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

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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 still in the recruitment/enrollment process.

15. SUBJECT TERMS
Low back pain, military readiness, primary care

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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	In the last year (Aug 1, 2012 thru July 31, 2013), we have screened 180 patients with LBP, and enrolled 43 subjects into the study. Total enrolled the entire duration of the study is 63.
	Other notes:	Met with Dr. Julie Fritz twice during this year, both while simultaneously attending a conference.

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 had 21 subjects complete the entire 1-year period of the study.

Aim 2: Compare the subsequent healthcare utilization associated with two management strategies for patients with a recent onset of 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 continues to be challenging. 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 3 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.

This still allowed for recruitment to stay relatively on target as evidenced by our ability to screen 117 Soldiers, and recruit 26 subjects. Shortly following that, right at the beginning of the new fiscal year, all 3 BCT units were deployed and our eligible recruitment pool significantly decreased. Two of those units began to return early 2013 and were finally processed back in and off of leave, ready for regular garrison life, by the beginning of May 2013. The other unit will be in the same situation by the end of September 2013.

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.

3. The government sequestration had 2nd and 3rd order affects that impacted this study. The hospital leadership has put a lot of pressure on miniminizing research and shifting priorities and resourcs to clinical care. The hospital had initially allotted the use of an additional civilian physical therapist for part-time help with this study. She was used often when MAJ Rhon had to travel for TDY or other mission-related travel. We lost the ability to use her. In this last quarter, MAJ Rhon was gone over 6 weeks on various temporary duty and mandatory military training trips, as well as annual vacation. The hired PTA/RA also took her 2-week vacation during this time. Usually this is covered by support from the hospital clinic, but in these cases we had no one to recruit/enroll during these periods of time. We do not know when/if we will get the assistance back of the physical therapist from the hospital to provide continued assistance.

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. We have moved to several different clinics over this last year, in an attempt to be available in the location that has the highest potential for LBP patient enrollment.

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.

We remain optimistic about this final year. We have discussed the impact of performing an analysis of the data if we only meet 50% of the enrollment target, and we feel there will still be significant value from that.

KEY RESEARCH ACCOMPLISHMENTS:

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

Mentorship/Career Development:
- MAJ Rhon is now an active peer reviewer for articles in the Journal of Orthopaedic and Sports Physical Therapy and Manual Therapy.
- MAJ Rhon and Dr. Fritz have been working 2 additional projects related to LBP, adding to the value of the mentoring relationship.

- 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.

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.

APPENDICES: None