

AD_____

Award Number: W81XWH-06-1-0343

TITLE: Self Managing the Consequences of Major Limb Trauma

PRINCIPAL INVESTIGATOR: Ellen J. MacKenzie, Ph.D.

CONTRACTING ORGANIZATION: Johns Hopkins University
Baltimore, MD 21205

REPORT DATE: March 2008

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

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.

REPORT DOCUMENTATION PAGE				<i>Form Approved</i> OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 01-03-2008		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 3 FEB 2007 - 2 FEB 2008	
4. TITLE AND SUBTITLE Self Managing the Consequences of Major Limb Trauma				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-06-1-0343	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Ellen J. MacKenzie, Ph.D. E-Mail: emackenz@jhsph.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Johns Hopkins University Baltimore, MD 21205				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The objective of this research is to develop and evaluate the efficacy 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. 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.					
15. SUBJECT TERMS Self Management, Trauma, Online Learning					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)
			UU	15	

Table of Contents

	Page
Introduction.....	3
Body	3
Task 1.....	3
Task 2.....	4
Task 3.....	4
Task 4.....	4
Task 5.....	4
Task 6.....	4
Task 7.....	4
Task 8.....	4
Task 9.....	5
Key Research Accomplishments.....	5
Reportable Outcomes	5
Conclusion	5
References	n/a
Appendices	7
Appendix 1: Interview Outline.....	7
Appendix 2: Lesson Outline	13

Self-Managing the Consequences of Major Limb Trauma Annual Report

March 2008

INTRODUCTION. The objective of this research is to develop and evaluate the efficacy 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 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 48-60 civilians treated at a large, Level I trauma center; and (4) to modify the Next Steps program for application in the military and to pilot the program in a group of 24 injured soldiers treated at Walter Reed Army Medical Center. 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.

BODY OF THE REPORT: ACCOMPLISHMENT OF YEAR TWO TASKS: Nine tasks were proposed for Year 2 of the project. These tasks relate to specific aims one and two of the research, namely piloting the in-person NextSteps Program intervention and the development of the online version. We have accomplished all of these goals during this project period.

Below we review the status of each task for Year 2 as outlined in our revised Statement of Work:

Task #1: Conduct 2nd Pilot of In-Person NextSteps Course. This task has been completed. The lesson content was originally developed and piloted (in person, face to face) in collaboration with the American Trauma Society (with seed funding made available through our Center for Injury Research and Policy). A first pilot revealed that too much information was covered and that the program had shortcomings pertaining to the ability to address the needs of participants who had sustained a mild traumatic brain injury (TBI). Although the intervention is NOT designed to be used with individuals with a major TBI, given the high prevalence of mild TBI (among those sustaining major limb trauma), we decided to re-design the intervention with this group in mind. The revised version was tested in a group of patients in March-April of 2007 and met with positive feedback.

Task #2 Develop Template for First Lesson. This task is completed. In translating the in-person version to the online version, a comprehensive catalogue of teaching techniques was developed, including XML-generated interactive slide lessons with audio, the ability to store and track participant responses, video testimonials, feedback forms at the end of lessons, ability to generate feedback based on algorithms, and PDF workbook generation compiling participant responses. This catalog was used to create static design layouts for the lessons and is now being programmed in flash. These templates serve as the model for all lesson-building and their development has accelerated the conversion of in-person content to the online format.

Task #3: Develop database to interact with lessons. This task is completed. Using an in-house programmer and in consultation with CommandCreate Design, the following database elements have been created and built:

- Password registration for study participants to enter the site
- User Login and Registration functionality to sign into the NextSteps site
- Contact Form on Participant Login site
- PHP-based Learning Management System
 - o Personal Announcements on NextSteps Home Page
 - o Course Dates for individual participants
 - o Comparative graphic of course progress versus individual's progress
 - o PDF Workbooks generated for Lesson and Workbook pages
 - o PHP-based Chat
 - o PHP-based Message Board
 - o Class list generated from Message Board with user names/nicknames and profiles
 - o Wordpress-based Private Journal

Task #4: Select Web-Designer. This task is completed. CommandCreate, run by Michelle Williamson, has been selected as our web designer and builder. Please see attached resume and scope of work.

Task #5: Develop Content for Website. This task is completed. All wireframes for website content have been completed, including text for each page, and approved by the project team. (Attach snapshots of “outside” info?)

Task #6: Complete Outline of Lesson Content for All Modules. This task is completed. This document is serving as a resource as online content is developed. (Appendix 1)

Task #7: Design website look, layout, community. This task is completed. CommandCreate has completed wireframes and design for every page of the website that supports the online learning modules where the course is delivered. Pages have been sent for production and a live site is expected to be delivered by March 31, 2008.

Task #8: Develop Survey Instrument. This task is completed. Please see attached outline (Appendix 2). The instrument will be piloted in April of 2008.

Task #9: Translation of Content to Web-Based Application. This task is in-process. Four of nine modules are complete; all modules will be complete by June. Once content has been converted to the online format, Flash/SML Production will begin.

KEY RESEARCH ACCOMPLISHMENTS:

Our *Consumer Advisory Committee*, consisting of 5 individuals who have sustained an injury and who participated in the face to face self-management pilot at Inova Fairfax Hospital met once during the year to provide guidance on the direction we were taking the program. They will continue to work closely with the investigators in reacting to various components of the web based program and will assist us in assuring it meets the needs of the consumer. They have already provided valuable ad-hoc feedback on name/logo selection and page layout. This committee will continue to meet face to face 1-2 times over the next year, although the majority of the communication with the Consumer Advisory Committee will be via the web and telephone conferencing as this group tests each module developed for the program.

The study design has been refined based on input from our scientific advisory committee. Given we underestimated the time needed to fully develop the web-based intervention, we will limit our evaluation to a smaller group of civilian trauma survivors (48-60). Data collected from these survivors on usability and satisfaction will provide valuable information in planning to test the intervention in a randomized controlled trial. We have established a relationship with Carolinas Medical Center, a high-volume, Level I trauma center located in Charlotte, North Carolina. Patients with major lower-extremity trauma will be consented into the study and referred to the Next Steps Program Coordinators. Outcome data will be collected at baseline (before the start of the intervention), after completion of the program, and 3 months following the end of the program. All assessments will be administered by telephone interviewers based at Johns Hopkins.

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.

REPORTABLE OUTCOMES:

Based on our work this year, by the end of Year 3, we will have a fully-functioning website and our first cohort of participants will be consented into the study.

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. 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. While there is a growing body of literature that supports the potential cost-effectiveness of such programs, the planned trial utilizing an online SM intervention is critical to establish the efficacy of this class of intervention in persons with acute limb trauma.

Year 2 was a critical year to developing a foundation for the launch of such a trial. We have tested the technology that will facilitate an interactive program and developed a platform that provides a simple, attractive way for program participants to form personal relationships with classmates and enhance their online learning experience. The lesson development is well underway and will provide the final piece of the intervention.

In the coming year, we will complete website development, test the intervention in two cohorts at Carolinas Medical Center, convene an advisory committee tasked with adapting the program to a military population, and begin enrollment of patients from Walter Reed Army Medical Center. We will also gather baseline data on all participants and follow-up data from the first cohort of civilian patients. Through a no-cost extension of nine months, we will complete data collection on civilian participants, run the program with a military cohort and collect follow-up data, and analyze results.

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: Lesson Outlines

Week One – Lesson One – Intro to SM

- Welcome
- Road to Recovery – graphic
- Survivor video – how did SM help them
- Checklist - Identifying Problems
- Visualization

Week One – Lesson Two – Intro to SM

- Check in on activity from end of last session (list ways you want this course to help you move down).
- Flip Chart – What have you done to keep yourself healthy?
- Slides – Patients and Family as Health Care Workers (WS 1.2)
- Scientist video – Benefits of SM in layman's terms
- Flip Chart – Think about something you accomplished something on your own? Share what it was and how it made you feel. Split screen – flip chart and video of survivor describing experiences.
- Home Activity
- Visualization

Week Two, Lesson One – Goal Setting

- Check in on home activity
- Survivor example – problems currently facing related to injury
- Opportunity to enter text box – their main problems
- Slides with text – problem = challenge; goal setting = way to move towards solving problems
- Slides – Goal Setting (specific, measurable, realistic)
 - Animation of example – state problem, possible solutions, let learner check off each solutions are specific, measurable, and realistic
 - Short worksheet for practice (Goals R Us)
- Slides – Introduce Confidence Scale
- Group video – rating confidence levels
- Home Activity – Turn previous challenge (populate with their problems id'ed before) into goals. Share next session.
- Visualization

Week Two, Lesson Two – Problem Solving

- Check in on home activity
- Slides - Explain SOLVED
- Survivor example – how did problem solving help?
- Activity – put steps in correct order
- Go through PS steps
 - Animation of example
- Activity – PS steps for 2-3 goals (quit smoking, go on vacation, etc)
- Home Activity
- Visualization

Week Two, Lesson Three – Effective Communication

- Check in on home activity
- Slides explaining “I” statements
 - Two video examples of same scenario, one with “you” one with “I” statements
- Activity – WS 2.6 – Turn “I” into “You” statements
- Group video - Why is it hard to ask for help, say no to requests, express gratitude etc
- Survivor story – what was hard for them
- Slides introducing the 4 types of communication styles, with video examples of each one.
- Home Activity
- Visualization

Week Three, Lesson One – Taking Stock of your Health and Health Habits

- Check in on home activity
- Slides – Introduce “Healthy Me”
- Exercise – Taking stock of your Health and Health Habits (WS 3.1)
 - Group video - have group members discuss answers to each of these
 - Note: May need pop up boxes with more explanation, or a “help me” link to email questions
- Slides – summarize what we learned about health changes following traumatic injury
- Expert video – general description of biopsychosocial model
- Home Activity
- Visualization

Week Three, Lesson Two – Health Care Access and the Insurance System

- Check in on home activity
- Slides – Health care access
- Survivor stream – share experience, with positive, negative aspects of experience. Have “notes” appear from their testimony on common themes from problems and positive responses
- Flip chart – ask them to contribute positive or negative experiences with health care system.
- Slides – review of common health problems following trauma – general
- Home activity
- Visualization

Week Three, Lesson Three – Common health problems

- Check in – flip chart to get people’s responses to how health problems can be seen as challenges
- Slides – Describe pain
- Activity – take pain scale – if above level, refer to extra set of slide summarizing WS 3.3
- Slides – Describe sleeplessness
- Activity – respond to sleep questions. If sleep a problem, refer to extra set of slides summarizing WS 3.4

- Slides – describe inactivity and exercise
- Activity – respond to exercise questions. If exercise a problem, refer to extra set of slides summarizing WS 3.5
- Slides – Describe substance problems
- Activity – substance abuse screener questions – if a problem, refer to extra set of slides summarizing WS 3.6
- Group video - complete SOLVED worksheet to develop a plan to start improving health during this week. Participants share goals on flip chart
- At home activity
- Visualization

Week Four, Lesson One – Common Psychological Reactions After Traumatic Injury

- Check in
- Slides – describe some of the changes in feelings since the injury – populate flip chart with positive and negative things
- Group video – group members list positive, negative changes - instructions should include that these can be emotions, social consequences, physical symptoms, or spiritual experiences
- Slides – point out that there are shared and different experiences
 - o Use chat to address myths that come up, making sure not to promote them
 - o Describe emotional responses to injury
- Expert video – Describe symptoms of major depression
- Activity – review WS 4.1 – give instructions re: what qualifies as major depression
- At Home Activity
- Visualization

Week Four, Lesson Two – Grief, Anxiety, and Resilience

- Check in
- Slides – remind group of some of the things people listed feeling in last session
 - o Describe feelings of grief people may have
 - o Acknowledge anger
 - o List resources
- Survivor – Describe feelings of anger and grief following trauma
- Slides – resilience
- Video class – discuss and list things that have helped you bounce back, respond to ones other people listed that you have also done
- Video class – list things that help you manage negative emotions
- Summarize
- At home activity
- Visualization/Relaxation

Week Four, Lesson Three – The PARTS approach and Increasing positive emotions

- Check in
- Slides – Introduce PARTS
- Survivor – describe PARTS
- Slides – Link PARTS and SOLVED – give example and animate analysis
- Slides – Increasing positive emotions

- Video Class – describe a positive emotion after trauma populate flip chart – how can positive emotions help us?
- Activity – WS 4.3 give example of survivor's
- Flip chart - what has worked for you to make you feel good emotionally?
- Slides – Tools for Mood Management
 - o Timeline
 - o Mood Journal
- Home activity
- Visualization/Relaxation

Week Five, Lesson One – Understanding Stress Reactions

- Check in
- Slides – difference between fear and anxiety
- Expert video – describe stress response, PTSD
- Group video – discuss how PTSD and severe anxiety affect a person – participant has opportunity to add to flip chart
- Slides – the anxiety cycle and tools to break it
- Survivor video – value of using daily thought record
- Activity
 - o Opportunity to be introduced to DTR, fill out a section
 - o Link between roles of thinking in eliciting anxiety and avoiding in maintaining anxiety
- Home activity
- Visualization/Relaxation

Week Five, Lesson Two – Relaxation: 3 exercises

- Check in
- Slides – rationale for relaxation to break anxiety cycle
- Practice 2 relaxation activities
 - o Present sensory focusing
 - Sight
 - Touch
 - Sound
 - o Diaphragmatic Breathing Exercise
- Home activity
- Visualization/Relaxation

Week Five, Lesson Three – Realistic Thinking

- Check in
- Group video – reflect on what situations provoke anxiety, thoughts surrounding these situations. What magnifies, minimizes pain?
 - o Survivor adds comments to flip chart
- Slides – Helpful and Unhelpful thinking
 - o Review WS 5.6 – common types of negative self-talk
- Expert video - catastrophizing
- Practice daily thought record
- Home activity

- Visualization/Relaxation

Week Six, Lesson One – Getting Back on Track – Where do you want to be?

- Check in
- Group video – what were you doing before your injury? Participant adds activities to flip chart.
- Slides – goal setting to return to usual activity
- Expert video – getting back on track
- Practice setting goals
- Home activity
- Visualization/Relaxation

Week Six, Lesson Two – Barriers to Getting Back on Track

- Check in
- Group video – Explore Challenges and Resources. Participant adds activities to flip chart.
- Slides – review problem solving approach
- SOLVED activity, drawing from previous goals
 - o List interim steps
 - o List challenges
 - o Problem solve challenges – work on this in chat
- Home activity
- Visualization/Relaxation

Week Six, Lesson Three – Applied Communication

- Check in
- Slides – review types of communication with video examples
- Survivor video (3) – experiences communicating with co-workers following injury; experiences looking for work following injury; experiences going back to school following injury
- Activity – Convert work-related “you” statements to “I” statements”
- Group video – Review “Say what you mean” activity
- Home activity
- Visualization/Relaxation

Week Seven, Lesson One – Employee and Employer Rights and Responsibilities

- Check in
- Slides – Importance of returning to UMA, resources available (legal and disability)
- Expert video – ADA policy
- Slides – Skills related to Return to Work
 - o Maintain contact with employer (good and bad voicemail message examples)
 - o Asking for/Pursuing job leads
 - Video class discussing networking, job leads
 - o Preparing for Job Interview
- Slides – Looking at the big picture and big goals (Chat topic)
- Home activity
- Visualization/Relaxation

Week Eight, Lesson One – Social Support and Unhelpful Support

- Check in
- Slides – Social health
- Expert video – importance of social support to recovery
- Video Class – Discussion of social roles
 - o Participant completes WS 8.1
- Slides + Activity – walk participant through WS 8.2 “Taking stock of Social Roles and Health”
 - o Role, Help Given and Help Received Pre Injury
 - o Help Given and Help Received Currently
 - o Unhelpful aspects of Current Relationships
- Home activity
- Visualization/Relaxation

Week Eight, Lesson Two – Core Beliefs

- Check in
- Slides – Core Beliefs – what is the difference between core beliefs and social roles?
- Video Class – Discussion of core beliefs in WS 8.4
 - o Participant adds core beliefs
- Slides – Impact of Trauma on Core Beliefs
 - o Participant completes exercise re: how core beliefs have changed since injury
- Slides – the importance of Goal Setting for our Social Health
- Home activity
- Visualization/Relaxation

Week Nine, Lesson One – Staying on Track

- Check in
- Video Class – Affirmation
- Slides congratulating achievement
- Slides – tips for staying on track
 - o Managing setbacks
 - o Staying on track
 - o Warning signs and Red Flags
 - o Getting back on track
- Visualization/Relaxation

Appendix 2: Interview Outlines

In-Hospital Assessment

Items	Measures
Section Two	
1-4	Internet Access
5	Date of Birth
Section Two	
1-2	General Health Status Pre-Injury
Section Three	
1-20	CES-D
Section Four	
1-12	Social Support (MPSS)
Section Five	
1-3	Occupation (Usual Major Activity)
Section Six	
1-6	Single Statement Stages of Change Questionnaire
Section Seven	
3-11	Demographics

Pre and Post Telephone Interview

Items	Measures
Section One	
1-2	General Health Status
3-8	Other Support Group Participation
Section Two	
1-7	Chronic Pain Grade Scale
Section Three	
1-5	Self-Efficacy of Pain Scale
Section Four	
1-10	Measure of Coping Mechanisms
Section Five	
1-40	S-MFA
Section Six	
1-20	CES-D
Section Seven	
1-10	Positive Affect Schedule
Section Eight	
1-9	General Self-Efficacy Questions
Section Nine	
1-13	Patient Activation Measure
Section Ten	
1-6	Single Statement Stages of Change Questionnaire
Section Eleven	
1-18	Body Symptom Index Anxiety Scale
Section Twelve	
1-17	PTSD Checklist
Section Thirteen	Post Only
1-6	Satisfaction with NextSteps
Section Fourteen	
1-4	Usual Major Activity