Award Number: W81XWH-11-2-0063

TITLE: Effectiveness of Telerehabilitation for OIF/OEF returnees with Combat Related Trauma

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REPORT DATE: February 2012

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release; distribution unlimited

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The objectives of this proposed study are to 1) Coordinate medical care to meet the physical and mental health needs OIF/OEF veterans with injuries incurred in combat 2) Determine the immediate and sustained effects of telerehab on patient outcomes on a variety of physical, psychological and social functions over the period of the study 3) Examine the perceived benefits and limitations of telerehab from the veteran and caregiver perspectives and 4) Evaluate the effectiveness of telerehab on health outcomes and resource utilization. Study design: This 3 year study will use a randomized design to extend the present study to 1) recruit 50 veterans each at the Tampa and Miami VA hospitals divided equally among the two groups receiving telerehab and those with traditional care as controls at each site. Methods: We will utilize qualitative and quantitative analysis for evaluating changes in functional and mental health status, community participation, VA healthcare utilization, and veteran/family perceptions of telerehab.
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Purpose and scope of the research effort.

**Goals:** This is one project in a planned program of research to improve care for injured Operation Enduring Freedom/Operation Iraqi freedom (OEF/OIF) veterans. Building on the successful, currently funded, CDMRP study “Effectiveness of Telerehabilitation for OIF/OEF returnees with Combat Related Trauma”: W81XWH08-2-0091 we propose with this research to extend our analysis to evaluating the effectiveness of the telerehabilitation intervention for veterans with combat related trauma. We plan to test its effectiveness with a cohort of OIF/OEF returnees discharged from the James A Haley Veterans Hospital in Tampa, FL. (Tampa VA) and the Bruce B Carter VA Medical Center at Miami (Miami VA).

The *long term* goal of this program of research is to optimally define telerehabilitation services for all veterans with polytrauma, including accurate and efficient screening instruments, educational material for patients and families, family support, and family counseling to enhance care coordination and to maximize functional outcomes and quality of life.

Overall progress to date and problem areas

**Statement of Work**

**Obtain Institutional Review Board and conduct literature review.**

1) Modified IRB and Informed Consents for the study have been approved by the University of South Florida and the Miami VA to facilitate enrollment of subjects. All required documents for project approval have been forwarded to USAMRMC. Clearance has been obtained from HRPO (DoD) to commence our study.

**Care Coordination Team**

Our telerehabilitation care coordination team is organized under Steve Scott, MD, Chief Physical Medicine and Rehabilitation Services VA at the Tampa VA and Stuti Dang, MD at the Miami VA. Sue Brock, ARNP and Vilma Rosada, RN will be in charge of care coordination and recruitment of combat wounded OEF/OIF veterans via telerehabilitation at Tampa. Assisting her will be William Lapcevic, MSST, MPH, MCSE an expert in information technology and data management together with Steve Moore, MS, website coordinator. Andrea Spehar, JD, DM, MPH will be the project manager. Her counterpart at Miami will be Lisa Johnson-Greene. Teresita Manahan, ARNP will lead the care coordination efforts at The Miami VA.

**Data collection and Care Coordination.**

Instruments for data collection will be posted on **Surveymonkey** a commercial website that was cleared by VA Information Security at the James Haley Veterans Hospital as meeting the requirements for a secure data gathering portal. Details on Surveymonkey can be found at surveymonkey.com. Participants in the study will access the website to answer surveys which will be downloaded and maintained in SAS datasets for analysis purposes. We maintain a secure
messaging website hosted at VA WebOps that serves as the main conduit for communication between care coordinators and study enrollees. Separate “virtual rooms” have been setup on the VA server to facilitate care coordination at the two sites without compromising patient confidentiality. At least once a week communication will be initiated between care coordinators and study participants.

Body

Statement of Work

Effectiveness of Telerehabilitation for OIF/OEF returnees with Combat related Trauma.

Task 1. Administrative tasks, Months 1-3          Completed
   a. Obtain Institutional Review Board and conduct literature review.
   b. Recruit care coordinator (ARNP) and program manager at the Miami VA facility.
   c. Order computers, load software programs/survey instruments and set up web site on VA servers.
   d. Recruit veterans for the control group at the Tampa VA.

Task 2. Patient recruitment and programming, Months 3-32:     Ongoing
   1. Finalize list of all OEF/OIF returnees discharged from the Miami VA with a primary or secondary diagnosis of TBI.
   2. Contact patients who meet inclusion criterion and agree to participate in telerehab and have informed consents signed at the Tampa and Miami VA facilities.
   3. Provide access privileges to enrollees to telerehab website.

Task 3. Data Collection: Months 5-32.          Ongoing
   1. Abstract from the Veterans’ health Information Systems & Technology Architecture (VistA) medical record abstracts pertaining to health care utilization and treatments of combat wounded veterans.
   2. Abstract from the VA Decision Support System (DSS) cost estimates of VA Health Care Utilization.
   3. Obtain responses to instruments to capture function, cognition, ability, integration into society
   4. Conduct patient/caregiver satisfaction surveys and perceptions on facilitators and barriers to telerehabilitation.

Task 4. Data Analysis: Months 32-36.            To be addressed
   a. Conduct multivariate statistical analysis and economic modeling to:
      a) Determine changes in functional/cognition and community integration
b) Characterize changes in veterans with of Post Traumatic Stress Disorders.
c) Identify changes in patterns of healthcare utilization and related costs
d) Evaluate the cost effectiveness of telerehabilitation.

b. Conduct interviews to synthesize facilitators and barriers to providing telerehabilitation for TBI.

**Task 5. Report Writing and dissemination: Months 36-40**

- Prepare final report and initial manuscripts.
- Disseminate findings to the VA Polytrauma Quality Enhancement Research Imitative.
- Present findings at VA conferences.

**Baseline Surveys**

Baseline surveys were conducted to: 1) To characterize rehabilitation trajectories over time in the areas of function, cognition, psychosocial adjustment, integration into society and mental health disorders over time and 2) To individualize treatment patterns customized to each veteran's needs so as to maximize the effect of telerehabilitation.

Veterans will input responses to ten survey instruments at six month intervals including baseline. They are the Functional Independence Measure and Functional Assessment Measure (FIM/FAM); CHART, The Mayo-Portland Adaptability Inventory (MPAI-4); The Patient Health Questionnaire: (PHQ-2); The Patient Competency Rating Scale (PCRS); Short Form of the PTSD Checklist - Civilian Version (PCL-C); Short Post-Traumatic Stress Disorder Rating Interview (SPRINT); Alcohol Use Disorders Identification Test (AUDIT); and the SF-12 Health Survey will all be administered at baseline, 6-months and 12-months. The Patient/Caregiver satisfaction surveys will be conducted after six months and 12 months of continuous enrollment in telerehabilitation.

**Patient Recruitment**

A total of 24 veterans equally distributed among the intervention and control groups have been recruited at the Tampa VA. Due to late clearance from HRPO (DoD) the Miami VA site has consented 3 veterans to date. We expect to enroll our entire cohort of 50 subjects by summer 2012 at Tampa with expected completion of enrollment at Miami by the end of calendar year 2012. To date 21 Tampa subjects have completed the baseline survey instruments. Tampa VA patient demographic characteristics are presented in Table 1.
Table 1. Demographic characteristics (Tampa VA).

<table>
<thead>
<tr>
<th></th>
<th>Control Group n=12</th>
<th>Telerehab Group n=12</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td>Male, %</td>
<td>10 (83.33)</td>
<td>12 (100.0)</td>
</tr>
<tr>
<td>Female %</td>
<td>2 (16.57)</td>
<td></td>
</tr>
<tr>
<td>Ethnicity, %</td>
<td>2 (72.1)</td>
<td>5 (41.67)</td>
</tr>
<tr>
<td>Not Hispanic</td>
<td>2 (72.1)</td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>10 (24.6)</td>
<td>7 (58.33)</td>
</tr>
</tbody>
</table>

**Initial findings**

Though subjects consented were randomized a few differences exist between enrollees in the two groups in function and cognition as self reported on health questionnaires. We conducted t-tests to determine significant differences if any at baseline for all items in the survey instruments. Those in the telerehab group fared slightly better than their counterparts (p<.10) in the areas of climbing stairs and employability in the FIM + FAM and understanding instruction in the Patient Competency Rating scale. Table 2 outlines the related statistics.

Table 2. Differences between control and telerehab group at baseline.

<table>
<thead>
<tr>
<th>Scale</th>
<th>Item</th>
<th>Control (n=10)</th>
<th>Telerehab (n=11)</th>
<th>Prob</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIM + FAM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Climbing stairs</td>
<td>5.3</td>
<td>6.5</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td>Employability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCR</td>
<td>How much of a problem understanding</td>
<td>3.1</td>
<td>3.7</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>instructions</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Conclusions**

We expect to accelerate the recruitment of veterans in the coming months. However, due to delays in the procurement of clearances to conduct the research we may have to request an extension.