

Report Date : August 16, 2000

DETAIL SUMMARY SHEET

TITLE: Demonstration Treatment Program for Gulf War Veterans

KEYWORDS: Gulf War, Gulf War Illness, Treatment, Quality of life, Health care utilization

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VA SITE: Cincinnati & Cleveland **STATUS:** ___Ongoing ___X___Complete

APPROVAL DATE: July 8, 1998
REVIEW DATE: August 22, 2000

FUNDING: **Total: \$ 700,000**

STUDY OBJECTIVE

1. To determine health-related quality of life in a group of GWVs with and without "Gulf War Illness" as defined by CDC criteria over time (Fukuda et al., 1998). Primary outcome measures will include the SF-36 and the Basis-32. The comparison time points will be at baseline, 3, 6, 12 and 18 months. It is hypothesized that veterans with Gulf War Illness will report poorer quality of life than GW veterans without the illness.
2. To longitudinally determine health care service utilization in a group of GWVs with and without Gulf War Illness over time. Health care utilization data will be collected from all study participants at the time of enrollment into the study and at 3, 6, 12 and 18 months. It is hypothesized that GWVs with Gulf War Illness will report greater health care utilization compared to those without the illness.

TECHNICAL APPROACH

The protocol and informed consent were revised on July 8, 1999. The revision was approved by the Cincinnati Veteran's Affairs Research and Development Committee on July 13, 1999 and by the University of Cincinnati Institutional Review Board on July 14, 1999. Dr. Murphy reviewed and approved of the changes in a letter dated August 9, 1999. Please find the revised protocol and informed consent enclosed as well as the letters of approval.

PRIOR AND CURRENT PROGRESS

During the past two years, one hundred and seventy-six (176) Gulf War veterans were screened in the Demonstration Treatment Project (DTP). Cleveland's clinic functions as a Gulf War primary care clinic comprised of a physician, Dr. McQuarrie, who completes the medical examination and has follow up visits with GWV patients. Psychological assessments and laboratory tests are administered by study research assistants as soon as possible following the physical examination. Information from these tests is used by Dr. McQuarrie on follow up visits with the GWVs. Cincinnati's Gulf war clinic functions as a multi-disciplinary team. Assessments are completed in an 8-hour day, or on 2 days (4-hour appointments), by a team of practitioners including a physician, nurse practitioner, psychologist, nurse care manager, and physical therapist. Any treatment recommendations for follow-up care are made in a separate appointment after this assessment.

At the Cincinnati VAMC, 122 GWVs were screened and 98 veterans were enrolled. Of these veterans, 96 were active participants and 24 withdrew from the study. Veterans withdrew from study participation for reasons including lack of interest in research (n=6), work schedule conflicts (n=5) and too far to travel for follow-up assessments (n=3). A few were excluded because they met exclusion criteria for active drug or alcohol use (n=4); current Axis I disorder other than anxiety or depressive disorder (n=4) or non-deployment to Gulf War (n=2).

At the Cleveland VAMC, fifty-four veterans were screened and forty-four have been enrolled in the DTP. No statistical difference by site emerged for rate of attrition.

Only four participants have experienced adverse events. These four veterans from Cincinnati were all hospitalized for psychiatric treatment for depressive-spectrum disorders, including bipolar affective disorder.

CONCLUSIONS

We have complete demographic data on one hundred and seventy-six (176) participants (Cincinnati n=122; Cleveland n=54). Gender distribution was similar at both sites. Eighty-nine percent (87.0% in Cleveland and 89.3% in Cincinnati) of participants were male, and about 11% (13.0% in Cleveland and 10.7% in Cincinnati) were female. The mean age (\pm standard deviation) was 36.57 ± 8.3 in Cincinnati and 40.28 ± 10.5 in Cleveland. The difference in age was statistically significant ($t=2.30$, $p<.02$). The racial composition between sites was similar. Seventy eight percent and 74.6% of participants were Caucasian and 18.5% and 20.5% were African American decent in

Cleveland and Cincinnati, respectively. The remainder of GWVs were of Hispanic, American Indian and Asian origin. One hundred fifty of the 176 participants who completed demographic data completed full medical and psychiatric assessments. Ten of the 150 veterans were excluded from enrollment based on inclusion/exclusion criteria.

Ninety-three percent (93% of n=140) of the enrolled veterans were assigned one or more medical and/or psychiatric diagnoses. Of the 130 who were ill, 59 (45%) had a medical but not a psychiatric diagnosis. The remaining 71 (55%) had both a medical and a psychiatric diagnosis as determined by both clinical interviews and structured interviews (CIDI, CAPS, Ham-D).

Of the 96 active patients in Cincinnati, 90 patients were screened for Gulf war illness by the CDC developed by Fukuda *et al.* Of the 90 screened, 77.8% met CDC criteria for Gulf War illness. The average number of symptoms reported by this group was 6.4 (Standard Deviation 2.1). In Cleveland, 44 patients were enrolled. Of these, 40 were screened for GWI by CDC criteria. 90.9% of the 40 patients screened met CDC criteria, with the average number of symptoms being 5.0 (SD 1.5). There was no statistical difference by site. We found that GWVs with GWI experienced more combat exposure, presented more clinical symptoms, and scored higher on measures of depression, PTSD, and fibromyalgia compared to GWVs without GWI.

At baseline, on a measure of health-related quality of life (SF-36), GWVs without GWI had physical component scores (PCS = 48.30) and mental health component scores (MCS = 48.23) equivalent to the national norm. Conversely, veterans with GWI had lower scores (35.84 and 37.77 for PCS and MCS respectively). Almost all GWVs with depression (94%), PTSD (100%) and fibromyalgia/chronic fatigue (100%) had GWI by CDC criteria.

We examined change in SF-36 scores from study entry (baseline) to 6-month follow-up. We have data on a total of 58 patients from both sites. We show a trend for improvement in the SF-36 sub-scale General Health (baseline mean 40.2 ± 22.7 ; 6-month follow-up 45.4 ± 26.6 ; paired t test; $t = 1.78$, $p = .078$). We show a trend for improvement in the SF-36 sub-scale Mental Health (baseline mean 58.6 ± 24.1 ; 6-month follow-up 63.6 ± 24.4 ; paired t test; $t = 1.95$, $p = .057$). When patients were classified by whether they had medical diagnoses only or medical and psychiatric diagnosis, we found that improvement in SF-36 sub-scales consistent with presenting problem. For example, in the medical sub-group, there was a statistically significant improvement in the General Health sub-scale score ($t=2.03$, $p = .05$) and in the medical + psychiatric diagnostic sub-group there was a significant improvement in the Mental Health sub-scale score ($t = 2.22$, $p = .03$).

We chose a sub-sample of questions from the VA Patient Satisfaction Survey for analysis. Questions #32, 33, 34, 52, 53, 54, 55, and 56 were selected because they pertain to the veteran's overall impression of their most recent clinic visit and to their overall impression of the clinic care in the past two months. At baseline, there were no differences between sites on patient satisfaction, however differences emerged at 6-month follow-up. Statistically significant site differences emerged on question #32 "Was the main reason you came for this visit addressed to your satisfaction?" (Responses: Yes, completely; Yes, somewhat; NO) (Fisher's Exact Test; $p = .006$) and on question #55 "VA medical care is as good as that provided anywhere?" (Responses Never or almost never; Rarely; Sometime; Often; Always or almost always) (Fisher's Exact Test;

p = .053). A statistical trend emerged for question #54 "If you could have free care outside the VA, would you choose to come here again?" (Response: Definitely would not; Probably would not; Probably would; Definitely would) (Fisher's Exact Test; p = .07). In each case, the Cincinnati site yielded higher patient satisfaction scores compared to the Cleveland site.

Within the Cincinnati site, a statistical improvement emerged for question #54 (Fisher's Exact test, p = .009) and trend on question #55 (Fisher's Exact test, p = .088). Within the Cleveland site, there was a trend toward statistical improvement for #55 (Fisher's Exact test, p = .08). These results suggest that over time, patients showed a greater preference for VA care compared to care in the private sector and a trend towards endorsing that VA care is as good as care provided anywhere else.

Service utilization was assessed via archived data measures of VA health care records that are maintained electronically for each veteran by the Veterans Health Administration in Austin, TX and Ann Arbor, MI. All clinic stops for GWVs enrolled in the DPT from the Cincinnati and Cleveland VAMC's were included. The centralized records are stored in hundreds of different files, created for each fiscal year (October through September). Data from FY98 - FY00 were analyzed for this report.

GWVs averaged 33.7 visits per year. This represents a three-fold increase in VA services compared to the average VA patient and reflects the intensive assessment and follow-up procedures of the research protocol. Visits to address medical conditions occurred two and a half times more often than visits related to psychiatric conditions. When patients were classified by whether they had medical only or medical + psychiatric diagnoses, the med + psych group showed a two and half-fold increase in VA services. Preliminary analysis suggests the med + psych group used medical services with greater frequency compared to the medical only group. Clinic stops for research purposes have been included in this data set; therefore a true estimation of health care utilization cannot be determined at this time.

In conclusion, our data suggests that Gulf War veterans seeking care at the VA because they are symptomatic. Across Ohio (VISN 10), GWVs seeking VA care are similar in demographic composition. Our preliminary findings suggest that: 1) Approximately one half of GWVs seeking treatment have diagnosable medical conditions and one half have diagnosable medical and psychiatric conditions. 2) Veterans tend to show improvement in health related quality of life when the treatment is targeted to their presenting problems. 3) A multi-disciplinary team model, which includes mental health professionals, yields slightly higher patient satisfaction scores than a primary-care model.

Enclosure 1

FY 99 CONTINUING REVIEW OF RESEARCH

INSTRUCTIONS: Please answer the following questions and sign at the bottom of the page. Give an explanation for all negative responses.

YES

NO

 X

1. Research files are being maintained by the principal investigator.

 X

2. These files are ready to be inspected as part of the continuing periodic review process as required by VHA and other federal regulations.

*see below

3. If human use, subject participation or risk has not been influenced by new developments or literature.

 X

4. If human use, the current risk/benefit ratio is about the same (or lower) as when the study was first approved.

 X

5. If human use, I have reviewed the consent form during this report period to ensure its appropriateness (give date of review:_____). The consent form has been revised and updated, if required, to meet HUC/IRB guidelines.

* The wording of this question is confusing. To our knowledge no new developments have emerged which would have influenced our subject participation or risk.

Signature

Date

PROVIDE A COPY OF THE CURRENT CONSENT FORM AND, IF REQUIRED, A COPY OF THE REVISED/UPDATED VERSION.

Enclosure 2

Report Date : August 16, 2000

FY99 LIST OF PUBLICATIONS

DIRECTIONS: List publications (P), presentations (Pr), and abstracts (A) resulting from this study. Please provide complete citations. IF THERE HAVE BEEN NONE, PLEASE SO STATE,

Presentations:

(Pr)

Baker, DG, McQuarrie, I, Murray, MG, Lund, L, Reynolds, D (1999).
Demonstration Treatment Project in Gulf War Veterans. Conference on
Federally Sponsored Gulf War Veterans' Illnesses Research, Washington, DC.

Murray, MG. (1999). Gulf War Veterans: Recent findings and ongoing research.
U.S. Food and Drug Administration and Forensic Chemistry Center, Cincinnati,
Ohio.

Baker, DG, Murray, MG, Dashevsky, BA (1999). Diagnostic Status and Health-
related Quality of Life in Gulf War Veterans with Multiple Non-specific Symptoms.
Alternative Medicine Seminar, Department of Family Medicine, University of
Cincinnati College of Medicine

Murray, MG (2000) Gulf War Veterans: Recent findings and ongoing research.
Post Traumatic Stress Disorder Program, Veteran's Affairs Medical Center,
Indianapolis, Indiana.

(P):

Baker, DG, McQuarrie, I, Murray, MG, Lund, L, Dashevsky, BA, Mendenhall, CL
(manuscript submitted to Archives of Family Medicine) Diagnostic Status and
Treatment Recommendations for Gulf War Veterans with Multiple Non-specific
Symptoms.

(A):

Baker, DG, McQuarrie, I, Murray, MG, Lund, L, Reynolds, D (1999).
Demonstration Treatment Project in Gulf War Veterans. Conference on
Federally Sponsored Gulf War Veterans' Illnesses Research, Washington, DC.

Enclosure 3: See informed consent

