem: In chronic non-malignant pain patients (P), what are the effects of cognitive behavioral therapy (I) on pain intensity, quality of life, and physical and emotional function (O)?

The second question addresses the clinical innovation: In the AdventHealth University Hope Clinic (P), what is the feasibility for the development of a cognitive behavioral therapy program (I) for chronic non-malignant pain management (O)?

### **Search Strategy/Results**

The search strategy used included the following search engines: CINAHL, PubMed, Google Scholar, and MEDLINE. Out of 3,173 articles that were initially retrieved, 20 met

inclusion criteria. Inclusion criteria included CBT, chronic pain management, CNMP, and non-pharmacological pain management. We reviewed abstracts, titles, and the body of the document to ensure keywords were present. Key search terms included: pain management, AND pain relief, AND pain control, AND pain reduction, AND cognitive behavioral therapy, AND chronic non-malignant pain, AND therapeutic, AND approach, AND opioid, AND epidemic, AND effects, AND intensity, AND quality of life. The search limits were human subjects, journals, research articles, English language, and within the last five years.

### **GRADE Level of Evidence**

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria was used to evaluate the level of evidence that demonstrates the effects of CBT for patients with CNMP. The GRADE level of evidence was high. A majority of literature was derived from randomized control trials, systematic reviews, and meta-analysis, rendering the initial rating of the evidence as high. Due to methodological flaws and publication bias in the high-quality studies, the literature was graded down -1. Methodological flaws included a lack of blinding and selective outcome reporting. Problems associated with publication bias consisted of authors, medical personnel, and psychotherapists being part of the committee that conducted and reviewed the study. Some studies have found that incorporating the use of cognitive behavioral therapy in patients with chronic non-malignant pain is likely to produce minimal to no undesirable effects when used as an adjunct treatment (Broderick et al., 2016; Dysvik, Kvaloy, & Furnes, 2014; Knoerl, Lavoie Smith, & Weisberg, 2016; Stratton, Bender, Cameron, Pickett, 2015). Research supports the idea that incorporating CBT as an adjunct treatment can have positive and negative correlations on pain related outcome variables. Since the quality of evidence is moderate, inclusion of CBT within clinical practice is highly recommended.



### **Literature Review**

For the purpose of this scholarly project, chronic pain is defined as pain that lasts greater than 3 months or beyond the normal tissue healing time (Dysvik, Kvaloy, & Furnes, 2014; Knoerl, Lavoie Smith, & Weisberg, 2016; Majeed & Sudak, 2017). Chronic non-malignant pain is a subjective persistent pain not associated with malignancy or end-of-life/palliative care (Majeed & Sudak, 2017). CNMP causes unwanted physiological, psychological, emotional, behavioral, and spiritual effects that are affected in varying degrees (Dysvik, Kvaloy, & Furnes, 2014; Institute of Medicine, 2011; Knoerl, Lavoie Smith, & Weisberg, 2016). CBT has been utilized for management of chronic non-malignant pain, which includes its unwanted effects, as part of a multimodal treatment.

Cognitive behavioral therapy within the CNMP program reduces suffering by changing maladaptive feelings and has the potential to relieve pain, along with improved quality of life (Dysvik, Kvaloy, & Furnes, 2014; Majeed & Sudak, 2017). A form of psychological treatment, CBT, attempts to change one's negative perceptions about pain through behavioral modifications to improve their ability to cope with pain and physical limitations (Shpaner et al., 2014; Bernardy, Klose, Welsch & Hauser, 2018). Those that produced the greatest impact with the use of CBT included group therapy sessions, one on one interviews (in person or via telephone), relaxation, exercise, psychotherapy, and pain coping skills. The forms of CBT stated above produced minimal to no undesirable effects for patients with CNMP when used as adjunct treatments (Broderick et al., 2016; Dysvik, Kvaloy, & Furnes, B. 2014; Knoerl, Lavoie Smith, & Weisberg, 2016; Stratton, Bender, Cameron, Pickett, 2015). The most common studied range of CBT was six to ten weeks, with six to ten total hours showing effects on pain related variables (Knoerl, Lavoie Smith, & Weisberg, 2016). However, the duration of CBT treatment ranging

from six to twelve weeks did not produce consistent results when it came to pain related outcomes. As such, a standardization in therapy length that would achieve optimal benefits cannot be determined.

Evidence showed positive and negative correlations with the use of CBT and pain related outcome variables. CBT had positive correlations on pain related outcome variables which include quality of life, self-efficacy, acceptability, pain coping skills, and self-management. In comparison, negative correlations on pain related outcome variables include pain, pain intensity, catastrophizing, use of pain medication, and negative mood. In addition, other pain related outcome variables with negative correlations that have been reported are traumatic pain, anxiety, depression, brain activity changes, and sleep disturbance.

Chronic non-malignant pain can have a profound impact on the sufferer, their family, and the community as a whole. Inadequate pain management can cause stress, depression, functional limitations, and a decrease in quality of life (Knoerl, Lavoie Smith, & Weisberg, 2016). Factors that may influence the effects of CBT on pain related outcome variables include pain coping style, patient expectations, disease severity, age, education, anxiety, depression, and dose therapy. These moderators have shown varying degrees of significance in pain related outcome variables. Unfortunately, most patients do not have adequate knowledge on how to manage their chronic pain effectively and are unaware of the resources that are available to assist them (Institute of Medicine, 2011). Healthcare providers are not able to explore diverse management techniques due to lack of knowledge, biases, insurance coverage, and limitations set forth by organizations they work for or government regulations (Institute of Medicine, 2011). This current issue also exists within the local Orlando community specifically in the AdventHealth University Hope Clinic.

The AdventHealth University Hope Clinic has limited accessibility to resources and is currently not offering alternative pain management therapies to its patients suffering from CNMP. Due to the limited resources, we were unsure of the feasibility of a CBT program within the AdventHealth University Hope Clinic. Therefore, we proposed determining the feasibility of the development of a CBT program for CNMP in AdventHealth University Hope Clinic, with a goal of connecting with an underserved and uninsured population in the community. This project will increase awareness of non-pharmacological adjunct treatments, determine the feasibility and viability of a CBT program in the AdventHealth University Hope Clinic, and provide the community with alternative treatments to help improve their coping strategies with CNMP.

### **Applicability to Practice**

Evidence based practice supports the use of CBT as an adjunct treatment to CNMP management due to its effects on improved pain coping and perception, maladaptive feelings, improved quality of life, decreased anxiety, depression, and opioid use. CBT has shown benefits as part of a multidimensional approach to effectively manage CNMP and its associated comorbid conditions. Further research is needed to assess the current cost effectiveness of CBT against the standard treatment and the barriers limiting its use. The CDC suggests clinicians consider multimodal treatments for chronic pain management because opioids present serious risk of overdose, drug use disorders, and death (Dowell, Haegerich, Chou, 2016). A practitioner's lack of knowledge and familiarity with CBT, lack of funding, and duration of treatment to yield results are all contributing factors to the barriers limiting its use (Majeed & Sudak, 2017).

The effects of CBT on outpatient adjunct treatments are supported by the literature. The feasibility of developing a CBT program in AdventHealth University's Hope Clinic determined the viability of a CBT program with hopes of helping patients with CNMP who are underserved

and uninsured. If implemented as suggested, patients in this facility would have the option of participating in CBT programs free of charge and would be educated on other forms of treatment to assist with the management of their chronic pain. Pain management should be administered by highly qualified clinicians including CRNAs. The extensive education regarding pain and its management received by CRNAs meets the Institute of Medicine's criteria of clinicians best suited for the chronic pain management role (Snell, Hughes, Fore, Lukman & Morgan, 2019).

### **Aims**

The primary aim of the proposed scholarly project was to determine the feasibility for the development of an evidence-based CBT program for CNMP within the AdventHealth Hope Clinic. The project objectives are delineated below.

1. Perform a qualitative evaluation to explore the feasibility of the delivery and implementation of a CBT program for CNMP within the AdventHealth Hope Clinic.
2. Perform an economic evaluation to determine the viability and identify potential resources for CBT implementation within the AdventHealth Hope Clinic.
3. Delineate potential implications and make recommendations for the implementation of a CBT program for CNMP patients presenting to the AHU AdventHealth University Hope Clinic.

### **Methods**

#### **Study Site**

A small university faith-based clinic: AdventHealth University Hope Clinic

#### **Sample Group and Sample Size**

In this scholarly project snowball sampling was employed. This sampling method was selected to align with the planning phase process of the feasibility study delineated in the

methods section below. The number of participants selected for the first wave of interviews consisted of eight participants and are discussed below. It was not possible, however, given the selected framework, to predetermine if the final sample would be primarily homogenous or heterogenous in nature. Due to the aforementioned inherent difficulty in sample characterization, evidence saturation for this scholarly project was anticipated to be achieved with a final sample size ranging from twelve to twenty (Vasileiou, Barnett, Thorpe, & Young, 2018). The final sample size consisted of 8 first wave respondents and three second wave respondents.

## **Methods**

This proposed scholarly project used a descriptive, qualitative approach, based on a feasibility study framework. In-depth interviews of key players, lasting approximately one hour, were employed guided with a student developed, semi-structured, face validated, questionnaire (See Appendix B).

## **Framework**

While lacking a singular framework, feasibility studies are routinely used in business to determine the advisability of exploring a given intervention. For the purposes of this scholarly project, the four phases of project management delineated by the Harvard Business Review (Porter, Kim, Mauborgne, 2011), were employed.

## **Planning Phase**

Upon approval from SRC/IRB, the planning phase was initiated. The planning phase resulted in a concise description of the nature, scope, and time frame of the project as well as a clear delineation of expected results. Deliverables for the planning phase of a CBT program within the AdventHealth Hope Clinic included the following:

- Identification and delineation of facilitators, barriers, and major tasks through the interview of key stakeholders;
- Identification of project benefits for AdventHealth University and its Hope Clinic clients;
- Determination of major tasks;
- Formulation of CBT therapy program objectives

Key players were identified as part of the process of a feasibility study. Key players included but were not limited to, the Hope Clinic administrator and staff. Interviews were continued until data saturation occurred. For the purposes of this scholarly project data saturation was defined as interview responses having become redundant of data already collected. Further interviewees were identified via the administered questionnaire. The question that identified additional key players is as follows: Who, in your opinion, would be important team members, or key players, for the development and successful implementation of a cognitive behavioral therapy program within the AdventHealth Hope Clinic.

Informal interviews were performed as part of the requirements for DNAP 791, additional information was sought during the planning phase through qualitative semi-structured interviews with open-ended questions that covered the following topics: CNMP and non-pharmacological treatment, CBT feasibility, needed resources and staff for implementing a CBT program, facilitators and barriers, institutional characteristics, evaluation measures, procedures and outcomes. The interviewees were asked to provide any additional information that they felt would be helpful to the scholarly project team. This methodology was selected to gain more comprehensive information, to develop a clearer understanding of the project scope as well as, to allow for interviewees to provide a more candid response.

After obtaining informed consent (Appendix E), interviews were conducted and recorded either face to face or via telephone with face-to-face interviews being preferred. Telephone interviews were only considered if the key player's schedule was such that they would have been excluded otherwise. The same set of interview questions was asked of all interviewees. After completion of interviews, a narrative analysis was performed to identify main ideas and themes. Recorded interviews were stored in a password protected SharePoint file that will be automatically deleted in five years. Individuals allowed access to the SharePoint file included, Liberty Pagayon, Jennifer Nieves, and Sarah Snell. In addition to interviews, other community resources were explored either through interview or internet search. Completion of the planning phase occurred before the end of the spring academic trimester on April 17, 2020.

### **Build-Up Phase**

The build-up phase commenced after interviews were completed and analyzed. Deliverables for the build-up phase included the following:

- Identification of team members necessary to successfully implement a CBT therapy program;
- Plan assignments and the sequence of tasks for individual team members identified;
- We had several people that are not CBT experts. OT can implement certain areas of CBT but are not licensed therapists. Mrs. Betty Varghese and Dr. Yvette Saliba can practice CBT but not specifically for CNMP. Respondents recommended a committee which includes key players from AdventHealth University, AdventHealth Hospitals, pain management experts, psych majors, and the possibility of collaboration can be explored to fill the gap. We were not able to identify someone in the Central Florida area that has the expertise on CBT for CNMP so this would need to be explored through partnerships,

with possibly UCF or a licensed professional person with these credentials who might be able to identify the proper personnel to fill these roles;

- A GANTT Chart (See Appendix C) was created to implement a realistic schedule that achieved the CBT therapy program objectives;
- Delineated costs and available resources to offset those costs;
- Identified the legal and licensure implications of a CBT program within the Hope Clinic

The build-up phase concluded before the end of the summer academic trimester on November 30, 2020.

### **Implementation Phase**

The implementation phase consisted of the creation of the written feasibility study report, compiled from the deliverables of the planning and build-up phases. On completion of the report, scholarly project team members also developed evidence-based recommendations as to whether a CBT therapy program within the Hope Clinic should be implemented or abandoned. The implementation phase ended before the fall academic trimester on December 13, 2020.

### **Closeout Phase**

The final closeout phase consisted of a scholarly project team post feasibility study report and recommendation presentation to key players. The closeout phase ended before the conclusion of the spring academic trimester on April 17, 2021, on a date determined by the nurse anesthesia program faculty and key players.

## **Planning and Procedures/Limitations**

### **Planning**

Tia Hughes, OT, MBA, OTR/L was the department chair of occupational therapy at AdventHealth University (AHU) Hope Clinic who provided insight on the patient population,



feasibility of the program, and necessary resources. She believes that a CBT program in AdventHealth University Hope Clinic is feasible, but the success will depend on finding solutions to barriers that may be encountered during the process.

Charles Lammers, Ph.D. is a board-certified psychologist who specializes in pain management with CBT as an adjunct to a patient's current regimen. His knowledge on CBT and experience with its effects on the quality of life in patients with CNMP, provided insight into the barriers, resources needed, and feasibility of creating a program that offers alternatives to managing chronic non-malignant pain with CBT. He believes in the benefits of CBT and suggested group counseling as one of the therapies that will be applicable to our population.

Yvette Saliba, PhD, LMHC, NCC is a licensed mental health counselor and Assistant Professor in the Department of Health and Biomedical Studies at AdventHealth University. She is a proponent of CBT and will donate her time in supervising master level students of mental health counseling from UCF.

Bryce Hagedorn, PhD, LMHC, NCC, MAC, QCS is the professor and program coordinator at UCF's counselling program. He expressed interest in making AdventHealth University Hope Clinic a possible clinical site for several of his master program students who are learning how to operate group therapy.

### **Implementation**

Initially, we interviewed key players who provided knowledge regarding feasibility studies and steps to implementing a CBT program. Next, we identified the resources needed; staff, space, funds, and facilitators and barriers. Possibilities were explored on alternative collaborative opportunities with University of Central Florida (UCF) students who might be able to use the AdventHealth University Hope Clinic as a clinical rotation site for CBT therapy.

### **Facilitators and Barriers for Scholarly Project**

The main facilitator was Dr. Tia Hughes, former director of AdventHealth University Hope Clinic who was very receptive to our feasibility study and was willing to help in any way possible including provision of staff, space, and flyers. Occupational therapists at the AdventHealth University Hope Clinic are currently performing some forms of CBT such as relaxation techniques, coping skills, and anger management but not CBT for chronic pain management. Dr. Yvette Saliba, a licensed mental health counselor and Assistant Professor in the Department of Health and Biomedical Studies at AdventHealth University, is willing to facilitate collaboration with UCF master level students of mental health counseling. The students can be supervised while utilizing CBT and running groups.

Barriers that may be encountered include a lack of awareness of CBT, patient's willingness to participate, possible noncompliance due to a lack of transportation, a limited number of hours that staff can provide, scheduling, and needed approval from risk management. Dr. Hughes believes that a CBT program at the AdventHealth University Hope Clinic is possible if there is a way to properly screen for pain among patients, a way to bring awareness of CBT programs, pharmacological education among patients, and consistent scheduling of therapy sessions.

### **Results**

When completing the qualitative analysis, each author and the project chair identified themes and synthesized answers from respondents for every question included in the questionnaire. Data saturation was achieved in the second wave after interviewing eleven respondents. Three themes were consistent across responses which were knowledge gaps, AdventHealth University Hope Clinic resources, and facilitators and barriers.

**Knowledge Gaps Regarding CBT for CNMP**

While respondents were able to define CBT therapy, their experience with the use of CBT was varied and ranged from most individuals having no exposure, others having limited experience in the provision of CBT but only for disorders not related to CNMP, with a single individual having experience in the provision of treatment for specific subsets of individuals experiencing CNMP.

**Care Gaps for CNMP**

Most providers were able to identify general health resources which included the limited prescription of rescue/emergency medications for CNMP. There was a gap, however, in knowledge regarding CNMP focused resources. When asked about community resources available for uninsured or underserved patients with CNMP, the majority of respondents were either unsure or not aware of any. One respondent said, “That's a very interesting question because I don't know what resources really are available in our community that are free, especially in today's environment where we have such restrictions on drugs and everything else that is going on” (Personal Communication, March 20, 2020). A single, limited government funded CNMP resource was mentioned, but access was reported as strictly limited to those individuals who have met stringent criteria for inclusion.

Cognitive behavioral therapy as a resource for those with CNMP specifically was found to be rare at both the macro and micro levels. The respondent with the most experience with CBT for the treatment of CNMP cited only rare state and national resources which were private in nature. When these facilities were contacted by the authors, reticence to share information on current practices was met. In addition, phone calls or emails of inquiry were not returned.

With regards specifically to CBT programs offered in the community, the respondents were overwhelmingly unaware of any CBT resources for CNMP. One respondent said, “I don't know of any specific pain programs-like when somebody here wants to go to a major pain program where they are gonna (sic) be getting cognitive behavioral treatment along with physical therapy and occupational therapy and so on and so forth- they have to go up to the Mayo clinic up there has a program like that” (Personal Communication, June 19, 2019). Another respondent mentioned two to three psychiatrists in Central Florida who provide CBT but was unsure if they treat CNMP. A final respondent cited a single case within the AdventHealth University Hope Clinic that required interdisciplinary pain management in which an anesthesia provider was consulted but was unaware if CBT for CNMP was incorporated. Thus based on the investigations completed by the study's authors and interviews conducted, the actual gap was determined to be a lack of CNMP resources, not a gap in the knowledge of respondents regarding available resources.

### **AdventHealth Hope Clinic Resources**

From an institutional resource perspective, not all respondents were familiar with the AdventHealth University Hope Clinic, therefore, some spoke in generalities and stressed the importance of ensuring that adequate staff, an interested client base, money, equipment, space, time and marketing are in place for successful implementation. Those respondents who were familiar with the clinic focused on three resource categories that need to be addressed before a CBT program could be successful. These resource categories were (1) Staff : additional staff are needed to support or run a CBT program in the clinic, (2) Money: in the form of consistent funding from grants and donations, and (3) Legal assistance: to address liability coverage, contracts and sovereign immunity issues. While a consistent client base and space for client

interaction are traditionally needed for the development of a CBT program, respondents familiar with the AdventHealth University Hope Clinic stated that these resources are readily available.

### **Facilitators and Barriers for Implementation of CBT for CNMP**

Respondents identified facilitators and barriers, both current and needed, that may be encountered in the process of developing a CBT program for CNMP within a free occupational therapy clinic. Key players and multidisciplinary engagements were stressed.

AdventHealth University Hope Clinic possesses many current facilitators. These facilitators include: Established faculty who are experts in their field, the presence of doctoral programs which focus on addressing practice education and patient care gaps, a consistent client source with space available for multidisciplinary engagement, and a partnership with AdventHealth, one of the largest non-profit healthcare systems in the nation. A further facilitator is the alignment of the biopsychosocial model inherent in CBT for CNMP with the mission and vision of whole person care at AdventHealth hospital and AdventHealth University.

Needed facilitators ranged from obtaining national professional organization support to engagement of Hope Clinic clients who are interested in trying something new. An education program for faculty and Hope Clinic staff on the process of CBT would also need to be implemented. Respondents also stressed the importance of engaging community mental health professionals possibly in the form of a collaborative relationship with the University of Central Florida and mental health professionals in the greater Orlando area.

Multiple barriers were also identified which must be addressed for program success. The barriers included: Overall client health and participation limitations, the stigma of mental health issues, significant practitioner knowledge gaps, a need for mental health experts, workload for both staff and faculty, inconsistent transportation, legal and licensure issues, a need to transition

client records from paper to electronic storage, and the sustainability of the program once implemented (Appendix D).

### **Discussion and Implications**

Currently, there is a gap in care for individuals experiencing CNMP and there is nothing available at the state or local level particularly for individuals who are resource poor. It is best practice to provide care based on the biopsychosocial model which includes CBT. However, due to a lack of resources for this population, a feasibility study was performed to determine if the development of a CBT program for CNMP management is viable.

Based on the completed qualitative evaluation, AdventHealth University Hope Clinic clients are projected to benefit as a result of closure in care gaps, improvement of pain with subsequent reduction or elimination of opioid use, an improvement in functionality, as well as through the development of lifelong coping skills. The community would benefit through a university led program created to reduce or eliminate dependence on opioids and as an expansion of services in support of the medical and surgical management of individuals experiencing CNMP who are resource poor. The University and Clinic would benefit through expansion of mission aligned community engagement, development of collaborative relationships with other institutions, and possibly increased enrollment of students interested specifically in community engagement. Finally, students and faculty would benefit from community engagement as they participate in the provision of care.

The development of a CBT program for CNMP will necessitate collaboration with other institutions. Collaboration, however, will require time to establish relationships, frequent and transparent communication, the formation of institutional contracts and planning for the sharing

of costs incurred during program development. A CBT program would also require each entity to contribute equally and be respectful of client privacy.

Given the presence of significant facilitators and the viability of collaboration as a method for overcoming barriers, a CBT program is feasible within the AdventHealth University Hope Clinic. Viability will require, however, that identified barriers be addressed and facilitators pursued. To that end, we recommend the formation of a multidisciplinary committee address the identified barriers, obtain legal consultation, further evaluate and address financial and economic implications, create a GANTT chart, establish program objectives, and seek multiple viable avenues for patient education.

### **Recommendations**

#### **Formation of A Committee**

For the implementation of a CBT program, it is necessary to create a committee that consists of key players and experts whose personal mission aligns with AdventHealth University. Committee members should include a licensed psychologist or mental health counselor supported by an interdisciplinary team that contains occupational therapists (OTs), physical therapists (PTs), CRNAs, and other pain management experts to manage the CBT program. A mental health counselor who is certified in CBT will also be needed to supervise or conduct the program ideally with a terminal degree of MD or PhD. We also recommend consulting with a legal professional to confirm the minimum level of provider educational expertise necessary, all pertinent licensure and insurance requirements, and governmental policies that apply to the creation of a CBT program within a small faith-based clinic.

#### **Economic and Financial**

Given the lack of response from those individuals with expertise in development and management of CBT programs for CNMP it was not possible to clearly outline the exact expenses that would be incurred during program development as well as maintenance. Individuals who were interviewed did identify financial barriers as well as make recommendations for mitigation of these issues.

The financial barriers resulting from the need for adequate clinic staff could be partially overcome by the integration of Hope Clinic participation into course curriculums and the development of collaborative relationships. Faculty should integrate participation in the Hope Clinic within appropriate AHU program courses. Collaboration with other institutions with students engaged in mental health specialties at the master's or doctoral level who are in need of clinical experience and hours would also help decrease the burden of cost. Collaborative efforts would also contribute to the closure of practice, education, and patient care gaps. Therefore, we recommend seeking collaborative opportunities within the AdventHealth University, AdventHealth systems, and the greater Orlando community.

Other economic barriers such as credentialing, business and professional insurance, transportation, and marketing should be addressed by seeking financial assistance through grants or community donors. Grants could be sought through national organizations and pharmaceutical companies who support holistic care to assist with the financial costs and sustainability of the program. Traditionally, a grant writer is an additional issue for the development of an CBT program, however, that is a resource already in place within the Hope Clinic.

## **GANTT**

A GANTT chart detailing the stages of project development should be created to assist with the planning and scheduling of tasks to be completed (Mind Tools, 2021). GANTT charts



aid in the identification of needed resources, depiction of a project timeline, and sequence of events for project completion. They also manage the relationship between tasks and required time frame (Mind Tools, 2021). Therefore, we recommend the creation of a GANTT chart to identify methodology, the steps required for the development of a CBT program and all necessary cyclical assessments.

### **Program and Client Objectives**

In the creation of a CBT program within the AdventHealth University Hope Clinic program and client-centered objectives should be developed. Program-centered objectives should include:

1. Develop a program mission statement.
2. Construct evidence-based content for a CBT for CNMP program in collaboration with mental health and chronic pain experts.
3. Cultivate community relationships that are mutually beneficial and align clearly with the mission of all engaged institutions,
4. Pursue funding through grant applications and private donations.
5. Examine legal implications of governmental policies and licensure requirements.
6. Standardized documentation to meet HIPAA and AdventHealth policies to facilitate multidisciplinary communication and interventions.

Client-centered objectives should include:

1. Employ the Short Form-36 as a validated reliable tool for the identification and progress assessment of those clients who are the most likely to benefit from a CBT for CNMP program.
2. Reduce client pain

3. Improve quality of life and vocation
4. Reduce pain medication utilization.
5. Provide safer pain management through alternative treatments such as CBT for CNMP.
6. Address psychosocial gaps in client care
7. Provide client support in the form of written plans and videos for home management.
8. Engage client family members in the education process.

With regards to measuring the effectiveness of CBT, respondents recommended the use of validated tools to assess pain and quality of life, specifically the SF-36. According to the literature the SF-36 is the most comprehensive form that will incorporate both quality of life and pain (Dysvik, Kvaloy, & Furnes, 2014; Elliott, Renier, & Palcher, 2003). The SF-36 assesses a total of eight domains which consist of physical, emotional, and social limitations, pain, mental health, perceptions on health, and vitality (National Multiple Sclerosis Society, 2020). Currently, the Hope Clinic staff uses the SF-36 for their clients and are familiar with its entirety. Therefore, we recommended that this specific form be employed.

### **Education for Clients and Providers**

At the conclusion of interviews, it was determined that most providers have limited to no exposure to CBT as a treatment for CNMP. This significant health care provider knowledge gap should be addressed through the provision of educational opportunities for clinic staff, university faculty and community health care providers. Education should focus on what CBT is and how it can be used as an effective multidisciplinary evidence-based approach to CNMP management as recommended by the IOM and CDC (Dowell, Haegerich, Chou, 2016; IOM, 2011). Education through written materials and the employment of online learning platforms such as Echelon

could be utilized by both clients and staff. We also recommend seeking online alternative methods for education and continuity of care due to the current COVID-19 pandemic.

Both individual and group therapy were recommended by respondents as a good medium of instruction to employ in a CBT program for clients with CNMP. We therefore propose the use of digital learning and meeting platforms as an alternative method of instruction that could incorporate both a group and individual experience for clients during the pandemic. In the development of the CBT program, we recommend the use of Bloom's Taxonomy as a guide for the development of online learning module outcomes and objectives (Armstrong, 2021). This model has been used for decades by instructors to design teaching methods that classify the learning processes used to evaluate outcomes related to the objectives (Armstrong, 2021).

In addition, we recommend The Community of Inquiry Framework be employed for both clients and healthcare education as an evidence-based method for the creation of an online learning space which can be utilized to provide not just the teaching and cognitive presence necessary for an online learning environment but a social presence as well (Huang, Hurt, Richardson, Swan, & Caskurlu, 2020). Staff modules should be developed through interdisciplinary consultation with a psychologist, pain management specialist, and mental health counselor. The client modules can be developed via interdisciplinary consultation with a psychologist, pain management specialist, occupational therapist, physical therapist, and mental health counselor. Upon creation of the module, the Hope Clinic can provide a password to clients to access online learning. From an institutional perspective creation of an online learning module would help offset the cost of transportation issues while still providing a functional environment.

Unfortunately, we were unable to assess the limitations regarding computers and internet access of clients should online learning be available.

### **Limitations**

The primary limitation of this scholarly project was the use of a student developed, face-validated questionnaire. In addition, while face to face interviews were initially intended, due to the COVID-19 global pandemic some first and second wave interviews were done via virtual meetings thus changing methodology. A final limitation resulted from reservations on the part of CBT experts to share information regarding the development and implementation of a CBT for CNMP program. The authors sought to gain insight on current practices and costs of care provision from private clinics who currently conduct CBT but were unable to obtain adequate responses. One psychologist who is advertised as conducting CBT referred the authors to two CBT institutions in New York. These two institutions did not respond to emails or phone calls made. Educational institutions for CBT and professional organizations for pain management also never returned phone calls after multiple attempts.

### **Conclusion**

In conclusion, CBT has shown to be an evidenced based alternative to treating CNMP when used as part of a multidisciplinary approach. The development of a CBT program within the Hope Clinic is deemed feasible based on the information gathered through interviews of key players, current available resources, identified facilitators, assessment of need, and projected benefits of the client, university, and community. Although a significant and varying number of barriers were identified, they can be overcome by utilizing current resources and seeking out alternative facilitators to offset the issues that may be encountered along the way.

### **Timeline**

In fall of 2019 an application to IRB/SRC was submitted and project approval received on February 7, 2020. In summer of 2020 active engagement in the development of a feasibility study commenced with first wave interviews, followed by second wave interviews, and ended with the qualitative analysis of responses from the respondents. Then, a written feasibility study report with evidence-based recommendations from the deliverables of the planning and build-up phases was created. In spring of 2021 findings were disseminated to AHU faculty, key players, and AdventHealth University Hope Clinic administrators through an oral power point presentation, poster, and written feasibility study with recommendations. The dissemination was scheduled according to the key players availability and took place in spring of 2021 at AHU.

### **Dissemination**

The findings and recommendations of our scholarly project were disseminated in spring of 2021 at AHU and scheduled at the convenience of key players. In addition, as part of the Doctor of Nurse Anesthesia Practice requirements, this scholarly project was disseminated to all students and faculty at AHU via a Canvas course tile created for that purpose.

### **Budget**

Feasibility studies can incur cost; however, this was a qualitative study with most interviews performed via zoom and electronic platform, so no monetary costs were incurred. However, there was a significant time commitment needed.

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Appendix A

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Purpose	Variables	Setting/Subjects	Measurement and Instruments	Results	Evidence Quality
<p><b>Study one:</b> Evaluate the efficacy, acceptability and safety of cognitive behavioral therapies (CBTs) in Fibromyalgia Syndrome (FMS)</p> <p><b>Study two:</b> To examine different responses to CBT that will guide clinical decisions for chronic pain treatment</p>	<p><b>Study one:</b> Negative mood, acceptability, pain quality of life, coping with pain</p> <p><b>Study two:</b> Primary outcome: Outcome variables; Pain, intensity fatigue, self efficacy, QOL, catastrophizing, pain meds</p> <p>Secondary outcome: Moderators of pain; pain coping style, patient expectations, disease severity, age, education</p>	<p><b>Study one:</b> RCT- 29 Subjects- 2509 Exclusion- patients with anxiety or depression</p> <p><b>Study two:</b> CNMP &gt;6 months, hip and knee OA in community doctor's office N= 256</p>	<p><b>Study one:</b> PRISMA-statement, Recommendations of Cochrane Collaboration, Smythe criteria- Adults (1 study), Yunus criteria- children, American College of Rheumatology 1990 classification criteria- Adults</p> <p><b>Study two:</b> Multidimensional Pain Inventory, Brief Pain Inventory, Coping Strategies Questionnaire, Quality of Life Scale, End of Day Symptom Diaries</p>	<p><b>Study one:</b> CBT's did not differ in efficacy- superiority for coping with pain and tolerability from recommended drug therapy.</p> <p><b>Study two:</b> Pain Coping Skills Training (a form of CBT) has significant improvements in pain related variables</p>	<p><b>Methodological flaws:</b> <b>Study one:</b> Incomplete report, underestimated treatment quality, patients/ personnel were not blinded, ethnicity not reported</p> <p><b>Imprecision</b> <b>Study one:</b> CI 95%</p>
<p><b>Design</b></p>				<p><b>Implications</b></p>	
<p><b>Study one:</b> Cross-over design Parallel design</p> <p><b>Study two:</b> Multisite RCT</p>				<p><b>Study one:</b> Acceptance/commitment therapy are superior</p> <p><b>Study two:</b> Effect of CBT on outcome variables are influenced by 5 moderators</p>	<p><b>Publication bias</b> <b>Study one:</b> Authors involved in FMS committee, Pain management MD and psychotherapist.</p>

Bernardy, K., Klose, P., Welsch, P., & Häuser, W. (2018). Efficacy, acceptability and safety of cognitive behavioural therapies in fibromyalgia syndrome - A systematic review and meta-analysis of randomized controlled trials. *European Journal of Pain*, 22(2), 242-260. <http://dx.doi.org/10.1002/ejp.1121>

Broderick, J. E., Keefe, F. J., Schneider, S., Junghaenel, D. U., Bruckenthal, P., Schwartz, J. E., Gould, E. (2016). Cognitive behavioral therapy for chronic pain is effective, but for whom? *Pain*, 157(9), 2115-2123. doi:10.1097/j.pain.0000000000000626

Purpose	Variables	Setting/Subjects	Measurement and Instruments	Results	Evidence Quality
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<p><b>Design</b></p>				<p><b>Implications</b></p>	
<p><b>Study one:</b> Cross-over design Parallel design</p> <p><b>Study two:</b> Multisite RCT</p>				<p><b>Study one:</b> Acceptance/commitment therapy are superior</p> <p><b>Study two:</b> Effect of CBT on outcome variables are influenced by 5 moderators</p>	

Olason M. (2004). Outcome of an interdisciplinary pain management program in a rehabilitation clinic. *Work*, 22(1), 9–15. Retrieved from <http://resource.adu.edu/login?url=https://search.ebscohost.com/login.aspx?direct=true&AuthType=ip&db=cin20&AN=106753039&site=ehost-live>  
 Majeed, M. H., & Sudak, D. M. (2017). Cognitive behavioral therapy for chronic pain-one therapeutic approach for the opioid epidemic. *Journal of Psychiatric Practice*, 23(6), 409-414. doi:10.1097/PRA.0000000000000262

Purpose	Variables	Setting/Subjects	Measurement and Instruments	Results	Evidence Quality
<p><b>Study one:</b> Increasing the patients’ functioning and eliminating analgesic drugs through an interdisciplinary rehabilitation program</p> <p><b>Study two:</b> Review existing article about use of opioids for chronic pain and evidence for use of alternative treatment, particularly CBT</p>	<p><b>Study one:</b> Low back pain, post traumatic pain, anxiety, and depression</p> <p><b>Study two:</b> Primary outcome: Opioids for chronic pain Secondary outcome: CBT for chronic pain</p>	<p><b>Study one:</b> 158 patients- 3-year period/ 7 weeks prog Reykjalundar Rehab</p> <p><b>Study two:</b> Patients with chronic pain of varying etiologies</p>	<p><b>Study one:</b> Numeric rating scale (NRS), self- reporting questionnaire, Arner and Meyerson (pain)</p> <p><b>Study two:</b> One study used neuroimaging changes in the brain before and after CBT. Not mentioned but implied that pain scale was used in all studies.</p>	<p><b>Study one:</b> P&gt; 0.0001 at discharge P&gt; 0.001 at follow up 18.4% worked 48.1% worked after dis. 59.2 work at follow up</p> <p><b>Study two:</b> CBT has the potential to relieve pain and improve QOL.</p>	<p><b>Methodological flaws:</b> <b>Study one:</b> Research team maintained assessor blinding, but patients sometimes reveal their experimental condition</p> <p><b>Study two:</b> Total number of studies, tools used, negative outcomes not mentioned</p>
<b>Design</b>				<b>Implications</b>	
<p><b>Study two:</b> Systematic review of studies evaluating effect of CBT on chronic pain through an electronic research</p>				<p><b>Study one:</b> Decrease opioid use and increase functionality</p> <p><b>Study two:</b> CBT can be considered as an adjunct to treatment of chronic pain, yet it’s underutilized due to lack of familiarity, slow onset of response and financial issues</p>	

Shapner, M., Kelly, C., Lieberman, G., Perelman, H., Davis, M., Keefe, F. J., & Naylor, M. R. (2014). Unlearning chronic pain: A randomized controlled trial to investigate changes in intrinsic brain connectivity following cognitive behavioral therapy. *NeuroImage: Clinical*, 5, 365-376. doi:10.1016/j.nicl.2014.07.008

Nascimento, S. S., Oliveira, L. R., & DeSantana, J. M. (2018). Correlations between brain changes and pain management after cognitive and meditative therapies: A systematic review of neuroimaging studies. *Complementary Therapies in Medicine*, 39, 137- 145. <http://dx.doi.org/10.1016/j.ctim.2018.06.006>

Purpose	Variables	Setting/Subjects	Measurement and Instruments	Results	Evidence Quality
<p><b>Study one:</b> Understand the correlation of CBT related functional neuroplasticity and effects on chronic pain</p> <p><b>Study two:</b> The evidence on brain activity changes after CMT, which include CBT, mindfulness and/or meditation, for pain management as well as to evaluate clinical pain outcomes.</p>	<p><b>Study one:</b> Primary outcome: Brain changes in chronic pain Secondary outcome: CBT effects in the brain and chronic pain</p> <p><b>Study two:</b> Brain activity changes, self-management, pain intensity, pain coping, quality of life, anxiety and depression</p>	<p><b>Study one:</b> Patients with chronic musculoskeletal pain= 38 Age=18-60 19= with CBT 19= educational materials</p> <p><b>Study two:</b> N=9, 280 adults (18-59 years old)139 chronic pain, 148 healthy subjects</p>	<p><b>Study one:</b> MRI scanning, Treatment Outcomes in Pain Survey, The Chronic Pain Self Efficacy Scale, Pain Catastrophizing Scale, Beck Depression Inventory</p> <p><b>Study two:</b> PRISMA-statement and Cochrane Handbook for Systematic Reviews and Interventions.</p>	<p><b>Study one:</b> Patients who show significant changes in self efficacy and pain symptoms after CBT had a significant correlation with brain changes</p> <p><b>Study two:</b> CMT reduced the affective experience of pain, while reductions of pain intensity rating were less consistent</p>	<p><b>Methodological flaws:</b> <b>Study two:</b> The independent authors weren't blinded to the study or authors of RCTs.</p> <p><b>Publication bias:</b> <b>Study two:</b> 8:9 RCTs were unclear on blinding and source of funding bias</p> <p><b>Indirectness:</b> <b>Study one:</b> 2 different types of pain catastrophizing scale were used by different patients.</p>
<b>Design</b>				<b>Implications</b>	
<p><b>Study one:</b> Systematic review of studies evaluating effect of CBT on chronic pain through an electronic research</p> <p><b>Study two:</b> RCT</p>				<p><b>Study one:</b> Modifications in the brain after CBT and effects on chronic pain shows some correlation and provides basis for further research</p> <p><b>Study two:</b> Effect of expertise (newly trained vs long term practitioners)</p>	

Knoerl, R., Lavoie Smith, E. M., & Weisberg, J. (2016). Chronic pain and cognitive behavioral therapy: An integrative review. *West J Nurs Res*, 38(5), 596-628. doi:10.1177/0193945915615869  
 Naylor, M. R., Keefe, F. J., Brigid, B., et al. (2008). Therapeutic Interactive Voice Response for chronic pain reduction and relapse prevention. *Pain*. 134:335–45

Purpose	Variables	Setting/Subjects	Measurement and Instruments	Results	Evidence Quality
<p><b>Study one:</b> Examine the efficacy of CBT for chronic pain based on dose delivery and IMMPACT related outcomes</p> <p><b>Study two:</b> In patients with chronic pain who have completed a pain coping skills programme, does Therapeutic Interactive Voice Response (TIVR) enhance maintenance of treatment gains.</p>	<p><b>Study one:</b> Primary outcome: Dose, delivery of CBT</p> <p>Secondary outcome: IMMPACT related outcomes of CBT (pain intensity, QOL, physical function, depression, anxiety</p>	<p><b>Study one:</b> Total of 35 RCT studies of patients from groups of 20-442 who are in CBT program for chronic non malignant pain, ages 39-74</p> <p><b>Study two:</b> University hospital in Vermont, USA, 55 patients &gt;= 18 years of age (mean age 46 y, 84% women) who had chronic musculoskeletal pain for &gt;= 6 months with severity scores &gt;= 4 out of 10 and had completed 11 weeks of group cognitive-behavioural therapy (CBT) for pain management</p>	<p><b>Study one:</b> CINAHL, EMBASE, PubMed, PsycInfo, SCOPUS database were searched for RCT published between 2009-2015 testing CBT intervention in adults with chronic pain</p> <p><b>Study two:</b> Randomized controlled trial and therapeutic Interactive Voice Response (TIVR)</p>	<p><b>Study one:</b> CBT was effective for pain relief intensity in 43% of trials and treatment for many pain related variables (anxiety, depression, physical function, QOL)</p> <p><b>Study two:</b> Four month TIVA initiated after an 11-week cognitive behavioral educational programme, was associated with decreased pain ratings, improved coping, and reduced risk of relapse into pain behavior</p>	<p><b>Methodological flaws:</b> <b>Study one:</b> Risk of bias as only the primary author reviewed the studies</p> <p><b>Study two:</b> Unblinded</p>
<p><b>Design</b></p> <p><b>Study One</b> Design was not stated but appears to be longitudinal with assessments performed at 4 separate time points within one year.</p> <p><b>Study Two</b> Design not stated, but appeared to be a randomized control trial</p>	<p><b>Study two:</b> Pain, functioning, and pain coping</p>			<p><b>Implications</b></p> <p><b>Study one:</b> Different doses/types of CBT delivered have varying effects on pain related outcomes</p> <p><b>Study two:</b> Adjunct therapy can help with chronic pain</p>	

*Appendix B***Interview Questions Asked of Key Stakeholders**

## Interview Questionnaire

1. What are the current resources available in the community for uninsured or underinsured patients with chronic non-malignant pain? (Planning Phase)
2. Do you have experience with cognitive behavioral therapy for the treatment of chronic non-malignant pain? (Planning Phase)
3. What is cognitive behavioral therapy and how is it used to treat chronic non-malignant pain? (Planning Phase)
4. What current cognitive behavioral therapy programs are offered in the community? (Planning Phase)
5. What would be the benefits of developing a cognitive behavioral therapy program for AdventHealth University and its Hope Clinic Clients? (Planning Phase)
6. What do you think are the major steps or tasks necessary to develop a cognitive behavioral therapy program? (Planning Phase)
7. What objectives for a cognitive behavioral therapy program would be advisable? (Planning Phase)
8. What would be the best medium of instruction to employ in a cognitive behavioral therapy program for patients regarding chronic non-malignant pain management in a free occupational therapy clinic? (Planning Phase)
9. What are some facilitators that may be encountered in the process of developing a cognitive behavioral therapy program for chronic non-malignant pain within a free occupational therapy clinic? (Planning Phase)
10. What are some barriers that may be encountered in the process of developing a cognitive behavioral therapy program for chronic non-malignant pain within a free occupational therapy clinic? (Planning Phase)
11. What are the resources necessary for the development of a cognitive behavioral therapy program? (staff/money/equipment/space/time/marketing) (Build-Up Phase)
12. What are the governmental policies or licensures needed to implement a cognitive behavioral therapy program within a clinic? (Build-Up Phase)
13. How would you measure the effectiveness of a cognitive behavioral therapy program? (Build-Up Phase)
14. Who must run a cognitive behavioral therapy program from a licensure/qualification's perspective? (Build-Up Phase)
15. Who can determine its effectiveness? (Build-Up Phase)
16. What do you think about collaborating with another institution to increase the number of staff that can perform cognitive behavioral therapy? (Build-Up Phase)
17. What would be the needed resources, facilitators, barriers, and cost associated with collaboration? (Planning Phase)
18. Are you familiar with a feasibility study? (Planning Phase)
  - a. Follow up questions if interviewee says yes:
  - b. In what context have you seen a feasibility study employed? (Planning Phase)
  - c. How did it assist in program planning and implementation? (Planning Phase)

19. What do you feel should be included in a feasibility study regarding the development of a cognitive behavioral therapy program within a free occupational therapy clinic? (Build Up Phase)
20. Who, in your opinion, would be important team members or key players for the development and successful implementation of a cognitive behavioral therapy program within the AdventHealth Hope Clinic? (Build-Up Phase)
21. Is there anything else you would like to add that may be helpful to us in this project? (Build-Up & Planning Phases)



Appendix C

GANTT Chart

	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Nov-20	Dec-20	Jan-21	Apr-21
<b>Planning</b>	Identification of key players			1st wave of interviews		2nd Wave of interviews				
<b>Build Up</b>				Synthesis of interview responses Identification of team member Delineation of cost and resources Identification of legal and licensure implications						
<b>Implementation</b>						Creation of written feasibility study report and creation of poster for presentation				
<b>Close Out</b>								Post feasibility study report and recommendation presentation to key players		

*Appendix D*

**When asked about facilitators and barriers that may be encountered in the process in developing a CBT program for CNMP within a free occupational therapy clinic, respondents focused on current and needed facilitators and identified a significant and varied number of barriers.**

Facilitators	Barriers
Sovereign immunity	Licensure, credentialing, and liability insurance
There is available space for program implementation	Workload, scheduling, and balancing time (# of people and clients to prevent overcrowding)
Collaborative opportunities within the university, AdventHealth systems and the greater Orlando area.	Inconsistent key players commitment
Faculty open to interprofessional collaboration	Participation of appropriately credentialed providers with CNMP management and CBT experience who are a good mission fit
Clinicians currently in the hope clinic who support CBT for CNMP	Medical prescriptions as a primary method of treating CNMP
Consistent client load that would support the inclusion of CBT for CNMP in the Hope Clinic	Lack of knowledge regarding on CBT for CNMP
Clients are committed to self-help and trying something new	Development of a clear definition of CNMP for Hope Clinic
Obtain support from National Association for Mental Illness, the American Medical Association as well as pharmaceutical companies who support holistic care. (important for financial resources)	Need for financial assistance/grants for staff, transportation, and resources
	Referral source physicians
	Travel for faculty and students to clinic
	Transportation, social (limited # of care givers), and economic challenges that may impact consistent attendance
	Medical challenges, the stigma on mental health issues, resistance to any treatments that are not a quick fix, and cultural and language differences that may require different materials

*Appendix E*

**AdventHealth University (AHU)  
Consent Document to  
Participate in a Human Research Study**

**Study Title:** Chronic Non-Malignant Pain and Feasibility of Cognitive Behavioral Therapy  
Within the Hope Clinic

**Principal Investigator & Contact Information**

Sarah Snell, DNP, CRNA, APRN

[sarah.snell@ahu.edu](mailto:sarah.snell@ahu.edu)

**Co-Investigators & Contact Information**

Jennifer Nieves BSN, RN

Liberty Pagayon BSN, RN

**Introduction of the Study**

We are Jennifer Nieves, SRNA and Liberty Pagayon, SRNA, and we are asking you to participate in this research study entitled “Chronic Non-Malignant Pain and Non-Pharmacological Management”. You are invited to take part in this research study because we feel that your experiences and insights as an expert in your field can contribute to our understanding and knowledge. As part of this research we are conducting interviews to learn more about the feasibility for the development of a Cognitive Behavioral Therapy program for chronic non-malignant pain management at the AdventHealth Hope Clinic in Orlando, Florida. Your participation in this study is completely voluntary. You are not required to participate. You may take as much time as you want to decide whether to participate. It is important that you understand your rights as a scholarly project participant and what will be expected of you during this project. We will explain this document to you, but please ask as many questions as you wish during the consent process.

**Purpose of This Scholarly Project**

The purpose of this research study is to determine the feasibility for the development of a cognitive behavioral therapy program for chronic non-malignant pain management in the AdventHealth Hope Clinic and identify facilitators and barriers to the feasibility of a cognitive behavioral therapy program for chronic non-malignant pain management in the AdventHealth Hope Clinic.

**Procedures**

You will be asked to participate in this research study in the following ways. Your participation will take approximately 60 minutes to complete in a face to face or telephone interview that will be recorded for future reference and asked questions about your knowledge and understanding related to a feasibility study, cognitive behavioral therapy, pain management, and business aspects of developing a cognitive behavioral program. The information provided through the interview and recording process will be used as a reference throughout the study and may be included as part of an article submitted to a peer reviewed journal. The interview recordings will be stored in a password protected SharePoint file that will be automatically deleted in five years.

### **Permission to Use Information from Key Player Interview Obtained for DNAP 791**

If you were interviewed as part of our DNAP 791 Key Player Interview course requirement, we would like to potentially decrease your interview time requirements and provide an opportunity to provide further information for this research study. To achieve this, we would like to use the previous information you provided as part of these interviews.

Please select one:

\_\_\_\_\_ I do consent to the use of my responses from the DNAP 791 Key Player interview conducted in summer 2019 as a reference for this research project and for potential publication.

\_\_\_\_\_ I do not consent to the use of my responses from the DNAP 791 Key Player interview conducted in summer 2019 as a reference for this research project and for potential publication.

### **Possible Risks and Discomforts Associates with the Scholarly Project**

The risks associated with participation in this study are minimum. You are being asked to share personal information with the researcher, and you may feel uncomfortable discussing the topics. In addition, although the risks of a breach of confidentiality or privacy are low, we cannot guarantee that your privacy or confidentiality will not be breached.

### **Potential Benefits**

We cannot and do not guarantee or promise that you will receive any benefits from participation in this study. However, you may benefit in the following ways. You will be able to help doctoral students complete their required scholarly project, given acknowledgment for your contribution to our project, possibility of changing the future of healthcare for the underserved and uninsured persons of the community by helping them gain resources that will aid in improved treatment and quality of care. In addition, there may be benefits to other healthcare professionals (mental health counselor's, occupational therapists and students, nursing students) who are looking for opportunities to gain clinical experience or credit for community service. Lastly, if deemed feasible organizations or future cohorts can build upon this scholarly project

and make the feasibility study a reality. We will disseminate the finding through a written feasibility study, poster, and oral presentation to the AHU faculty, key players, and AdventHealth Hope Clinic administrators and possibly through publication in a peer reviewed journal.

## **Confidentiality**

The research team will work to protect your confidential information. The information that you share will be kept private and will be stored in a password protected SharePoint file that will be automatically deleted in five years. We will take steps to protect your privacy and confidential information, however we are unable to guarantee or promise that your privacy will not be breached. Governmental agencies and the IRB may request access to study related data. We will work to ensure that your privacy is being protected.

## **Sharing the Results**

The knowledge that we obtain from your participation will be shared in the following ways; referencing the information obtained through interviews and presenting to the research committee at AdventHealth University, IRB, AdventHealth Hope Clinic administrators, and possible publication. No information you shared with us will be presented with your name or any identifying factors. All information presented will be de-identified without any links to you and will be presented as group data.

## **Right to Refuse or Withdrawal from the Study**

Your participation in this study is voluntary. You may choose not to participate. The decision to participate or not participate in this research study is completely up to you. If you choose not to participate, your refusal to participate in this research study will involve no penalty or loss of benefits to you. If you choose to participate, you can change your mind later and withdraw your consent and discontinue participation from this study at any time. If you chose to withdraw inform the PI of your wishes.

## **Compensation**

There will be no incentives or compensation for participants in this study.

## **Contact Information**

There is no conflict of interest, financial gain or other inducements offered to any of the researchers in this project.

If you have questions, concerns, or complaints regarding this study you may contact the Principal Investigator Dr. Sarah Snell at 407-303-9331. You may also email her at sarah.snell@ahu.edu. You may also contact AHU research office at (407) 609-1388 or AHU.Research.Office@ahu.edu or the IRB Office at (407) 303-5619.

## **Other Information**

We thank you for your participation in this research study. The information that we gathered during this research will not be used or distributed to any other researcher for any other research purposes not clearly outlined in this consent form.

**This research has been reviewed and approved by AdventHealth University Institutional Review Board, which is tasked to protect research participants from harm. If you want to learn more about the Institutional Review Board and its role in protecting research participants feel free to contact AdventHealth University IRB at (407) 303-5619.**

### **Participant's Understanding**

- I have been invited to participate in a research project about to determine the feasibility for the development of a cognitive behavioral therapy program for chronic non-malignant pain management in the AdventHealth Hope Clinic.
- I understand that my participation is voluntary.
- I understand that all data collected will be limited to the use disclosed above.
- I understand that I will not be identified by name in any presentation or publication.
- I am aware that all my information will be kept confidential and secured by the research team.
- I understand that I may withdraw from this research project at any time.

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**Printed Name of Participant or Representative (required)**

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**Signature of Participant or Representative (required)**

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**Date Day / Month/ Year**

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**Name of Person Obtaining Consent (required)**

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**Signature of Person Obtaining Consent (required)**

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**Date Day / Month/ Year**