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TITLE: Validation of the STarT Back Screening Tool in Primary Care Management of Back Pain in the Military Health System: A Randomized Trial of Risk-stratified Care

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14. ABSTRACT

The management of LBP imposes significant economic burden on individuals, health care delivery systems and society. Total annual direct healthcare costs in the United States incurred by patients with LBP were estimated at 90 billion dollars in 1998, 60% higher than costs for individuals without LBP. Increasing amounts of research point to the importance of even the earliest care decisions made about the management of patients with LBP towards predicting the outcomes of care including work readiness, and the likelihood of utilization of high cost procedures. A novel approach is to determine whether stratified care according to the estimated risk of poor prognosis improves clinical outcomes. The STarT Back Screening Tool (SBST) does precisely this, classifying patients into one of three risk categories (low, medium, and high) for targeted treatment based on the presence of modifiable physical and psychological indicators of persistent, disabling symptoms. Recent studies have shown improved outcomes and significant costs saving associated with using the tool in primary care settings. However, it is unknown whether a similar stratified care approach will achieve similar results in the primary care management of patients with low back pain in the Military health System.

The purpose of this study is to validate the clinical and cost effectiveness of the STarT Back Screening Tool in the primary care management of patients with LBP in the MHS. The overall hypothesis is that, for patients seeking care for low back pain, treatment decisions based on risk stratification will result in significantly better long term outcomes and decreased overall healthcare utilization compared to the usual care method of making treatment decisions.

15. SUBJECT TERMS back pain, risk stratification, military service members, screening, conservative management

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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TABLE OF CONTENTS

1. INTRODUCTION:

ThArmy Medical Centers that have a primary complaint of LBP. Subjects will complete screening questionnaires at is is a pragmatic Randomized Clinical Trial where 290 subjects will be recruited from primary care clinics within two

baseline to assess all patients on key psychosocial and physical factors that have prognostic implications for predicting risk of delayed recovery. The SBST will be utilized to classify patients into one of three risk categories (low, medium or high) for targeted treatment, based on the presence of potentially modifiable physical and psychological prognostic indicators for persistent, disabling symptoms. Physical factors such as acuity and location of symptoms also have

prognostic implications for predicting immediate benefit for spinal manipulation. All subjects will be assessed at baseline according to these factors, then randomized to receive risk-stratified care based on the results of the SBST

and spinal manipulation screening (Risk Stratified Care) or care based on current clinical practice guidelines (Usual Care). The experimental aspect of this study is to see if the risk stratification tool will do a better job at dictating the specific type and timing of treatment provided to the patient, compared to usual care.

2. KEYWORDS:

back pain, risk stratification, military service members, screening, conservative management

3. ACCOMPLISHMENTS:

What were the major goals of the project?

	Timeline Months	**Status**
Initial Task IRB submission, personnel hiring, and study-related training		
Subtask IT1. Hiring of research assistants	0-3	Completed Q1Y1
Subtask IT2: Submission of protocol at primary **IRB (BAMC – months 0-2) and then sub-site IRBs (after approval at primary site)	0-6	Completed Q1Y1
Subtask IT3: Submit IRB approval and necessary documents for ***HRPO review.	6-9	Completed Q1Y1
Subtask IT4: Establish administrative support for enrolling subjects. A. Research Assistants will create all subject data collection packets B. Provide the appropriate documentation to all relevant clinicians C. Establish databases for data collection and follow-up tracking D. Manual of Procedures (MOPs) and training guidelines will be created.	6-9	Completed Q1Y1
Milestone 1: IRB approval and HRPO Approval	9	BAMC Completed Q1Y1 WHASC IRB approval Completed Q2Y1 WHASC HRPO approval Completed Q3Y1

Specific Aim 1: Compare clinical outcomes between risk-stratified care according to the SBST and usual care approach in the management of patients with LBP in the primary care setting.	**9-33**	
Task 1a: Enrollment of 290 subjects between 2 sites		Completed Q2Y2
Subtask 1: Subjects are consented and study measures, that include self-report and physical performance tests, are taken	9-21	Completed Q2Y2
Milestone 2: Target enrollment met	21	Completed Q2Y2
Task 1b: Follow-up occurs for a 1-year period, with follow-ups at 6 weeks, 6 months, and 1 year.	11-33	Complete
Subtask 1: Follow-ups occur each time point Subtask 2: Track compliance with follow-ups	11-33	Completed Q2Y3 -Compliance with follow-up at 6-weeks was 87%, with all 290 subjects reaching 6 week by 12 JUN 2020. -Compliance with follow-up at 6-months was 78% with all 290 subjects reaching 6 months by 11 DEC 2020. -Compliance with collecting the primary outcome at 1 year was 81%, with all 290 subjects reaching 1 year by 26 FEB.
Task 1c: Prepare data for analysis	30-34	Complete
Subtask 1: Organize database for analysis	34	Complete for baseline data, 90% complete for follow up data
Task 1d: Analyze data for AIM 1	34-35	In progress
Specific Aim 2: Compare direct and indirect costs associated with risk-stratified versus usual.	34-36	
Task 2a: Analyze data for AIM 2. (This is a dataanalysis task and requires no additional subject testing beyond Aim 1.)	34-36	Currently working on flagging healthcare utilization data from MDR, which is needed to assess costs.
Task 2b: Perform sensitivity analyses	34-36	Future
Specific Aim 3: Compare the cost-effectiveness of risk-stratified care versus usual care.	35-36	
Task 3a: DSAs as needed to access MDR data	27-33	Complete
Subtask 1: Submit amendment to IRB that addresses collection of healthcare utilization data from MDR database	27	COMPLETE – Already approved in current protocol
Subtask 2: Data request submitted to MEDCOM/PASBA for data extraction	30	Complete
Task 3b: Consolidate and organize healthcare utilization data. (This is a data-analysis task and requires no additional subject testing beyond Aim 1.)	33-34	In progress
Subtask 1: Match MDR data with appropriate subject ID numbers	34	Future

Subtask 2: Consolidate data from clinical data and MDR, and organize by individual subject ID to obtain master spreadsheet for analysis	34	Future
Task 3c: Compare healthcare utilization costs between groups. (A data-analysis task and requires no additional subject testing beyond Aim 1.)	35-36	Future

What was accomplished under these goals?

1)

Major Activities:

1. Ensured all therapists delivering trial interventions attended training and continuing education session 14FEB2017.
2. Completed enrollment at core site (08AUG2019) and began enrollment at sub-site (04JUN2019).
3. 100% of total recruitment goal met by 3FEB2020.
4. Completed all 6 week and 6 months follow up attempts
5. Received healthcare utilization data from MDR, and working to flag and merge with outcomes data

2)

Specific Objectives:

1. Milestone 1: IRB and HRPO Approval
   a. Project (Protocol C.2016.047d) approved by BAMC IRB at both the core site (BAMC approved 28APR2016) and sub-site (WHASC approved 13MAR2019).
   b. HRPO Approval for all sites received 08 MAY 2019 – Log numbers E00590.1a (BAMC), E00590.1b (WHASC), E00590.1c (DU), and E00590.1d (UF).
2. Milestone 2: Target Enrollment (Completed)
   a. Met 100% of total enrollment goal as of 3FEB2020
3. Milestone 3: 1-year Follow-Up Period (Completed)
   a. Subjects reaching 6-week follow-up period is 290 with an 87% compliance rate.
   b. Subjects reaching 6-month follow-up period is 290 with an 78% compliance rate.
   c. Subjects reaching 1-year follow-up period is 290 with a 81% compliance rate.

What opportunities for training and professional development has the project provided?

All therapists delivering trial interventions at the MTFs attended training and continuing education session.

How were the results disseminated to communities of interest?

Nothing to Report yet

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

During the next reporting period we will be continuing with data cleaning and data analysis

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

No results to report yet at this time.

What was the impact on other disciplines?

No results to report yet at this time.

What was the impact on technology transfer?

No results to report yet at this time.

What was the impact on society beyond science and technology?

No results to report yet at this time

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

In the last year: Because our enrollment is complete and all of our participants received their active treatment prior to closures related to COVID-19, recruitment/enrollment is not an issue. However, the secondary effects of COVID-19 on the outcomes could be influential and impact the outcomes of this study (are changes in groups based on the interventions, or are changes in some individuals more reflective of changes in lifestyle brought on with COVID). We are adding a couple of survey questions to try and better understand the influence of COVID for relevant participants.

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Since last quarter, no additional problems to report

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

No other foreseeable problems at this time.

Changes that had a significant impact on expenditures

Nothing to report**.**

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

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

Nothing to report

Significant changes in use of biohazards and/or select agents

Nothing to report

6. PRODUCTS:

- **Publications, conference papers, and presentations**

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:	Dr. Daniel Rhon
Project Role:	Primary Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-4320-990X
Nearest person month worked:	2.9
Contribution to Project:	Grant PI – coordinate studies across all sites
Funding Support:	This award

Name:	Maj Jeremiah Samson
Project Role:	Site PI - WHASC
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Site PI at the WHASC location – responsible over all local research activities at this location. (site closed at WHASC)
Funding Support:	Government employee

Name:	MAJ Bryan Pickens
Project Role:	Site PI – BAMC
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Site PI at the BAMC location – responsible over all local research activities at this location.
Funding Support:	Government employee

Name:	Mary Laugesen
Project Role:	Research coordinator at BAMC/WHASC/Research Physical Therapist
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	0.9
Contribution to Project:	Coordinates execution of project at BAMC – recruitment, enrollment, follow-ups.
Funding Support:	This award

Name:	Katie Foster
Project Role:	Follow-up Coordinator/Research Physical Therapist
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2.2
Contribution to Project:	Coordinates and manages follow-ups across the sites
Funding Support:	This award

Name:	Mariah Callas
Project Role:	Research Physical Therapist

Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Coordinates execution of project at BAMC – recruitment, enrollment, follow-ups.
Funding Support:	This award

Name:	Nicole Curel
Project Role:	Clinical Social Worker
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1.5
Contribution to Project:	Coordinates execution of project at BAMC – recruitment, enrollment, follow-ups.
Funding Support:	This award

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

Not for the overall grant PI, Dr. Rhon. There was the addition of Maj Danielle Anderson as site investigator at WHASC. This Amendment was acknowledged by the BAMC IRB on 24APR2020.

What other organizations were involved as partners?

Organization name: Duke University

Location of Organization: Durham, NC

Partner's contribution to the project: **Collaboration:** Planning the project, helped with training the PTs in the Psychologically
Informed PT approach, and will help with data analysis.
Facilities: N/A

Organization name: University of Florida

Location of Organization: Gainsville, FL

Partner's contribution to the project: **Collaboration:** Informed PT approach, and will help with data analysis. Planning the project, helped Jason Beneciukwith training the PTs in the Psychologically

Facilities: N/A

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: Attached.

9. APPENDICES: N/A