

Web-based Pain Self-Management: Nurse-Guided

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Protocol

SPECIFIC AIMS:

The primary objective of this application is to test the feasibility of a care model where clinic nurses play a vital role in promoting the adoption of web-based CBT pain program in the ambulatory setting. We will accomplish this objective through successful completion of the following **Specific Aims**:

1. To evaluate the adoption of a clinic process that introduces web-based CBT to patients and providers in the clinic
2. To determine engagement of patients in the use of web-based CBT by comparing 2 treatment arms:
 - a. Six telephone contacts over an 8-week period by a trained clinic nurse in motivational interviewing (MI)
 - b. Six computer generated email reminders (control arm) over an 8-week period
3. To assess feasibility of clinic nurses to provide telephone support, using MI technique, to increase patient engagement on the use of web-based CBT program

SIGNIFICANCE:

Pain is the most common symptom reported in both the general population and in primary care¹. Pain complaints account for more than 40% of all symptom-related outpatient visits and over 100 million ambulatory encounters in the U.S. alone each year². Pain costs the United States (US) over \$550 billion each year in health care and lost productivity³. Persistent pain may lead to excessive surgery or other expensive or invasive procedures⁴ and is among the most common reasons for temporary and permanent work disability⁵.

Musculoskeletal pain is consistently the most common, disabling, and costly of all pain complaints^{1,6}. Two-thirds of pain-related outpatient visits are due to musculoskeletal pain, accounting for nearly 70 million outpatient visits in the U.S. each year². The functional and economic impact of musculoskeletal pain on both the working and the retired population is enormous⁷. Back pain and joint pain alone result in an estimated 200 million lost work days per year⁸. Among patients with osteoarthritis, rheumatoid arthritis and low back pain, pain is one of the most important determinants of physical disability⁹⁻¹¹. In addition to the physical health consequences, chronic musculoskeletal pain (CMP) can have a profound negative impact on an individual's emotional and social well-being¹²⁻¹⁵.

Despite the enormous individual and societal burden of CMP, pain management remains suboptimal. Pharmacological treatments often provide minimal pain relief¹⁶, and opioids for chronic musculoskeletal pain are fraught with problems. The evidence for a number of non-pharmacological treatments is limited, except for those using cognitive behavioral therapy (CBT) for chronic pain¹⁷.

Patients with chronic pain often develop maladaptive thought patterns (i.e., catastrophizing) and behaviors (i.e., kinesiophobia, or fear of movement) that contribute to physical and emotional suffering. The goal of CBT is to aid the patient in reconceptualizing his or her personal view of pain and role in the process of healing to promote being proactive rather than passive. There is substantial evidence for face-to-face delivery of CBT in low back pain, neck pain, temporomandibular joint pain, knee osteoarthritis, and fibromyalgia¹⁷.

Despite the proven efficacy of CBT¹⁸, access to care is one major limitation. Barriers to accessing face-to-face programs are numerous and include cost, stigma, and availability of psychologists that are trained in pain management. Thus, use of CBT in primary care (and even subspecialty care) where most patients with CMP are seen is almost unheard of. Effective, accessible and scalable psychoeducational treatments are needed to manage CMP in real world clinic settings¹⁹.

Internet-delivered CBT is one innovative approach to increase access to pain management programs. Internet-delivered programs use the same principles, content, and components as face-to-face programs but can be provided with varying levels of clinician support ranging from regular clinician contact through email or telephone to no clinician support at all. Systematic reviews have found *small but clinically significant* improvements in several important domains including disability (effect size= 0.39) and pain severity (effect size= 0.33)^{20,21}. However, as with face-to-face programs, clinical improvements have **not** been consistently observed in all studies and the magnitude of improvements has varied considerably across studies.

There are two possible explanations for the inconsistent outcomes of internet-delivered CBT for pain: (1) poor participant engagement and (2) absence of regular clinical support in most published studies^{20,21}. In support of these two explanations, an Australian study that examined an internet-delivered CBT program involving regular clinical support by a clinical psychologist (i.e., average 81 minutes per participant) found *moderate-to large* improvements in various domains including disability²². Moreover, while many internet-delivered programs reported high **non**-completion, this same Australian study reported a high completion rate ~ suggesting that participants were well engaged in the program²². Based on these findings, it appears that some level of clinical support is required to increase participant adherence (or engagement) in order to enhance clinical outcomes.

With our proposed line of research, we hope to address several important unanswered questions: (1) What is the amount (or extent) of clinical support needed to yield the best outcome? (2) Could a health care professional without formal degree in psychology provide the clinical support (or guidance)? and (3) Is adherence-focused guidance enough to achieve acceptable treatment outcomes? Adherence-focused guidance entails adherence monitoring, including reminders by email or telephone, to foster treatment completion. On the other hand, content-focused guidance includes provision of personalized feedback for completed treatment modules. In a pooled analysis of 3 RCTs of internet-based stress management for employees with high level of perceived stress, adherence-focused guidance was equivalent to content-focused guidance in terms of completion of the required learning modules²³. Importantly, compared to content-focused guidance, adherence-focused guidance only required a quarter of the coaching resources, which has cost benefit implication.

Our proposed line of research is **significant** because it will potentially make CBT, a significantly underutilized modality in pain management, more affordable and accessible. Without overburdening the already “stressed” US Health Care System, nurse-guided web-based CBT may reduce the enormous burden of chronic pain at the individual and societal levels.

INVESTIGATORS:

Dennis C. Ang, MD will be responsible for the overall conduct of the project that includes: collaborate with the Australian team that operates the web based CBT; work with Wake One builder to build the new clinic process in Wake One; interact with Dr. Sebastian Kaplan to ensure adequate training of the triage nurses in time for the start of recruitment, and with Dr. Claudia Campos to enhance adoption of the proposed new clinic process.

Dr. Claudia Campos, MD is the main supervisor of the OPD at Janeway 7th floor. She will work with Dr. Ang to address issues affect the implementation of the new clinic process by the triage nurses, residents, CMA/LPN in the clinic.

Dr. Sebastian Kaplan is an Associate Professor in the Department of Psychiatry and Behavioral Medicine. He will supervise the initial and ongoing training of the triage nurses. He will also assess treatment fidelity to the principles of motivational interviewing (MI).

Dr. Brian Bush is a first year rheumatology fellow who will be in charge of implementing the proposed new clinic process in the rheumatology outpatient clinic. He will participate in collecting measures related to health care use and completion of the research dataset.

Drs. Christina Rinaldi and David Ansley are internal medicine (IM) residents in charge of implementing the proposed clinic process at OPD. They will work with their co-residents, nurses and physician supervisors to increase buy-in of the proposed project. They will both participate in collecting measures related to health care use.

INNOVATION:

Our study is the first study on web-based CBT that is specifically designed for implementation and adoption in the ambulatory medical setting. As opposed to mental health professional, utilizing clinic nurses to provide support and guidance is relatively new in internet-based psychoeducational interventions for chronic pain.

APPROACH:

Study Design: Hybrid effectiveness-implementation

- I. **Effectiveness.** Sixty subjects (N=60) with CMP will be randomized into one of two treatment arms: (1) free 4-month subscription to web-based CBT and six telephone contacts over an 8-week period by a trained clinic nurse (n=30), and (2) free 4-month subscription to web-based CBT and six computer-generated email reminders (n=30). The purpose of (trained) nurse contact is to support and enhance participants’ motivation to engage in the web-based CBT program, rather than providing psychological treatment. The active intervention phase is for 8 weeks

and the follow-up phase is for another 8 weeks. During the follow-up phase, all participants will maintain access to the web-based CBT program, but will not receive any communication or support from the nurse. Outcome assessments will be conducted at baseline, week 8 (at the completion of the active intervention phase), week 16 (primary endpoint).

II. **Implementation.** We propose a *new clinic process* to be implemented in the primary care clinics, and rheumatology practices throughout the Wake Forest Baptist Health System. At the vital sign station, certified medical assistant (CMA) or licensed practice nurse (LPN) will ask 1-3 questions:

1. Do you have a computer at home with a reliable internet access?
 - a. Yes (Proceed to next question)
 - b. No (No further question)
2. Over the last 6 months, do you have DAILY or almost daily PAIN that interfered with your general activity or enjoyment of life?
 - a. Yes (Proceed to next question)
 - b. No (No further question)
3. Have you ever wondered if there is something that you could do on your own to better manage your pain?
 - a. Yes (Proceed)
 - b. No (End)

An affirmative response to the 3rd question would prompt the provider (via a pop-up message) to request an educational video on pain self-management by entering an order in Wake One. After the order is made, the provider will receive a message, “*Your patient has been sent a video on Pain Self-Management via Emmi. Please let your patient know to expect an e-mail, phone call or portal message with more information*”.

The order is received by EMMI, a Wake-approved vendor and an industry leader in patient education. EMMI will send the video to the patient and makes follow-up contact if the video has not been viewed within 48 hours of delivery. The educational video, which provides an overview of the web-based CBT program, also contains the contact info of Judy Hooker, the research coordinator.

Seventy-two hours after the clinic visit, if a patient has not made a phone call to the research coordinator, Ms. Hooker will contact the patient to elicit interest to participate in the study. We are adding the option to review the informed consent by email or through RedCap after a phone assessment, then the participant can agree to participate by checking boxes for date and time in RedCap in place of a physical informed consent. We also will have the subjects complete follow up questionnaires in the RedCap program itself. There are no PHI within RedCap.

Study Eligibility

The study inclusion criteria will include: 1) patients at the primary care or rheumatology clinic with daily pain for 6 months or longer affecting the low back, neck, hip, knee or widespread pain; 2) at least moderate in average pain severity, defined as a weekly average pain severity score of 5 or greater²⁴; 3) at least 18 years of age; 4) reliable phone (landline or cell), and 5) have home computer with reliable internet access.

The study exclusion criteria include: (1) planned elective surgery during the study period; (2) active suicidal ideation or very severe symptoms of depression (i.e., PHQ8 score of ≥ 20); (3) ongoing unresolved disability claims; (4) cancer-related musculoskeletal pain; (5) history of bipolar disorder or schizophrenia; (6) takes daily opioid for more than one year; and (7) physician-diagnosed active inflammatory arthritis (e.g., lupus, rheumatoid arthritis, ankylosing spondylitis, etc.).

For subject who is actively suicidal, we will advise them to go to the nearest emergency room. For subject with PHQ8 score of ≥ 20 , we will provide the contact information of the nearest mental health professionals.

We will recruit 60 subjects for this pilot study. Because of the disproportionately greater impact of chronic pain on individuals in the low socioeconomic status²⁵⁻²⁷, efforts to reduce the burden of disabling chronic pain should prioritize socioeconomically disadvantaged groups, who may have the least access to multimodal pain management program. Thus, we will make every effort to recruit 36 (60%) subjects on Medicaid.

Web-based CBT program.

The web-based CBT program (“PainTrainer”) consists of eight online lessons, to be completed over 8-12 weeks by the participant²⁸. The release of content is staged throughout the course duration (one new lesson released every 7-10 days). Lesson content is focused on (1) understanding pain and relaxation, (2) brief relaxation with mini-practices, (3)

activity/rest cycles, 4) pleasant activity scheduling, (5) coping thoughts, (6) pleasant imagery, (7) problem solving, and (8) looking back and moving forward. With each lesson, the participant has access to a downloadable lesson summary with practical homework exercises, related educational videos, relaxation audio files, and an “at home” exercise program. Participants are only able to progress to the next lesson if they have accessed each component of the current lesson.

Randomization

Participants will be randomized and will be stratified by depression status (PHQ8<10 vs. ≥ 10) into one of the 2 treatment groups: (1) trained MI nurse phone contacts, and (2) computer-generated email reminders (control group). Ms. Hooker, who will be blinded to treatment group assignment, will be responsible for outcome data collection.

Intervention

As previously stated, the primary purpose of (MI-trained) nurse contact is to support and enhance participants’ motivation to engage in the web-based CBT program, rather than providing psychological treatment. Subjects randomized to the trained MI phone contact group will receive 6 phone calls from the MI-trained nurse at week 2, 3, 4, 5, 6, and week 8. Subjects randomized to control group will automatically receive six computer-generated email to encourage to complete 1 lesson every week.

Importantly, the MI-trained nurses will use MI technique to encourage completion of all the required learning modules and to continuously practice newly learned pain coping skills. MI is an effective counseling approach to elicit behavior change (e.g., medication adherence, increase physical activity, reduction in caloric intake for weight loss, etc.) and promote healthy lifestyle ²⁹⁻³³. In contrast to delivering simple advice, an MI-trained nurse helps a patient discuss the pros and cons, and the barriers and solutions to completing all the web-based learning modules; consequently, enhancing self-efficacy. Self-efficacy determines whether an individual attempts a given task, the degree of persistence when difficulty is encountered and ultimate success or failure of the behavior. **Dr. Sebastian Kaplan**, a member of the Motivational Interviewing Network of Trainers (MINT), will provide the initial and ongoing training of the nurses, including assessment of treatment fidelity. To assess treatment fidelity, all nurse phone sessions will be audiorecorded for quality control.

Outcome Measures. We will collect outcome measures at baseline, week 8, week 16 (primary endpoint). The study visits at baseline, week 8, and week 16 will require an in person visit.

Primary outcome: PROMIS pain intensity and PROMIs pain interference

Secondary outcome: Number of completed phone calls by the nurse; and number of completed learning modules per treatment arm

Exploratory:

I. Acceptability (the extent that patients and health care personnel perceive that an ‘intervention’ is agreeable or reasonable. In the current proposal, there are two interventions: the new clinic process, and the web-based CBT program with nurse support.)

- a. Proportion of patients who expressed an interest in pain self-management
 - i. Numerator: # of patients who answered ‘yes’ to “Have you ever wondered if there is something that you could do on your own to better manage your pain?”
 - ii. Denominator: # of patients who answered ‘yes’ to “Over the last 6 months, do you have daily or almost daily pain that interfered with your general activity or enjoyment of life?”
- b. Proportion of patients who actually watched the educational video on web-based CBT
 - i. Numerator: # of patients who watched the video from EMMI
 - ii. Denominator: # of patients who received the video from EMMI
- c. Proportion of patients who called the research coordinator to participate in the study
 - i. Numerator: # of patients who made a phone call to the research team after watching the video
 - ii. Denominator: # of patients who watched the video
- d. Ratings of perceived disruption of the clinic standard operating procedures by the health care personnel

II. Adoption (the extent of participants’ motivation to engage in the web-based CBT program)

- a. Uptake rates: number of times participants log-in (yes or no) to web based CBT

- b. Self-report frequency of practicing pain coping skills
- c. Participant overall satisfaction on web-based CBT program

III. Feasibility (the extent in which clinic nurses can provide MI-consistent phone support)

- a. Nurses time
 - i. Number of minutes spent on study-related phone calls
 - ii. Time spent during the initial and ongoing MI training
- b. Rating of perceived 'additional' work load by the nurses
- c. MITI scale to assess treatment fidelity to the principles of MI.

IV. Health care burden or utilization

- a. Mean daily dose of opioid
- b. Non-study (pain-relevant) related phone calls
- c. New referrals to other musculoskeletal-related specialties
- d. Number of emergency room visits related to pain

V. Clinical measures

- a. PROMIS Adult Self-reported Measures on physical health (fatigue, physical function, sleep disturbance, pain behavior and sleep-related impairment) and social health (ability to participate in social roles and activities); BPI-pain severity and BPI-pain interference^{34,35}; Pain Catastrophizing Scale (PCS)^{36,37}; Global Rating of Change^{38,39}; Patient Health Questionnaire 8-Item Depression Scale (PHQ-8)⁴⁰⁻⁴³; and Generalized Anxiety Disorder 7-item scale (GAD-7)^{44,45}.

Relevance to Wake Baptist Health Care System

We surveyed 86 patients with CMP (48% females; mean age= 51 years old) at Downtown Health Plaza (DHP). We found that 58 (67%) patients continue to have a significant amount of pain despite current treatments, and also reported that pain prevented them from working or doing the things they enjoy almost every day. From these 58 patients, 50 (86%) have expressed willingness to participate in clinical studies to help reduce their pain and improve their quality of life.

In both traditional and in new technology-based mode of delivery, psychological treatment options for chronic pain are cost-effective⁴⁶⁻⁴⁸. In a recent meta-analysis, Pike et al found that psychological interventions in chronic pain are successful in reducing the use of healthcare services (consultations and resource use)⁴⁹. During an 18-month follow up period, female participants with chronic spinal pain who received CBT had lower risk of early retirement compared to the usual care group⁵⁰. If nurse guided web-based CBT can be shown to be effective and implementable, Wake Baptist can potentially leverage web-based CBT as one component in a multidisciplinary pain management program to prospective employers in North Carolina. With assistance from Wake Forest Innovation, Wake Baptist may also develop its own web-based CBT that can be commercialized in the future.

	Milestones	Activities
April 1-May 30, 2019	1. Set up the research infrastructure	<ul style="list-style-type: none"> - Work with Wake One Builder - Training of triage nurses - Finalizing arrangement with the Australian-based web-based CBT - IRB approval
June 1-Dec 31, 2019	2. Start date of new clinic process	<ul style="list-style-type: none"> - Implement new Wake One clinic process
	3. Enroll 8-9 subjects per month	<ul style="list-style-type: none"> - Ms. Hooker recruit eligible patients
Jan 2020-Feb 2020	4. Phone intervention	<ul style="list-style-type: none"> - Phone calls or computer generated email reminders.
March-April 2020	5. Follow-up assessment	<ul style="list-style-type: none"> - Collection of outcome data
May-June 2020	6. Data analyses	<ul style="list-style-type: none"> - Data cleaning and analyses
June 2020	7. Study results	<ul style="list-style-type: none"> - Data presentation

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