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Award Number: W81XWH-06-1-0343

TITLE: Self Managing the Consequences of Major Limb Trauma

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CONTRACTING ORGANIZATION: Johns Hopkins University Baltimore, MD 21205

REPORT DATE: March 2009

TYPE OF REPORT: Annual

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

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Form Approved REPORT DOCUMENTATION PAGE 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) 2. REPORT TYPE 3. DATES COVERED (From - To) 1 March 2009 Annual 3 FEB 2008 - 2 FEB 2009 4. TITLE AND SUBTITLE 5a. CONTRACT NUMBER 5b. GRANT NUMBER Self Managing the Consequences of Major Limb Trauma W81XWH-06-1-0343 **5c. PROGRAM ELEMENT NUMBER** 6. AUTHOR(S) 5d. PROJECT NUMBER Ellen J. MacKenzie, Ph.D. 5e. TASK NUMBER 5f. WORK UNIT NUMBER E-Mail: emackenz@jhsph.edu 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) 8. PERFORMING ORGANIZATION REPORT **NUMBER** Johns Hopkins University Baltimore, MD 21205 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) 10. SPONSOR/MONITOR'S ACRONYM(S) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012 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 selfmanagement 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

17. LIMITATION

OF ABSTRACT

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18. NUMBER

15

OF PAGES

Self Management, Trauma, Online Learning

b. ABSTRACT

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16. SECURITY CLASSIFICATION OF:

a. REPORT

19a. NAME OF RESPONSIBLE PERSON

19b. TELEPHONE NUMBER (include area

USAMRMC

code)

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Self-Managing the Consequences of Major Limb Trauma Annual Report

April 2009

INTRODUCTION. The objective of this research is to develop and pilot of a computerbased 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 on 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. We requested and received a no cost extension to complete the study.

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.

ACCOMPLISHMENT OF YEAR THREE TASKS:

In Year 3 we had planned to (1) complete the translation of content to the Web based application; (2) complete development of the website for accessing lessons; (3) pilot the Next Steps Program with survivors treated at Carolinas Medical Center; and (4) revise the content of the lessons to be more specific to military needs. We are significantly behind schedule due to the unanticipated complexities and cost of translating the self management lessons to an on line format. Nevertheless, we have made substantial progress towards meeting the overall goals of the project. The last 6 months were largely devoted to compressing the number of lessons to 6 weeks (12 lessons) from 8 weeks (16 lessons) - based on input from our consumer advisors; completing the scripts for all 12 lessons and producing videos to be embedded in the lessons; completing the development of graphic elements for the lessons; recording the narration for each lesson; and programming lessons in flash. To facilitate the programming of all lessons into flash (and facilitate the development of similar programs in the future, including the version of NextSteps for the military) we have developed a generic *Course Builder*. This course builder will significantly reduce the time and effort needed to translate lessons into an on-line format. Although to

date we have only translated lessons 1 and 2, we anticipate that the development of the remaining 10 lessons will proceed quickly and be completed by August 1.

Because of the unanticipated cost and time involved in developing the web based NextSteps program, we are asking for a no cost extension until March 1, 2010. We are also proposing a change in scope of work. Specifically, we are asking that (1) the pilot of Next Steps be reduced in size to include 12-15 survivors instead of the 48 survivors as originally planned; and (2) we 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 test the military version of NextSteps at Walter Reed as originally planned.

Also, please note Dr. Renan Castillo (<u>rcastill@jhsph.edu</u>) has been added to the study team as the Project Director and Co-investigator.

A revised timeline is attached (Appendix 1). We are asking for a no cost extension until March 1, 2010 to complete all tasks.

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 reviewed with the CDRMP on March 30, 2009. A copy of the slides for this presentation are attached.

The investigators will be making two presentations about NextSteps in the coming months at the Annual Meetings of the American Telemedicine Association (April, 2009) and at the Third Military Health Research Forum.

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. 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.

Year 3 was a critical year in the development of the on-line program. The lesson development is well underway and will provide the final piece of the intervention. In the coming year, we will complete the lessons and pilot the intervention in two cohorts at Carolinas Medical Center, and convene an advisory committee tasked with adapting the program to a military population.

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 IV

Critical Event	Projected Completion
Website Development	
Complete XHTML Production	July 1, 2009
Develop Chat Functionality	July 1, 2009
Ruby on Rails Prduciton	July 1, 2009
Lesson Development	
Complete Videos	May 30, 2009
Complete Recording of Narration for all Lessons	June 15, 2009
Complete Course Builder	May 15, 2009
Complete Interactive Flash Programming – Lessons 1-3	June 15, 2009
Complete Interactive Flash Programming – Lessons 4-6	August 1, 2009
Beta Test Program with Consumer Advisors & Make	September 15, 2009
Revisions	
Pilot Next Steps in Civilian Population	
Obtain Preliminary Approval from Carolinas IRB	Completed
Obtain FINAL Approval from Carolinas IRB and DOD	September 15, 2009
Screen Eligible Patients in Trauma Centers	October 1, 2009
Enrollment and Baseline Assessment	November 1, 2009
Analysis and Recommendations	January 15, 2010
Make Revisions Suitable to a Military Population	
Convene Advisors	October 15, 2009
Make Recommendations for Changes to Program	February 15, 2010
Development of Final Report and Recommendations	February 28, 2010



Development of NextSteps: An On-Line Self Management Program for Trauma Patients

Update for Congressionally Directed Medical Research Programs October, 2009

A Partnership . . .

- Johns Hopkins Schools of Medicine and Public Health
- Command Create
- Bricka Bracka
- The American Trauma Society

Our Survivor and Family Advisors:



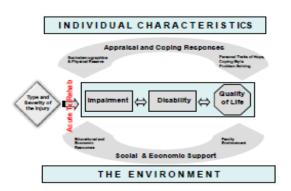


- Robert G. Baldassari (from Fairfax, VA)
- Adam Biomberg, MD (from Boston, MA)
- Brenda Breitenbach (from Severna Park, MD)
 Pam Bryan (from Madison, TN)
- 6.000 mag
 - Sherry Chapman (from Coventry, CT)
 Carrie Krug, DPT (from Baltimore, MD)
 - Scott Shields, M.B.A. (from Upper Mariboro, MD)
 - Steve Wilkinson (from Mlami, FL)









Opportunities for Improving Outcomes

- Self management (SM) Programs target these mutable characteristics using cognitive behavioral interventions
- Shown to be efficacious and have gained widespread application in arthritis and other conditions for which pain and disability common, but . . .
- Not customized for specific needs following trauma

Self Management Interventions

- 6-8 weekly group sessions facilitated by a trained group leader
- > Emphasis in each session on:
 - > Knowledge Acquisition
 - > Problem Solving
 - > Skill acquisition
 - Self Monitoring
 - > Identifying and Building on Strengths

Self Management Programs

Core Value of Patient Centered Care



- ✓ Empowers patients to become active participants in their own care
- ✓ Patients (along with their care providers) are held accountable for good outcomes

Self Management for Amputees



- Course developed in collaboration with the Amputee Coalition of America (and funded by CDC)
- Evaluated in a RCT: 50 peer support groups (450 people) were randomized
- Now being implemented by the ACA and at Walter Reed

Arch Phys Med and Rehabil 90(3):373, 2009.

Self Management for Trauma Survivors nextsteps -_



- Focus on prevention of secondary conditions
- · Emphasize return to work
- Acknowledge high prevalence of acute anxiety and PTSD
- Integrated into the Trauma Survivors Network - TSN

The Trauma Survivors Network

http://www.traumasurvivorsnetwork.org

The TSN is designed to help trauma patients and families survive, connect and rebuild



- Access to practical, every-day information
- ✓ Keep family members in the loop
 ✓ Join an on-line community forum
- ✓ Sign up for peer visitation, peer
- support group or NextSteps classes

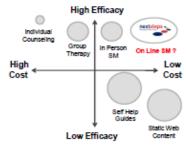
 ✓ Give back: volunteer and contribute

Extending our Reach: Online SM Programs

- SM works . . . but often difficult to access services due to limited program availability and practical barriers such as transportation, timing of classes
- Web based interventions can overcome these barriers & provide convenient access to expert information and cognitive behavioral therapies supported by on line communities
- Growing literature supports the benefits, but more research is needed to firmly establish their efficacy
- Low cost, good reach . . . potentially high efficacy!

Relative Advantages of Interventions Designed to Modify Behavior

Adapted from www.healthmedia.com



On line SM Programs Challenges . . . Opportunities

- Wide range of participant needs ... web based platform allows for tailoring
- Participants at varying levels of computer selfefficacy . . . Also have access to wide range of hardware/connectivity
- Engaging survivors & maintaining their active participation on line vs. in-person
- High cost of producing materials to meet the needs of the young, computer savvy crowd
- · The cutting edge is moving fast!



- Online, interactive <u>SM Lessons-</u> 2 per week for 6 weeks
- 2. Ongoing Support Services
 - One-on-one telephone orientation to program
 - Weekly on-line chats among class participants, facilitated by a SM Coach
 - · Electronic bulletin board monitored by coaches
 - Computer and telephone based "help" desks
- 3. Access to Resources
 - · Toolbox, workbook, private journal



6 Weeks 12 Lessons



Lesson Content

Week 1: Taking Stock	Explore where you are on the Road to Recovery. Learn more about self management and the importance of being a self-manager. Improve your communications skills and begin to practice relaxation
Week 2: Moving Forward	Learn about problem-solving. Identify problems, turn them into goals you can reach, and learn how to tell if you are making progress.

Lesson Content

Week 3: Managing Your Emotions 1	Learn the differences between normal emotional ups and downs following an injury and major depression. Discover new ways to improve your mood.
Week 4: Managing Your Emotions 2	Focus on the body's natural stress response and anxiety. Learn how you can change your thinking to improve your health. Discover new relaxation techniques to deal with physical symptoms of stress.

March 30, 2009 3

10

Lesson Content

Week 5: Family and Friends Learn to identify helpful and unhelpful help. Focus on how your injury impacts your family and friends. Learn about Caregiver Stress and how you can help others manage challenges they are facing. Week 6: Looking Ahead Think big and explore your hopes and dreams. Discover how to manage setbacks and celebrate your success in NextSteps.

Format of Lessons is Standardized

- Welcome and Objectives
- · Focus of this Week's Chat
- · Opportunity to Review Last Lesson
- Review Practice Activity from Last Lesson
- · Self Check- In with Feedback

LESSON CONTENT

- Take Home Message
- · Home Exercise
- · Relaxation Exercise

Learning Techniques Used

- 1. Interactive Didactics
- 2. Self Monitoring with Feedback
- 3. Videos
 - Survivor stories
 - Expert videos
 - Video demonstrations
 - Relaxation videos
- 4. Take Away Activities

Progress to Date - Overall Tasks

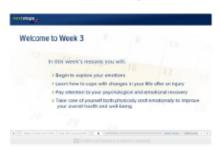
Website Development	
Wireframing	×
Graphic Design	×
XHTML Production	
Ruby on Rails Production	
Develop Learning Management System	×
Develop Online Community	×
Develop Chat	
Lesson Development	
Develop Course Builder	×
Build Editor for Lessons	×
Beta Testing	
Pliot Testing	
Modify for Application to Military	

Progress to Date - Lesson Specific

	WEEK							
	1	2	3	4	6	8		
Develop Content	×	×	×	×	×	×		
Identify and Design Active Learning Activities	×	×	×	×	×	×		
Write Lesson Scripts	×	×	×	×	×	×		
Record and Edit Audio	×							
Produce Videos	×	×	×	×	×			
Develop Wireframes	×	×	×	×	×	×		
Develop Graphic Elements	×	×	×	X	×	×		
Develop Interactive Flash Movies w/ Audio (XML)	×	×	×	×	×	×		



Welcome and Objectives



Subject of this Week's Chat



Opportunity to Review Previous Lesson



Review Practice Activity



Self Monitor HOW You are Doing



Feedback



Monitor WHAT You are Doing



Monitor WHAT You are Doing



Didactic Material



Survivor Stories
Illustrating Key Messages



Exercises - Fill In



Flip Chart Option



Summary and Feedback



Self Screening – e.g. for Depression



Feedback



Fact or Fiction



Fact or Fiction



Expert Videos



Tools



Putting it Into Practice



Relaxation



Pulling it all Together VIEW LESSON 1 'On-Line'



Timeline for Remaining Activities



Timeline for Remaining Activities

	WEEK					
	1	2	3	4	6	8
Develop Content	×	×	×	X	X	X
Pilot and Obtain Consumer Input	×	×	×	X	X	×
Identify and Design Active Learning Activities	×	×	×	×	X	×
Write Lesson Scripts	×	×	×	×	X	×
Record and Edit Audio	×	APRIL				
Produce Videos	×	×	×	×	×	AP
Develop Wireframes	×	×	×	X	X	×
Develop Graphic Elements	×	×	×	×	×	×
Develop Interactive Flash Movies w/ Audio (XML)	×	APRIL - JULY				