

Abstract

Background: Many military personnel who participated in the Gulf War in 1990-1991 reported negative health consequences subsequent to the deployment. The most prevalent of these health concerns involves a triad of unexplained physical symptoms (fatigue, arthralgias / myalgias and concentration/memory disturbances) commonly referred to as "Gulf War Syndrome," which for many continues into the present. No clear, unifying pathophysiological process or etiologic agent has been identified for Gulf War Syndrome (GWS). Training in mindfulness has been shown to result in reduced stress perception and improved quality of life for individuals with symptoms akin to those associated with GWS. Mindfulness involves bringing attention to present moment experience, including cognitions and bodily sensations without judgment. The most common format for teaching mindfulness in the health care setting is through an 8-week class called Mindfulness-Based Stress Reduction (MBSR).

Aims: **1.** To assess the safety and feasibility of recruiting and retaining veterans with GWS to complete a study that involves randomization to treatment as usual (TAU) or TAU plus MBSR. **2.** Obtain symptom-based outcome measures for veterans with GWS, before and after randomization, to assess fatigue, pain, cognitive function, physical functional status. **3:** Obtain objective measures of attention, concentration, and working memory in order to assess if MBSR results in a change in these parameters.

Design: Two-arm randomized controlled trial (RCT) comparing MBSR and TAU. **Participants:** 60 veterans with GWS. **Intervention:** 8-week group-based MBSR based on Kabat-Zinn's model.

Assessment: Three in-person assessments (baseline, post-treatment, 6-month follow-up) will include symptom measures of pain, fatigue and cognitive failures, as well as objective measures of attention and memory (PASAT, Trail making test A/B, California verbal learning test, symbol digit coding and digit span test). **Hypotheses and Analyses:** We hypothesize that the intervention and study protocol will be acceptable to patients and we will be able to recruit at least 60 GWS veterans willing to participate. We also hypothesize that at least 80% of those randomized to MBSR will complete 4 or more treatment sessions and at least 85% of study participants will be assessed at each follow-up point. We anticipate that MBSR will have improved patient-reported outcomes, and improved measures of concentration and working memory, as compared to TAU. We will compare MBSR versus TAU at baseline and follow-up to determine whether MBSR is associated with changes in pain, fatigue, cognitive failures, physical component summary score of the SF-36-V, attention, concentration and working memory. If improvement in outcomes is associated with MBSR, this would support performing a larger clinical trial of MBSR for GWS.