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Enhancing the success of functional restoration using complementary and integrative therapies: Protocol and challenges of a comparative effectiveness study in active duty service members with chronic pain

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ABSTRACT

Chronic pain significantly impairs physical, psychological and social functioning. Among military populations, pain due to injuries sustained both on and off the battlefield is a leading cause of short and long-term disability. Improving the quality of pain care for active duty service members is a major priority of the Department of Defense. This article describes an ongoing comparative effectiveness study which aims to (1) evaluate the benefit of a multimodal complementary and integrative health (CIH) pain management program when added to standard rehabilitative care (SRC) prior to an intensive functional restoration (FR) program compared to SRC alone, and (2) identify factors that predict improvement in pain impact following treatment completion. Using a randomized controlled trial design, active duty service members with pain related to musculoskeletal injury are assigned to a 3-week course of either SRC or SRC combined with CIH therapies prior to beginning a 3-week course of FR. Outcomes are collected at baseline, at the end of stage 1 treatment, post-FR, and at 3- and 6-months post-FR. Outcome measures include provider-measured functional assessments and patient-reported assessment through the Pain Assessment Screening Tool and Outcomes Registry (PASTOR). The military health system provides a supportive environment for implementation of this research protocol. Challenges to conducting the study have included new technology systems at the study site, slower than projected enrollment, and program delivery issues. These challenges have been successfully managed and have not significantly impacted study participant enrollment and completion of study treatments.

1. Background

Chronic pain significantly impairs physical, psychological and social functioning and is an important public health concern [1,2]. Among military populations, pain due to injuries sustained both on and off the battlefield is a leading cause of short and long-term disability [3–5]. An estimated 65.5% of military veterans report experiencing pain and nearly 50% of those who seek care in Veterans Health Administration facitities are diagnosed with a pain condition [6,7]. In 2012, 63% of all active duty non-deployed service members enrolled in TRICARE – the military's health insurance program – were diagnosed with a pain condition and a musculoskeltal condition was the most common reason for seeking medical care [8]. Deployment (particularly Gulf deployment) has been associated with higher rates of chronic widespread pain compared with nondeployed veterans [9].

Improving the quality of pain care for active duty service members is a major priority of the Department of Defense. The Army Medical Command's Comprehensive Pain Management Plan (CPMP) includes a Musculoskeletal Action Plan that emphasizes the prevention, early identification and proper rehabilitation and reintegration of service members suffering from acute and chronic musculoskeletal injuries related to pain [10]. The management of pain in the military health system includes a holistic, multi-disciplinary, and multi-modal approach. Standard rehabilitative care (SRC) is comprised of physical and occupational therapies, cognitive behavioral therapy, and pharmacotherapy. Functional restoration (FR) also is used to treat chronic

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musculoskeletal pain. FR is an intensive, medically-supervised interdisciplinary program, combining quantitatively-directed exercise progression with a multimodal disability management approach, and incorporating psychological and case management techniques [11]. With the military health system's recent focus on complementary and integrative health (CIH) approaches for pain management [8], acupuncture, mind and body therapies, and manual therapies of chiropractic manipulation and therapeutic medical massage also are used to treat chronic pain.

To improve pain management and function for military personnel, it is important to facilitate timely and appropriate use of CIH pain therapies along with a FR program. Currently, there is insufficient published data on the potential benefits of combining FR with CIH pain therapies. Thus, our goal is to compare the effectiveness of SRC combined with CIH pain therapies to SRC alone, followed by FR in active duty service members with chronic pain. Furthermore, we will identify prognostic factors for successful completion of the intensive FR program and for maintaining long-term outcomes. This article describes the protocol for an ongoing study that evaluates the effectiveness of CIH pain therapies along with a FR program for management of chronic pain in active duty service members.

2. Overview of the study

This comparative effectiveness study, approved by the Madigan Army Medical Center (MAMC) Institutional Review Board (IRB), uses a randomized controlled trial design. The study aims are to: (1) evaluate the benefit of a multimodal CIH pain management program combined with SRC compared to SRC alone, when completed prior to an intensive FR program; and (2) identify factors that predict improvement in pain impact following treatment completion.

Potential prognostic factors include demographic characteristics (age, military rank, household income, race), depression, anxiety, anger, sleep disturbance, fatigue, opioid use, and physical disability.

Potential study participants are identified by their medical provider at the MAMC Interdisciplinary Pain Management Center. The rehabilitation team (physical or occupational therapists) conducts baseline functional assessments to determine study eligibility. Participants who meet the study's functional and inclusion criteria (Table 1) are given the option to participate in the study. Those who agree to participate complete an informed consent conducted in accordance with good clinical practice with a research staff member. No compensation is offered to participants. The study aims to enroll 210 participants over three years based on a desired power of 80% to detect a moderate size of effect and an estimated 20% attrition rate and 5% incomplete data rate.

After informed consent is obtained and baseline measures completed, participants are randomized to the intervention (SRC + CIH) or to the control (SRC) arm. The simple random allocation sequence was generated by the study statistician and participants were informed by study staff of their assignment. There are two stages of treatment.

Stage 1 is a three-week course of SRC plus CIH therapies (SRC + CIH) or SRC alone. During stage 2, all participants are enrolled in the intensive FR program for the duration of three to six weeks. Outcomes are collected at (1) baseline, (2) completion of the first stage of treatment, (3) completion of the FR program, (4) 3-months post-FR, and (5) 6-months post-FR. Fig. 1 illustrates the study design and the multiple points of outcomes assessment.

3. Description of the intervention

SRC during the first stage of treatment is comprised of twice-weekly physical therapy, once- or twice-weekly occupational therapy, and twice-weekly health psychology education. For patients who randomize to the SRC + CIH treatment group, CIH treatment is comprised of twice-weekly acupuncture and chiropractic treatment, once-weekly yoga and once-weekly myofascial release instruction by a massage therapist. If indicated, biofeedback and individual massage may also be included.

The intensive FR program includes four full days of therapy per week for three weeks. Each FR program treatment day includes approximately 4 h of physical activity, 1 h of health psychology group therapy, and 1 h of pain education. Participants who are otherwise eligible for FR program participation but cannot commit to 4 days of therapy for a 3 week period are given the option of 2 days of therapy per week over a 6 week period for the same number of contact hours. We attempt to improve attendance by asking each participant's military supervisor to review and sign off on the treatment schedule prior to the start of the treatment program. If participants miss more than two appointments, a nurse case manager attempts to reach them to reinforce the importance of full participation. During data analysis, we will analyze the number of appointments of each discipline in which each participant engaged to determine if there is a minimum level of participation necessary to achieve improvement.

Physical therapy is supervised by a licensed physical therapist and carried out by a licensed physical therapist or physical therapy assistant. Occupational therapy is supervised by a licensed occupational therapist and carried out by a licensed occupational therapist or certified occupational therapy assistant. Chiropractic care is delivered by a licensed doctor of chiropractic medicine. Acupuncture is delivered by a licensed acupuncturist. Yoga is taught by a certified yoga therapist. Foam roller instruction is taught by a licensed massage therapist or certified physical therapy assistant. Health psychology care is delivered by a licensed health psychologist. Psychoeducation classes are conducted by a psychological technician. Didactic sessions are taught by a nurse educator or clinicians on the SRC or CIH teams.

4. Study measures

4.1. Patient-reported outcomes

The Pain Assessment Screening Tool and Outcomes Registry

Table 1
Study inclusion and exclusion criteria.

Inclusion	Exclusion
1. Active duty service members referred to an Interdisciplinary Pain Management Center for the management of chronic pain. 2. Physically able to participate in up to 4 h of physical activity (strength, flexibility, endurance training) per day: a. Can stand up from and sit down on floor independently. b. Can complete at least 6 min of the modified Naughton Treadmill Protocol. c. Able to complete at least 2 of the following: - Lift 20 lbs. from floor to waist height. - Lift 20 lbs. from waist to shoulder height. - Carry 20 lbs. at least 40 feet. 3. Inadequate response to previous less intensive treatment. 4. Expresses motivation to take active role in regaining function.	1. Major surgeries within past 6 months or planned within next 6 months. 2. Unstable psychological disorders 3. Active substance use disorder 4. High dose opioids of ≥90 mg of morphine equivalent doses (MED)/day 5. In the Medical Evaluation Board process and without defined availability for any treatment scheduling.

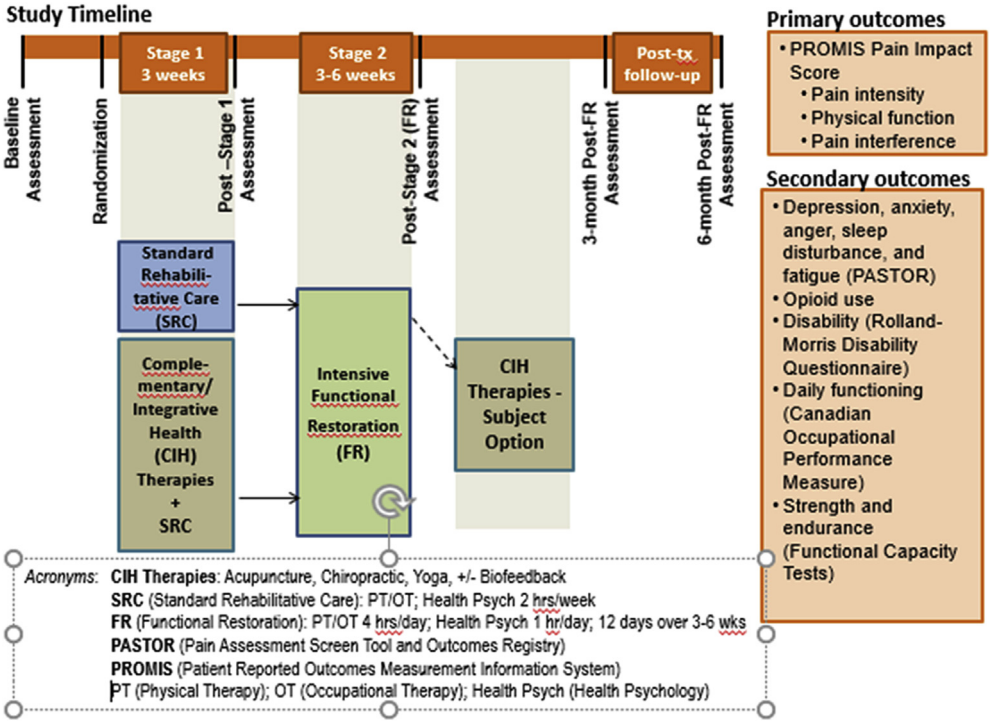

Fig. 1. Schematic diagram of the study design and timeline.

(PASTOR) is the primary tool employed to assess treatment outcomes. PASTOR is a web-based patient-reported outcomes tool developed by the Defense and Veterans Center for Integrative Pain Management in collaboration with Northwestern University in direct response to the Army Medical Command's CPMP [12]. It uses the computerized adaptive learning system of the National Institutes of Health (NIH) Patient Reported Outcome Measurement Information System (PROMIS) which contains a large, validated databank of patient-reported outcome surveys. PASTOR serves two major purposes: first, it collects actionable information that can be used by clinicians to assess response to treatment and to guide pain management; and second, when aggregated from large numbers of respondents, it can identify best clinical practices [13].

Primary Outcome. The study's primary outcome is the pain impact score. Pain impact is based on the recommendation of the NIH Taskforce on Research Standards for Chronic Low Back Pain [14] and is a composite score of pain intensity, pain interference with normal activities, and functional status. These items have major prognostic and discriminatory importance [15] and are calculated in this study from the Defense and Veterans Pain Rating Scale (DVPRS) [16], and the PROMIS Physical Function [17] and Pain Interference [18] items. The DVPRS average pain intensity during the previous 7 days is rated on a 0–10 scale (0 = no pain, 10 = worst possible pain) with color, graphic and verbal descriptors associated with each number. The PROMIS physical function item bank contains a large pool of physical function items ranging from self-care to strenuous activities. The PROMIS pain interference items specifically focus on pain interference, defined as interference of pain in daily activities involving physical, psychological, and social functioning.

Secondary Outcomes. PROMIS measures are used to evaluate factors that may predict improvement in pain impact following treatment completion. These include depression [19], anxiety [19], emotional distress – anger [19], sleep disturbance [20], and fatigue [21]. In addition, other potential prognostic factors collected by PASTOR include demographic characteristics (age, military rank, household income, race), opioid use, and physical disability (Roland-Morris Disability Questionnaire [22]).

4.2. Provider-measured outcomes

Two potential prognostic factors are measured by trained healthcare providers. These measurements include the Canadian Occupational Performance Measure (COPM) [23] and functional capacity tests of strength and endurance. The COPM is conducted at baseline and at the conclusion of FR. Functional capacity tests are completed at the same time as the patient-reported outcome measures.

Functional capacity tests on endurance and lifting strength are standard outcome measures used in Army FR programs to complement patient-reported outcomes. It is expected that participants will have improved functional capacity after CIH and thus, will show improvement on all functional capacity tests. These functional measures, similar to those used to screen participants for study inclusion criteria, include the modified Naughton Treadmill Test, tests of lifting strength, and the 7-to-1 Pyramid Test [24].

- **Modified Naughton Treadmill Test:** Measures the pace and duration of time on a treadmill. Each stage of the treadmill test represents a certain Metabolic Equivalent of a task (MET).
- **Floor-waist Lift Test:** Lifting weights from floor to waist height.
- **Waist-Shoulder Lift Test:** Lifting weights from waist to shoulder height.
- **40-ft Carry Test:** Carrying a weight and walking at least 40-feet in distance.
- **7-to-1 Pyramid Test**: The 7-1 pyramid is a functional physical assessment that consists of push-ups, back extensions, rowers, squats, dips, and burpees and was developed for use in environments with limited access to advanced therapeutics, typical of some military duty locations. The participant begins with 7 repetitions of the listed exercises, then 6 repetitions of each exercise, and so on down to 1 repetition of each exercise. The participant completes as many as possible in 6 min. If the participant is able to complete the circuit, then the pyramid starts over with 8 repetitions of each exercise, then 7, and so on down to 1. There are 3 specific modifications for each of the 6 different exercises. If a participant is unable to complete the exercise in the specified way then the participant is shown

modification #1 and so on through modification #3 if necessary. The participant is scored on total repetitions completed.

5. Analysis plan

Aim #1: Evaluate the benefit of a multimodal CIH pain management program combined with SRC compared to SRC alone, when completed prior to an intensive FR program.

Hypothesis: Participants who complete the three-week CIH + SRC program prior to FR will show significantly improved outcomes on pain impact relative to SRC alone. Improved pain impact score will be demonstrated at the end of the pre-FR treatment phase, following FR, and 3- and 6-months post-FR.

Analytical Technique: All analyses will be based on the intent-to-treat principle. Mixed-effect models using hierarchical linear modeling (HLM) [25] with time nested within participants will be used to analyze participant outcomes. HLM affords an integrated approach to studying the structure and predictors of individual change, and provides the appropriate standard errors and correct statistical inferences for clustered data. The primary participant outcome variable is change in pain impact score [14] measured at the conclusion of FR. The minimum important difference in pain impact score is suggested to be 3 on a scale of 8–50 [15] and we will conduct a sub analysis to test this proposition.

Aim #2: Identify factors that predict improvement on pain impact following treatment completion.

Hypothesis: Service members with the lowest and highest levels of baseline functional status will show lower levels of improvement in pain impact compared with those with intermediate baseline functional status. If true, this will have important implications in selecting patients for these treatment approaches.

Analytical Technique: In addition to baseline functional status, other prognostic factors (psychological distress, age, military rank, race, military occupation, sleep quality, fatigue and opioid use) will be analyzed using a Sequential Multiple Regression model [26]. The model will adjust for baseline measures of the primary outcome (pain impact) and pre-FR treatment groups, before assessing the relative importance of secondary outcomes. Relative importance of predictors among these secondary outcomes will be reported by their respective regression beta weight coefficients. To control for inflation of Type I error rates due to co-primary outcomes, alpha will be set to 0.025 for each test of the outcome variables in their respective regression models.

6. Strengths, challenges and lessons learned

The military health system is one of the largest healthcare systems in the world and is committed to enhancing military medical readiness and the quality of life of service members, which is aligned with the mission of the Army Medical Command's CPMP and the goals of this study. The CPMP promotes collaborative research to explore CIH pain management approaches and leads the way in providing an evidence-based interdisciplinary approach to pain management. These strengths of the military health system provide a strong foundation for implementation of this research protocol. However, as with most research endeavors, the current study has experienced some challenges.

Thus far, challenges include technical issues, enrollment, and program delivery. Technical issues have been related to: (1) a new electronic medical record system (2) a new electronic IRB system, and (3) a new computer operating system. These three changes occurred during a six-month period during the third year of the study period and impacted the ability to schedule participants' appointments, delayed approval of addition of new research staff to the study protocol, and reduced electronic communication among providers about participants. The reduced communication subsequently affected the rehabilitation team's ability to capture secondary measures such as COPM measures and pyramid measures in a timely manner. The research team addressed the appointment scheduling issue by making arrangements for “make-up” clinical appointments so participants could receive the intended number of treatment hours. Although this created longer wait times for participants waiting to engage in the study treatment, it did not deter participants from completing the study activities.

Enrollment challenges also have been encountered. Originally, this was related to the strict functional inclusion criteria (e.g. treadmill and lifting tests) which limited the pool of eligible participants for the study. To address this issue, the protocol was amended to make the functional criteria less stringent. While this modification increased the number of participants eligible for study participation, functional inclusion criteria remained a rate-limiting step. A second rate-limiting step is provider buy-in for referrals. Although most participants could benefit from non-interventional, non-pharmacological therapies such as SRC, CIH, and FR, not all medical providers at the study site consistently refer participants for these options. Employing an “opt-out” of non-interventional, non-pharmacologic pain therapies for clinic flow instead of an “opt-in” process has helped to mitigate this issue and improve enrollment rates. The original enrollment goal was 10 participants per month, but the actual enrollment was 7 participants.

Conducting clinical research within an active duty military population that is highly mobile also makes participant enrollment challenging. Participants in this study suffer from complicated pain conditions which require multiple multimodal appointments. The studied rehabilitation programs range from 87 to 96 treatment hours depending on the treatment group. Overall time spent in programs can extend to over two months, with a 24-h per week time commitment for three of the weeks. To engage in the study, participants must be excused from their work duties to attend appointments. This requires that a treatment letter be prepared and sent to their commander for approval, and at times requires further communication with the service member's military commander to justify the time commitment required of the treatment plan. In addition, treatment plans are often interrupted by last minute military training or exercises in which service members are required to participate. Other times, participants realize that they have personal schedule conflicts shortly before the start of their treatment program, which requires them to reschedule programming dates. However, even with these schedule challenges and the time commitment of these treatment programs, we have found that military personnel are receptive to SRC, CIH, and FR therapies.

Attrition from the military has impacted completion of 3- and 6-month follow-up assessments. Many participants seen at the MAMC Interdisciplinary Pain Management Center are engaged in the military medical retirement process. If a participant completes the medical retirement process before the end of their scheduled study participation, they may leave the military and drop out of the study. Participants have also discontinued study participation due to leaving military service at the end of their commitment period or moving to a new duty station. At the completion of the clinical phase of the study, the overall attrition rate is 20%.

Lastly, problems have existed with full program delivery due to fluctuations in clinic staffing. Treatment is provided to participants through a combination of permanent and contract staff. Turnover of permanent staff positions is an ongoing issue and it often requires several months to hire a replacement for federally-funded positions. In particular, keeping the yoga and massage therapists positions filled has been especially challenging. Also, because enrollment has extended past the projected recruitment period, several study contract staff were lost since their contracts were only funded through the originally projected treatment phase of the study. This issue was remedied by optimizing clinic capacity among permanent staff members. To ensure fidelity of the treatment protocol, we monitor the completion of scheduled treatments daily and work closely with the clinic staff to problem solve when staff are not available to deliver treatment.

7. Conclusions

Studying the effectiveness of pain treatments among the military population who commonly suffer from musculoskeletal injuries is critical to physical functioning and the quality of life of active duty service members suffering from chronic pain. Furthermore, understanding the prognostic factors which may improve treatment outcomes will help to ensure implementation of appropriate individualized pain management treatment plans. Because this research involves participants with complicated pain conditions requiring multiple multimodal appointments within the context of a highly mobile population, challenges in implementing the protocol were not uncommon. These challenges were successfully managed within a health system where quality pain care is a priority and thus, have not significantly impacted study participant enrollment and completion of study treatments. If the study's findings support the effectiveness of CIH added to SRC prior to FR, it will lend support for expanding access to these therapies at other military sites, to other beneficiaries of the Military Health System such as retirees and family members of military personnel, as well as to civilian populations.

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