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Yoga for veterans with chronic low back pain: Design and methods of a randomized clinical trial

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ABSTRACT

Chronic low back pain (CLBP) afflicts millions of people worldwide, with particularly high prevalence in military veterans. Many treatment options exist for CLBP, but most have limited effectiveness and some have significant side effects. In general populations with CLBP, yoga has been shown to improve health outcomes with few side effects. However, yoga has not been adequately studied in military veteran populations. In the current paper we will describe the design and methods of a randomized clinical trial aimed at examining whether yoga can effectively reduce disability and pain in US military veterans with CLBP. A total of 144 US military veterans with CLBP will be randomized to either yoga or a delayed treatment comparison group. The yoga intervention will consist of 2× weekly yoga classes for 12 weeks, complemented by regular home practice guided by a manual. The delayed treatment group will receive the same intervention after six months. The primary outcome is the change in back pain-related disability measured with the Roland-Morris Disability Questionnaire at baseline and 12-weeks. Secondary outcomes include pain intensity, pain interference, depression, anxiety, fatigue/energy, quality of life, self-efficacy, sleep quality, and medication usage. Additional process and/or mediational factors will be measured to examine dose response and effect mechanisms. Assessments will be conducted at baseline, 6-weeks, 12-weeks, and 6-months. All randomized participants will be included in intention-to-treat analyses. Study results will provide much needed evidence on the feasibility and effectiveness of yoga as a therapeutic modality for the treatment of CLBP in US military veterans.

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1. Background

Military veterans have higher rates of chronic low back pain (CLBP) than the general US population because of both training and combat-related incidents, with 28–44% of US Gulf War veterans reporting back pain between 2 and 5 years after active duty [1]. In addition to the discomfort of pain, people afflicted with CLBP are at risk for decreased functional ability [2], increased presence of psychological symptoms such as depression [3,4] and anxiety [5,6], as well as reduced health-related quality of life (HRQOL) [7,8]. Moreover, CLBP tends to be associated with increased health care costs [9,10].

Most cases of CLBP (85%) are nonspecific and cannot be directly linked to physical abnormalities [11]. Standard treatment for nonspecific CLBP typically begins with medication management and self-care instruction [12], followed by a variety of non-pharmacological interventions such as physical therapy, spinal manipulation and acupuncture. Since the prolonged use of pain medication and narcotic agents can lead to significant side effects, addiction risks, and increased mortality [13–16], non-pharmacological treatments are increasingly used in primary care [15].

Mind-body approaches such as yoga offer another treatment option. The components of yoga interventions vary depending on the type of yoga that is used, but typically include a combination of physical postures and/or movement sequences, conscious regulation of the breath, and techniques of concentration and/or meditation [17]. Thus, yoga might impact CLBP both directly through increased strength and flexibility from practice of specific physical postures, and indirectly through the effects of breathing and meditation techniques that promote stress reduction and increased parasympathetic tone which in turn modulates pain tolerance [18]. One advantage of yoga-based interventions over other non-pharmacological treatments mentioned above, is that they can be taught in a group setting, do not require any expensive

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equipment, and can be self-administered long-term. Hence, if research can more firmly establish the effectiveness of yoga for CLBP, yoga interventions are potentially a sustainable, low-cost treatment option.

Although there is evidence that yoga can be effective for CLBP [19,20], it is unknown whether these results will generalize to Veterans Affairs (VA) patients. VA patients are a subset of all US veterans, with VA patients tending to be older, less educated, employed fewer hours, and have lower incomes than both non-VA veterans and the general US population [21]. Most importantly, VA patients are typically 95% male and have elevated rates of psychological disorders and substance use [22]. The samples studied in the most well known previous RCTs for CLBP [19,20] were 65–70% female and there was no evidence of elevated rates of substance use or psychological disorders. It is therefore important to examine whether yoga will be accepted and attended by VA patients, and whether they will experience similar benefits. Preliminary data suggest that VA patients will attend yoga sessions offered at VA facilities and that yoga can reduce pain and depression levels, and increase energy and health-related quality of life (HRQOL) in this population [23]. The goal of the current study is to test the effectiveness of yoga for treating CLBP in VA patients in a single site, two-arm, 12-week randomized clinical trial with six-month follow-up.

1.1. Aims and hypotheses

The primary aims of the current study are to:

a) further demonstrate that yoga is an acceptable treatment for VA patients with CLBP through recruitment, retention, attendance, and satisfaction data.
b) determine whether a yoga intervention can effectively improve symptoms and functioning among VA patients with CLBP.

The main hypotheses are:

1) Improvement in function (reduced disability) among patients assigned to the yoga intervention will be greater than that in patients in the delayed treatment control at the 12-week assessment;
2) Improvements in pain, depression, anxiety, energy, HRQOL, and self-efficacy among patients assigned to the yoga intervention will be greater than that in patients in the delayed treatment control at the 12-week assessment;
3) Attendance of yoga sessions and amount of home practice will be related to improved health outcomes.

2. Methods

2.1. Study design

In the current study we will recruit 144 VA patients with CLBP, who will be randomized to either a yoga intervention group or a delayed treatment comparison group. The yoga intervention participants will be asked to attend yoga immediately after randomization, while the delayed treatment comparison participants will receive ongoing usual care until they are invited to attend the same yoga intervention starting 6 months after randomization. Participants in both treatment groups and their primary care physicians will be asked to not start or stop other medical treatments during the time of the yoga intervention unless medically necessary. Assessments will be conducted at baseline, 6-weeks, 12-weeks, and 6 months, and VA electronic medical records will provide additional data. The study will be conducted at a large VA Medical Center in southern California. The study protocol is registered with ClinicalTrials.gov (study# NCT02524158).

2.2. Recruitment

The primary recruitment methods for the study will be referrals by VA clinicians. The primary study physician has worked in primary care for many years, and will regularly notify colleagues that the study is recruiting participants. In addition, study investigators will notify and remind clinical care providers in other clinics such as Physical Medicine and Rehabilitation (PM&R), Anesthesia Pain, Psychology, Behavioral Medicine, Psychiatry, and Substance Use services about the study recruitment. Flyers will be posted at waiting rooms, bulletin boards, and other locations at the VA Medical Center. Recruitment information will also appear on televisions in medical center waiting rooms, and in a semi-annual research newsletter. Interested parties will be instructed to call the project coordinator who will explain further details of the study and ask a series of pre-screening questions. Potential participants will then be scheduled to attend a screening interview and examination with a study research physician who will determine eligibility according to the criteria detailed below. To allow access to the medical record for research purposes, participants are required by the local VA IRB to provide informed consent and HIPAA authorization prior to the study screening examination. Eligible participants will be invited to a group baseline assessment visit following which they will be randomized to either the experimental or delayed treatment group. Eligible participants who do not attend the baseline assessment will not be randomized or further assessed that time, but can participate in a future cohort.

2.3. Inclusion and exclusion criteria

Inclusion and exclusion criteria for study participation are shown in Table 1. Criteria will be applied based on the informed consent process and a thorough review of the participant's VA medical record, followed by a clinical interview and physical examination by a study physician. All screening visits were conducted at a single VA Medical Center.

The screening physician will review the medical record and conduct a brief balance test (Romberg) [24]. Participants with a positive Romberg test will be excluded for safety purposes. In contrast, those with some evidence of minor sensory neuropathy but no balance problems will be allowed to participate. Although we will exclude participants with serious uncontrolled mental illness or substance use disorders, we will include patients with depression, anxiety, and post traumatic stress disorder (PTSD), as these conditions are prevalent and contribute to disability of VA patients with CLBP. Moreover, research suggests that yoga treatment has beneficial effects on psychiatric symptoms [25]. We will exclude patients who report active suicidal ideation at baseline or have a recent history of suicide attempts. These patients will be referred to the appropriate VA Psychiatric Emergency Clinic and/or Emergency Department. Patients who have recently started, stopped, or changed any professionally-delivered pain treatment (e.g., pain medications or acupuncture) will not be screened until their treatment has been stable for one month. Once enrolled, participants will be asked to keep all treatments stable during the 12-week intervention period unless a change of treatment type or dosage is seen as medically necessary.

2.4. Enrollment and randomization

We plan to recruit 144 participants over the course of 33 months. The intervention will be conducted across 6 cohorts of about 24 participants, allowing 5.5 months to recruit each cohort, and providing a recruitment target of 4.4 patients per month. Once 25–30 VA patients provide informed consent and have been fully screened to meet inclusion criteria, they will be scheduled for a baseline assessment. Participants who provided informed consent but do not attend the baseline will not be enrolled or randomized. They will instead be invited to attend a future cohort if they remain eligible. Following completion of the baseline assessment, participants will be randomized via a computer program to either the yoga intervention or the delayed treatment