# Telemedicine Treatment for Veterans With Gulf War Illness

**This study is currently recruiting patients.**
Verified by Department of Veterans Affairs September 2006

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| **Sponsored by:** | Department of Veterans Affairs |
| **Information provided by:** | Department of Veterans Affairs |
| **ClinicalTrials.gov Identifier:** | NCT00129454 |

## Purpose

Numerous studies have shown that poorly defined medical conditions are commonly reported in the aftermath of military conflict. At least as far back as the American Civil War, soldiers have reported nonspecific ailments that could not be attributed to an underlying medical cause. The most frequent symptoms include persistent fatigue, palpitations, headache, muscle or joint pain, disturbed sleep, and cognitive difficulties. Recent epidemiologic studies suggest that war-related syndromes are exceptionally common in deployed personnel and may affect 45% to 60% of returning soldiers. Despite an uncertain etiology, these post-deployment symptoms have substantial consequences that include increased medical visitation, increased physical disability, and increased psychological distress. The fact that America is now engaged in military conflict abroad and threatened with weapons of mass destruction at home raises the possibility that a large number of veterans (and civilians) may eventually develop similar war-related illness. Unfortunately, the number of veterans at risk is likely to increase rather than decrease in the years ahead. In order to address this anticipated increase, new and more efficient treatments for symptom-based illness are urgently needed to augment or replace standard VA care. Fortunately, an effective treatment using cognitive-behavioral techniques (CBT) has been developed to ameliorate symptom-related distress and reduce unnecessary healthcare utilization. Despite convincing evidence of therapeutic efficacy, a major limitation of this treatment is that patients must attend sessions in person. This requirement may undermine the clinical effectiveness of CBT since fewer than half of those who need treatment are likely to attend. A recent trial of CBT for veterans with Gulf War Illness found that only 38% were treatment adherent. Any sudden increase in the number of veterans seeking care could overwhelm the limited resources of a local VA healthcare center. The proposed study will address this important public health problem by testing a cost-effective and innovative strategy for delivering CBT over the phone.

| Condition | Intervention |
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| Gulf War Syndrome | Behavior: Cognitive Behavioral Therapy |

MedlinePlus related topics: Veterans and Military Health

Study Type: Interventional
Study Design: Educational/Counseling/Training, Randomized, Open Label, Active Control, Factorial Assignment, Efficacy Study

Official Title: Telemedicine Treatment for Veterans With Gulf War Illness

Further study details as provided by Department of Veterans Affairs:

Primary Outcomes: Frequency of medical visitation
Secondary Outcomes: quality of life
Expected Total Enrollment: 150

Study start: September 2005; Expected completion: January 2008
Last follow-up: October 2007; Data entry closure: October 2007

Background:

Numerous studies have shown that poorly defined medical conditions are commonly reported in the aftermath of military conflict. At least as far back as the American Civil War, soldiers have reported nonspecific ailments that could not be attributed to an underlying medical cause. The most frequent symptoms include persistent fatigue, palpitations, headache, muscle or joint pain, disturbed sleep, and cognitive difficulties. Recent epidemiologic studies suggest that war-related syndromes are exceptionally common in deployed personnel and may affect 45% to 60% of returning soldiers. Despite an uncertain etiology, these post-deployment symptoms have substantial consequences that include increased medical visitation, increased physical disability, and increased psychological distress. The fact that America is now engaged in military conflict abroad and threatened with weapons of mass destruction at home raises the possibility that a large number of veterans (and civilians) may eventually develop similar war-related illness. Unfortunately, the number of veterans at risk is likely to increase rather than decrease in the years ahead. In order to address this anticipated increase, new and more efficient treatments for symptom-based illness are urgently needed to augment or replace standard VA care. Fortunately, an effective treatment using cognitive-behavioral techniques (CBT) has been developed to ameliorate symptom-related distress and reduce unnecessary healthcare utilization. Despite convincing evidence of therapeutic efficacy, a major limitation of this treatment is that patients must attend sessions in person. This requirement may undermine the clinical effectiveness of CBT since fewer than half of those who need treatment are likely to attend. A recent trial of CBT for veterans with Gulf War Illness

found that only 38% were treatment adherent. Any sudden increase in the number of veterans seeking care could overwhelm the limited resources of a local VA healthcare center. The proposed study will address this important public health problem by testing a cost-effective and innovative strategy for delivering CBT over the phone.

Objectives:

The specific aims of the study are to: (1) Determine the clinical efficacy of Telephone CBT for veterans with GWI who are frequent consumers of ambulatory medical care; (2) Determine whether CBT for veterans with GWI leads to a reduction in the cost of VA health care; and (3) Develop a statistical model of treatment seeking in veterans with GWI who are frequent consumers of ambulatory medical care.

Methods:

Participation is limited to veterans who satisfy a validated case definition of GWI and whose utilization is at (or above) the 80th percentile. A long-term goal of the proposed research is to make specialized Telephone CBT services widely available to veterans regardless of their geographic location. A previously validated CBT program for GWI has been adapted in consultation with Dr. Charles Engel. The proposed study represents the first randomized (multicenter) trial of Telephone CBT designed to ameliorate GWI and reduce unnecessary reliance on VA health care services. A total of 150 eligible veterans will be assigned to one of three groups: (I) Telephone CBT + Customary Medical Care; (II) In-Person CBT + Customary Medical Care; or (III) Customary Medical Care only.

Findings:

Revised study procedures were developed and approved by our local IRB. CBT manual was refined and adapted for telephone use. Two postdoctoral fellows were recruited, trained in CBT, and study assessment techniques. A large pool of high utilizing veterans was identifed. Of the first 1000 veteran names, 523 were not viable after chart review (outside catchment area; medical rule out; moved; deceased; etc); of 477 remaining 147 were not reachable; 102 declined; 46 were deemed ineligible after inital screening; 49 were eligible and scheduled for psychiatric interview; thus far 20 of these have been completed and randomized to treatment.

Status:

Project is ongoing.

Impact:

Given the prevalence of symptom-based illness and the likelihood that many of those affected may seek VA medical services, there is an urgent need to develop and test more cost effective methods of reducing unnecessary utilization. The development of a telephone intervention may benefit the VA by increasing readiness to treat veterans (and civilians) in the wake of military deployment, in the event of domestic terror attacks, or in the aftermath of war. We know that deployment and especially war-related trauma lead to increased care seeking in veterans with ill-defined or symptom-based medical illness. The proposed study is expressly intended to reduce unnecessary utilization of VA services while, at the same time, preserving or improving physical function, patient satisfaction and other quality of life indicators. If found effective, the treatment can be made readily available to veterans regardless of their geographic location. Long-term benefits may also include: lower costs for medical care; improved allocation of VA resources; improved quality of life; lower levels of psychiatric morbidity; and lower risk of iatrogenic injury.

## Eligibility

Ages Eligible for Study: 18 Years - 70 Years, Genders Eligible for Study: Both

Criteria

Inclusion Criteria:

Top 20% of medical care utilizers; satisfies criteria for multisymptom illness; enrolled in the New Jersey VA Healthcare System for at least one year

Exclusion Criteria:

Psychotic disorders; Dementia or other cognitive disorders; Brain damage; Anorexia/other eating disorders Pregnancy Heart failure Cancer Chronic renal insufficiency Severe hepatic disease Active Substance Abuse/Dependence

## Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00129454
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**New Jersey**

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## More Information

Study ID Numbers: GWI 04-355
Last Updated: September 8, 2006
Record first received: August 9, 2005
ClinicalTrials.gov Identifier: NCT00129454
Health Authority: United States: Federal Government
ClinicalTrials.gov processed this record on 2006-11-24

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# Prospective Study of Veteran Health in Previously Deployed Soldiers

**This study is currently recruiting patients.**
Verified by Department of Veterans Affairs August 2006

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| **Sponsors and Collaborators:** | Department of Veterans Affairs<br>Walter Reed Army Medical Center |
| **Information provided by:** | Department of Veterans Affairs |
| **ClinicalTrials.gov Identifier:** | NCT00285246 |

## Purpose

Previous deployments like that to the Persian Gulf in 1991 produced veterans with post-deployment symptom-based health problems with no medical explanation. This was termed Gulf War illness or medically unexplained illness (MUI). If previous wars are any indication, some soldiers currently deployed to hostile areas also will return home with unexplained symptom-based illnesses. However, there is virtually no pre-war, prospective data on risk and resilience factors associated with MUI. This study will attempt to fill that gap.

| Condition | Phase |
|---|---|
| Combat Disorders | Phase I |

MedlinePlus related topics: Anxiety

Study Type: Observational
Study Design: Natural History, Longitudinal, Defined Population, Prospective Study

Official Title: Prospective Study of Functional Status in Veterans at Risk for Unexplained Illnesses

Further study details as provided by Department of Veterans Affairs:

Expected Total Enrollment: 700

Study start: December 2005; Expected completion: December 2010
Last follow-up: December 2009; Data entry closure: January 2010

Background: Previous deployments like that to the Persian Gulf in 1991 produced veterans with post-deployment symptom-based health problems with no medical explanation. This was termed Gulf War illness or medically unexplained illness (MUI). If previous wars are any indication, some soldiers currently deployed to hostile areas also will return home with unexplained symptom-based illnesses. However, there is virtually no pre-war, prospective data on risk and resilience factors associated with MUI. This study will attempt to fill that gap. Objectives: Our goals are to: (a) determine pre- and immediate post-deployment factors predicting later MUI and poor functional status, (b) improve previous methodological problems (e.g., selection bias, recall bias and lack of baseline controls) in studies of MUI, and (c) relate pre-deployment risk factors (e.g., personality, stressor reactivity) and resilience factors (e.g., coping style, social support) to post-deployment functional status. Methods: This study uses a prospective, longitudinal observational design to assess risk and resilience factors for post-war MUI in Reserve and National Guard enlisted personnel. A stratified random sample of 700 subjects will be drawn from those undergoing pre- and post-mobilization readiness processing at Fort Dix, New Jersey. Personnel will be tested pre-mobilization (Phase 1), immediately after mobilization (Phase 2) and at 3 months and 1 year post-deployment (Phases 3 & 4). Predictor variables include personality, social support, coping style, non-specific symptoms, sympathetic cardiac stress reactivity, and cortisol stress reactivity. Control variables include prior traumatic events, current distress, PTSD symptoms, socially desirable responding, body mass index, deployment experiences, environmental exposures and demographics (e.g., age, gender). Outcome variables include functional status, healthcare utilization, and MUI status (using CDC criteria for chronic multisymptom illness developed after the first Gulf War). Findings: We completed a pilot study to demonstrate the feasibility of our methods. Our pilot study showed that the procedures are feasible and the response burden is reasonable. We have recently begun collecting Phase 1 data at Fort Dix from soldiers deploying to hazardous areas. Status: Project work is ongoing. Impact: The

larger, prospective study with soldiers will help us to identify pre- and early post-deployment risk and resilience factors important in MUI, functional status, and healthcare utilization. There is an urgent need for both pre- and post-deployment predictors of later MUI uncontaminated by recall bias, and the selection bias of studying only treatment-seekers. If we are to understand how to best treat veterans presenting with unexplained symptoms, then we need to know which pre-war factors are most useful in predicting who is most likely to be resilient and who is most likely to be at risk for later unexplained illness.

## Eligibility

Ages Eligible for Study: 18 Years - 60 Years, Genders Eligible for Study: Both

Accepts Healthy Volunteers

Criteria

Inclusion Criteria:

Army Reserve and National Guard soldiers deploying to a hazardous deployment from Fort Dix, NJ

Exclusion Criteria:

There are some drug exclusions for anything that substantially affects cardiovascular function.

## Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00285246
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**New Jersey**

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Study chairs or principal investigators

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## More Information

Study ID Numbers: IIR 02-296
Last Updated: August 9, 2006
Record first received: January 30, 2006
ClinicalTrials.gov Identifier: NCT00285246
Health Authority: United States: Federal Government
ClinicalTrials.gov processed this record on 2006-11-24



Information on Research Study Enrolling Veterans of the 1990-1991 Gulf War

**The following federal research project is currently enrolling veterans who served in the 1990-1991 Gulf War. For more information contact the research team at the number below.**

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| **Study** | **"Patterns of Microarray Gene Expression in Gulf War Illness"** |
| **Location** | **Miami , FL, VA Medical Center** |
| **Purpose** | **The purpose of this research is to identify mechanisms that underlie Gulf War illnesses. The study will use recently-developed methods to identify markers potentially linked to these conditions.** |
| **Principal Investigator** | **Nancy Klimas M.D.** |
| **Study Eligibility** | • **Gulf War veterans who served in theater between 8/8/90 and 7/31/91**<br>• **Healthy veterans, as well as veterans with chronic symptoms such as fatigue, cognitive problems, and muscle or joint pain**<br>• **Male or female**<br>• **Willing to comply with study protocol, including two visits to the Miami VA Medical Center**<br>• **Local to Miami area; no travel or lodging reimbursement is** |

**provided**

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| **Compensation** | **Compensation provided for veterans' time** |
| **Contact** | **Lottie Cason, telephone: (305) 575-7000, ext.** |