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TITLE: MORE Resiliency in the Rehabilitation of Active Duty Service Members

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## **1. INTRODUCTION:**

The overall objective of this multicenter prospective study is to develop and validate a standardized measure to objectively assess resiliency following neuromusculoskeletal injury. The measure will be specifically tailored to the injured Service Member. Results from the proposed study will provide an evidence-based resiliency instrument that can be integrated into rehabilitation care in the military setting with the end goal of improving rehabilitation outcomes.

This study has 4 specific aims: 1) To select items for a resiliency instrument that address multiple dimensions of resiliency for active duty military Service Members 2) To perform a pretest of the resiliency instrument in active duty military Service Members with lower-extremity injury for item reduction 3) To determine the reliability and construct validity of a resiliency instrument in active duty military Service Members with lower-extremity injury 4) To determine the predictive validity of a resiliency instrument in active duty military Service Members with lower-extremity injury 4) To determine the predictive validity of a resiliency instrument in active duty military Service Members with lower-extremity injury 4).

This project will leverage the infrastructure of the Maximizing Outpatient Rehabilitation Effectiveness (MORE) study that is currently being funded by the Bridging Advanced Developments for Exceptional Rehabilitation Consortium (W81XWH-11-2-0222). We propose a three-phase design. In Phase 1, we will identify the most relevant resiliency items to active duty Service Members by conducting interviews and focus groups with individuals who are currently enrolled in the MORE study (up to N=44). In Phase 2, pre-testing will be conducted to refine and eliminate items that perform poorly (N=60). In Phase 3, we will conduct a prospective cohort study to determine reliability and construct and predictive validity (N=310). We plan to recruit up to 404 MORE participants from the Center for the Intrepid and Carl R. Darnall Army Medical Center.

## 2. KEYWORDS:

resiliency, instrument development, reliability, validity, lower-extremity trauma, rehabilitation outcomes

## **3. ACCOMPLISHMENTS:**

## What were the major goals of the project?

	Timeline (Months)	% Complete
Major Task 1: Regulatory Approval	•	
Milestone(s) Achieved		
Local IRB Approval	12	100%
USAMRMC HRPO Approval	14	100%
Personnel Hired	12	100%
Major Task 2: Participant Interviews		
Milestone(s) Achieved:		
Interviews Completed	19	100%
Qualitative Model and Narratives Completed	20	100%
Major Task 3: Participant Focus Groups		
Milestone(s) Achieved:		
Focus Groups Completed	21	100%

Initial Resiliency Instrument Completed	22	100%
Major Task 4: Pre-Test of Instrument		
Milestone(s) Achieved:		
50 Participants Complete the Pre-test	26	60%
Resiliency Instrument Finalized	28	0%
Major Task 5: Test-Retest Reliability		
Milestone(s) Achieved:		
Test-Retest Reliability Completed	34	0%
Major Task 6: Construct Validity		
Milestone(s) Achieved:		
Construct Validity Completed	40	0%
Major Task 7: Predictive Validity		
Milestone(s) Achieved:		
Predictive Validity Completed	48	0%
Final Report Completed	48	0%

#### What was accomplished under these goals?

For this reporting period, major activities included obtaining HRPO approval and completing 12 interviews and 4 focus groups. The interview and focus group participants reviewed a 44-item resiliency instrument that was created from 3 well-established resiliency instruments for civilians (i.e., Connor-Davidson, Resilience Scale for Adults, and the 25-item Resilience Scale). These 44 items covered the following resiliency constructs: hardiness, persistence, personal competence/strength, acceptance of self/life, personal structure, social competence, and family cohesion/social support. A copy of the interview/focus group script and initial resiliency instrument is submitted with this report. Of the 28 participants who completed a focus group or interview for Aim 1 of the study, 8 were female (29%) and 3 identified as Hispanic or Latino (11%). The race break down is as follows: 1 Asian, 7 Black or African American, 1 Native Hawaiian or Other Pacific Islander, 16 White, 1 more than one race, and 2 individuals of unknown race. Transcripts were analysed and the qualitative analysis team (Dr. Schlundt and Ms. Bonnet) provided the PI and all coinvestigators (Drs. Wegener, Wilken, Bowles, Frazier, Snyder, Keizer) with a summary of proposed changes based on participant feedback. The investigative team made several changes to the initial resiliency instrument, which included changes to the instructions, removal of 18 of the items, and minor rewording of 6 of the items.

The pre-test phase was then initiated in the 4<sup>th</sup> quarter of year 2 after IRB approval was obtained for the study's revised 26-item resiliency instrument. A copy of the pre-test resiliency instrument is submitted with this report. Pre-test enrollment is occurring at Carl R. Darnall Army Medical Center at Fort Hood. Patients are approached for enrollment in the physical therapy clinic and can either complete the instrument by survey or through an interview with study staff. To date, we have enrolled 41 out of 60 participants for the pre-test. Of those enrolled in the pre-test, 39 patients have completed the instrument by survey and 2 have participated in the interview. Demographics of the pre-test participants are as follows: 7 females (17%) and 34 males (83%); 1 American Indian or Alaskan Native, 14 Black or African American, 20 White, 5 more than one race, and 1 unknown race; 12 individuals are Hispanic or Latino (29%). The study personel conducting the interviews follow the same interview script included with this report. The study protocol for phase 3 was submitted to the BAMC IRB in the 4<sup>th</sup> quarter of year 2 and is still under review.

## **What opportunities for training and professional development has the project provided?** Nothing to Report

## How were the results disseminated to communities of interest?

Nothing to Report

## What do you plan to do during the next reporting period to accomplish the goals?

During the next reporting period, we plan on completing the pre-test and finalizing the resiliency instrument for prospective testing. We also plan on receiving BAMC IRB and HRPO approval for Phase 3 testing of the resiliency instrument. After HRPO approval, we plan on completing test-retest reliability of the resiliency instrument in the next reporting period.

## 4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project? Nothing to Report

What was the impact on other disciplines? Nothing to Report

What was the impact on technology transfer? Nothing to Report

What was the impact on society beyond science and technology? Nothing to Report

## 5. CHANGES/PROBLEMS:

## Changes in approach and reasons for change

The major change for this project was the change in site PI for the BAMC site. Dr. Wilken left BAMC and started a position at the University of Iowa. Amy Bowles MD, Deputy Chief in Department of Rehabilitation Medicine at BAMC, became the designated site PI for this project. This led to a revised SOW and budget and a delay in IRB submission at BAMC.

## Actual or anticipated problems or delays and actions or plans to resolve them

The change in site PI at BAMC has delayed this project, which was reported in the previous annual report. There has also been a change to the clinical recruitment site. For Phase 2 and Phase 3 of this research project only presonnel at Carl R. Darnall Army Medical Center will be recruiting for the project. Center for the Intrepid will not be a recruiting site. While this change did not impact recruitment for the pre-test, there is the possibility that recruitment will be delayed for the prospective Phase 3 research milestones (Major Task 5-7).

## Changes that had a significant impact on expenditures

Due to the delay in IRB approval and the need for a revised budget, the personnel and research related expenditures have been lower than expected for the reporting period.

## Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report

## Significant changes in use or care of human subjects

Nothing to Report

## Significant changes in use or care of vertebrate animals.

Not Applicable

## Significant changes in use of biohazards and/or select agents

Not Applicable

**6. PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- Publications, conference papers, and presentations
   Nothing to Report
   Journal publications. Nothing to Report
   Books or other non-periodical, one-time publications. Nothing to Report
   Other publications, conference papers, and presentations. Nothing to Report
- Website(s) or other Internet site(s) Nothing to report
- **Technologies or techniques** Nothing to report
- **Inventions, patent applications, and/or licenses** Nothing to report
- Other Products
  Nothing to report

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS What individuals have worked on the project?

Name: Kristin Archer Project Role: PI Nearest person month worked: 1 Contribution to project: Developed protocol and all IRB documents, HRPO submission, oversee qualitative analysis and finalizing of instrument, completed quarterly reports and annual report

Name: Amy Bowles Project Role: Site PI BAMC Nearest person month worked: 1 Contribution to project: Oversight of BAMC IRB submission and recruitment

Name: Dana Fenster Project Role: Project Director Nearest person month worked: 1 Contribution to project: Assisted with preparing amendments and IRB submission for Aims 3 and 4, participated in weekly team conference calls

Name: Shannon Block Project Role: Project Director Nearest person month worked: 1 Contribution to project: Assisted with preparing amendments and IRB submission for Aims 3 and 4, participated in weekly team conference calls

Name: Molly Pacha Project Role: Collaborator Nearest person month worked: 1 Contribution to project: Helped prepare documents for HRPO amendment submissions and scheduled weekly conference calls for the team

Name: David Schlundt Project Role: Co-investigator Nearest person month worked: 1 Contribution to project: Conducted focus groups and qualitative analysis, trained study personnel in cognitive interviewing

Name: Kemberlee Bonnet Project Role: Collaborator Nearest person month worked: 1 Contribution to project: Conducted interviews, assisted with focus groups and qualitative analysis

Name: Tiffany Prusinowski Project Role: Research Assistant Nearest person month worked: 2 Contribution to project: Enrolled participants for the focus groups, interviews, and pre-test and helped reschedule appointments when needed

Name: Andrew Valantine Project Role: Research Assistant Nearest person month worked: 2 Contribution to project: Enrolled participants for the focus groups, interviews, and pre-test

Name: Pamela Jahelka Project Role: Research Assistant Nearest person month worked: 1 Contribution to project: Help with IRB amendments and data collection

Name: Mathew Frazier Project Role: Site PI Nearest person month worked: 1 Contribution to project: Oversee recruitment

Name: Benjamin Keizer Project Role: Co-investigator Nearest person month worked: 1 Contribution to project: Provided expert advice on resiliency and helped interpret analysis to finalize pre-test instrument

Name: Christine Snyder Project Role: Co-investigator Nearest person month worked: 1 Contribution to project: Provided expert advice on resiliency and helped interpret analysis to finalize pre-test instrument

Name: Jason Wilken Project Role: Co-investigator Nearest person month worked: 1 Contribution to project: Provided expert advice on enrollment and amendments, participated in weekly team conference calls

Name: Stephen Wegener Project Role: Co-investigator Nearest person month worked: 1 Contribution to project: Provided expert advice on resiliency and helped interpret analysis to finalize pre-test instrument

# Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

## What other organizations were involved as partners?

<u>Organization Name:</u> University of Iowa <u>Location of Organization:</u> Iowa City, IA <u>Partner's contribution to the project</u>: Collaboration on protocol and IRB documents as well as development of resiliency instrument

<u>Organization Name:</u> Johns Hopkins Medicine <u>Location of Organization:</u> Baltimore, MD <u>Partner's contribution to the project</u>: Collaboration on protocol and IRB documents as well as development of resiliency instrument

## 8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

**QUAD CHARTS:** Submitted

## Appendix I: Interview/Focus Group Script

## Introduction

Good Morning/Afternoon/Evening. My name is \_\_\_\_\_\_ and I'll be your interviewer/Focus Group Moderator today. We would like your opinions on a questionnaire that we are developing for service men and women. We are going to walk through the questionnaire together from beginning to end. I would like for you to read each item out loud and then think out loud about how you would answer the item. I may ask you some additional questions about each item.

Before we begin I would like to go over some basic information about our discussion.

- This session is being audio recorded. This allows me, as the interviewer/moderator, to focus on you, instead of trying to jot down specific details about the discussion. Please speak in a voice as loud as mine, so the microphone can pick it up.
- My team will write a report using the recordings. Our report will not mention your name. By assuring your privacy, I hope that you will speak openly and honestly about the survey.
- Our purpose is to <u>evaluate the questionnaire</u>. There aren't any right or wrong answers, so please provide us with both positive and negative viewpoints. Whatever you tell us will be very helpful.

Note to interviewer/moderator: Be sure the participant has a clean copy of the questionnaire in hand. Be sure the recorder is turned on now.

## **Instructions Section**

I want to start with the questionnaire instructions. Please read the instructions out loud.

For each item, please mark an "x" in the box below that best indicates how much you agree with the following statements as they apply to you over the last month. If a particular situation has not occurred recently, answer according to how you think you would have felt.

After they read the instructions out loud, ask the participant:

"Is there anything about these instructions that you did not understand or that you find confusing?"

Note: If they say "no", go on and start the questions. If they say "yes" ask: "Specifically, what about the instructions is confusing or hard to understand?" If they give you an answer, follow up with the question, "What could be changed to make the instructions easier to understand?"

## **Item Section**

You will proceed through the questionnaire one item at a time. Have the participant state the question number and read the item out loud. Begin by asking these questions each time. After a few questions, most participants catch on and will just start talking. Only use the questions below if they are leaving something out.

1. How would you answer this question? (Pause for an answer)

Use the next few questions as prompts to elicit more discussion.

- 2. What were you thinking about as you answered this question?
- 3. What kind of situation does this question make you think about?
- 4. What would make this a better question?
- 5. If they are having a hard time deciding on an answer, ask, "What makes it hard to choose a single answer?"
- 6. If the participant asks you what a word/concept means, ask them, "Please tell me how you interpret that. One thing I am trying to understand is how people interpret the words."

#### Appendix II: Interview/Focus Group Questionnare

For each item, please mark an " $\mathbf{x}$ " in the box below that best indicates how much you agree with the following statements as they apply to you over the last *month*. If a particular situation has not occurred recently, answer according to how you think you would have felt. **Connor-Davidson Resilience Scale 10** Not true Rarely Sometimes Often True nearly Hardiness (1,4,6,7,8,14,16,17,19) at all true true true all the time Persistence (11) (0) (1) (2) (3) (4) 1. I am able to adapt to changes that occur. 2. I can deal with whatever comes my  $\square$ way. I try to see the humorous side of things 3. П  $\square$ when I am faced with problems. 4. Having to cope with stress can make me stronger. I tend to bounce back after illness, 5.  $\square$  $\square$ injury, or other hardships. 6. I believe I can achieve my goals, even if there are obstacles. 7. Under pressure, I stay focused and think clearly. I am not easily discouraged by failure. 8. 9. I think of myself as a strong person when dealing with life's challenges and difficulties. I am able to handle unpleasant or 10.  $\square$  $\square$ painful feelings like sadness, fear, and anger. **Personal Competence/Strength** Not true Sometimes Often True nearly Rarely at all true true true all the time (0) (1) (2) (3) (4) When something unforeseen happens 11. I always find a solution 12. I know how to solve my personal problems I strongly believe in my abilities 13.  $\square$  $\square$ 14. I trust completely my judgements and decisions 15. In difficult periods I have a tendency to find something good that helps me thrive 16. I manage to come to terms with events in my life that I cannot influence 17. I know how to accomplish my future goals

18.	I feel that my future looks very promising			
19.	When I make plans I follow through with them.			
20.	I usually manage one way or another.			
21.	I am able to depend on myself more than anyone else.			
22.	I feel that I can handle many things at a time.			
23.	I am determined.			
24.	I have self discipline.			
25.	In an emergency, I'm someone people generally can rely on.			
26.	I can usually look at a situation in a number of ways.			
27.	Sometimes I make myself do things whether I want to or not.			
28.	When I'm in a difficult situation, I can usually find my way out of it.			
29.	I have enough energy to do what I have to do.			

	Acceptance of Self/Life	Not true	Rarely	Sometimes	Often	True nearly
		at all	true	true	true	all the time
		(0)	(1)	(2)	(3)	(4)
30.	I can usually find something to laugh about.					
31.	My life has meaning.					

	Personal Structure	Not true	Rarely	Sometimes	Often	True nearly
		at all	true	true	true	all the time
		(0)	(1)	(2)	(3)	(4)
32.	I am at my best when I have a clear goal to strive for					
33.	I am good at organizing my time					

	Social Competence	Not true at all (0)	Rarely true (1)	Sometimes true (2)	Often true (3)	True nearly all the time (4)
34.	I enjoy being together with other people					
35.	For me, thinking of good topics for conversation is difficult					

	Family Cohesion/Social Support	Not true at all (0)	Rarely true (1)	Sometimes true (2)	Often true (3)	True nearly all the time (4)
36.	My family's understanding of what is important in life is very similar to mine					
37.	I feel very happy with my family					
38.	My family is characterized by disconnection					
39.	In difficult periods my family keeps a positive outlook on the future					
40.	In my family we like to do things together					
41.	I can discuss personal issues with friends/family members					
42.	The bonds among my friends are strong					
43.	I get support from friends/family members					
44.	When needed, I have someone who can help me					

## Appendix III: Pre-Test Resiliency Instrument

For each item, please mark an "**x**" in the box below that best indicates how much you agree with the following statements as they apply to you in your military or personal life. If a particular situation has not occurred recently, answer according to how you think you would have felt.

	contred recently, answer according to no	Not true at all (0)	Rarely true (1)	Sometimes true (2)	Often true (3)	True nearly all the time (4)
1.	I am able to adapt to changes in my life					
2.	Having to cope with stressful situations can make me stronger					
3.	I tend to bounce back after illness or injury					
4.	I believe I can achieve my goals, even if there are obstacles					
5.	I am not easily discouraged by failure					
6.	I think of myself as a strong person when dealing with life's challenges and difficulties					
7.	I am able to handle unpleasant or painful feelings					
8.	When something unforeseen happens I find a solution					
9.	I strongly believe in my ability to solve problems					
10.	I trust my judgements and decisions					
11.	In difficult periods, I have a tendency to find something that helps me thrive					
12.	I manage to come to terms with events in my life that I cannot influence					
13.	I feel that my future looks very promising					
14.	I am able to depend on myself more than anyone else					
15.	I feel that I can handle many things at a time					
16.	I am determined					
17.	I have self discipline					

18.	I can usually look at a situation in a number of ways			
19.	Sometimes I make myself do things whether I want to or not			
20.	I can usually find something to laugh about			
21.	My life has meaning			
22.	I am at my best when I have a clear goal to strive for			
23.	I enjoy being together with other people			
24.	I discuss personal issues with friends/family members			
25.	I get support from friends/family members			
26.	When needed, I have someone who can help me			

## **MORE Resiliency in the Rehabilitation of Active Duty Service Members** OR150140 W81XWH-16-2-0061



**PI:** Kristin R. Archer

Org: Vanderbilt University Medical Center

## Study/Product Aim(s)

• Aim #1: To select items for a resiliency instrument that address multiple dimensions of resiliency for active duty Service Members.

• Aim #2: To perform a pre-test of the resiliency instrument in active duty Service Members participating in the MORE study.

• Aims #3/4: To determine the reliability and validity of the resiliency instrument in Service Members participating in the MORE study.

## Approach

Conduct a prospective observational study in 310 active duty Service Members who have experienced lower limb injury and are participating in the MORE study at Brooke Army Medical Center. Psychometric statistics and multivariable linear regression will establish reliability and construct and predictive validity.

Timeline and Cost				
Activities CY	16	17	18	19
Regulatory Approval				
Item Selection				
Item Reduction (Pre-Test)				
Reliability and Validity Testing				
Estimated Budget (\$K)	\$0	\$12	\$150	\$338



Award Amount: \$499,999

An improved understanding of resiliency and its relative contribution to rehabilitation success and physical function and performance is needed to effectively guide the use of limited clinic resources and facilitate efforts to maximize outpatient rehabilitation effectiveness.

## **Goals/Milestones**

CY16-17 Goal – Regulatory approval

☑ BAMC IRB and HRPO approval obtained

CY18 Goal – Enrollment and data collection

- $\ensuremath{\boxdot}$  Interviews and focus groups conducted
- $\ensuremath{\boxtimes}$  Initial resiliency instrument developed
- $\hfill\square$  Enroll 50 participants and complete pre-test of instrument

 $\hfill\square$  Start enrollment for validity testing cohort

CY19 Goal - Follow-up, data analysis

 $\Box$  Collect complete follow-up data on 85% of cohort participants

- $\hfill\square$  Complete reliability and validity analyses
- $\hfill\square$  Presentation of results to clinical staff and national meetings
- $\hfill\square$  Manuscript and final report submission

**Comments/Challenges/Issues/Concerns:** Change in BAMC and Fort Hood site PI, only enrolling clinical site is Fort Hood

## **Budget Expenditure to Date**

Projected Expenditure: \$499,999

Actual Expenditure: \$70,653