Contemporary Clinical Trials xxx (xxxx) xxx–xxx

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Comprehensive vs. Assisted Management of Mood and Pain Symptoms (CAMMPS) trial: Study design and sample characteristics

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ARTICLE INFO

Keywords:
Pain
Patient-reported outcome
Depression
Anxiety
Telemedicine
Telehealth
Clinical trial

ABSTRACT

Background: Pain is the most common presenting somatic symptom in medical outpatients, and depression and anxiety are the two most common mental disorders. They frequently co-occur, are under-treated, and result in substantial disability and reduced health-related quality of life.

Objectives: The *Comprehensive* vs. *Assisted Management of Mood and Pain Symptoms* (*CAMMPS*) study is a randomized comparative effectiveness trial designed to test the relative effectiveness of a lower-resource vs. a higher-resource technology-assisted intervention for the management of patients suffering from pain plus anxiety and/or depression.

Methods/design: CAMMPS has enrolled 294 primary care patients with chronic pain plus comorbid anxiety and/or depression and randomized them to either: 1) *Assisted Symptom Management* (ASM) consisting of automated symptom monitoring by interactive voice recording or Internet and prompted pain and mood self-management; or 2) *Comprehensive Symptom Management* (CSM) which combines ASM with optimized medication management delivered by a nurse-physician specialist team and facilitated mental health care. Outcomes are assessed at baseline, 1, 3, 6, and 12 months. The primary outcome is a composite pain-anxiety-depression (PAD) severity score. Secondary outcomes include individual pain, anxiety, and depression scores, health-related quality of life, disability, healthcare utilization, and treatment satisfaction.

Discussion: CAMMPS provides an integrated approach to PAD symptoms rather than fragmented care of single symptoms; coordinated symptom management in partnership with primary care clinicians and psychologists embedded in primary care; efficient use of health information technology; attention to physical and psychological symptom comorbidity; and the coupling of self-management with optimized medication management and facilitated mental health care.

Trial registration: clinicaltrials.gov Identifier: NCT01757301.

1. Introduction

Pain is the most common symptom reported in both the general population and in primary care [1]. Pain complaints account for > 40% of all symptom-related outpatient visits and over 100 million ambulatory encounters in the U.S. each year [2]. In the United States alone, chronic pain conditions cost more than $500 billion annually in direct medical costs and lost productivity [1]. Pain medications are the second most prescribed class of drugs (after cardiac-renal drugs), accounting for 12% of all medication prescribed during ambulatory office visits in the United States [3]. Indeed, persistent pain is a major international health problem, prompting the World Health Organization to endorse a global campaign against pain [4].

Musculoskeletal pain is consistently the most common, disabling, and costly of all pain complaints [5]. Indeed, two-thirds of pain-related outpatient visits are due to musculoskeletal pain, accounting for nearly 70 million outpatient visits in the U.S. each year [2]. In a study assessing pain as the 5th vital sign in 9 Veteran Administration (VA)

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http://dx.doi.org/10.1016/j.cct.2017.10.006
Received 24 July 2017; Received in revised form 5 October 2017; Accepted 10 October 2017
1551-7144/ Published by Elsevier Inc.

clinics, > 80% of all pain complaints expressed by Veterans were musculoskeletal in nature [6]. Two Institute of Medicine reports have summarized the enormous functional and economic impact of musculoskeletal pain on both the working and the retired population [1,7].

Depression and anxiety are the two most common mental health problems seen in the general medical setting, each being present in 10%–15% of primary care patients [8–10]. They produce substantial disability and decrements in health-related quality of life, often exceeding the impairment seen in patients with chronic medical disorders [11,12]. Additionally, depression and anxiety each result in substantial health care costs as well as indirect costs due to lost work productivity [13,14].

Pain, anxiety, and depression are often inextricably linked (i.e., the *PAD triad*), such that disentanglement is scientifically and clinically impractical [15–17]. Moreover, PAD symptoms have reciprocal negative effects on treatment response of one another, and additive adverse effects on health outcomes [18–20]. Thus, interventions that target the PAD symptoms collectively rather than individually are desirable. Also, since most patients with PAD symptoms are treated predominantly or exclusively in primary care, PAD interventions that are collaborative with or integrated into primary care are likely to have the greatest impact [10].

Comprehensive vs. Assisted Management of Mood and Pain Symptoms (CAMMPS) is a randomized comparative effectiveness trial comparing two pragmatic interventions (an intensive vs. a low-resource approach) for treating the pain plus anxiety and/or depression. The assisted symptom management arm (ASM) intervention consists of automated symptom monitoring and prompted pain and mood self-management. The comprehensive symptom management (CSM) intervention combines ASM with optimized medication management and facilitated mental health care by a centralized nurse-physician team. The primary aim is to compare the 12-month effectiveness of CSM vs. ASM in improving overall pain and mental health. Secondary outcomes will include health-related quality of life, disability, health care utilization, and treatment satisfaction.

2. Methods

2.1. Overview of study design and research aims and hypotheses

CAMMPS is a 12-month randomized comparative effectiveness trial comparing a low-resource entirely automated intervention to a more intense comprehensive intervention that complements the automated intervention with a nurse-physician team collaborating with the primary care team through a largely telecare approach (i.e., most communication with patients and providers is by telephone or through secure e-mails and websites). Outcomes are assessed at 1, 3, 6, and 12 months. The study was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki). CAMMPS has been reviewed and approved by the Indiana University Institutional Review Board and the VA Research Review Committee.

CAMMPS has one primary aim, two secondary aims, and one exploratory aim.

Aim 1. To compare 12-month effectiveness of CSM vs. ASM in improving overall pain and mental health. Our hypothesis is that CSM will be superior to ASM in reducing a composite pain-anxiety-depression score.

Aim 2. To compare 12-month effectiveness of CSM vs. ASM in improving specific PAD symptoms. Our hypothesis is that CSM will be superior to ASM in reducing individual pain, anxiety, and depression scores.

Aim 3. To compare the effects of CSM vs. ASM on secondary outcomes, including health-related quality of life, disability, treatment satisfaction, and health care utilization.

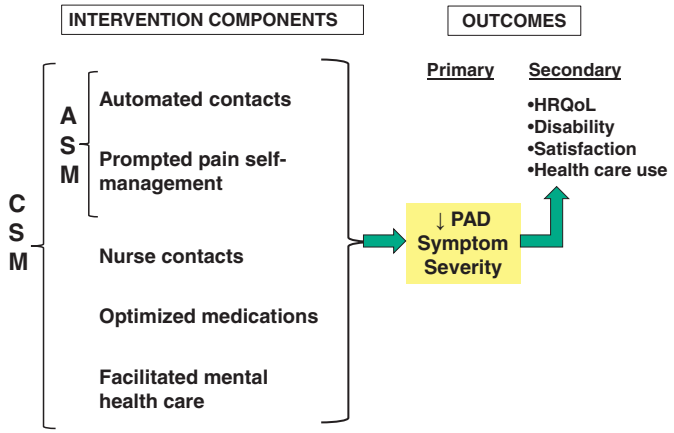

Fig. 1. Conceptual model for CAMMPS trial, illustrating the 2 components of the automated symptom management (ASM) intervention and the 3 additional components of the comprehensive symptom management (CSM) intervention. Also, the primary outcome that the intervention is hypothesized to benefit is depicted as well as the secondary outcomes postulated to parallel improvements in the primary outcome.

Aim 4. To explore patient-perceived barriers and facilitators of the CAMMPS intervention and the relative contribution of each intervention component to overall symptom improvement.

2.2. Conceptual model

Fig. 1 depicts the conceptual model underlying the CAMMPS trial. The ASM arm has 2 components that enhance usual care: automated PAD symptom monitoring and automated prompting of the patient to use pain and mood self-management strategies. The CSM arm adds 3 additional components to ASM: nurse contacts; optimized medication regimens for PAD symptoms; and facilitated mental health care. Collectively, these 5 components constitute the active intervention ingredients which may lead to an improvement in the primary (proximal) outcome, namely symptom burden as measured by the composite PAD symptom score. Secondary (distal) outcomes postulated to benefit from reduced PAD symptom burden include health-related quality of life (HRQoL), disability, patient satisfaction, and health care utilization.

2.3. Eligibility

The study population consists of Veterans 18 years and older receiving care from one of 5 primary care clinics at a large VA Medical Center in the Midwest. Patients are eligible if they have pain plus psychiatric comorbidity.

Pain must meet all of the 3 following criteria: (1) musculoskeletal, either localized (in the arms, legs, back, or neck) or widespread (fibromyalgia); (2) persistent for 3 months or longer [21,22] despite a trial of at least one analgesic medication; (3) at least moderate in severity, defined as a Brief Pain Inventory average severity score of 5 or greater in the past week [23] or having at least moderately interfered with work or other activities in the past month.

Psychiatric comorbidity must meet any 1 of the following 3 criteria.

(1) *Depression* must be of at least moderate severity, defined as a PHQ-8 score of 10 or greater with either depressed mood and/or anhedonia being endorsed. In previous studies, > 90% of patients fulfilling this PHQ-8 criterion had major depression and/or dysthymia, and the remaining patients had clinically significant depression with substantial functional impairment [24,25].
(2) *Anxiety* must be of at least moderate severity, defined as a GAD-7 score of 10 or greater. In previous studies, the majority of patients fulfilling this GAD-7 criterion had one or more common DSM-IV