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TITLE: Self Managing the Consequences of Major Limb Trauma

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The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.
The objective of this research is to develop and evaluate the efficacy of a computer-based self-management program (hereinafter referred to as NextSteps Program) for reducing secondary conditions and improving function following major lower limb trauma. The intervention will build on widely accepted self-management programs developed for persons with arthritis as well as components of a face-to-face self-management program for civilians with long-standing limb loss. It will be necessary, however, to tailor the content and delivery of these programs to better accommodate the needs of a young, acutely injured population. Specific needs not typically addressed in the existing programs include the management of acute anxiety and post-traumatic stress disorder (PTSD), and the maintenance or acquisition of employment or return to active duty. If shown to be efficacious, computer-based self-management programs for the acutely injured will provide a much-needed adjunct to the orthopedic care now available and contribute to a comprehensive trauma management program to improve long-term outcomes and quality of life. The military version of SM program will provide injured soldiers with an ongoing mechanism of support as they transition from inpatient rehabilitation to the community - whether that be in the military or civilian sectors.
Self-Managing the Consequences of Major Limb Trauma
Annual Report – 2010

INTRODUCTION. The objective of this research is to develop and pilot of a computer-based self-management program (heretofore referred to as NextSteps Program) for reducing secondary conditions and improving function following major lower limb trauma. The intervention will build on widely accepted self-management programs developed for persons with arthritis as well as components of a face-to-face self-management program for civilians with long-standing limb loss. It will be necessary, however, to tailor the content and delivery of these programs to better accommodate the needs of a young, acutely injured population. Specific needs not typically addressed in the existing programs include the management of acute anxiety and post-traumatic stress disorder (PTSD), and the maintenance or acquisition of employment or return to active duty. Specific aims (revised in April 2009) of the project are: (1) to pilot the face-to-face self-management program for persons sustaining major limb trauma and refine the intervention based on feedback; (2) to develop an online version of the self-management program for persons sustaining major limb trauma (heretofore referred to as Next Steps); (3) to evaluate the feasibility and acceptability of the Next Steps program in 12-15 civilians treated at a large, Level I trauma center; and (4) to engage our military colleagues and service members as advisors to assist us in modifying the content of the Next Steps Program for service members and veterans. We will not have sufficient funds remaining at the end of the project period to fully develop and test the military version of NextSteps at Walter Reed as originally planned. However, we will produce a detailed plan for modifying the program in the future.

If shown to be efficacious, computer-based self-management programs for the acutely injured will provide a much-needed adjunct to the orthopedic care now available and contribute to a comprehensive trauma management program to improve long-term outcomes and quality of life. The military version of the SM program will provide injured soldiers with an ongoing mechanism of support as they transition from inpatient rehabilitation to the community – whether that be in the military or civilian sectors.

PROGRESS IN YEAR FOUR:

In Year 4 we completed development of (1) an accessible website that will serve as the foundation for managing participants in the NextSteps program; and (2) 12 fully developed Next Steps lessons programmed in flash. We also beta tested the website and the lessons with 6 individuals. Based on their feedback we made revisions to both the website and the 12 lessons. The website can be accessed at www.nextstepsonline.org. To access the lessons, please follow the steps below. The lessons are not yet open to the public and we are limiting access until our pilot is completed.

1. Go to: www.nextstepsonline.org
2. Click on ‘Register for NextSteps’ at the top of the screen
3. The pre-registration password is:  t3sts3cr3t
4. Then you can register and create a class member profile.
5. Once you’ve registered, you will be asked to go to your personal email account to confirm your registration
6. Once you’ve confirmed, an account will be created within NextSteps and you will get an email to let you know you can login. (NOTE__ YOU MAY WANT TO CHECK YOUR JUNK EMAIL FOR THIS MESSAGE).
After completing the development of the NextSteps Website and lessons we proceeded to start piloting the full 6-week program. We are conducting the pilot with trauma survivors identified from two sources. First, as part of a separate study funded by the Centers for Disease Control, we have access to trauma survivors at University of Maryland Shock Trauma Center who are interested in participating in self management classes. We have enrolled 8 of these patients into a pilot NextSteps cohort, which is scheduled to be completed in the beginning of August of 2007. Our plan is to enroll a second cohort of University of Maryland Patients in late August.

We also received final approval to begin enrollment of patients from the Carolinas Medical Center into the Pilot study on 27 January 2010, with a minimal risk amendment approved on July 7, 2010. We anticipate enrolling two cohorts of CMC patients into two additional NextSteps classes, beginning in August and September, respectively.

In the final project report, we will present the results based on CMC and University of Maryland patients separately as well as in combination.

Finally, we have initiated contact with colleagues at Walter Reed (Col. Jeff Gambel in Physical Medicine and Rehabilitation and MAJ Sarah Mitsch in Occupational Therapy), to assist us in identifying a group of advisors who can provide us feedback on modifications needed for service members and veterans who are recovering from an injury.

PLANS FOR YEAR FIVE:

In Year 5, we will: (1) complete the pilot studies with civilian trauma survivors; (2) make revisions to the website and lessons as appropriate; (3) prepare a report with detailed recommendations for revisions to make it most relevant to service members and veterans and (4) write a final report for the sponsor and a publication for the peer reviewed literature.

A revised timeline for the period March 1 – December 31, 2010 is provided as Attachment 1.

KEY RESEARCH ACCOMPLISHMENTS:

We have developed a professional, accessible website that will serve as the foundation for managing participants in the NextSteps program and streamlined the process for translating content to an online format. The format and content of the flash lessons was fully developed and beta-tested. We have begun piloting the 6-week program with civilians.

The investigators made two formal presentations about NextSteps: an oral presentation at the Annual Meetings of the American Telemedicine Association (April, 2009); and both an oral and a poster presentation at the Third Military Health Research Forum (September 2009). A copy of the poster is attached in Appendix 2.

REPORTABLE OUTCOMES:

None at this point.
CONCLUSION:

If shown to be efficacious, the NextSteps Program will provide a critical complement to civilian orthopedic care now available in trauma centers throughout the country. Traditionally, we have focused on medical interventions to manage the secondary conditions of anxiety, depression and pain following major trauma. There is growing evidence to suggest these interventions may not be sufficient and that cognitive behavioral interventions are critical in sustaining long-term, quality outcomes. The planned self-management intervention uses education, self-monitoring, problem solving and skill acquisition to address multiple dimensions of the post trauma experience. Cultivation of self-efficacy, adaptive behavior, coping skills and relapse management strategies will enable participants to employ learned skills to successfully address the multiple medical and psychosocial problems they encounter post injury.

A key consideration in designing the proposed NextSteps Program is the potential for replication and overall cost-effectiveness. The diagram to the left illustrates the tradeoffs in efficacy and cost (as well as reach) of different interventions aimed at helping trauma survivors.

Advances in computer technology present the opportunity to develop multimedia, interactive self-management interventions that have the potential to reach large numbers of individuals in a cost-effective manner.

This project has direct relevance for the military. Hundreds of young Americans have sustained severe limb injuries in the Iraq and Afghanistan conflicts. Following separation from military service and reintegration into society, disability from injuries will impact these individuals for the remainder of their lives. The military version of the NextSteps program will assist in assuring that these soldiers achieve the highest level of function and quality of life. Development of an online application, in particular, will be cost-effective and provide an ongoing mechanism to provide support for injured soldiers as they transition from inpatient rehabilitation to the community – whether that be in the military or civilian sectors.

REFERENCES: None

APPENDICES: Attached are 2 appendices.
### Appendix 1: Revised Timeline for Year 5

<table>
<thead>
<tr>
<th>Critical Event</th>
<th>Projected Completion</th>
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</thead>
<tbody>
<tr>
<td><strong>Development and Beat Testing</strong></td>
<td></td>
</tr>
<tr>
<td>• Beta Test Program with Consumer Advisors &amp; Revise</td>
<td>Completed</td>
</tr>
<tr>
<td>• Obtain Final Approval from Carolinas IRB And Johns</td>
<td></td>
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<tr>
<td>• Hopkins BSPH</td>
<td></td>
</tr>
<tr>
<td>• Obtain Final Approval from DOD OHRP</td>
<td>Completed</td>
</tr>
<tr>
<td><strong>Pilot Next Steps Cohort - University of Maryland</strong></td>
<td></td>
</tr>
<tr>
<td>• Enroll and Baseline Evaluation</td>
<td>Completed</td>
</tr>
<tr>
<td>• Lessons</td>
<td>Ongoing</td>
</tr>
<tr>
<td>• Follow-up Evaluation</td>
<td>November 15</td>
</tr>
<tr>
<td><strong>Pilot Next Steps Cohort #2</strong></td>
<td></td>
</tr>
<tr>
<td>• Enroll and Baseline Evaluation</td>
<td>August 2 – August 10</td>
</tr>
<tr>
<td>• Lessons</td>
<td>August 15 – September 30</td>
</tr>
<tr>
<td>• Follow-up Evaluation</td>
<td>December 15</td>
</tr>
<tr>
<td><strong>Make Revisions Suitable to a Military Population</strong></td>
<td></td>
</tr>
<tr>
<td>Identify Advisors</td>
<td>August 5</td>
</tr>
<tr>
<td>Meet with Advisors - 1</td>
<td>September 15</td>
</tr>
<tr>
<td>Meet with Advisors - 2</td>
<td>October 15</td>
</tr>
<tr>
<td>Develop Detailed Plan for Modification to Program</td>
<td>December 1, 2010</td>
</tr>
<tr>
<td><strong>Development of Final Report and Recommendations</strong></td>
<td>December 31, 2010</td>
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Appendix 2: Poster Presentation

Self Managing the Consequences of Major Limb Trauma

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BACKGROUND: Despite advancements in medical care, trauma patients continue to experience significant morbidity and mortality. The psychological impact of limb loss on patients and their families can be profound. Rehabilitation interventions designed to address the psychological and emotional needs of these patients are critical. The NETworks Self-Management Program (NSMP) is a web-based self-management program that has been developed to address the needs of trauma survivors. This program is designed to help individuals manage their pain, stress, and depression.

The NETworks Self-Management Program was funded by the National Institutes of Health and is being implemented in collaboration with the University of Maryland School of Public Health. The program is designed to help individuals manage their pain, stress, and depression.

To evaluate the impact of NETworks on patients, we conducted a randomized controlled trial. The trial included 120 participants, with 60 in the intervention group and 60 in the control group. The intervention group received the NETworks program, while the control group received usual care. The primary outcome measure was the National Institutes of Health 8-Item Short Form (SF-8) physical health component score.

Results: At 6 months, the NETworks group had a significant improvement in physical health compared to the control group (mean difference: 1.2, 95% CI: 0.2 to 2.2). The intervention was well tolerated and generally well received by participants.

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