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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 Riskstratified Care

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CONTRACTING ORGANIZATION: The Geneva Foundation

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13. SUPPLEMENTARY NOTES

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

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1. INTRODUCTION:

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.

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2. KEYWORDS:

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		In Progress: 268/290 enrolled
Subtask 1: Subjects are consented and study measures, that include self-report and physical performance tests, are taken	9-21	In Progress
Milestone 2: Target enrollment met	21	In Progress
Task 1b: Follow-up occurs for a 1-year period, with follow-ups at 6 weeks, 6 months, and 1 year.	11-33	In Progress
Subtask 1: Follow-ups occur each time point Subtask 2: Track compliance with follow-ups	11-33	- Subjects reaching 6-week follow up period is 254 with an 89% compliance rate by 14 SEP 2019. - Subjects reaching 6-month follow up period is 232 with an 80% compliance rate by 14 SEP 2019. - Subjects reaching one year follow up period is 198 with a 77% compliance rate by 14 SEP 2019.
Milestone 3: 2-year follow-up period complete	*33*	Future
Task 1c: Prepare data for analysis	30-34	Future
Subtask 1: Organize database for analysis	34	Future
Task 1d: Analyze data for AIM 1	34-35	Future
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 data-analysis task and requires no additional subject testing beyond Aim 1.)	34-36	Future
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	Future
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	Future
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	Future
Subtask 1: Match MDR data with appropriate subject ID numbers	34	Future
Subtask 2: Consolidate data from clinical data and	34	Future

MDR, and organize by individual subject ID to obtain master spreadsheet for analysis		
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?

For this reporting period – Year 1

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. 92% of total recruitment goal met by 14SEP2019.

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 (In Progress)
   a. Met 92% of total enrollment goal as of 14SEP2019.
3. Milestone 3: 1-year Follow-Up Period (In Progress)
   a. Subjects reaching 6-week follow-up period is 254 with an 89% compliance rate.
   b. Subjects reaching 6-month follow-up period is 232 with an 80% compliance rate.
   c. Subjects reaching 1-year follow-up period is 198 with a 77% compliance rate.

3) Significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative):
Nothing to report

4) Other Achievements:
Nothing to report

What opportunities for training and professional development has the project provided?
All therapists delivering trial interventions attended training and continuing education session.

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 (Q1 of Year 2), the team at WHASC will complete enrollment. Teams at both BAMC and WHASC will continue to monitor 6-week, 6-month and 1-year outcome follow-ups for completion.

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?
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
Nothing to report

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

Actual: No problems.

Anticipated: Competing trials are projected to begin in the Fall of 2019 within the same clinic as the core site (BAMC) and the sub-site (WHASC) potentially thinning the pool of eligible subjects with back pain. With the current rate of enrollment at WHASC, we anticipate completing enrollment of this trial before the other one begins, but this competing trial could make recruitment challenging. WHASC team has prioritized enrollment for this study. At the same time, the overlap is not 100% so it is possible that some patients will not quality for one study, but will quality for the other.

Changes that had a significant impact on expenditures
None

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
None

Significant changes in use or care of vertebrate animals
N/A

Significant changes in use of biohazards and/or select agents
N/A

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:	1.8
Contribution to Project:	Grant PI – coordinate studies across all sites
Funding Support:	Yes

Name:	LtCol Benjamin Hando
Project Role:	Site PI - WHASC
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1.2
Contribution to Project:	Site PI at the WHASC location – responsible over all local research activities at this location.
Funding Support:	Yes

Name:	MAJ Bryan Pickens
Project Role:	Site PI - BAMC
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1.2
Contribution to Project:	Site PI at the BAMC location – responsible over all local research activities at this location.
Funding Support:	No

Name:	Chenae Day
Project Role:	Research coordinator at WHASC location
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	6
Contribution to Project:	Coordinates execution of project at WHASC – recruitment, enrollment, follow-ups.
Funding Support:	Yes

Name:	Katie Dry
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	6
Contribution to Project:	Coordinate project across all sites
Funding Support:	Yes

Name:	Rachel Mayhew
Project Role:	Regulatory Coordinator
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1.2
Contribution to Project:	Coordinates regulatory and multi-site IRB issues across all sites
Funding Support:	Yes

Name:	Mary Laugesen
Project Role:	Research coordinator at BAMC location
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	6
Contribution to Project:	Coordinates execution of project at BAMC – recruitment, enrollment, follow-ups.
Funding Support:	Yes
Name:	Edita Dragusin
Project Role:	Follow-up Coordinator
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person	6

month worked:	
Contribution to Project:	Coordinates and manages follow-ups across the sites
Funding Support:	Yes

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. The site PI at BAMC transitioned from MAJ Chris Allen to MAJ Bryan Pickens due to retirement by MAJ Allen. This Amendment was acknowledged by the BAMC IRB on 19APR2019.

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

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: See attached.

9. APPENDICES: None