

Award Number: W81XWH-11-1-0657

TITLE: Treatment-Based Classification versus Usual Care for Management of Low Back Pain

PRINCIPAL INVESTIGATOR: MAJ Daniel Rhon

CONTRACTING ORGANIZATION: Geneva Foundation, Lakewood, WA 96499

REPORT DATE: August 2012

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				Form Approved 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 01-08-2012		2. REPORT TYPE Annual		3. DATES COVERED 1 Aug 2011 - 31 Jul 2012	
4. TITLE AND SUBTITLE Treatment-Based Classification versus Usual Care for Management of Low Back Pain				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-11-1-0657	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) MAJ Daniel Rhon Dr. Julie Fritz Dr. Joshua Cleland LTC Deydre Teyhen E-Mail: daniel.rhon@us.army.mil				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Geneva Foundation, Lakewood, WA 96499				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 PURPOSE: Compare the effectiveness and subsequent healthcare use associated with early physical therapy access compared with a stepped usual care approach based on current low back pain management guidelines. SCOPE: Active duty Soldiers with low back pain – 1 year follow-up period MAJOR FINDINGS: No research findings to report at this time as we are early in the recruitment/enrollment process. During the one year period described in this report, the majority of the time was spent on attaining IRB approval, hiring research personnel, and adequate training to begin the research study. All plans were in place and the study was ready to begin enrollment in March 2012. Not enough data has been collected from which to make any conclusions or summarize any substantial findings.					
15. SUBJECT TERMS Low back pain, military readiness, primary care					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 7	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	6
Reportable Outcomes.....	7
Conclusion.....	7
References.....	7
Appendices.....	7

INTRODUCTION:

Low back pain is the most significant contributor to lost workdays related to injury in the entire U.S. Armed Forces. The detrimental impact on combat readiness of low back pain cannot be understated as back problems are the number one cause of evacuation from Iraq and Afghanistan, making it one of the largest causes of attrition in Soldiers in combat.

This randomized clinical trial seeks additional evidence to determine if early physical therapy access using a treatment based classification (TBC) algorithm will result in greater improvements in function and quality of life and decreased healthcare utilization over 1 year as compared to a stepped “usual care” strategy in 220 active duty Soldiers presenting with low back pain.

BODY:

SOW Tasks:

Initial Task (months 1-7): Coordinate IRB approval, investigator participation and subject recruitment in conjunction with ongoing standard of care for patients at MAMC healthcare clinics.

Task #	Task Title	Status
a.	Submit study protocol to MAMC IRB (months 0-2)	Submitted successfully June 2011
b.	Educate participating clinicians in the 2 treatment algorithms (months 2-4)	PTA research assistant has been hired. She has completed training. Have held 2 meetings with staff at the medical clinic where enrollment will occur (once in December 2011 and in January 2012)
c.	Receive approval for study by MAMC IRB (month 6)	Completed August 2011
d.	Receive approval for study by CIRO (months 6-11)	Completed November 2011
e.	Establish administrative support for enrolling subjects (months 5-8)	Had a face to face meeting with Dr. Fritz and Dr. Cleland at a conference in November 2011 and also in February 2012. We walked through the entire methods. Subject folders have been created for data collection.
f.	Trial registered with clinicaltrials.gov (months 8-9) http://clinicaltrials.gov/ct2/show/NCT01556581	Trial registered in March 2012

Aim 1: Compare the effectiveness of two primary care management strategies for patients with a recent onset of combat-related LBP.

Task 1a (months 11-22): Enrollment into study (220 subjects). Active duty Soldiers with low back pain are randomized into one of two primary care management strategies (usual care stepped approach or early referral to physical therapy for treatment-based classification approach). Subjects are consented, baseline measures taken, randomization to treatment group occurs, and then allocated intervention is given.

Task #	Task Title	Status
1a	Recruitment and enrollment of subjects began in March 2012	Through August 25, 2012, we have screened 117 patients with LBP, and enrolled 26 subjects into the study
	Other notes:	Dr. Julie Fritz came out to Madigan for a site visit over a period of 3 days in March to oversee and provide internal audit of the process as recruitment began.

Task 1b (months 12-34): Track outcomes at 4 weeks, 12 weeks, and 1 year after initial enrollment.

Method of tracking outcomes: Follow-up re-assessments will be performed 4 weeks, 12 weeks and 1-year after the baseline examination. Follow-up assessments will be performed by a Research Assistant blinded to the patient's treatment group assignment. Subjects will be called 2 weeks prior to their projected follow-up date and scheduled a follow-up appointment. Subjects will arrive at their appointment and fill out the appropriate outcome measures. The data from the outcomes will be placed in a patient folder with only their subject ID for identification. Data will then be entered into a protected spreadsheet as described in the protocol.

Task #	Task Title	Status
1b	Follow-up of Subjects began	We have appropriate follow-ups on all subjects for all relevant time periods (through August 25, 2012)

Dr. Julie Fritz came out to Madigan for a site visit over a period of 3 days in March to oversee and provide internal audit of the process as recruitment began. This provided a valuable opportunity to discuss the project, refine near and long term goals, and discuss expectations.

Aim 2: Compare the subsequent healthcare utilization associated with two management strategies for patients with a recent onset combat-related LBP.

The tasks (2) for Aim 2 cannot be started or completed until all the data collection from AIM 1/ Task 1 is completed.

Aim 3: Compare and contrast any differences in psychosocial factors between success and failures within both groups of treatment.

The tasks (3) for Aim 3 cannot be started or completed until all the data collection from AIM 1/ Task 1 is completed.

Challenges:

The task of recruitment of eligible subjects has encountered some unanticipated challenges. Fort Lewis continues to be a prime location for access to active duty Soldiers. Our plan was detailed and the approach researched in detail, but there were 2 unanticipated events that have occurred affecting recruitment.

1. We were unable to anticipate combat deployment schedules for the Soldiers as that information is classified and was not available at the time we formulated and submitted our grant proposal. At the start of the recruitment phase, two (2) of the three (3) Brigade Combat Teams (BCT) on Fort Lewis were deployed. The third BCT began an increased training regimen to include regular multi-week training trips to other sites in May 2012, and will be deploying for combat in the fall timeframe. This significantly decreased the numbers of patients seeking healthcare in the clinics we had access to.
2. The sick call (walk-in) procedures that have been used for many years recently changed. Historically, patients have been able to come in for walk-in appointments in the morning. Traditionally, this is where we have been able to capture a high number of low back pain patients. Earlier this year, the Madigan Healthcare System rolled out an online and telephone appointment booking service, which gives Soldiers the option to call or schedule a same day appointment online. As we evaluated the use of this system we saw that more patients with LBP were opting to schedule an appointment later in the day rather than come in for the walk-in clinic in the morning. Even accounting for this, the overall numbers of patients seeking care for low back pain was unusually small.

PLAN: Coordination of care at the primary care level takes considerable planning because it involves capturing the patient at the entry point into care for their low back pain complaint. The month of March began well with 8 subjects enrolled. At the end of April, we acknowledged and researched the decreased LBP presentation to better understand the problem. This resulted in planning several meetings with primary care providers, clinic chiefs, and administration officers to determine how best to capture these patients with the constraints that we have. Finally, we looked to incorporate multiple clinics. Eventually we moved over to another clinic on the other side of Fort Lewis that was less convenient, but appeared to be getting larger numbers of patients with LBP. It took 2 months to coordinate meetings with the new providers, train and educate primary care providers, and begin the recruitment process at the new clinic. From April through July, due to the events described above, there was not more than 1-2 subjects enrolled, but we are finishing the last of the coordination activities with the other clinics (mid-August) and numbers are starting to increase.

We have created referral packets for providers with specific referral criteria and we offer an LBP education class for all providers to refer patients to. After the class we can present the opportunity and what the study is about to see if any patients are interested in enrolling. We send bi-monthly email reminders to the primary care providers to keep them engaged, continually remind them of this opportunity, and remain available to answer any questions they might have.

One of the two currently deployed BCTs will begin to arrive late fall and the other in the early part of 2013. We have adapted to the unexpected situations, and, with our new plan in place, we anticipate a regular enrollment rate, as this month has already started to prove. An even greater rate of recruitment, needed to reach our target enrollment, is anticipated at the start of 2013 as the BCTs return from deployment. This may have implications for the timeline of the PTA research assistant who is currently budgeted for 18 months of effort. Currently her employment is scheduled to end in the summer of 2013. The Geneva Foundation will continue to monitor the budget and will make adjustments as needed to ensure the success of the project.

KEY RESEARCH ACCOMPLISHMENTS:

Research:

- IRB Approval by CIRO and MRMC
- Trial registered with ClinicalTrials.gov
- Enrollment of subjects initiated

Mentorship/Career Development:

- MAJ Rhon is now an active peer reviewer for articles in the Journal of Orthopaedic and Sports Physical Therapy
- MAJ Rhon and Dr. Fritz have been working on developing another research protocol, prospective in nature, looking at the effectiveness and safety of interventions used for managing low back pain.

- MAJ Rhon was able to use what he learned from mentoring and this current experience to lead the efforts as the PI for submission of a protocol for a randomized clinical trial, through another CDMRP award mechanism, for a different and unrelated research question.

REPORTABLE OUTCOMES:

No presentations have yet been generated from data collected in this study as we are still early in the data collection phase. Because the purpose of this initiative is dual in nature as a career development award, to both execute a relevant research trial and to focus on development of an independent clinician-scientist researcher, we have progress to report for both sections of this grant.

What is of indirect relevant importance to this particular research study however, is a recent study published by MAJ Rhon's primary mentor, Dr. Fritz in the May 2012 issue of Spine. These findings further support the rationale for our current study, and indicate the potential fiscal benefits and reduction in healthcare costs that may be associated with early physical therapy. In a retrospective review of over 30,000 patients in a civilian setting with a primary complaint of low back pain, patients that were referred to physical therapy early (less than 14 days) compared to late (after 14 days) had a significant reduction in overall healthcare utilization and healthcare costs over the following 18-month period. Specifically, early physical therapy timing was associated with decreased risk of advanced imaging (OR = 0.34, 95% CI: 0.29, 0.41), additional physician visits (OR = 0.26, 95% CI: 0.21, 0.32), surgery (OR = 0.45, 95% CI: 0.32, 0.64), injections (OR = 0.42, 95% CI: 0.32, 0.64), and opioid medications (OR = 0.78, 95% CI: 0.66, 0.93) as compared with delayed physical therapy. Total medical costs for LBP were \$2736.23 lower (95% CI: 1810.67, 3661.78) for patients receiving early physical therapy. These findings need to be validated in a prospective trial and in a military setting, which our current project has the potential to do.

PMID: <http://www.ncbi.nlm.nih.gov/pubmed/22614792>

CONCLUSION: There are no significant outcomes to report as the trial is still early in the recruitment and enrollment phase. Obstacles to recruitment were identified and consisted of both access routes and decrease in the number of Soldiers due to deployment, however modifications have occurred and plans put into place to maximize success with enrollment. The potential relevance and importance of this work was highlighted by Dr. Fritz's recent publication as discussed above.

REFERENCES:

Fritz JM, et. al. Primary Care Referral of Patients with Low Back Pain to Physical Therapy: Impact on Future Healthcare Utilization and Costs. Spine (Phila Pa 1976). 2012 May. PMID: [22614792](http://www.ncbi.nlm.nih.gov/pubmed/22614792)

APPENDICES: None