

A Randomized Controlled Pilot Study of a Mindfulness-Based Intervention for Gulf War Syndrome  
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**Summary:** A randomized, controlled clinical trial to evaluate whether a standardized course of Mindfulness-Based Stress Reduction (MBSR) results in improved outcomes for Gulf War Syndrome (GWS) as compared to treatment as usual.

**What is mindfulness?** Mindfulness has been defined as “the awareness that emerges by way of paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment”.<sup>1</sup> Mindfulness interventions are increasingly applied in health care, supported by evidence of benefit for a variety of conditions, including depression, general stress, cancer quality of life, psoriasis, chronic pain and fibromyalgia.<sup>2-8</sup> In a mindfulness education program, a person is taught to bring an attitude of curiosity, kindness, non-judging and openness<sup>9</sup> to present moment experience, including thoughts, emotions and physical sensations. Prior studies show that mindfulness skills are increased by participation in a structured mindfulness program that includes formal mindfulness meditation practice,<sup>10</sup> and that participation in even a relatively brief program in mindfulness meditation leads to beneficial changes in brain function<sup>11</sup> and structure.<sup>12</sup>

**What is MBSR?** A common clinical method of teaching mindfulness is a standardized class series called Mindfulness-Based Stress Reduction (MBSR),<sup>13</sup> which is available throughout the U.S. In MBSR, participants meet once per week (2.5 hours per session) for 8 weeks, as part of a group of 15-25 participants. During each meeting, participants practice meditation and yoga, receive instruction from the teacher, and discuss homework assignments. Between the sixth and seventh week, participants meet for 7 hours for a daylong mindfulness retreat. Techniques taught in MBSR include the “body scan” (an exercise in which attention is systematically directed through the body), sitting meditation (focusing on the breath), and yoga (taught as a practice of ‘mindful movement’, intended to develop present moment awareness of bodily sensations). Homework of daily meditation or yoga for 45 minutes per day is assigned six days per week, with CDs used as a guide. Follow-up studies of MBSR show that at 1 year 75-80% continue to meditate and 33% practice yoga.<sup>8, 13</sup>

**Study Design:**

At least 60 Veterans meeting criteria for GWS will be randomized to MBSR plus treatment as usual (TAU), or TAU only. **Inclusion Criteria:** at least 2 of 3 of the following: Fatigue that limits usual activities (work, recreation, and/or social), Musculoskeletal pain involving two or more regions of the body, neurocognitive dysfunction (self-reported difficulty in memory, concentration, and/or attention). Study measures will be collected at baseline, immediate post-MBSR, and 6 months post intervention, and at equivalent time points for Veterans randomized to TAU only.

**Hypotheses:**

1. Veterans randomized to MBSR will report greater improvement in measures of fatigue, pain and cognitive function, and improvement in functional status as compared to TAU at each of the follow-up points.
2. Veterans with GWS randomized to MBSR will show significantly greater improvement on objective measures of attention, concentration, and working memory than those randomized to treatment as usual.

**Overview of Measures:**

**Symptom Measures:** Assessments of pain, fatigue, cognitive function, and health status:

1. The Short-form McGill Pain Questionnaire (SF-MPQ-2).
2. The Multidimensional Fatigue Inventory (MFI)
3. The Cognitive Failures Questionnaire (CFQ)
4. Medical Outcomes Study SF-36-V

**Neuropsychological measures** of attention, memory and concentration:

1. Paced Auditory Serial Addition Test (PASAT)
2. Trail making test A/B
3. California verbal learning test
4. Symbol digit coding and digit span test.

Other Measures:

1. PTSD Symptom Scale-Interview (PSS-I)
2. Five Facet Mindfulness Questionnaire (FFMQ)
3. Daily mindfulness practice diary
4. The NIH PROMIS measures: global health, physical function, fatigue, functional impairment related to pain (pain-behavior and pain-impact), sleep disturbances, wake disturbances, anxiety, anger and depression.

**Recruitment Progress to Date:**

We have contact Veterans by mail using the Persian Gulf Registry, and advertised appropriately:

- The study has been well-received by Veterans, who seem appreciative that we are undertaking the study, and interested and open to the mindfulness intervention.
- 26 eligible Veterans have completed initial screening and meet eligibility criteria
- 10 have completed baseline assessments and randomization; the remainder are undergoing evaluation and randomization.
- We anticipate that we will meet or exceed our projected enrollment of 60 Veterans with GWS by the end of calendar year 2011.

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