AWARD NUMBER: W81XWH-14-2-0146

TITLE: A Pilot Study to Test the Efficacy of Psychologically Based Physical Therapy Training for Treating Deployed U.S. Sailors and Marines with Musculoskeletal Injuries

PRINCIPAL INVESTIGATOR: Dr Sherri Weiser-Horwitz NYU

RECIPIENT: New York University School of Medicine
New York, NY 10016-6402

REPORT DATE: OCTOBER-2018

TYPE OF REPORT: FINAL

PREPARED FOR: U.S. Army Medical Research and Material Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
OCT 2018	Final	30 SEPT 2014 - 29 SEPT 2018

4. TITLE AND SUBTITLE

A Pilot Study to Test the Efficacy of Psychologically Based Physical Therapy Training for Treating Deployed U.S. Sailors and Marines with Musculoskeletal Injuries

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-14-2-0146

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S) Sherri Weiser PhD, Marco Campello PT PhD, Angela Lis PhD, Rudi Hiebert ScM, Danielle Faulkner, Tara Brennan MPH, Mike Lashbaugh MS PT.

E-Mail:sherri.weiser@nyumc.org

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

New York University School of
Medicine,
Occupational and Industrial
Orthopedic Center
63 Downing Street,
New York, NY 10014

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
The purpose of this study was to demonstrate the effectiveness of a PBPT intervention for the prevention of disability in ADSM who sustain an MSI during deployment in support of combat operations on a carrier. This includes testing the feasibility of the implementation and documenting psychological risk factors aboard two carriers. We have successfully completed the training of the control carrier.

15. SUBJECT TERMS
Back pain, military, musculoskeletal injury, musculoskeletal pain, physical therapy, cognitive behavioral therapy, yellow flags, psychological intervention, psychosocial intervention, pain coping skills, outcome, randomized controlled trial, risk factor, disability, attrition.

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
Unclassified					USAMRMC
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			**19b. TELEPHONE NUMBER** *(include area code)*
Unclassified	Unclassified	Unclassified	Unclassified	173	

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

Table of Contents

1. Introduction

This is a pilot study to test the efficacy of a psychologically based physical therapy (PBPT) training for treating deployed U.S. sailors and marines with musculoskeletal injuries (MSI). The study has resulted in the development of a training manual for Navy physical therapist (PT) personnel on how to address important psychological factors during treatment and how to recognize when to refer a patient to a mental health professional for further evaluation. It may serve as a model for standardized training for all Navy PT personnel. This training has the potential to help all service members who sustain MSI by improving care, reducing the need for ongoing medical utilization and reducing disability.

2. Keywords

- Back pain
- Military
- Musculoskeletal Injury
- Musculoskeletal Pain
- Cognitive behavioral therapy
- Physical Therapy
- Yellow Flags
- Psychological intervention
- Psychosocial intervention
- Pain coping skills
- Outcome
- Randomized Controlled Trial
- Risk factor
- Disability
- Attrition
- Psychologically-based Physical Therapy/Psychologically-informed Physical Therapy

3. Accomplishments

What were the major goals of the project?

- Demonstrate the feasibility of implementing psychological based physical therapy (PBPT) on board an aircraft carrier (referred to as "carrier");
- Document and compare risk factors related to disability from musculoskeletal injury (MSI) aboard two aircraft carriers;
- Demonstrate the effectiveness of the PBPT intervention in a comparative effectiveness trial.

<u>Scope of Work (SOW) Major Goals and Milestones Months 1-46</u>

Months 1-6; The goal of this phase is to prepare regulatory documents for the pilot study

- Finalize Navy Observational Clinical Cooperative Research and Development Agreement (NCRADA) between Naval Medical Center Portsmouth (NMCP), New York University (NYU) and University of Delaware
- Prepare and submit protocol to NMCP Internal Review Board (IRB) and revise as required
- Submit protocol for United States Army Medical Research and Material Command Human Research Protection Office (USAMRMC HRPO)

Months 1-8; The goal of this phase is to hire and train personnel for the study

- Hire research assistants; credential them according to Navy regulations.
- Train research assistants in the study protocol including the preparation of training and study materials, data collection and quality assurance of study data, coding physical therapy notes for analysis, and recording minutes of clinical meetings with carrier physical therapy staff.
- Identify a carrier to act as a control site and train and certify the physical therapy staff including the certification in the Collaborative Institutional Training Initiative tutorial as required by IRB, train staff in the study protocol and questionnaire administration and data collection.
- Identify a carrier to act as the intervention site and train and certify the physical therapy staff and psychologist in the Collaborative Institutional Training Initiative tutorial as required by IRB, train staff in the study protocol and questionnaire administration and data collection. Train the physical therapy staff and psychologist in the PBPT protocol.
    - Education about the biopsychosocial model of treatment
    - Training to identify "yellow flags"
    - Training to respond to "yellow flags"
    - Training to complete patient notes
    - Training in triaging for psychological evaluation
- Role playing to test acceptance of training protocol and change of treatment paradigm
    - Ongoing training by research staff prior to deployment to reinforce the intervention protocol.
    -

Months 7-33; The goal of this phase is to implement the pilot study

- All subjects reporting to medical aboard the intervention carrier for a primary complaint of a new MSI will be eligible for the study. A subject can be enrolled for a new complaint or a recurrence of the original complaint if no treatment was received within 30 days.
- The physical therapy staff of the intervention carrier will inform potential study candidates about the study and if they agree to participate, proceed with informed consent
- We estimate 600 potential study candidates in each arm and we estimate we will be able to consent 300 subjects in each arm
- The study protocol for both arms includes:
    - Patient assessment through patient interview, physical evaluation and study questionnaires designed to identify "yellow flags". Before treatment the following data will be collected:
        - Demographics
        - MSI related information
        - Pain Interference
        - Psychological distress
        - Outcome expectations
        - Self-efficacy
        - Fear of work activity
        - Organizational Commitment
        - Social Support
        - Job Satisfaction
        - Job Stress
        - Barriers to treatment
        - PTSD symptoms
        - Depression
        - Anxiety

- Satisfaction with current condition

- Subjects are followed up after one month of treatment using the follow- up questionnaire which includes in addition to base-line measures satisfaction with treatment.
- Limited duty assignments will be assessed 6 months after enrollment as a secondary outcome
- Evaluation of physical therapy notes will be done to document the implementation of the intervention by coding notes based on predetermined categories that correspond to the training.
- Subjects will be asked to indicate the most important things they learned in physical therapy and answers will be assessed based on apriori categories corresponding to the intervention and control conditions. This will allow us to further assess intervention implementation
    - Intervention arm only:
        - Physical therapy staff will educate the patient in the biopsychosocial model of pain and disability and reassure the patient of a good outcome.
        - Physical therapy treatment involves active, progressive and goal-oriented exercises focused on improving function instead of pain reduction. Treatment will take place for 4weeks prior to follow- up approximately twice a week.
        - Physical therapy staff encourages self-care to instill a sense of control in the patient
        - Subjects who began treatment during deployment and return to base during treatment will continue to receive treatment aboard their carrier. They will be followed up in the same manner as all subjects.
- Ongoing support provided to the physical therapy staff in both arms during periodic conference calls with the investigators to reinforce data collection and proper completion of therapy notes and to reinforce the intervention in the intervention arm.

Months 8-46; The goal of this phase is to conduct data analysis and report the results

- Data collection rates and quality of data will be monitored
- All investigators will participate in data analyses
- Study findings will be disseminated in the form of abstracts, scientific papers and lectures

Months 26-46; The goal of this phase is to prepare a Manual of Operations and Procedures (MOOP)

- The MOOP will describe a model of care and the finalized PBPT protocol
- The document will be prepared for Triservice review

What was accomplished under these goals?

- NYU and NYUMC IRB approval;
- IRB protocol submitted to HRPO and approved;
- Site visit to carrier by three study personnel;
- Establishment of study advisory board;
- Establishment of weekly research conference call meetings;
- Preparation of training materials for control carrier;
- Control carrier training package passed by advisory board;
- Pilot control carrier training;
- Training of control carrier physical therapy staff;
- UDEL IRB approved;
- NCRADA signed for both carriers;
- Lesson plans and Standard Operating Procedures Manual specific to the control carrier;
- Established data recording procedures with data base administrator from BADER;
- Study registered in the clinical trials data base;
- Start of the recruitment of control carrier participants;
- Intervention training protocol and materials completed;
- Intervention training package passed by advisory board;
- Operations Procedures manual created for the intervention carrier;
- Intervention carrier training dates scheduled;
- Data sharing agreement application completed and submitted.
- Completed data collection on the control carrier;
- Training of the intervention carrier physical therapy personnel;
- Evaluated intervention carrier personnel;
- Study procedures successfully piloted with patients before deployment;
- PBPT intervention implemented;
- Ongoing support provided to the physical therapy staff during periodic conference calls with the investigators to reinforce data collection and proper completion of therapy notes and to reinforce the intervention in the intervention arm;
- Data collection completed for the intervention carrier;
- Data entry completed for both carriers;
- Clinical Trials database updated bi-annually (December 2015 and July 2016);
- Data Sharing Agreement Finalized;
- Quality control measures where completed for the control carrier and intervention carrier questionnaire data. If discrepancies were found between baseline and follow-up main complaints SOAP notes where reviewed and rules established;
- A subsample of intervention carrier SOAP notes reviewed during deployment;
- Control carrier SOAP notes retrieved from the carrier situated at Naval Base San Diego;
- Research team completed “Research Integrity” training required by the Navy;
- Advisory board updated on study status;
- Baseline descriptives generated.

- The open ended question in the follow-up questionnaire (Please list the most important things you learned in physical therapy) was analyzed based on apriori categories to confirm PBPT implementation.
- Short-term data analysis completed;
- Five abstracts submitted and accepted to national and international conferences based on short-term results;
- Manuscript "Feasibility of Training Physical Therapists to Implement a Psychologically-Informed Physical Therapy Program for Deployed US Sailors and Marines with Musculoskeletal Injuries" submitted to the Journal of Military Medicine
- Manuscript "What do patient's learn from psychologically based physical therapy?" in progress
- SOAP Notes analysis completed to ensure intervention integrity;
- Clinical Trials database updated bi-annually (December 2016 and May 2017);
- Data Sharing Agreement Finalized;
- Advisory board updated on study status.
- Two abstracts submitted and to MHSRS based on baseline descriptive data;
- One abstract was presented at the Joint Sessions APTA in February, 2018.
- Manuscript "Feasibility of Training Physical Therapists to Implement a Psychologically-Informed Physical Therapy Program for Deployed US Sailors and Marines with Musculoskeletal Injuries" accepted by the Journal of Military Medicine
- Manuscript "What do patient's learn from psychologically based physical therapy?" in progress
- Manuscript "The efficacy of PiPT in deployed US Navy Sailors and Marines with musculoskeletal injuries: a pilot study" in progress
- Submitted and granted study extension request.
- Health care utilization data tabulated
- LIMDU data retrieved and analyzed
- MOOP Finalized

Summary of Major Findings

The feasibility of training Navy PT staff to implement PBPT was demonstrated (Weiser et al, 2018 attached, abstract #1 attached). Feasibility of implementing PBPT was assessed by measuring PT staff knowledge and adoption of skills in PT practice following the training. PBPT knowledge was assessed by a written test and role-playing skills. The success of the adoption of the training was determined by analysis of PT notes and verbal responses of the PT staff during phone conferences. Both PT staff members received passing knowledge test scores and demonstrated role-playing proficiency. Clinical note assessment and discussions during conference calls also indicated successful implementation.

Our findings suggest that PBPT may be effective in modifying psychological risk factors for disability. Effectiveness of PBPT was partially assessed by comparing short-term change in psychological risk factors on the intervention and control carriers (abstract #6 attached). Patient outcomes were assessed on both carriers at 4 weeks post enrollment which took place at the initial PT evaluation. Confounding factors were accounted for in the analyses. The intervention group expressed significantly greater satisfaction with care than the control group after treatment (abstract #3 attached). Pre-post changes in psychological risk factors between the study groups were not significant. However, they all trended in the hypothesized direction for the intervention group, with this group showing a greater reduction in distress and greater increase in positive coping than the control group (Weiser et al. in preparation)

Subjects who received PBPT showed a better understanding of the psychological aspects of pain than those who received usual care (Weiser et al, pending submission approval by US Navy, draft attached). At 4 weeks, all patients completed an open-ended question: "Please list the most important thing(s) you learned in physical therapy" designed to determine if messages patients received from PTs differed between groups. Four general concepts consistent with PBPT messages were established a priori by investigators and were used to guide the qualitative analysis. Results indicated that the number of responses reflecting PBPT concepts were 29 (34%) in the intervention group and zero in the control group (abstract #2 attached).

Clinical depression was prevalent in the study population with lower levels of PTSD and anxiety (abstract #4 attached). Of the one hundred and ninety-five subjects who completed the psychiatric questions in our baseline survey, 16 (8.2%) reported elevated PTSD scores, 32 (16.4%) reported moderate or greater anxiety and 73 (37.4%) reported moderate or greater depression.

This analysis found that back and shoulder disorders were most prevalent in deployed Navy ADSM (abstract #7 attached). Knee injuries were also common. More than half of the participants reported a MSI comorbidity, which, in previous studies of civilians, is associated with poor outcomes. Although almost half of the ADSM reporting to PT had injuries with an insidious onset, a large number of injuries reported were work related and have the potential to be reduced through work and exercise injury prevention education (abstract #8 attached). Falls and lifting comprised two thirds of specific MOIs

Conclusions

Our study results add to the growing body of literature that supports a psychologically based approach to MSI. Though only satisfaction with treatment was significantly higher in the treatment group, all other study variables trended in the expected direction. One reason that this finding was not more robust may be that subject accrual fell short of the projected sample size due, in part to IRB delays.
We also found that subjects who received PBPT were more likely to learn PBPT concepts than those who did not suggesting that PBPT concepts were transferred to patients from the PT staff.

We were unable to analyze the long-term outcomes of health care utilization and LIMDU status due to inaccessible and low quality data. Therefore, a limitation of this study was that we could not assess whether short-term trends result in long-term benefits to ADSM and the military in this study. Our study also found that depression was present in a third of our sample. This problem may need to be addressed in order to ensure a combat-ready force. Finally mechanisms of injuries identified in this study should be addressed through injury prevention programs.

Future Directions

Our findings indicate that PBPT has the potential to limit attrition due to musculoskeletal injuries in Navy personnel. However more research is needed to support this idea. Future studies should aim to enlist larger sample sizes and explore alternative forms of long-term data collection and retrieval. Outcomes other than health care utilization and LIMDU, such as ongoing functional limitations should be studied. While we have demonstrated that PT staff can be successfully trained in PBPT is also important to understand the mechanisms through which PBPT works to ensure its success. For example, we need to understand how and under what conditions information is successfully transferred from the PT to the patient, whether or not patient-knowledge results in behavioral changes and if changes in patient knowledge lead to better outcomes. It is still unknown for whom and for which conditions this approach works best. This needs to be explored in future studies so that treatment can be tailored to meet the needs of the patient. Finally, injury prevention strategies for this population need to be explored.

Goals not met as of this period are:

Due to restrictions in accessing health care utilization outside of physical therapy visits and missing ICD codes on shore-based data we determined the data to be unreliable. Therefore, we were unable to analyze health care utilization data as planned. In addition, only 2 subjects in the control carrier and 1 subject in the intervention carrier progressed to LIMDU status within the study period. Therefore, we are unable to statistically compare the carriers on this outcome.

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

The PT personnel of the control carrier have been trained in detecting psychological risk factors from the baseline questionnaires and facilitating referrals as needed. Training of the intervention carrier resulted in the creation of an evidence based PBPT training protocol and physical therapist and patient educational materials.

Abstract submissions and presentations at national and international conferences reporting on short-term results has advanced knowledge in the area of PBPT among the professional community.

How were the results disseminated to communities of interest?

Over the course of the study period we submitted and presented a total of eight abstracts. We are currently awaiting Navy approval to submit our second paper entitled "What Do Patients with Musculoskeletal Injuries Learn from Psychologically-informed Physical Therapy?" In addition our manuscript "Feasibility of Training Physical Therapists to Implement a Psychologically-Informed Physical Therapy Program for Deployed US Sailors and Marines with Musculoskeletal Injuries" was successfully published by the Journal of Military Medicine.

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

NA

4. Impact

What was the impact on the development of the principal disciplines of the project?

As part of the PBPT protocol implementation on the intervention carrier, the PT personnel now have a goal of promoting a fast and optimal recovery by removing psychological obstacles, obviating the need for referral to a psychologist in patients at risk and to facilitate triage to other health professionals when needed in a timely manner.
Feedback received by the intervention carrier PT personnel that indicate development of their discipline through a PBPT approach includes their understanding of the importance of patient education to facilitate patient buy-in during PT, the use of graded activity to restore confidence and reduce fear and enhanced understanding of the patient's perspective. The positive results of the study in terms of the physical therapy personnel and patient short-term outcomes will likely make an impact on how treatment will be delivered by the trained PT personnel within the Navy.

What was the impact on other disciplines?

The protocol is likely to make a long-term impact on the discipline of psychology as it facilitates referrals from physical therapy and promotes interdisciplinary care.

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Our results add to the growing body of literature that supports a PBPT approach to MSI and has demonstrated the feasibility and utility of this type of treatment in military personnel. If training in this approach is offered to PTs, we would expect a decrease in pain and disability associated with MSI.

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

Nothing to Report

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

1. Manuscript published in The Journal of Military Medicine. Weiser S, Lis A, Ziemke G, et al. Feasibility of Training Physical Therapists to Implement a Psychologically Informed Physical Therapy Program for Deployed U.S. Sailors and Marines with Musculoskeletal Injuries. Mil Med 2018;**183**(suppl_1):503-09 doi: 10.1093/milmed/usx229[published Online First: Epub Date]|

-Books or other non-periodical, one-time publications

Nothing to report

-Other publications, conference papers, and presentations

<u>Abstracts</u>

1. "Feasibility of Training Physical Therapists to Implement a Psychologically-Based Physical Therapy Program for Deployed US Sailors and Marines with Musculoskeletal Injuries" (Military Health System Research Symposium – Accepted and Presented 2016)
2. What do patients learn from psychologically based physical therapy? (World Congress of Physical Therapy – Accepted and Presented 2017)
3. How does psychologically informed physical therapy affect treatment satisfaction in active duty service members with musculoskeletal injuries aboard a United States Air Craft Carrier (Military Health System Research Symposium – Accepted and Presented 2017)
4. Mental Disorders In Deployed Navy Active Duty Service Members Reporting Musculoskeletal Injuries Aboard Two United States Air Craft Carriers(Military Health System Research Symposium – Accepted and Presented 2017)
5. What do patients with spine pain learn from psychologically informed physical therapy? (EUROSPINE-Accepted and Presented 2017)
6. Short-term outcomes of a psychologically-informed physical therapy (PIPT) treatment in marines and sailors with musculoskeletal injuries (MSI) aboard a United States Navy Air Craft Carrier Manuscript (APTA Combined Sections Meeting- Accepted and Presented 2018)
7. Mechanism of Injury for Musculoskeletal Injuries in Active Duty Service Members (ADSM) reporting to Physical Therapy aboard two naval aircraft carriers (Military Health System Research Symposium –Accepted and Presented 2018)

8. Musculoskeletal Injury Incidence In Deployed Navy Active Duty Service Members (ADSM) Reporting Musculoskeletal Injuries Aboard Two United States Air Craft Carriers(Military Health System Research Symposium –Accepted and Presented 2018)

Manuscripts

1. Feasibility of Training Physical Therapists to Implement a Psychologically-Informed Physical Therapy Program for Deployed US Sailors and Marines with Musculoskeletal Injuries (Published, see above)
2. What Do Patients with Musculoskeletal Injuries Learn from Psychologically-informed Physical Therapy? (pending submission approval by the US Navy)
3. Does psychologically-informed physical therapy (PIPT) modify psychological risk factors for disability in marines and sailors with musculoskeletal injuries (MSI)? (in process)
4. Incidence and mechanisms of musculoskeletal injuries in deployed Navy Active Duty Service Members aboard two United States Air Craft Carriers (Invited to submit to The Journal of Military Medicine- In process)

Website or other internet site

The study was registered on the clinical trials website which is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

URL: https://clinicaltrials.gov/ct2/show/NCT02472067?term=psychologically+based&rank=1

Technologies or techniques

Nothing to report.

Inventions, patent applications, and/or licenses

Nothing to report.

Other Products

Data results

7. Participant's & other collaborating organizations

What individuals have worked on the project?

Name:	*Sherri Weiser-Horwitz*
Project Role:	*Principal Investigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	No change
Contribution to Project:	*Dr Weiser oversaw all research activities, including preparation of documentation to IRB, preparation of training material for control group, preparation of material for HRPO application, weekly research meetings, preparation of intervention training program, training the research associate, monitoring data collection, registering the study through clinical trials and preparing quarterly reports.*
Funding Support:	NA

Name:	*Marco Campello*
Project Role:	*Co- Principal Investigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	No change
Contribution to Project:	*Dr Campello assisted the PI in all aspects of the study and in particular, prepared study procedure training materials for the control and intervention group and trained control carrier physical therapists and oversaw preparation of study procedures and training materials for the intervention group. He prepared documentation for NCRADA and participated in weekly research meetings.*
Funding Support:	N/A

Name:	*Mike Lashbaugh MS PT*
Project Role:	*Co-Principal Investigator (Navy)*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	*Mr Mike Lashbaugh participated in research meetings, assisted in IRB preparations and amendments and assisted with advisory board material preparation.He has been working very closely with the Navy IRB to get the amendments approval. Mr Lashbaugh has assumed the Co-PI role this year and completed all required prior approval.*
Funding Support:	*NA*

Name:	*Angela Lis*
Project Role:	*Research Coordinator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	No change
Contribution to Project:	*Dr Lis supervised the preparation of training materials for the control group, participated in weekly research meetings, participated in the development of the intervention group training program and training tools. Assisted with ongoing literature searches and trained the research associate.*
Funding Support:	*NA*

Name:	*Tara Brennan*

Project Role:	*Research Associate*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	No change
Contribution to Project:	*Ms. Brennan has completed ongoing literature searches to update the investigators and assisted in the creation of training materials and tools for the intervention group. She assisted with registering the trial at Clinical Trials.Gov and preparing quarterly and year end reports. She participated in weekly research meetings and assisted in piloting data collection.*
Funding Support:	NA

Name:	*Rudi Hiebert*
Project Role:	*Associate Investigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	No change
Contribution to Project:	*Mr. Hiebert assisted in the preparation of IRB material and study procedure training material, prepared data collection materials, data recording procedures and data use agreement, participated in weekly research meetings and assisted in control carrier training. He piloted data collection procedures and is responsible*
Funding Support:	NA

Name:	*Gregg Ziemke*
Project Role:	*Co-Principal Investigator (SEPT 2014- JUNE 2015), Volunteer*
Researcher Identifier (e.g. ORCID ID):	

Nearest person month worked:	No change
Contribution to Project:	*CAPT Ziemke prepared study procedure training material for the control group, prepared documentation for NCRADA, participated in weekly research meetings and assisted in the IRB preparation. He also took part on the training of the control carrier personnel. As Co-PI, he also helped in the identification of the control and intervention carriers. CAPT Ziemke was instrumental in reaching out the Physical Therapy teams of both carriers as well as their respective commanders.*
Funding Support:	NA

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

Nothing to report for this final annual period. The Navy PI CDR Brian Iveson left his PI role and was replaced by Mr Mike Lashbaugh, MS PT. This change was reported and approved by HRPO and the IRB in March 2017

What other organizations were involved as partners?

Organization Name

Bridging advanced developments for exceptional rehabilitation (BADER Consortium)

Location of Organization

University of Delaware
STAR Campus
540 South College Avenue,
Suite 102
Newark, DE 19713

Partners Contribution to the project

Led by the University of Delaware BADER Consortium is establishing evidence-based orthopedic rehabilitation for wounded warriors so that each patient can reach his or her optimal level of function. The BADER Consortium brings together researchers, health professionals and physicians from across the U.S. The overarching goal of the BADER Consortium is to work in concert with four Department of

Defense Medical Treatment Facilities to strengthen and support evidence-based orthopedic rehabilitation care.

The BADER Consortium has provided support staff located at NMCP that provide day-to-day research support to this project. Rudi Hiebert serves as an Associate Investigator on this study and is involved in training materials development, data collection procedures, statistical analysis, and the data use agreement. Danielle Faulkner supports the study by preparing and submitting IRB documentation, serving as the point of contact for carrier staff, and managing carrier data collection.

The BADER Consortium has also assisted this project by allowing use of their Clinical Trials Database System (CTDB). The CTDB is a protocol and data management system used to assist investigators to capture and manage de-identified data. De-identified data will be entered in a CTDB, by the BADER staff on this project. All data will be stored in an access-controlled database with end-to-end government grade encryption. Data exchanged between sites will also occur in a secure manner through the Clinical Trials Database (CTDB).

8. Special reporting requirements

Collaborative Awards

N/A

Quad Charts

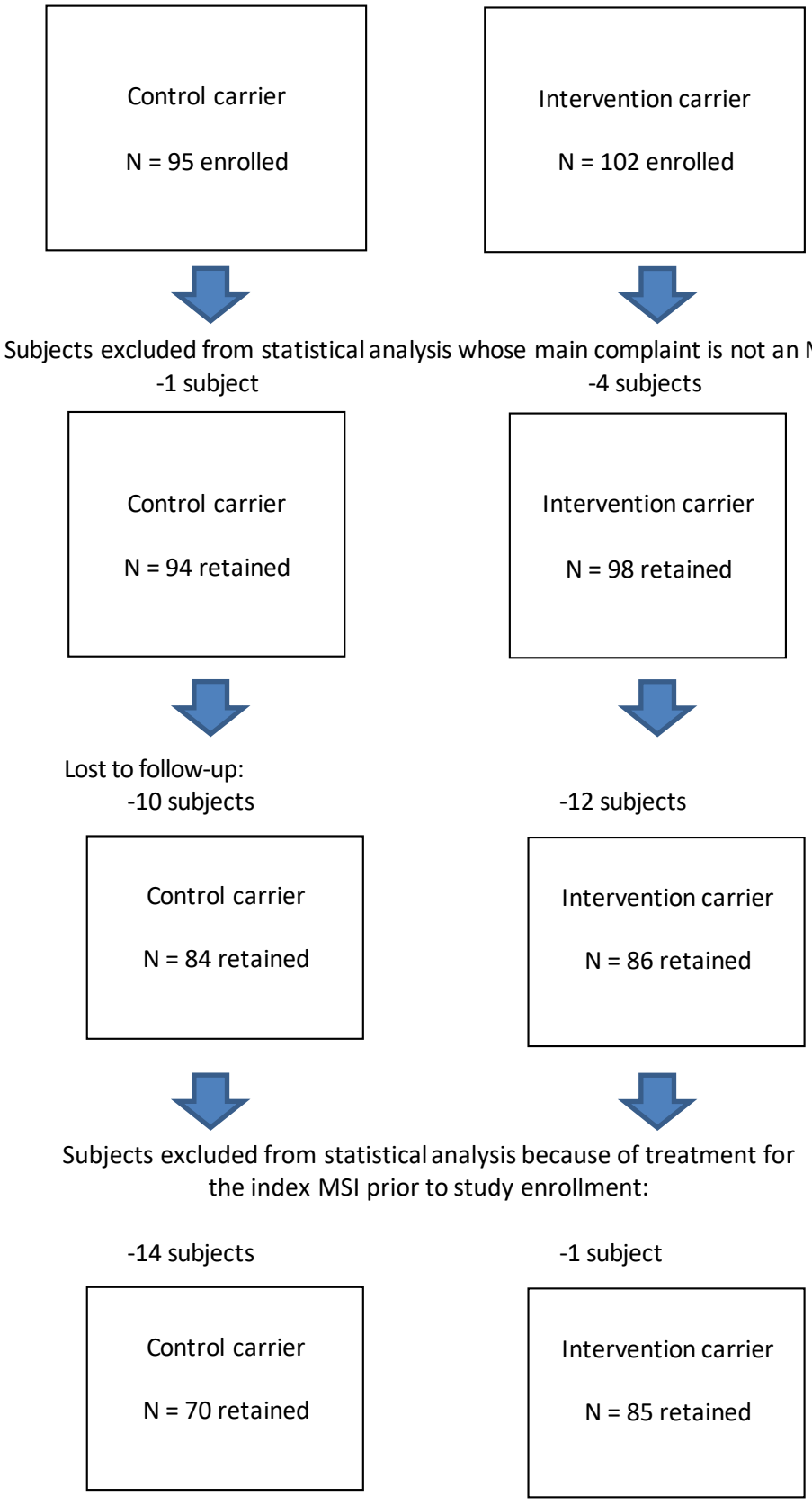
Please see appendices for updated Quad Chart.

4. Appendices

Appendices attached below include:

- Study Recruitment Flowchart;
- Baseline demographics and descriptives;
- Short-term outcomes;
- Long-term outcomes;
- Qualitative results of assessment of intervention implementation;
- Quad Chart (final);
- Abstract Presentations;
- Publication;
- Paper pending Navy approval for publication submission;
- Manual of Operating Procedures (MOOP)

Study exclusion flow chart



Final Baseline Descriptives: All study variables

Table 1					
Flags	**N=155 (follow-up only, exclusion applied)**		**Control (n=70)**	**Intervention (n=85)**	**Baseline Comparison**
RED	Data not available		Unknown	Unknown	
ORANGE	CES-D		13.1 (10.0)	14.1 (11.3)	MW p = 0.65
	PCL-M		27.6 (10.4)	29.3 (13.1)	MW p = 0.57
	GAD		4.6 (4.5)	5.2 (5.4)	MW p = 0.68
YELLOW	SBT (distress)		1.0 (1.1)	1.2 (1.2)	MW p = 0.0899
	Expectations of recovery		8.2 (2.0)	6.7 (2.5)	*MW p < 0.01
	Self-Efficacy		8.2 (2.4)	7.3 (2.4)	*MW p = 0.017
	Fear of work		1.7(2.5)	2.3 (2.4)	MW p = 0.068
	Perceived Disability		2.7 (1.2)	3.1 (1.0)	*MW p = 0.040
	Pain Interference		3.3 (2.3)	4.0 (1.9)	MW p = 0.043
BLUE	Job Satisfaction	Very dissatisfied	7 (10%)	7 (8%)	Chi Square p= 0.254
		Somewhat dissatisfied	4 (6%)	10 (12%)	
		Mixed	28 (40%)	25 (29%)	
		Somewhat satisfied	19 (27%)	19 (22%)	
		Very satisfied	12 (17%)	24 (28%)	
	Work Stress	Not stressful at all	2 (3%)	7 (8%)	Chi Square p= 0.316
		Slightly stressful	18 (26%)	10 (12%)	
		Moderately stressful	16 (23%)	25 (29%)	
		Stressful	26 (37%)	19 (22%)	
		Extremely stressful	8 (11%)	24 (28%)	
	Organizational Commitment		1.7 (3.6)	1.8 (3.7)	MW p=0.933
	Job social support		40 (9.9)	40 (10.3)	MW p=0.503

BLACK	Phase of deployment when injury occurred	95 enrollments during 'on station' phase'		13 enrollments during transit outbound; 90 enrollments during 'on station'		
	No of previous deployments	Data not available		Data not available		
Demographic & Other baseline info		**Control (n=70)**		**Intervention (n=85)**		
	Duration of follow-up	31.9 (12.3)		37.5 (19.7)		MW p << 0.001
	Pain Intensity	5.6 (2.1)		5.0 (1.7)		MW p=0.0657
	Pain Duration	More than 12 weeks	10 (14%)	More than 12 weeks	50 (59%)	Chi-square p<<0.001
		4-12 weeks	15 (21%)	4-12 weeks	19 (22%)	
		<4 weeks	45 (64%)	<4 weeks	16 (19%)	
	Age	26.3(6.1)		29.5 (7.3)		MW p=0.004
	Gender	Female	21 (30%)	Female	19 (22%)	Chi Square p=0.279
		Male	49 (70%)	Male	66 (78%)	
	Race	Data not available				
	Length of service	Data not available				
	Rate	Data not available				
	Current MSI Comorbidity	22 (31%)		59 (69%)		Chi-Square p=<0.001

Primary MSI (follow-up, exclusion applied)	**Intervention N = 85**	**Control N = 70**	**Chi-square**
Shoulder problem	19 (22%)	18 (26%)	0.055
Arm or hand problem	2 (2%)	8 (11%)	
Neck problem	1 (1%)	0 (0%)	
Mid-back problem	8 (9%)	3 (4%)	

Low back pain problem	38 (45%)	20 (29%)	
Hip problem	2 (2%)	3 (4%)	
Knee problem	11 (13%)	8 (11%)	
Ankle or foot problem	3 (4%)	8 (11%)	
Other	1 (1%)	2 (3%)	

Mechanism of Injury

Table 2		
Mechanism of Injury		**Incidence (All baseline, n=197)**
Pre- Deployment		
Prior Injury		21 (10.6%)
Deployment		
Work Related	Insidious	92 (46.5%)
Work Related Specific MOI	Falls/Slips/Trips	15 (7.6%)
	Lifting/Carrying	15 (7.6%)
	Pulling/Pushing Object	8 (4%)
	Struck by Object	4 (2%)
	Manipulation of Object	1 (0.5%)
	Sudden Movement	1 (0.5%)
	Injury by other person unintentional	1 (0.5%)
	Awkward Working Position	1 (0.5%)
Sports/Exercise		38 (19.2%)
Unknown		1 (0.5%)

Table 3 **Barriers**	**Control (n=95)**	**Intervention (n=103)**
Working conditions (food, technology, time)	16 (17%)	22 (22%)
Supervisor/unit attitudes (fear of others/lack support)	4 (4%)	4 (4%)
Health care conditions (facilities/consistent providers)	2 (2%)	3 (3%)
Policies and procedures	0 (0%)	2 (2%)
No barriers	73 (77%)	72 (70%)
Total	95	103

*Even though we observed differences in these factors at baseline between the control and intervention carriers, these factors produced no meaningful change in our estimate of treatment effect and were not statistically significant in multivariable analysis. Therefore these factors were not retained in the final analysis being reported.

Short-Term Outcomes :Final Analysis Exclusion Criteria Applied *

Table 4 **Short-term outcome**	**Comparison and Direction**	**Significance**
Psychological Distress	Both carriers improved. Adjusted OR= 1.04	p = 0.928
Pain Intensity	Both carriers improved. Intervention carrier showed greater likelihood of improving. Adjusted OR=1.37	p = 0.536
Outcome Expectation	Both carriers improved. Intervention carrier showed greater likelihood of improvement. Adjusted OR=1.22	p= 0.644
Self-Efficacy	Both carriers improved. Intervention carrier showed greater likelihood of improvement. Adjusted OR=1.15	p = 0.746
Fear of Work	Both carriers improved. Intervention carrier showed a greater likelihood of improvement. Adjusted OR=1.02	p = 0.966
Pain Interference	Both carriers improved. Intervention carrier showed a greater likelihood of improvement. Adjusted OR=1.27	p = 0.631
Perceived Disability	Both carriers improved. Intervention carrier showed a greater likelihood of improvement. Adjusted OR=1.20	p = 0.700
Satisfaction with process of care	Both carriers improved. Intervention carrier showed a greater likelihood of improvement. Adjusted OR=2.64	p = 0.024
Satisfaction with outcome	Both carriers improved. Intervention carrier showed a greater likelihood of improvement. Adjusted OR=1.334	p = 0.508
Quality of life.	Both carriers improved. Intervention carrier showed a greater likelihood in improvement. Adjusted OR=1.38	p = 0.463

*Adjusted for baseline depression, symptom duration, pain interference and concurrent MSI.

Training Feasibility and Results

Feasibility Assessment

Feasibility of implementation of PIPT on board a carrier was guided by recommendations from Yates et al. (2005) for assessing the treatment quality of clinical trials. Criteria for feasibility were as follows:

- Knowledge of main PIPT concepts: Assessed by a knowledge test given at the end of the training in which a passing score was 85%.
- Demonstration of PIPT skills: Demonstrated by the ability to use eight case studies and three role playing scenarios to screen for yellow flags and delineate interventions following the training. A scored of pass or fail was given. A two person inter-rater agreement of 100% was required to obtain a passing score.

- Demonstration of PIPT application: Assessed by analysis of clinical notes during the deployment.
- Demonstration of PIPT acceptance: Demonstrated by verbal responses of PT staff during phone conferences

Results

Training and reinforcement during deployment was conducted over 9 months. At the end of the training both the physical therapist and the physical therapy technician received passing knowledge scores (100% and 85% respectively). Both PT staff members demonstrated their capacity to score the screening tools, screen patients during role playing, and outline PIPT interventions to modify yellow flags. Both trainees passed this assessment with 100% agreement of the trainers.

During implementation, 19 clinical notes were independently evaluated. Evaluators looked for the documentation of the presence or absence of yellow flags in clinical notes demonstrated by information such as: “increased stress levels and fear of re-injury”, “fears not being able to work again”, or “no flags”. They also looked for a plan to address yellow flags when present shown by phrases such as, “patient education in pain coping techniques.” Functional goals such as: “improve quality of sleep”, “return to lifting activities”, “return to regular exercise program” and “return to full duty” were also reviewed in the treatment plan section. If any of this information was missing, it was addressed during the next conference call and corrected in future notes. This was done until no missing information was detected, such that all notes were complete at the end of the deployment.

Both PT staff members participated in all nine conference calls. These calls took place only when the ship was able to establish ship-to-shore communications. The PT staff presented challenging cases during these meetings to demonstrate how they managed the cases and to get feedback from the investigators. These discussions indicated that they were applying PIPT skills consistently and proficiently throughout the deployment.

Assessment of intervention implementation

Patients were asked “Please list the most important things you learned in physical therapy”

Three blinded raters were asked to review the answers and search for the following key words (or similar) that might reflect PBPT intervention

Biopsychosocial understanding of pain: Key words:

- Mind-body
- Biopsychosocial
- Stress, Fear, Depression, Anxiety, Anger … can affect pain
- A positive attitude is important when dealing with pain, injury ...

Self-care techniques such as: Key words:

- I am taking care of my pain, injury etc.
- I am staying active
- I am practicing relaxation

- I am practicing positive thoughts
- I am moving as much as possible
- I am working at full capacity

Adaptive pain beliefs such as: Key words:

- I can control my pain
- I can manage my pain
- Activity, work is good for recovery
- Pain does not mean damage
- Pain does not mean harm
- I can cope with pain

Knowledge such as: Key words:

I understand my pain, symptoms, condition

Steps:

1. Three raters independently reviewed all open ended question answers.
2. Following this a meeting was held and all three raters created a final list of statements that matched/similar to the PBPT "proxy key words".
3. Statements in which all three raters agreed on where automatically included in the final list.
4. If not all raters agreed on certain statements a discussion was held and if a consensus was not reached they were excluded.

Statements shown below that all raters agreed on;

De-Identified Subject Number	**Subject Statement**
4	Physical therapy has teached me the tolerance levels of damaged tissues, the slow road to recovering, learning how to strengthen other muscles to help support a weaker more damage/inflamed muscle, and to keep pushing through mental barriers of pain to overcome the non effort to make an injury better
6	Stress and pain feed into each other. Physical exercises to strengthen supporting muscles. How to lower a raised rib.
8	To be patient when recovering from my injury and not all pain is bad.
10	More ways to stretch to easy my pain.^How to cope with my injury.
11	I learned how to self treat myself when the injury started to flare up. I learned ho back injuries can also go hand in hand with depression.
16	Learned what my condition is.^- Learned what causes my condition.^- Learned how to cope with flare ups to stay loose and prevent further pain.
27	Pain relief techniques, strengthening exercises lifting exercises and that my condition is manageable and can/has get better
34	I learned how to practice proper posture and strengths that will help me to deal with my pain levels. I also learned various techniques on how to trick the brain to defeat pain. Through my stretches, posture, and breathing

	techniques I feel a tremendous difference in my body and my pain has lowered a lot
36	I learned how to do exercises that can help cope with my pain. I learned that through time it will get better the more I attend physical therapy. Additionally I learned that pain can affect your mental stability and emotions over time if the issues is not being handles properly. I learned to listen to my body more when something is wrong and notice early symptoms to prevent further injury.
38	Strategies to relieve pain, importance of posture
41	1. Stress and physical pain have a connection.^2. Stretching is good to relieve pain^3. Exercises that help my condition
50	I have learned what is causing my pain and that it can be treated without surgery. Some small lifestyle changes to improve my condition. Attitude is everything to improve treatment.
54	The cause of my condition^How to prevent injuries like this in the future^Stretches/exercises to help the pain/reduce swelling^The physical activities I am still able to do (I.e. bike run
60	Stress and pain go hand in hand. My body will respond to my stress by tensing up the muscles and creating pain as well as discomfort
62	Spinal stretches, how to stay active and manage the pain while reaching full range of motion. Building the core to help support the lower back. Most important not to be afraid of the motion but to use correct form, listen to my body and stretch/walk the muscles to build back and core strength.
64	I have learned correct posture, stretching, exercises, how to cope with my uncomfortness on a day to day basis.
68	Pain mng.
69	Learned how to get my range of motion back. My therapist explained how the bone work and move. Also how I can prevent further injury. I learned how to deal with weight and pressure on my wrist without being afraid of irritation and injury.
71	How to manage my back pain.^-How to manage my stress level and how stress contributes to pain.^-Stretch properly!!
72	The key thing I have taken away from PT so far is how to manage pain/work thru discomfort to achieve my PT goals, of strength and stability of my injured knee.
77	That there are ways to manage. That my pain is real and I just needed to find the right person who understood my pain and how I can get the right care and treatment.
79	Overall the best physical therapy received thus far! Stretches and proper form for exercises where excellent and are working. I've learned how to maintain proper posture and how to deal with pain, when it arises. This experience and treatment has been beneficial.
83	More exercises to reduce the pain by strengthening the muscles. The link between stress and the muscles. Learned how to spot the symptoms before it becomes a major issues
87	I learned how to do things on my own to prevent and get rid of my pain and how to prevent other issues from occurring.

90	My pain is/was normal^-My pain can be managed at home^-I appreciated the gradual approach to maintenance by introducing a few stretches at a time
93	How to prevent pain/issues in the future through exercises/stretches. Also, how to deal with and minimize pain when it does pop up. This type of information and support should definitely be standard for all helicopter crews given the documented history of back pain caused by Navy helicopters.
95	The stretches help the most, knowing better ways to stretch changes the level of pain. Stress plays a larger role than I had thought and finding stress relievers.
98	My condition is mostly posture driven.^- Stress does contribute to my condition^- I've learned exercises and stretches that will help improve my condition.
100	Why I felt the way I did how to prevent it. Pain management.

Following de-identification the following results were yielded:

	No of follow-ups completed	**No of Statements reflecting PBPT "keywords"**	**No of subjects who completed follow-up questionnaires and did not answer the open ended question**
Control Carrier	90	0	22 (26%)
Intervention Carrier	85	29 (34%)	5 (5.8%)

Long-Term Outcomes

Health Care Utilization

Due to a restriction in accessing ship based health care data we were unable to compare all health care utilization between ships. The only data we were able to access was for Physical therapy visits on board. We planned to follow-up all patients for a six month period for health care utilization. However on shore health care utilization data we could not confirm whether the visit was for PT. Therefore data quality was compromised and we could not confirm its accuracy.

LIMDU

Carrier	**LIMDU Assignment**
Control	2
Intervention	0

*Due to low numbers we were unable to statistically compare the carriers LIMDU assignment.

A pilot study to test the efficacy of psychologically-based physical therapy training for treating deployed US Sailors and Marines with musculoskeletal injuries

ERMS/Log Number: OR130160

Award Number: GRANT11452369

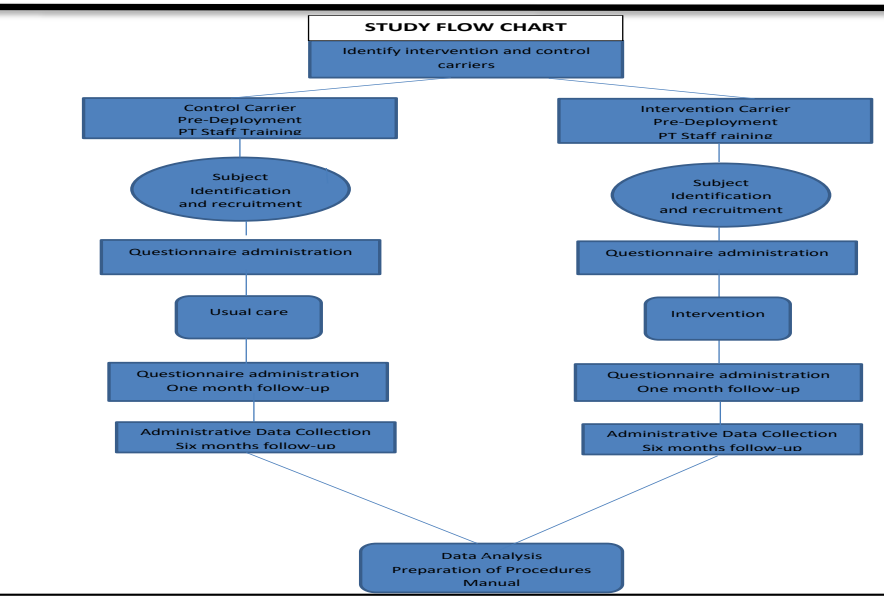
PI: Sherri Weiser, PhD **Org:** New York University School of Medicine **Award Amount:** $1,021,985

Study/Product Aim(s)

1. Training and certification of the intervention physical therapy staff
2. Training and certification of the control arm physical therapy staff in the
3. Enroll about 300 subjects onboard of control carrier
4. Enroll about 300 subjects onboard of intervention carrier
5. Follow up of participants for the entire duration of deployment following the date of the index MSI and an additional 6 months following case accrual.
6. Complete a technical report

Approach

This is a quasi-experimental, pre-post- test study with a non-concurrent control group to test the effectiveness of psychologically-based physical therapy for ADSM who sustain a musculoskeletal injury aboard a Carrier. This approach will consist of a study with one deployed carrier serving as the intervention and a second carrier serving as a control. Outcomes include psychological distress, well-being, and satisfaction at one month post-treatment and health care utilization and LIMDU assignment at 6 months post-deployment.



Timeline and Cost

Activities CY	14	15	16	17	18
IRB/Training of PTs					
Recruitment/Pilot Study					
Preparation of Manual					
Data Analysis					
Estimated Budget ($K)	$368,863	$345,360	$307,762		

Updated: (New York 25/06/2018)

Goals/Milestones

CY14-15 Goal – Approval of IRB and training of Physical therapists

- ☑ Have all IRB approval
- ☑ Proficiency of Physical therapist assessed after training

CY15-16 Goals – Recruitment and Pilot Study

- ☑ Achieve recruitment goal
- ☑ Complete the pilot study

CY16-17 Goal – Data Analysis and Results

- ☑ Analysis of the data
- ☑ Preparation of a Manual of Operations and Procedures

Comments/Challenges/Issues/Concerns

Budget Expenditure to Date

All study goals and milestones were reached within this quarter and a final technical report was generated. Due to compromised health care utilization data we were unable to analyze and compare this long-term outcome. In addition only two study subjects reached LIMDU therefore we did not have a large enough sample size to compare. Two abstracts were presented at MHSRS based on study findings, one manuscript is pending submission approval and two study manuscripts are in process. We were financially on track this final quarter.

Abstracts

Abstract 1

Military Health System Research Symposium (MHSRS) –August 2016

Feasibility of Training Physical Therapists to Implement a Psychologically-Based Physical Therapy Program for Deployed US Sailors and Marines with Musculoskeletal Injuries

Sherri Weiser, PhD* • Marco Campello, PT, PhD* • Angela Lis, PhD, PT* • CAPT (ret) Gregg Ziemke, PT, MS, MHA,OCS** • Rudi Hiebert, ScM** • Danielle Faulkner BS, CCRC** • Tara Brennan, MPH* • CDR Brian Iveson, DScPT, OCS, SCS***

* Occupational and Industrial Orthopedics Center, New York University Hospital for Joint Diseases, New York, NY.
**BADER Consortium, University of Delaware, Newark, DE.
***Department of Physical Therapy, Naval Medical Center Portsmouth, Norfolk VA.

Background

Recent data show that in 2011, 15.7 per 10,000 US Navy service members were sent to a Physical Evaluation Board for a disabling musculoskeletal condition and of these 39% were separated. Psychological factors are stronger predictors of musculoskeletal injury (MSI) outcomes than clinical factors in civilian and military populations alike. Numerous studies have identified specific modifiable psychological variables associated with poor outcomes such as pain and disability. Cognitive-behavioral therapy (CBT) aimed at modifying these factors in conjunction with physical therapy (PT) is shown to be superior to unimodal care when administered by a mental health professional. Recently, it has been proposed that PTs can be trained to identify and modify psychological risk factors using CBT principles as part of their clinical practice at treatment onset. This approach may be considered “psychologically-based physical therapy” (PBPT). Successful PBPT requires a shift from a purely biomedical approach to a biopsychosocial paradigm. PBPT has not been tested in a military environment, which has a unique culture. Successful implementation of PBPT in the Navy has the potential to reduce attrition. This study reports on the feasibility of training Navy PTs to implement PBPT during deployment on an Aircraft Carrier.

It is part of a larger study supported by the Office of the Assistant Secretary of Defense for Health Affairs through the CDMRP, Award No. W81XWH-14-2-0146.

Methods

PBPT training was developed by the researchers and piloted on the PT staff of an Aircraft Carrier. Training of the PT and PT Technician was conducted prior to deployment in the presence of the Carrier psychologist. Training was done over a three day period and included background of PBPT, models of care, skills development and application in the form of role-playing and case studies. A knowledge test was given at the end of the treatment for which a score of 85% was required to pass. Following deployment, bimonthly phone conferences were conducted to reinforce training, assess skill utilization and, discuss obstacles and solutions to implementation. Success of the training was further assessed by the presence or absence of predetermined indicators of PBPT implementation in the PTs' clinical notes

Results

Both trainees received passing knowledge scores (100% & 85%) after training. Clinical note assessment indicated that PBPT was being implemented successfully in all cases. The results of the conference calls showed that PTs were applying PBPT skills by discussing cases of patients at risk of disability and indicating how they responded.

Conclusion

The feasibility of training Navy PT staff to implement PBPT aboard a Carrier was demonstrated in this study. PTs were able to successfully translate training into practice. This is significant, since PBPT has the potential to limit attrition due to MSI in Navy personnel. Factors believed to be associated with the success of the training include adoption of the PBPT model by PT staff and training reinforcement during deployment. A study is currently underway to measure the effectiveness of the PBPT intervention by comparing patient outcomes between the present Carrier and a control Carrier.

Funding Acknowledgment

This abstract is part of a larger study supported by the Office of the Assistant Secretary of Defense for Health Affairs through the CDMRP, Award No. W81XWH-14-2-0146

Ethics Approval

Research data derived from an approved Naval Medical Center, Portsmouth, VA IRB [IACUC] protocol.

Disclaimers

The views expressed in this article are those of the author(s) and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the United States Government.

Human subjects statement

Research data derived from an approved Naval Medical Center, Portsmouth, Virginia Institutional Review Board (Institutional Animal Care and Use Committee) protocol number NMCP2014.0058.

Abstract 2

World Congress of Physical Therapy- July 2017

What do patient's learn from psychologically based physical therapy?

Authors

Sherri Weiser, PhD* Angela Lis, PhD, PT* Tara Brennan, MPH* CAPT (ret) Gregg Ziemke, PT, MS, MHA,OCS** Rudi Hiebert, ScM** Danielle Faulkner BS, CCRC**, CDR Brian Iveson, DScPT, OCS, SCS**, Danielle Southerst, DC*, Marco Campello, PT, PhD* Occupational and Industrial Orthopedics Center, New York University Hospital for Joint Diseases, New York, NY.

**BADER Consortium, University of Delaware, Newark, DE. ***Department of Physical Therapy, Naval Medical Center Portsmouth, Portsmouth, VA

Background

In the US Navy, musculoskeletal injuries (MSIs) comprise about 40% of sick call visits during deployment and are the main cause of separation. Modifiable psychological factors are associated with disability in patients with MSI. Modifying psychological factors requires a shift from a biomedical to a biopsychosocial model of care. The authors successfully trained physical therapists (PTs) aboard a US Navy Aircraft Carrier to do this using "psychologically-based physical therapy" (PBPT). PBPT uses concepts from cognitive-behavioral therapy, including identification and modification of psychological risk factors, patient education and active, goal-oriented treatment. The effect of this treatment on patients' understanding of their MSI has not been reported.

Purpose

This abstract describes what subjects learned from PBPT, using qualitative data from a larger study testing the effectiveness of PBPT for MSI in active duty service members (ADSM) aboard a US Navy Aircraft Carrier.

Methods

A quasi-experimental mixed methods study design was used to compare the results of PT intervention aboard two US Navy Aircraft Carriers. Physical therapists and physical therapy technicians (PT staff) on both Carriers received instructions on study procedures prior to deployment. Intervention carrier PT staff also attended a three day PBPT course. Once deployed, training was reinforced with bimonthly phone calls between investigators and PT staff. SOAP notes were analyzed to assess PBPT implementation. Four weeks post-enrollment, subjects completed follow-up questionnaires, including the open-ended question: "Please list the most important thing(s) you learned in physical therapy" designed to determine if messages that patients received from PT staff differed between groups. Concepts consistent with PBPT messages (e.g. mind/body connection, pain is not damage) were established a priori and used to guide the qualitative analysis. Statements by the subjects consistent with PBPT concepts were considered an indication that the PBPT message was received. Three blinded raters independently assessed subjects' responses. Only statements all three raters agreed on were considered to contain PBPT concepts. When raters disagreed responses were only considered to contain PBPT concepts if consensus was reached after discussion. PBPT concepts were considered absent from all other responses.

Results

Eighty-six intervention and 84 control subjects completed follow-up questionnaires. Of these, 26% (n=22) in the control carrier and 6% (n=5) in the intervention carrier did not answer the open-ended question. The number of responses reflecting PBPT concepts were 29 (34%) in the intervention carrier and 0 in the control carrier.

Conclusion

One third of the subjects exposed to PBPT reported learning PBPT concepts compared to zero control subjects. This is the first study to examine the transfer of PBPT knowledge from the PT staff member to the patient. This is an important step in establishing the efficacy of this approach.

Implications

PBPT aimed at improving outcomes for patients with MSI shows promise. This study demonstrates that a sizable proportion of subjects who received PBPT learned the messages they were taught compared to usual care controls. This suggests that PBPT may be effective in modifying patient beliefs in a way that is associated with less work disability. Future studies are needed to determine if such a change in patient beliefs is associated with better outcomes.

Keywords

Physical Therapy, Psychologically based, Musculoskeletal Injuries.

Funding Acknowledgment

This abstract is part of a larger study supported by the Office of the Assistant Secretary of Defense for Health Affairs through the CDMRP, Award No. W81XWH-14-2-0146

Ethics Approval

Human subjects statement: Research data derived from an approved Naval Medical Center, Portsmouth, Virginia Institutional Review Board (Institutional Animal Care and Use Committee) protocol number NMCP2014.0058.

Disclaimers

The views expressed in this article are those of the author(s) and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the United States Government.

Abstract 3

Military Health System Research Symposium (MHSRS) –August 2017

How does psychologically informed physical therapy affect treatment satisfaction in active duty service members with musculoskeletal injuries aboard a United States Air Craft Carrier

Sherri Weiser, PhD* • Marco Campello, PT, PhD* • Angela Lis, PhD, PT* • CAPT (ret) Gregg Ziemke, PT, MS, MHA,OCS** • Rudi Hiebert, ScM** • Cheongeun Oh , PhD*** • Danielle Faulkner BS, CCRC** • Tara Brennan, MPH* • CDR Brian Iveson, DScPT, OCS, SCS****

* Occupational and Industrial Orthopedics Center, New York University Hospital for Joint Diseases, New York, NY.

**BADER Consortium, University of Delaware, Newark, DE.

***Biostatistics, Department of Population Health, NYU Langone Medical Center, New York, NY.

****Department of Physical Therapy, Naval Medical Center Portsmouth, Norfolk VA.

Background

Patient satisfaction is a quality of healthcare indicator that has been linked to good patient outcomes. Psychologically informed physical therapy (PIPT) rooted in the biopsychosocial model of care entails helping patients to understand their physical condition, address maladaptive beliefs and increase self-efficacy. We hypothesized that PIPT would result in greater treatment satisfaction than traditional

biomedically-based physical therapy (PT). This study compares treatment satisfaction following PT on two aircraft carriers; one receiving PIPT and one receiving usual care. It is part of a larger pilot study to test the effectiveness of PIPT in this population.

Methods

Active duty service members (ADSM) with a musculoskeletal injury (MSI) who received PT aboard two carriers participated. Intervention carrier physical therapists received training in PIPT and met proficiency requirements described by the investigators elsewhere. Control carrier physical therapists received no training.

All subjects completed two post treatment satisfaction questions. Satisfaction with process of care was assessed with the eight item (ie. “my therapist answered all of my questions”) MedRisk assessment tool scored on a five point scale from “strongly agree” to “strongly disagree” with a possible total score of 40. A single item : “If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it?” scored on a five point scale from “very satisfied” to “very dissatisfied” from the Core Outcomes Measures Index assessed treatment outcome satisfaction.

Wilcox nonparametric tests were conducted to test for significance in univariate comparisons. Multivariate regression analyses were conducted while controlling for depression, pain interference and pain duration. Here, satisfaction with the process of care score was dichotomized at the median response value. Treatment outcome satisfaction was dichotomized into ‘Poor (combining ‘very dissatisfied,’ ‘somewhat dissatisfied’ and ‘neither satisfied nor dissatisfied’) and into ‘Good’ (combining ‘somewhat satisfied’ and very satisfied’).

Results

The intervention and control carriers consisted of 85 and 70 participants respectively. Univariate analysis showed a significant difference in satisfaction with process of care between groups ($p<0.001$), with the intervention carrier having a slightly larger satisfaction mean score (38.3 SD-3.8 v 35.8 SD 2.6). There was no significant difference in outcome satisfaction. In the multivariate analyses, intervention subjects were approximately 2.5 times more likely to report ‘High satisfaction’ with the process of care compared to control arm subjects(Adjusted OR = 2.5 $p=0.031$, 95% CL 1.1 – 5.9). Intervention subjects were nearly twice as likely to report ‘Good satisfaction’ with treatment outcome as compared to the control subjects, but this was not significant (adjusted OR =1.9, $p=0.173$, 95% CL 0.7 – 4.7)

Conclusions

Subjects who received PIPT were more satisfied with the process of care than those who received usual PT. As for treatment outcome satisfaction, although the univariate and multivariate analyses showed higher satisfaction for the treatment groups on both indicators, neither statistic reached significance. Replication of this study in larger samples is needed to provide adequate power to demonstrate significance. However, this pilot study suggest that patients are more satisfied with a PIPT approach than a biomedically oriented PT treatment.

Funding Acknowledgment

This abstract is part of a larger study supported by the Office of the Assistant Secretary of Defense for Health Affairs through the CDMRP, Award No. W81XWH-14-2-0146

Ethics Approval

Research data derived from an approved Naval Medical Center, Portsmouth, VA IRB [IACUC] protocol.

Disclaimers

The views expressed in this article are those of the author(s) and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the United States Government.

Human subjects statement

Research data derived from an approved Naval Medical Center, Portsmouth, Virginia Institutional Review Board (Institutional Animal Care and Use Committee) protocol number NMCP2014.0058.

Abstract 4

Military Health System Research Symposium (MHSRS) Abstract- August 2017

Mental Disorders In Deployed Navy Active Duty Service Members Reporting Musculoskeletal Injuries Aboard Two United States Air Craft Carriers

Sherri Weiser, PhD* • Marco Campello, PT, PhD* • Angela Lis, PhD, PT* • CAPT (ret) Gregg Ziemke, PT, MS, MHA,OCS** • Rudi Hiebert, ScM** • Cheongeun Oh , PhD*** • Danielle Faulkner BS, CCRC** • Tara Brennan, MPH* • CDR Brian Iveson, DScPT, OCS, SCS****

* Occupational and Industrial Orthopedics Center, New York University Hospital for Joint Diseases, New York, NY.

**BADER Consortium, University of Delaware, Newark, DE.

***Department of Population Health, NYU Langone Medical Center, New York, NY.

****Department of Physical Therapy, Naval Medical Center Portsmouth, Norfolk VA.

Background

Both musculoskeletal injuries (MSIs) and mental disorders are leading causes of separation from the US Navy. Data show that patients with a MSI who report high levels of post-traumatic stress disorder (PTSD), anxiety and depression have poorer outcomes than those without mental disorders. The prevalence of psychopathology associated with (PTSD), depression and anxiety varies with deployment status in active duty service members (ADSM) and tends to be highest during deployment. In non-combat deployed ADSM, PSTD has been reported as high as 7.3%, and depression has been reported as high as 18.5% for men and 23.7% for women. There are no estimates for the prevalence of anxiety in this group. The frequency of these disorders in ADSM with MSI is unknown. Identifying patients with MSI who may be at higher risk for separation from the Navy due to mental health comorbidities would permit early targeted care that may allow ADSM to remain on duty. This study reports on the prevalence of mental disorders in ADSM presenting to a physical therapy service with a MSI aboard a deployed Aircraft Carrier. It is part of a larger study supported by the Office of the Assistant Secretary of Defense for Health Affairs through the CDMRP, Grant No. GRANT11452369.

Methods

ADSM with a MSI who reported to physical therapy services aboard two carriers were recruited for the study. Subjects completed the PTSD checklist military version (PCL-M), The Center for Epidemiologic Studies Depression Scale (CES-D) and the Generalized Anxiety Disorder 7-item (GAD-7) as part of a larger questionnaire at baseline. Validated cut off scores of 50, 16 and 10were used respectively.

Results

One hundred and ninety-five subjects participated in the study. Of those 16 (8.2%) reported elevated PTSD scores, 32 (16.4%) reported moderate or greater anxiety and 73 (37.4%) reported moderate or greater depression.

Conclusions

The prevalence of mental disorders in ADSM aboard two non-combat deployed US carriers was variable. The PTSD rate was similar to other non-combat deployed populations and was relatively low (8.2%). The rate of anxiety was higher (16.4%). However, since this is the first study to look at the rate of anxiety in non-combat deployed ADSM, no comparisons can be made. Of particular interest is that 37.4% percent of the study population exceeded the cut-off for moderate depression compared to 18.5% to 23.7% percent in other non-combat deployed populations. This is notable because of the known effect of depression on the quality of life and self-harming behavior among ADSM. Since depression is associated with poor outcomes in patients with MSI, these individuals may be at particularly high risk for separation. Analysis of follow-up data to confirm this is ongoing.

Abstract 5

Eurospine –October 2017

What do patients with spine pain learn from psychologically informed physical therapy?

Authors

Sherri Weiser, PhD* Angela Lis, PhD, PT* Tara Brennan, MPH* CAPT (ret) Gregg Ziemke, PT, MS, MHA,OCS** Rudi Hiebert, ScM** Danielle Faulkner BS, CCRC**, CDR Brian Iveson, DScPT, OCS, SCS**, Danielle Southerst, DC*, Marco Campello, PT, PhD*

* Occupational and Industrial Orthopedics Center, New York University Hospital for Joint Diseases, New York, NY.

**BADER Consortium, University of Delaware, Newark, DE. ***Department of Physical Therapy, Naval Medical Center Portsmouth, Norfolk VA

Background

Psychologically informed physical therapy (PIPT) requires physical therapists (PTs) to address common psychological risk factors, such as patients' understanding and beliefs about spine pain (SP), to reduce the risk of disability. However, the effect of this treatment on patients' perceptions of their SP has not been studied. We developed a training program for PTs aboard a United States Aircraft Carrier aimed at modifying psychological risk factors in active duty services members (ADSM) with SP, and queried subjects about what they learned from physical therapy to determine the effect of PIPT on their SP beliefs.

Purpose

To determine what patients with SP learn from PIPT.

Methods

This is a qualitative analysis of data obtained from a larger controlled study on two US Navy Aircraft Carriers, testing the effectiveness of PIPT for all musculoskeletal injuries (MSIs) in ADSM. PTs in the intervention arm participated in a three day PIPT course that was reinforced during deployment. Four weeks post-enrollment, subjects completed an open-ended question: "Please list the most important thing(s) you learned in physical therapy", to determine if messages that subjects received from PTs differed between study groups. Concepts consistent with PIPT messages were established a priori and used to guide the qualitative analysis of the responses (e.g. I understand the mind/body connection, pain is not damage). Three blinded raters independently assessed subjects' responses. Subjects were considered to have understood the PIPT based message when all raters agreed that a response reflected PIPT concepts or when consensus was reached. PIPT concepts were considered absent from all other responses.

Results

Of the 47 SP intervention subjects, two (4.3%) did not answer the study question, compared to six (26.1%) of the 23 SP control subjects. Among patients with SP, 20 (42.6%) of the responses reflected PIPT concepts in the intervention carrier compared to zero in the control carrier. Only nine (23.7%) of the intervention subjects with all other MSIs listed statements reflecting PIPT concepts.

Conclusion

This is the first study to examine the transfer of PIPT knowledge from the PT to the patient. Almost half of the subjects with SP exposed to PIPT listed statements reflective of PIPT concepts among the most important things learned during physical therapy. In contrast, no subjects in the control arm did so. Subjects with SP also had a higher percentage of responses reflecting PIPT concepts than subjects with other MSIs, suggesting that this approach may be particularly helpful for patients with SP.

Implications

Effectiveness of PIPT requires that specific messages are communicated by the physical therapist and absorbed by the patient. Data from this study suggests that PIPT messages were absorbed and considered important by the study subjects in the intervention arm. Further studies to assess the impact of PIPT on patient beliefs and functional outcomes are ongoing.

Keywords

Physical Therapy, Psychologically Informed, Spinal Pain.

Funding Acknowledgment

This abstract is part of a larger study supported by the Office of the Assistant Secretary of Defense for Health Affairs through the CDMRP, Award No. W81XWH-14-2-0146

Ethics Approval

Research data derived from an approved Naval Medical Center, Portsmouth, VA IRB [IACUC] protocol.

Abstract 6

APTA Combined Sessions –February 2018

Short-term outcomes of a psychologically-informed physical therapy (PIPT) treatment in marines and sailors with musculoskeletal injuries (MSI) aboard a United States Navy Air Craft Carrier

Authors

Marco Campello, PT, PhD * Angela Lis, PT, PhD* Tara Brennan, MPH* CAPT (ret) Gregg Ziemke, PT, MS, MHA,OCS** Rudi Hiebert, ScM** Danielle Faulkner BS, CCRC**, CDR Brian Iveson, DScPT, OCS, SCS**, Cheongeun Oh, PhD, Danielle Southerst, DC*, Sherri Weiser, PhD

* Occupational and Industrial Orthopedics Center, New York University Hospital for Joint Diseases, New York, NY.**BADER Consortium, University of Delaware, Newark, DE. ***Department of Physical Therapy, Naval Medical Center Portsmouth, Norfolk VA

Purpose/Hypothesis: The purpose of this pilot study is to assess the short-term outcomes of PIPT compared to standard physical therapy (PT) in marines and sailors seeking care for a MSI while on board a carrier. The intervention arm PT staff received a 3-day training in PIPT by the research team. We hypothesized that subjects in the intervention arm would have greater improvement on important short-term patient outcomes compared to the control arm.
Subjects: Marines and sailors seeking care for a MSI while deployed.
Materials and methods: Therapists trained in PIPT were taught to detect and address psychological risk factors that predict poor outcomes in patients with MSI. Short-term outcomes variables were measured using single items and included: pain intensity and interference, self-efficacy, outcome expectation, fear of work and perceived disability. All variables were measured at enrollment and at four weeks post-enrollment. The STarT Back Screening Tool (SBST) was measured at baseline and used to identify psychological risk factors to be addressed during treatment. The odds of improvement on all study variables were compared using logistic regression and expressed as adjusted odds ratios. In addition measures of satisfaction with process of care, treatment outcomes and quality of life were collected at four-week post enrollment. The MedRisk Instrument was used to measure satisfaction with process of care and single items used in previous studies measured satisfaction with outcome and quality of life. Quality of life and satisfaction scores were compared between the carriers using the Mann-Whitney U test. The study was originally sized to detect a treatment effect of 0.1 with 80% power with a total sample size of 300.
Results: 86 intervention and 84 control subjects completed follow-up questionnaires Among clinical, demographic and study variables only duration of pain differed between the study groups with the intervention arm having more chronic patients than the control arm ($p<<0.001$). When adjusted for confounding factors, satisfaction with care was significantly higher in the intervention arm (Sig 0.015 OR 2.78). The intervention arm showed a greater likelihood of improvement in all other outcome measures, though none reached significance.

Conclusion: The intervention group expressed greater satisfaction with care. Findings for other short-term study outcomes were not significant. However, they all trended in the hypothesized direction for the intervention arm. A limitation of this study was that subject accrual fell short of the projected sample size. Additional follow-up is under-way to determine the effects of the intervention on long-term work outcomes.
Clinical Relevance: PIPT aimed at improving outcomes for marines and sailors with MSI shows promise. Findings suggest that future studies with larger samples and long term follow-up are needed.

References

1. Beneciuk, Jason M., et al. "The STarT Back Screening Tool and Individual PsychologicalMeasures: Evaluation of Prognostic Capabilities for Low Back Pain Clinical Outcomes in Outpatient Physical Therapy Settings." *Physical Therapy* 93.3 (2013): 321-33. *ProQuest.* Web. 25 May 2017.
2. Bryant, C., Lewis, P., Bennell, K.L., Ahamed, Y., Crough, D., Jull, G.A., Kenardy, J., Nicholas, M.K. and Keefe, F.J., 2014. Can physical therapists deliver a pain coping skills program? An examination of training processes and outcomes. *Physical therapy*, *94*(10), p.1443.
3. Pincus, T., Anwar, S., McCracken, L.M., McGregor, A., Graham, L., Collinson, M., McBeth, J., Watson, P., Morley, S., Henderson, J. and Farrin, A.J., 2015. Delivering an Optimised Behavioural Intervention (OBI) to people with low back pain with high psychological risk; results and lessons learnt from a feasibility randomised controlled trial of Contextual Cognitive Behavioural Therapy (CCBT) vs. Physiotherapy. BMC musculoskeletal disorders, 16(1), p.1.
4. Nielsen M, Keefe FJ, Bennel_l K, Jull GA.Physical therapist-delivered cognitive behavioral therapy: a qualitative study of physical therapists' perceptions and experiences. Phys 77Jer 2014; 94:197-209.

Keywords

Physical Therapy, Psychologically-informed, Musculoskeletal Injuries.

Funding Acknowledgment

This abstract is part of a larger study supported by the Office of the Assistant Secretary of Defense for Health Affairs through the CDMRP, Award No. W81XWH-14-2-0146

Ethics Approval

Research data derived from an approved Naval Medical Center, Portsmouth, VA IRB protocol.

Presenting Author Biography

Marco Campello holds a New York State physical therapist license. He has earned his Ph.D. in Ergonomics and Biomechanics from the Graduate School of Arts and Science at New York University. He is the Director of the Occupational & Industrial Orthopaedic Centre (OIOC), NYU Hospital for Joint Diseases and faculty of the Program of Ergonomics and Biomechanics (ERBI). He has a Clinical Associate Professor appointment from the Departments Orthopaedic Surgery, School of Medicine, New York University. His research interests are in prevention and treatment of work-related musculoskeletal disability, application of research findings in clinical settings with special interest in interdisciplinary intervention and work related health outcomes.

Abstract 7

Military Health System Research Symposium (MHSRS) –August 2018

Musculoskeletal Injury Incidence In Deployed Navy Active Duty Service Members (ADSM) Reporting Musculoskeletal Injuries Aboard Two United States Air Craft Carriers

Tara Brennan, MPH* • Marco Campello, PT, PhD* • Rudi Hiebert, ScM** •Angela Lis, PhD, PT* • CAPT (ret) Gregg Ziemke, PT, MS, MHA,OCS** • Danielle Faulkner BS, CCRC** • CDR Brian Iveson, DScPT, OCS, SCS**** • Sherri Weiser, PhD*

* Occupational and Industrial Orthopedics Center, New York University Hospital for Joint Diseases, New York, NY.

**BADER Consortium, University of Delaware, Newark, DE.

***Department of Population Health, NYU Langone Medical Center, New York, NY.

****Department of Physical Therapy, Naval Medical Center Portsmouth, Norfolk VA.

Background

Musculoskeletal injuries (MSI) pose a significant problem for ADSM. In a 2004 study conducted on two deployed United States Navy Aircraft Carriers (carriers), Herbert and Pasque found that MSI comprised 40% to 43% of all sick call visits during combat-related deployment with upper extremities comprising the highest incidence. MSI may compromise work readiness. These injuries sustained during deployment comprise 54% of limited duty (LIMDU) assignments and are the main reason for separation and long-term disability. No current data exists on the most common MSI sustained during deployment on non-combat related tours.

Methods

As part of a larger quasi-experimental non-randomized study data on MSI sustained aboard two naval aircraft carriers was collected Subjects presenting to the carrier physical therapy (PT) clinic completed a baseline questionnaire during an initial evaluation. Data collected included the MSI for which participants were seeking care in addition to other MSI comorbidities. To ensure accurate diagnoses researchers confirmed the self-reported MSI by conducting PT note analysis. MSI diagnoses were further categorized by the joint involved.

Results

A total of 195 subjects completed baseline questionnaires. Low Back Pain (LBP) (n=51) had the highest incidence followed by shoulder pain (n=50), knee (n=30), mid-back (n=14), arm/hand (n=14), neck (n=13) ankle (n=12), hip pain (n=6) and other (n=5). Of those reporting MSI more than half of the sample stated they had a MSI comorbidity (n=108, 55%). The most frequently reported comorbidity was mid-back (n=31) followed by, shoulder (n=28), LBP (n=27), knee (n=23), neck (n=19), ankle/foot (n=17), hip (n=10), other (n=8) and arm/hand (n=7). Of the full sample 44.2% (n=87) reported no comorbidities, 36.5 % (n=72) reported one comorbidity, 11.2% (n=22) reported two comorbidities, and 8.1% (n=16) had three or more comorbidities.

Conclusions

This analysis found that back and shoulder disorders were most prevalent in non-combat deployed Navy ADSM. Knee injuries were also common. This is in contrast to previous findings in combat deployed Navy personnel that found a higher frequency of complaints in the upper and lower extremities. Of interest is also the finding that more than half of the participants reported a MSI comorbidity, which, in previous studies of civilians, is associated with poor outcomes. In order to identify best injury prevention strategies and inform policy makers it is crucial that MSI diagnoses and rates among deployed navy ADSM are accurate and current. Additional studies should be conducted to confirm these findings and to explore the discrepancy in findings between combat and non-combat deployed members.

Funding Acknowledgment

This abstract is part of a larger study supported by the Office of the Assistant Secretary of Defense for Health Affairs through the CDMRP, Award No. W81XWH-14-2-0146

Ethics Approval

Research data derived from an approved Naval Medical Center, Portsmouth, VA IRB [IACUC] protocol.

Disclaimers

The views expressed in this article are those of the author(s) and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the United States Government.

Human subjects statement

Research data derived from an approved Naval Medical Center, Portsmouth, Virginia Institutional Review Board (Institutional Animal Care and Use Committee) protocol number NMCP2014.0058.

Abstract 8

Military Health System Research Symposium (MHSRS) –August 2018 (pending presentation)

Mechanism of Injury for Musculoskeletal Injuries in Active Duty Service Members (ADSM) reporting to Physical Therapy aboard two naval aircraft carriers.

Authors

Tara Brennan, MPH*, Marco Campello, PT, PhD*, Rudi Hiebert, ScM**, Angela Lis, PhD, PT* CAPT (ret) Gregg Ziemke, PT, MS, MHA, OCS**Danielle Faulkner BS, CCRC**, Sherri Weiser, PhD*

*Occupational and Industrial Orthopedics Center, New York University Hospital for Joint Diseases, New York, NY.

**BADER Consortium, University of Delaware, Newark, DE

***Department of Physical Therapy, Naval Medical Center Portsmouth, Portsmouth, VA

Background

Musculoskeletal injuries (MSI) pose a significant problem for ADSM and are the main reason for separation and long-term disability. Injuries occurring during deployment are an added burden due to limited physical therapy personnel and the demanding nature of the work environment. Research conducted within other branches of the military identified sports/exercise and intensive training as common mechanisms of injury (MOI). Two older studies that looked at ADSM aboard non-combat deployed aircraft carriers between 1993 and 2001 found “struck by object/aircraft” had the highest MOI incidence category. There have been no recent studies in this population that have looked at the main causes of MSI. Current and valid statistics on MOIs are crucial when determining injury prevention strategies and policy changes. Reductions in preventable MSIs have the potential to reduce health care utilization and long-term disability within this population ensuring a combat-ready force.

Methods

As part of a larger quasi-experimental study we reviewed study subject’s clinical notes to identify the MOI as reported by the patient during their initial PT evaluation. All MOI categories were formed using the CDC non-fatal injury definitions, prior studies that reported MOIs within the military population and investigator team decision categories based on subject answers. MOI’s were extracted and initially categorized into “pre-deployment injuries” and “during deployment injuries”. “During deployment injuries” were further broken down into work-related insidious onset, work-related specific MOIs or sports/exercise related. Work-related specific MOIs consisted of falls/slips/trips, lifting/carrying,

pulling/pushing object, struck by object, manipulation of object, sudden movement and injury by other person (unintentional).

Results

A total of 197 subjects completed an initial PT evaluation. 10.6% (n=21) reported their injury was due to an accident incurred prior to deployment. 88.9% (n=176) of reported MSIs occurred during the deployment period. One subject's MOI was unknown. In the full sample, insidious onset MOI comprised (n=92, 46.5%) and specific MOI comprised (n=84, 42.4%). Work-related specific MOIs consisted of falls/slips/trips (n=15, 7.6%), lifting/carrying (n=15, 7.6%), pulling/pushing object (n=8, 4%), struck by object (n=4, 2%), manipulation of object (n=1,0 .5%), sudden movement (n=1, .5%), injury by other person unintentional (n=1,0.5%), and awkward working position (n=1, 0.5%). Sports/Exercise related MOI's during deployment were report by nearly 20% of the sample (n=38).

Conclusions

Although almost half of the ADSM reporting to PT had injuries with an insidious onset, a large number of injuries reported were work related and have the potential to be reduced through work and exercise injury prevention education. Falls and lifting comprised two thirds of specific MOIs. Proper lifting techniques should be reinforced and the work environment should be evaluated to reduce falls/slips. Also, with close to 20% of injuries caused by sports participation in the deployed environment it is critical that ADSM are educated in proper exercise safety techniques during recreational time on deployments.

Funding Acknowledgment

This abstract is part of a larger study supported by the Office of the Assistant Secretary of Defense for Health Affairs through the CDMRP, Award No. W81XWH-14-2-0146

Ethics Approval

Research data derived from an approved Naval Medical Center, Portsmouth, VA IRB [IACUC] protocol.

Disclaimers

The views expressed in this article are those of the author(s) and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the United States Government.

Human subject's statement

Research data derived from an approved Naval Medical Center, Portsmouth, Virginia Institutional Review Board (Institutional Animal Care and Use Committee) protocol number NMCP2014.0058.

Feasibility of Training Physical Therapists to Implement a Psychologically Informed Physical Therapy Program for Deployed U.S. Sailors and Marines with Musculoskeletal Injuries

Sherri Weiser, PhD; Angela Lis, PT, PhD*; CAPT Gregg Ziemke, MSC, USN, (Ret.)†; Rudi Hiebert, ScM†; Danielle Faulkner, BS, CCRC†; Tara Brennan, MPH*; CDR Brian Iveson, MSC, USN‡; Marco Campello, PT, PhD**

ABSTRACT This study assesses the feasibility of training U.S. Navy Physical Therapy staff members (PT staff) aboard a U.S. Navy Aircraft Carrier in psychologically informed physical therapy (PiPT). Training was conducted prior to deployment over 3 d and included background information, skills development, and application in the form of role playing and case studies. During deployment, nine phone conferences were conducted to reinforce training, assess skills, and discuss implementation. PiPT knowledge was assessed by a written test and role-playing skills. The adoption of the training was determined by analysis of clinical notes and verbal responses of the PT staff during phone conferences. There were two PT staff members on the carrier. Both received passing knowledge test scores and demonstrated role-playing proficiency. Clinical note assessment and discussions during conference calls also indicated successful implementation. The feasibility of training Navy PT staff to implement PiPT was demonstrated. PT staff successfully translated training into practice. This is significant, since PiPT has the potential to limit attrition due to musculoskeletal injuries in Navy personnel. Factors believed to be associated with the success of the training include adoption of the PiPT model by PT staff and reinforcement of changes in clinical practice during deployment.

INTRODUCTION

Musculoskeletal injuries (MSIs) pose a significant problem for active duty service members (ADSMs) and are the main reasons for separation and long-term disability.[1–4] In a recent study by the current investigators, the rate of conversion from first career limited duty assignments to the Navy's fitness for duty assessment or physical evaluation boards was 15 % for MSI-related cases.[5] Only 28% of those referred to physical evaluation boards return to full duty.[6] The implications of this problem are both financial- and safety-related, in terms of the loss of trained ADSM and a potentially compromised existing workforce. Studies of MSI disability in civilian populations have shed light on this problem. It is well established that disability from MSI involves interplay of biological, psychological, and social factors.[7] Though numerous risk factors for disability have been identified, psychological factors are among the strongest predictors of MSI outcomes.[8–12] Recent studies have corroborated these findings in military populations.[13]

The fear-avoidance model provides an explanation for the association between psychological factors and functional outcomes.[14] In this conceptualization, if an injury is perceived as threatening, catastrophizing (imaging the worst) ensues, leading to fear and avoidance behavior. Avoidance behavior results in lack of activity leading to more pain and ultimately disability. If the pain perception can be reconceptualized, catastrophizing will cease, movement will commence, and recovery will result.[14] The psychological factors described in the fear-avoidance model have been labeled "yellow flags" and are known risk factors for disability. Yellow flags are maladaptive thoughts than can be successfully modified with cognitive-behavioral therapy (CBT).[12,15–17] CBT is rooted in the work of psychologist Aaron Beck, who observed that automatic thoughts or responses to stimuli result in affective states that may interfere with adaptive behaviors and proposed techniques to alter these thoughts.[18] CBT helps the patient develop adaptive pain coping strategies through the use of techniques such as acceptance, distraction, relaxation, imagery, cognitive restructuring, and goal setting.[19]

CBT for pain management administered by a mental health professional in conjunction with physical therapy (PT) is shown to be superior to PT alone in reducing disability in patients with subacute and chronic MSI.[20–22] This may be in part because standard PT is based on a biomedical model that emphasizes remediating the affected body part during treatment. In contrast, the biopsychosocial model emphasizes patient-centered care and focuses on the cognitive, emotional,

*Department of Orthopedics, Occupational and Industrial Orthopedics Center, New York University Hospital for Joint Diseases, 63 Downing Street, New York, NY 10014

†Department of Kinesiology, BADER Consortium, University of Delaware STAR Campus, 540 South College Avenue, Suite 102, Newark, DE 19713

‡Department of Physical Therapy, Naval Medical Center Portsmouth 620 John Paul Jones Circle, Norfolk, VA 23704

The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the U.S. Government.

doi: 10.1093/milmed/usx229

and behavioral responses to pain that are associated with outcomes. A combined treatment approach is recommended by back pain guidelines for patients beyond the acute phase of injury.[23,24] In a previous study, the present authors conducted a randomized controlled trial with ADSM at risk for disability from back pain in which we trained a multidisciplinary team of health care providers including physicians, physical therapists, and a psychologist in a combined approach.[22] We reinforced the training by providing weekly teleconferences to discuss cases and answer questions. Our study found that, following treatment, the intervention group had lower perceived disability and fear-avoidance beliefs than the control group who received usual care.

Recently, it has been proposed that physical therapists can be trained to identify yellow flags using CBT principles as part of routine clinical practice.[25–27] This approach has been described as "psychologically informed physical therapy" (PiPT).[28] If proven successful PiPT is an important advancement in broadening patient access to the benefits of CBT. Patients often see physical therapists early in care when there is an opportunity to modify maladaptive beliefs before the fear-avoidance cycle is reinforced. Additionally, patients who may benefit from CBT are sometimes unwilling to see a psychologist for fear of stigma, cost or time constraints.[28]

Studies that have evaluated PiPT training have shown mixed results.[25,29,30] Some physical therapists may not be receptive to the biopsychosocial paradigm and some who are, have stated they are not comfortable implementing elements of this approach.[31–33] Overmeer *et al*[29] developed an 8-d training course for physical therapists in PiPT that included addressing the biopsychosocial model, yellow flags, behavioral principles, communication, modifying fear of movement, and role playing.[29] They found that while attitudes and knowledge of the physical therapists shifted in the expected direction, their behavior did not. As a result, the training did not improve outcomes in patients overall.[29] The authors point out that a one-time training is insufficient for changing behaviors, even if attitudes are altered. Ongoing education and reinforcement that includes specific ways to address yellow flags is needed.

Successful implementation of PiPT in the Navy has the potential to reduce attrition and improve recovery time. However, PiPT has not been tested in ADSM. The military is a unique culture which may limit generalizability from civilian studies. For example, due to the demands of military duty, ADSM may be frequently exposed to working with pain and may not be able to avoid heavy work when injured. Also, seminal studies conducted by Henry Beecher during World War II suggest that injury itself has a different meaning for ADSM than for civilians such that ADSM have a higher tolerance for pain.[34] Training Navy PT staff to conduct PiPT is an important first step in understanding how this approach can be applied in the U.S. Navy and other military organizations.

U.S. Navy aircraft carriers provide an optimal environment in which to study this problem. Guidelines and studies done in the military clearly support early intervention as an effective approach to reducing risk of disability and poor work outcomes.[22,35] ADSM aboard a carrier have easy access to early care.[36] In addition, ADSM aboard a carrier do not have to leave their command for therapy, making treatment compliance likely. Also, the lack of communication between carriers allows us to rule out any contamination of training effect on PT staff aboard another carrier that may be used as a control group. Therefore, we developed a PiPT training course for U.S. Navy PT staff aboard a carrier.[37]

This study is part of a larger quasi-experimental pilot study supported by the Office of the Assistant Secretary of Defense for Health Affairs through the CDMRP, Award No. W81XWH-14-2-0146 to test the effectiveness of PiPT for ADSM with MSI aboard a carrier (in process). In order to ensure the internal validity of the intervention during the trial, it was necessary to demonstrate that PiPT training among the participating clinicians in the intervention arm was possible before assessing patient outcomes. Our experience can help other military clinicians, who are considering implementing PiPT, to determine the utility of this approach in their setting and inform future patient outcome studies. The purpose of this study is to assess the feasibility of training Navy PT staff to implement PiPT during a deployment.

METHODS

This paper reports on the PiPT training process, transfer of knowledge, and the translation of knowledge into practice in a military setting. Two carriers were available for the study during the study period. We selected one carrier to serve as the intervention arm for the larger pilot study. PiPT training was given to the PT staff of the intervention carrier only.

Trainees

The usual complement of PT staff on a carrier includes a physical therapist and a PT technician. Both staff members on the carrier served as trainees. Both had traditional professional training and backgrounds and neither were known to have had previous experience in CBT or PiPT.

Training of the Physical Therapist and PT Technician

Training of the PT staff was conducted by a psychologist and a physical therapist from the research team. Training took place in person 2 wk prior to deployment. The carrier psychologist was present during the training to provide feedback, assure buy-in, and see that referrals to psychology when appropriate would proceed smoothly. Training took place over a 3-d period. The first session included basic concepts of PiPT such as models of pain and disability, understanding the complexity of pain, evidence-based predictors of disability and delayed recovery, models of care and principles of cognitive behavioral pain management.

The second and third sessions were focused on skill development. This included identification of yellow flags through screening tools, demonstration of PiPT patient education and related behaviors, interviewing techniques, and how to develop a plan of care to modify psychological risk factors. The syllabus used for the training is shown in Table I. Emphasis was given to providing reassurance, improving patient coping skills and modifying pain behaviors. The PT staff was given visual tools to enhance patient education. The trainers utilized an interactive format that included role playing and case studies portraying specific characteristics of patients in a military setting (Table II). Role playing focused on developing skills required to educate patients at risk of delayed recovery and to implement a plan of care based on the principles of PiPT. Trainees were also coached in how to document yellow flags, if present, in their clinical notes and to indicate how the flags would be addressed in their plan of care.

Reinforcement of Training During the Deployment

Trainees were given a detailed manual following the training to support compliance. Two methods were used to ensure compliance with the training during deployment. First, teleconferences of 1 h duration were conducted to allow the PT staff to discuss complicated cases and engage in problem-solving with the investigators. Questions and concerns were addressed and successes were also discussed and reinforced. A second tool used to reinforce PiPT skills was the periodic

TABLE I. Training Syllabus

Day	Main Topic	Goals	Skills	Assessment
1	Basic concepts of PiPT	1. Understand the biopsychosocial model of pain and disability 2. Understand the concept of PiPT	Demonstrate understanding by utilizing examples from the rehabilitation setting	Knowledge test
2	Identifying yellow flags and other risk factors associated with delayed recovery.	1. Learn how to use study assessment tools to identify patients at risk 2. Learn how to use the clinical interview to identify patients at risk 3. Learn how to develop a plan of care based on the presence of psychological risk factors and their modification	1. Demonstrate how to identify obstacles to recovery 2. Demonstrate how to assess the need for a psychological evaluation 3. Demonstrate communication skills necessary to elicit risk factors for delayed recovery during the clinical evaluation 4. Demonstrate how to develop a psychologically informed plan of care	Role playing and case studies
2	1. Addressing yellow flags to prevent delayed recovery 2. Educating the patient at risk	1. Learn how to communicate with and educate patients at risk of delayed recovery 2. Learn how to implement a plan of care based on the principles of PiPT.	1. Demonstrate patient education skills 2. Demonstrate communication skills	Role playing and case studies
3	1. PT documentation 2. Feedback and review	Standardize evaluation and progress notes to ensure high-quality data	1. Demonstrate use of key phrases associated with the implementation of a plan of care based on PiPT 2. Demonstrate how to document changes in attitudes, beliefs, and behaviors through observation and communication during treatment 3. Demonstrate how to document changes in yellow flags and standardize questionnaires at the end of treatment	Role playing and clinical note analysis

TABLE II. Case Study Example

Frank G is a 20-yr-old male machinist mate third class (MM3). He is married with a 3-mo-old son. He does not smoke and maintains a normal body mass index. This is his first deployment. A couple of days ago, while lifting a heavy container overhead, as part of his usual duties, he hurt his right shoulder. At first it was a little sore, and he was able to continue working with no interruption of his usual duties. Today, however, when he woke up he could barely move his shoulder and is in excruciating pain. He tried to stretch it out, but it made the pain worse. He presents at medical with decreased range of motion on the right shoulder and reports pain at an 8 out of 10 level. Frank completes the intake questionnaire. When evaluated he appears extremely agitated and fearful about his shoulder pain. Frank reports poor sleep quality following his injury and feels that he will be unable to complete work tasks with his current pain level. When questioned, he explains that about 4 yr ago he had a football injury in the right shoulder that healed pretty well, but his doctor at that time warned him to be careful on that side. He had to stop playing football. He began to work out daily and get into excellent shape to enter the Navy.
Job description: MM3 – mainly repairs and other services to the ship. Assigned to the tender of repair ships.
Discussion points: Cognitive reassurance/ education – explaining the nature of the injury, developing effective communication skills, modifying maladaptive beliefs, setting realistic expectations.
Yellow flags: fear, catastrophizing, bothersomeness

audit of de-identified clinical notes. During training, the PT staff were taught how to indicate whether or not yellow flags were present for each patient and if so, how to address each flag during the therapy session. These sections of the notes were assessed by the investigators for thoroughness of documentation and appropriateness of the PT staffs' responses. During deployment, two independent investigators randomly sampled the PT staffs' clinical notes on a bimonthly basis using pre-established criteria. Deficiencies in implementation detected through this process were addressed with the PT staff during teleconferences.

Evaluation of the Training

Feasibility of implementation of PiPT on board a carrier was guided by recommendations from Yates *et al*[38] for assessing the treatment quality of clinical trials. Criteria for feasibility were as follows:

1. Knowledge of main PiPT concepts: assessed by a knowledge test given at the end of the training for which a passing score was 85% (Table III).
2. Demonstration of PiPT skills: demonstrated by the ability to use eight case studies and three role-playing scenarios to screen for yellow flags and delineate interventions following the training. A scored of pass or fail was given. A two person inter-rater agreement of 100% was required to obtain a passing score.
3. Demonstration of PiPT application: assessed by analysis of clinical notes during the deployment.
4. Demonstration of PiPT acceptance: demonstrated by verbal responses of PT staff during phone conferences.

RESULTS

Training and reinforcement during deployment was conducted over a 9-mo period. At the end of the training, both the physical therapist and the PT technician received passing knowledge scores (100 and 85%, respectively). Both PT staff members demonstrated their capacity to score the screening tools, screen patients during role playing, and outline PiPT interventions to modify yellow flags. Both passed this assessment with 100% agreement of the trainers.

During implementation, 19 clinical notes were independently evaluated. Evaluators looked for the documentation of the presence or absence of yellow flags in clinical notes demonstrated by information such as: "increased stress levels and fear of re-injury," "fears not being able to work again," or "no flags." They also looked for a plan to address yellow flags when present shown by phrases such as, "patient education in pain coping techniques." Functional goals such as: "improve quality of sleep," "return to lifting activities," "return to regular exercise program," and "return to full duty" were also reviewed in the treatment plan section. If any of this information was missing, it was addressed during the next teleconference and corrected in future notes. This was done until no

TABLE III. Knowledge Test

All Questions Are to be Answered Either True or False
1. PiPT should be used only for high risk patients.
2. Studies have shown that patients who are at high risk for disability tend not to benefit from medically based PT.
3. PiPT is based on principles of CBT for pain.
4. In the biopsychosocial model, the patient is a passive participant in treatment.
5. The neuromatrix theory emphasizes the importance of psychological factors in the progression of pain and disability.
6. Black, orange, and yellow flags are all categories of psychological factors.
7. All patients with yellow flags should be referred immediately to a psychologist.
8. Expectations of outcome can be modified by the health care provider.
9. A behavioral approach to PT can improve the patient's self-efficacy.
10. Health care providers with a biomedical perspective are more likely to follow guidelines for musculoskeletal injuries than those with a biopsychosocial perspective.
11. Fear of movement always indicates a poor prognosis.
12. The most important concepts to keep in mind when using a psychologically informed approach are self-care and self-blame.
13. Telling patients what to expect is an important part of patient education.
14. Positive Waddell signs mean a patient is faking.
15. Pink flags are associated with negative expectations.
16. Health care providers can cause yellow flags by focusing only on the medical aspects of an injury.
17. Studies have shown that it is easy to keep your own attitudes and opinions from influencing the patient.
18.Yellow flags improve with time on their own and do not need to be addressed.
19. Patients who think something is seriously wrong with them are more open to positive information than those who are not worried about their health.
20. Diagnostic tests should be used as much as possible to detect any and all pathology before treatment.
21. Pain is the most important thing to consider when designing your plan of care.
22. Physical activity should always be avoided when a patient is in pain.
23. PT can be successful even if pain is not resolved.
24. Pain is directly related to the amount of tissue damage.
25. Learning to cope with stress promotes recovery from back pain.

missing information was detected, such that all notes were complete at the end of the deployment.

Both PT staff members participated in all nine teleconferences. These calls took place only when the ship was able to establish ship-to-shore communications. The PT staff presented challenging cases during these meetings to demonstrate how they managed the cases and to get feedback from the investigators. These discussions indicated that they were applying PiPT skills consistently and proficiently throughout the deployment.

During the teleconferences and in separate email correspondence after deployment, the research staff received unsolicited feedback from the PT staff. Some of their comments were "Education is probably the most important thing we do in the clinic…," "It is important for patients to understand why they feel what they do, what it means, and what it doesn't mean…" "We get better buy-in and see good clinical progress as a result [of PiPT]" "Patients responded well to graded activity in order to restore confidence in movement and to overcome the pain memory and subsequent fear-avoidance behavior."

DISCUSSION

PiPT is an emerging approach to managing patients with MSI, a significant cause of disability and attrition in the Navy. This study demonstrated that PT staff aboard a U.S. Navy carrier can be successfully trained to practice PiPT. This was demonstrated in several ways. During the training, both PT staff members were actively engaged and open to learning about the treatment strategies. They were able to easily identify patients in their practice who could benefit from PiPT. Both PT staff members obtained passing scores on the PiPT knowledge test following training, indicating a high level of information retention. In addition, both trainees demonstrated their capacity to score the screening tools, screen patients, and outline PiPT interventions to modify yellow flags during role playing. During deployment, both PT staff members participated in all nine teleconferences demonstrating their commitment to improving their practice of PiPT. Through their discussion of challenging patients, their buy-in of PiPT was clear. As the study progressed, they became skilled at identifying and responding to yellow flags as demonstrated in their problem-solving skills and their clinical note documentation.

Previous studies that have sought to demonstrate the effectiveness of PiPT on patient outcomes have shown mixed results. A common explanation for this in the literature is the inadequacy of training or acceptance on the part of the PT.[31,33] Therefore, one important finding of our research lays in the identification of facilitators of training uptake. Both a paradigm shift and change in clinical practice are necessary. Central to the success of the PiPT training was the PT staff members' desire and ability to shift their treatment paradigm from a traditional biomedical approach to a biopsychosocial approach. This has been cited as a difficulty in previous studies on implementing PiPT.[31,33,39] We believe that the PT staff successfully made this transition based on their high level of performance during our monthly conversations and their feedback at the end of the study. We attribute our success to several things. Firstly, our training took place in a small, intimate setting allowing for a relaxed and open atmosphere. We encouraged questions and comments throughout the training and tried to make it as interactive as possible. The use of case studies that reflected actual ADSM experiences after MSI made the case studies highly relevant to the PT staff which further facilitated participation. Also, the staff had 2 wk before deployment to practice PiPT on shore. We were able to give specific recommendations for addressing yellow flags during that time. In addition, PiPT skills were reinforced on an ongoing basis during deployment through teleconference participation. We also provided visual materials to the PT staff to be used as tools, which made it easier and faster for them to educate patients so as to reduce yellow flags during treatment. Once the PT staff learned the benefits of PiPT, they realized the importance of the training and had confidence in the biopsychosocial approach. As the PT staff became more proficient in providing PiPT, they stated that it became an effortless and permanent part of their patient care for all patients.

Our findings indicate that PiPT training changed clinical practice in a number of ways. Clinical notes and conference calls demonstrated that the PT staff routinely evaluated yellow flags through questionnaires and clinical interviews, addressed yellow flags through education and the use of visual aids, and used a functional approach to PT that emphasized physical goals over pain relief. In addition, they discussed cases with each other to ensure seamless patient transfer and learned how to detect patients who required immediate referral to the psychologist. Changes in documentation notes included describing yellow flags and how they were addressed in treatment.

One advantage we had was that the PT staff we worked with had the latitude to increase the time of the initial evaluation to include patient education. While the time it takes to address yellow flags decreases as PT staff members become more comfortable with the approach, there is no doubt that adding this aspect to treatment takes more time than usual PT sessions allow. Taking additional time to evaluate the patient may not be possible in other settings, and potentially limits the generalizability of these findings. However, given the importance that yellow flags have in determining treatment outcomes, it may behoove PT staff to use some of their evaluation time on this issue. This would require the support of supervisors and management to be successful and it is important that results like those reported here are disseminated to promote this cause. It is also worth mentioning that the active goal-oriented approach to PT, which is guideline-based and was emphasized during the training, reinforces the messages of PiPT. Once patients see that they are able to function, even with pain, yellow flag beliefs such as "pain equals damage,"

"I will never get well," and "movement is bad for me," are challenged. Patients develop improved outcome expectancies and increased self-efficacy to manage their own pain. This type of PT requires no additional session time.

Our training also emphasized the importance of an interdisciplinary approach to care. The on-board psychologist was included in the training to learn the PiPT approach, give us feedback, and facilitate timely and appropriate referral to her services. All patients were screened for clinical levels of depression, anxiety, and PTSD prior to treatment. Those that exceeded the cut-off were offered a referral for psychological support. This permitted inter-professional discussion about patients and allowed for coordinated care which is key to a biopsychosocial approach to treatment. One potential drawback to PiPT is that increased referrals to other specialties may be taxing on other health care providers within a specific health care facility and this must be considered before PiPT is implemented. This study demonstrated feasibility in a unique study environment. Of note is that PiPT training required only 3 d of the U.S. Navy PT staff member's time and nine follow-up teleconferences between the study investigators and the ship's PT staff to support and reinforce maintenance of PiPT study protocols.

One limitation of this study is that the carrier PT staff consisted of only two members and therefore our sample size of trainees is small. This is the standard PT staff assignment aboard carriers. We were also limited by the realities of deployment schedules and therefore, could only train one carrier staff. However, our objective was to determine the feasibility of the training and sample size was not a priority. We note that neither of the study PT staff members had prior exposure to the PiPT concept nor is there reason to believe that their professional training or Navy experience was substantially different from other Armed Forces PT staff.

The ease of implementation with the study PT staff suggests that other PT staff in the Armed Forces could be trained as successfully in a similar manner. We believe the course syllabus and training material used in this study can be easily modified for other health care settings. For example, shore-based PT staff that treat large numbers of ADSM can also be trained in PiPT. It is not yet known if this would generate results similar to the present findings. We plan to test this in future large-scale studies.

CONCLUSIONS

This study demonstrated the feasibility of implementing PiPT on a U.S. Navy aircraft carrier. All four criteria for feasibility outlined by the investigators were met. This is significant, since PiPT has the potential to modify maladaptive beliefs associated with disability and attrition in U.S. Navy personnel. Successful training requires both a change in treatment paradigm and clinical practice. The use of actual case examples and reinforcement during deployment contributed to the success of the training. It is not known how this training will impact patient beliefs and functional outcomes. Currently, the investigators are assessing this question in a quasi-experimental study with a concurrent, non-equivalent control group.[37] Successful outcomes would support the implementation of this approach throughout the Navy and further the long-term goal of sustaining injured ADSM at full duty status, ensuring a healthy and combat-ready force.

ACKNOWLEDGEMENTS

The authors thank Elizabeth Plowman, PT, DPT, OCSLT, MSC, USN, Nicholas Azzaro HM2(FMF/EXW/IDW/SW), and Tahney C. Johnston, Psy. D LT/MSC/USN for their contribution to this study.

PRESENTATIONS

Presented as a poster at the 2016 Military Health System Research Symposium, Kissimmee, FL (Abstract number: MHSRS-16-0092).

FUNDING

This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs, through the Peer Reviewed Orthopaedic Research Program under Award No. W81XWH-14-2-0146. Opinions, W81XWH-14-2-0146. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.

HUMAN SUBJECTS STATEMENT

Research data derived from an approved Naval Medical Center, Portsmouth, Virginia Institutional Review Board (Institutional Animal Care and Use Committee) protocol number NMCP2014.0058.

REFERENCES

1. Cohen SP, Nguyen C, Kapoor SG, et al: Back pain during war: an analysis of factors affecting outcome. Arch Intern Med 2009; 169(20): 1916–23.
2. Goodman GP, Schoenfeld AJ, Owens BD, Dutton JR, Burks R, Belmont PJ: Non-emergent orthopaedic injuries sustained by soldiers in operation iraqi freedom. J Bone Joint Surg Am 2012; 94(8): 728–35.
3. Huang GD, Feuerstein M, Arroyo F: Back and upper extremity disorders among enlisted U.S. marines: burden and individual risk factors. J Mil Med 2001; 166(11): 1007–17.
4. Patzkowski JC, Rivera JC, Ficke JR, Wenke JC: The changing face of disability in the US army: the operation enduring freedom and operation iraqi freedom effect. J Am Acad Orthop Surg 2012; 20(Suppl 1): S23–30.
5. Ziemke GW, Campello M, Rennix CP, et al: Retrospective administrative limited duty outcome review lovelace respiratory research insitute. Report No.: Contract 2011.029. 2012. Available at https://clinicaltrials.gov/ct2/show/NCT02472067; accessed February 27, 2017.
6. Niebuhr DW, Powers TE, Krauss MR, Cuda AS, Johnson BM: A review of initial entry training discharges at fort leonard wood, MO, for accuracy of discharge classification type: Fiscal year 2003. J Mil Med 2006; 171(11): 1142–6.
7. Waddell G, Burton AK: Concepts of rehabilitation for the management of low back pain. Best Pract Res Clin Rheumatol 2005; 19(4): 655–70.
8. George SZ, Beneciuk JM: Psychological predictors of recovery from low back pain: a prospective study. BMC Musculoskelet Disord 2015; 16: 49.
9. Bishop FL, Yardley L, Prescott P, Cooper C, Little P, Lewith GT: Psychological covariates of longitudinal changes in back-related

disability in patients undergoing acupuncture. Clin J Pain 2015; 31(3): 254–64.
10. Campbell P, Foster NE, Thomas E, Dunn KM: Prognostic indicators of low back pain in primary care: five-year prospective study. J Pain 2013; 14(8): 873–83.
11. Nicholas MK, Linton SJ, Watson PJ, Main CJ: "Decade of the Flags" Working Group: early identification and management of psychological risk factors ("Yellow flags") in patients with low back pain: a reappraisal. PhysTher 2011; 91(5): 737–53.
12. Main CJ, Foster N, Buchbinder R: How important are back pain beliefs and expectations for satisfactory recovery from back pain? Best Pract Res Clin Rheumatol 2010; 24(2): 205–17.
13. Booth-Kewley S, Larson GE, Highfill-McRoy RM: Psychosocial predictors of return to duty among marine recruits with musculoskeletal injuries. J Mil Med 2009; 174(2): 139–52.
14. Vlaeyen J, Crombez G: Fear of movement/(re) injury, avoidance and pain disability in chronic low back pain patients. Man Ther 1999; 4(4): 187–95.
15. Keefe FJ, Rumble ME, Scipio CD, Giordano LA, Perri LM: Psychological aspects of persistent pain: current state of the science. J Pain 2004; 5(4): 195–211.
16. Turk DC, Meichenbaum D, Genest M: Pain and Behavioral Medicine: A Cognitive-Behavioral Perspective. New York, NY, The Guilford Press, 1987. Available athttp://link.springer.com/chapter/10.1007/978-3-319-01875-1_8; accessed February 27, 2017.
17. Foster N, Delitto A: Embedding psychosocial perspectives within clinical management of low back pain: integration of psychosocially informed management principles into physical therapist practice – challenges and opportunities. Phys Ther 2011; 91(5): 790.
18. Hofmann SG: An Introduction to Modern CBT: Psychological Solutions to Mental Health Problems. John Wiley & Sons, 2011. Available at https://www.goodreads.com/book/show/16974595-introduction-to-modern-cbt; accessed February 27, 2017.
19. Gatchel RJ, Theodore BR: Evidence-based outcomes in pain research and clinical practice. Pain Pract 2008; 8(6): 452–60.
20. Kamper SJ, Apeldoorn AT, Chiarotto A, et al: Multidisciplinary biopsychosocial rehabilitation for chronic low back pain: Cochrane systematic review and meta-analysis. BMJ 2015; 350: h444.
21. Pincus T, Anwar S, McCracken LM, et al: Delivering an optimised behavioural intervention (OBI) to people with low back pain with high psychological risk; results and lessons learnt from a feasibility randomised controlled trial of contextual cognitive behavioural therapy (CCBT) vs. physiotherapy. BMC Musculoskelet Disord 2015; 16: 147.
22. Campello M, Ziemke G, Hiebert R, et al: Implementation of a multidisciplinary program for active duty personnel seeking care for low back pain in a US navy medical center: a feasibility study. J Mil Med 2012; 177(9): 1075–80.
23. Chou R, Atlas SJ, Stanos SP, Rosenquist RW: Nonsurgical interventional therapies for low back pain: a review of the evidence for an american pain society clinical practice guideline. Spine (Phila Pa 1976) 2009; 34(10): 1078–93.
24. van Tulder M, Becker A, Bekkering T, et al: European guidelines for the management of acute nonspecific low back pain in primary care. Eur Spine J 2006; 15(Suppl 2): S169. Available at https://www.ncbi.nlm.nih.gov/pubmed/16550447/; accessed February 27, 2017.
25. Hall A, Richmond H, Copsey B, et al: Physiotherapist-delivered cognitive-behavioural interventions are effective for low back pain, but can they be replicated in clinical practice? a systematic review. Disabil Rehabil 2016; 1–9. Available at https://www.neuroscience.ox.ac.uk/publications/642739; accessed February 27, 2017.
26. van Erp R, Huijnen I, Köke A, Abbink F, den Hollander M, Smeets R: Development and content of the biopsychosocial primary care intervention 'back on track'for a subgroup of people with chronic low back pain. Physiotherapy 2017; 103(2): 160–6. Available at http://www.physiotherapyjournal.com/article/S0031-9406(16)30020–7/references; accessed February 27, 2017.
27. Hunt MA, Keefe FJ, Bryant C, et al: A physiotherapist-delivered, combined exercise and pain coping skills training intervention for individuals with knee osteoarthritis: a pilot study. Knee 2013; 20(2): 106–12.
28. Main CJ, George SZ: Psychologically informed practice for management of low back pain: future directions in practice and research. Phys Ther 2011; 91(5): 820–4.
29. Overmeer T, Boersma K, Denison E, Linton SJ: Does teaching physical therapists to deliver a biopsychosocial treatment program result in better patient outcomes? A randomized controlled trial. Phys Ther 2011; 91 (5): 804–19.
30. Nielsen M, Keefe FJ, Bennell K, Jull GA: Physical therapist-delivered cognitive-behavioral therapy: a qualitative study of physical therapists' perceptions and experiences. Phys Ther 2014; 94(2): 197–209.
31. Singla M, Jones M, Edwards I, Kumar S: Physiotherapists' assessment of patients' psychosocial status: are we standing on thin ice? a qualitative descriptive study. Man Ther 2015; 20(2): 328–34.
32. Sanders T, Foster NE, Bishop A, Ong BN: Biopsychosocial care and the physiotherapy encounter: physiotherapists' accounts of back pain consultations. BMC Musculoskelet Disord 2013; 14: 65.
33. Synnott A, O'Keeffe M, Bunzli S, Dankaerts W, O'Sullivan P, O'Sullivan K: Physiotherapists may stigmatise or feel unprepared to treat people with low back pain and psychosocial factors that influence recovery: a systematic review. J Physiother 2015; 61(2): 68–76.
34. Beecher HK: Relationship of significance of wound to pain experienced. J Am Med Assoc 1956; 161(17): 1609–13.
35. Shaw WS, van der Windt DA, Main CJ, Loisel P, Linton SJ: "Decade of the Flags" Working Group: early patient screening and intervention to address individual-level occupational factors ("blue flags") in back disability. J Occup Rehabil 2009; 19(1): 64–80.
36. Cohen SP, Brown C, Kurihara C, Plunkett A, Nguyen C, Strassels SA: Diagnoses and factors associated with medical evacuation and return to duty for service members participating in operation iraqi freedom or operation enduring freedom: A prospective cohort study. Lancet 2010; 375(9711): 301–9.
37. Weiser S, Lis A: A pilot study to test the efficacy of psychologically-based physical therapy training for treating deployed U.S. sailors and marines with musculoskeletal injuries. 2013. National Library of Medicine (US); identifier NCT02472067. Available at https://clinicaltrials.gov/ct2/show/NCT02472067; accessed June 16, 2016.
38. Yates SL, Morley S, Eccleston C, Williams ACDC: A scale for rating the quality of psychological trials for pain. Pain 2005; 117(3): 314–25.
39. Driver C, Kean B, Oprescu F, Lovell GP: Knowledge, behaviors, attitudes and beliefs of physiotherapists towards the use of psychological interventions in physiotherapy practice: a systematic review. Disabil Rehabil 2016; 1–13; Available at http://www.tandfonline.com/doi/abs/10.1080/09638288.2016.1223176?journalCode=idre20 accessed February 27, 2017.

What Do Patients with Musculoskeletal Injuries Learn from Psychologically-informed Physical Therapy?

Sherri Weiser, PhD*, Angela Lis, PhD, PT**, Tara Brennan, MPH*, Rudi Hiebert, ScM***, CAPT (ret) Gregg Ziemke, PT, MS, OCS***, Marco Campello, PT, PhD*

*Occupational and Industrial Orthopedics Center, New York University Hospital for Joint Diseases, New York, NY. **Department of Physical Therapy, Seton Hall University, IHS Campus, Nutley, NJ, United States. ***BADER Consortium, University of Delaware, Newark, DE.

Introduction

Guidelines support a biopsychosocial approach to the treatment of musculoskeletal injury (MSI) [1,2]. One outgrowth of this has been the development of psychologically-informed physical therapy (PiPT) protocols. In this approach, Physical Therapists (PT) are trained to apply psychological concepts to the evaluation and treatment of patients. There is some evidence to support the use of PiPT. However, its effectiveness has mostly been demonstrated through improvement in patient outcomes such as pain and disability [3]. There is a lack of information about how these outcomes are achieved. This is an important question because PiPT education can be costly and time consuming [4]. In order to justify the required investment in PiPT education, a positive outcome on patient care must be demonstrated. However, it is equally important to understand the mechanism by which a positive outcome is achieved so that effective PiPT education programs can be developed.

It is proposed that a shift from a biomedical to a biopsychosocial perspective is required for the patient as well as the physical therapist. A major component of PiPT is the use of biopsychosocial education to teach the patient about the nature of pain and to adopt behaviors that increase self-efficacy [5]. However, the transfer of knowledge from the PT to the patient has not been studied. One way to assess this is to evaluate what patients learn from PTs who have

been trained in PiPT and how that differs from what patients learn from PTs without this training. The purpose of this study is to determine if biopsychosocial PiPT messages given by the physical therapist are received by patients. Our research question is "What do patients with (MSI) learn from PiPT?"

Review of Literature

The psychological context in which an MSI occurs has been consistently linked to outcomes. It has been shown that certain psychological variables predict poor outcomes such as disability more reliably than clinical data [5-7]. While personality traits and mood disorders are stable factors that are difficult to alter, maladaptive psychological responses to MSI have been shown to be modifiable [8,9]. These predictive factors have been labeled "yellow flags" and include low mood, anxiety, catastrophic thinking, fear of movement and perceived disability [5,8,10]. Traditionally, modification of psychological risk factors has been the purview of mental health professionals who practice cognitive-behavioral therapy for pain. This approach has been proven successful, especially for patients with chronic pain [8,11-14]. However, this type of treatment may not be utilized by patients for several reasons. Access to mental health professionals who specialize in pain may be limited by geographic area and health care coverage. Patients may not understand the contribution their psychological state makes to the pain experience, or may be reluctant to consult with a mental health professional for fear of stigma. Moreover, health care professionals may be uncomfortable referring patients to mental health professionals because of an entrenched biomedical orientation [15-19].

These barriers to psychological treatment have led to the emergence of a "middle way" in which other health care professionals are trained to detect and address common maladaptive

psychological responses to injury [4]. Physical therapy is a common treatment approach for MSI [20,21]. PTs may see patients early in the course of an MSI when the likelihood of influencing patients' beliefs about their condition is the greatest [22,23]. With this in mind, the authors and other researchers have developed protocols to train PTs to adopt a biopsychosocial approach and address yellow flags [24-27]. This approach has been labeled "psychologically informed physical therapy" (PiPT).

PiPT uses concepts from cognitive-behavioral therapy aimed at modifying maladaptive thoughts and behaviors. Factors common to these types of interventions include education in the biopsychosocial model of pain and disability that includes normalization of pain; education in pain neurophysiology and behavioral modification techniques aimed at facilitating patient's self-efficacy and reducing fear of activity [28-33]. Studies on the effectiveness of PiPT in improving patient outcomes have yielded mixed results. Bostick et al. (2017) completed a systematic review of clinical trials aimed at identifying the effectiveness of psychological based interventions delivered by non-psychologists[3]. PiPT was found to be effective in more than half of the eleven studies included. Short-term pain intensity decreased significantly in eight; and this was maintained in seven studies at long-term follow-up. Disability decreased significantly in seven studies in both short and long-term follow-up.

In order for PiPT to have an impact on patient outcomes, the training of the PT must be effective. Some studies have found that, as a group PTs are not comfortable treating non-mechanical aspects of pain and may even stigmatize patients who show signs of psychological distress during treatment [15,16,34-36]. Given such beliefs, it is impossible to convey the important messages of PiPT to patients. Therefore, PiPT training must demonstrate a shift in treatment paradigm from biomedical to biopsychosocial. Overmeer (2016) studied the acceptance of a

biopsychosocial framework in PTs using patients as proxies, but not directly with PTs[37]. Patients were asked to evaluate the PTs attitudes and beliefs, knowledge, skills and perceived behavior addressing psychosocial factors in clinical practice. In a previous study, we demonstrated the impact of PiPT training directly on US Navy PTs [38]. Proficiency on the part of the PTs was demonstrated by knowledge of PiPT concepts and acceptance of the biopsychosocial model demonstrated through clinical practice.

Theoretically, the shift from biomedical to biopsychosocial understanding of MSI must occur for the patient as well as the provider. In a small qualitative study comparing patients who did well following a treatment similar to PiPT, Bunzli et al (2016) concluded that changing pain beliefs from biomedical to biopsychosocial was an important determinant of successful treatment [29]. Patients who understand the PiPT approach should be more likely to retain the information they learned, buy in to the treatment, and actively apply it to aid recovery and prevent recurrence. To date there have been no large studies that directly assess the effect of PiPT on patients' understanding of their MSI. This study addresses this question in a cohort of US Navy active duty service members. MSIs comprise about 40% of sick call visits during deployment and are the main cause of separation in the Navy [39-42]. Therefore, the Navy provides an excellent setting in which to study this approach. We hypothesized that patients who receive PiPT would retain more PiPT (biopsychosocial) messages than patients who receive usual physical therapy care.

Subjects

Subjects included ADSM deployed aboard a US Navy Aircraft Carrier who had sustained a MSI and were enrolled as part as a larger study that aimed to test the effectiveness of PiPT.

Methods

This study is part of a larger, quasi-experimental study that compared the results of two physical therapy interventions (PiPT and standard physical therapy care) aboard two US Navy Aircraft Carriers. PTs on both carriers received instructions on study procedures prior to deployment. The intervention carrier PTs also attended a three day PiPT course. The results of role-playing and knowledge testing demonstrated that the PiPT concepts had been learned by the PTs. Once deployed, training was reinforced with bimonthly phone calls between investigators and trained PTs. Subjective, Objective, Assessment and Plan (SOAP) notes, prepared by the Intervention ship's physical therapist and physical therapy aide, were also analyzed on an ongoing basis to confirm PiPT implementation using two specific criteria: 1) evidence of yellow flag identification through observation and a standardized screening tool and 2) evidence of addressing yellow flags (if present). Results of this random sample analysis indicated that PIPT was implemented on the intervention carrier.

The Start Back Screening Tool (SBST) was used to identify patients at risk for persistent pain and disability. The five psychological risk factors on the SBST include: fear-avoidance, catastrophizing, depression, anxiety and pain bothersomeness. Cut-offs exist for both the total score and for the individual items. Intervention PTs used cut-off scores to guide treatment that addressed elevated risk factors. All subjects completed the SBST at baseline. Four weeks post-enrollment, subjects completed follow-up questionnaires, including the open-ended question: "Please list the most important thing(s) you learned in physical therapy" designed to determine if messages patients received from PTs differed between groups. Four general concepts consistent with PiPT messages were established a priori by investigators and were used to guide the qualitative analysis (see Table 1). Examples for each concept were generated by group consensus among investigators including a psychologist, three PTs, a chiropractor, an

epidemiologist and a statistician. Statements were considered consistent with PiPT when key words or similar phrasing were used in the subjects answer. Statements by the subjects consistent with PiPT concepts were considered an indication that the PiPT message was received. Three blinded raters independently assessed subjects' responses. Raters were asked to view each response in its totality and indicate if they reflected one of more of the PiPT concepts. Only statements all three raters agreed on were considered to contain PiPT concepts. When raters disagreed, responses were only considered to contain PiPT concepts if consensus was reached after discussion. PiPT concepts were considered absent from all other responses.

The responses of subjects in the control and intervention groups were compared to determine whether there were differences in the types of messages they received from treatment. Furthermore, SBST subscale scores were analyzed for both groups to determine the number of subjects in each group who exceeded individual item and total score cut-offs. Those who exceeded STarT Back cut off scores in both groups where compared to those who did not on the types of messages they received. This was done to determine if subjects with high psychological risk would report the same number of PiPT messages received as those with low risk.

Table 1.

Guide for analysis of open-ended question	
PIPT Concepts	**Examples**

Biopsychosocial understanding of pain	• Mind-body or Biopsychosocial
	  ○ Stress, Fear, Depression, Anxiety, Anger … can affect pain
	  ○ A positive attitude is important when dealing with pain, injury ...

Knowledge	• I understand my pain, symptoms, condition etc
Adaptive pain beliefs	• I can control my pain • I can manage my pain • Activity, work is good for recovery • Pain does not mean damage

	• Pain does not mean harm • I can cope with pain
Self-care techniques	• I am taking care of my pain, injury etc. • I am staying active • I am practicing relaxation • I am practicing positive thoughts • I am moving as much as possible • I am working at full capacity

Results

One hundred and ninety seven subjects were enrolled in the study. Of these, 85 (83%) intervention and 90 (95%) control subjects completed follow-up questionnaires. MSIs were reported in the low-back (28.5%), shoulder (22.9%), neck (8.6%) mid-Back (7.4%), knee (14.3%), ankle/foot (7.4%), arm/hand (6.3%), hip (2.9%) and other (1.7%). Of those who completed a follow-up questionnaire, 26% (n=22) in the control group and 6% (n=5) in the intervention group did not answer the open-ended question. The number of responses reflecting PiPT concepts were 29 (34%) in the intervention group and 0 in the control group. Therefore, those subjects who received PiPT were more likely to learn PiPT concepts than those who did not.

Typical statements from the control subjects about what they learned from PT were; "Stretch, drink water", "How good a foam roller is to use" and "How to strengthen [the] area of injury". None of these responses mapped to any of the a priori PiPT concepts. Similar statements were also made by intervention subjects. However, intervention subject's responses also indicated PiPT understanding. Statements related to the a priori keywords included; "[I know] how to manage pain/work through discomfort to achieve my PT goals" (Adaptive pain beliefs), "Stress and pain go hand in hand" (Biopsychosocial understanding of pain), "Not all pain is bad" (Knowledge), and "I learned how to self-treat myself when the injury started to flare up" (self-

care techniques). A computer generated random numbers table was used to select 10 verbatim responses that reflect PiPT concepts and 10 verbatim responses that did not reflect PiPT concepts. Responses are displayed in Table 2.

Table 2. Patient identified 'most important thing(s) learned in physical therapy'.

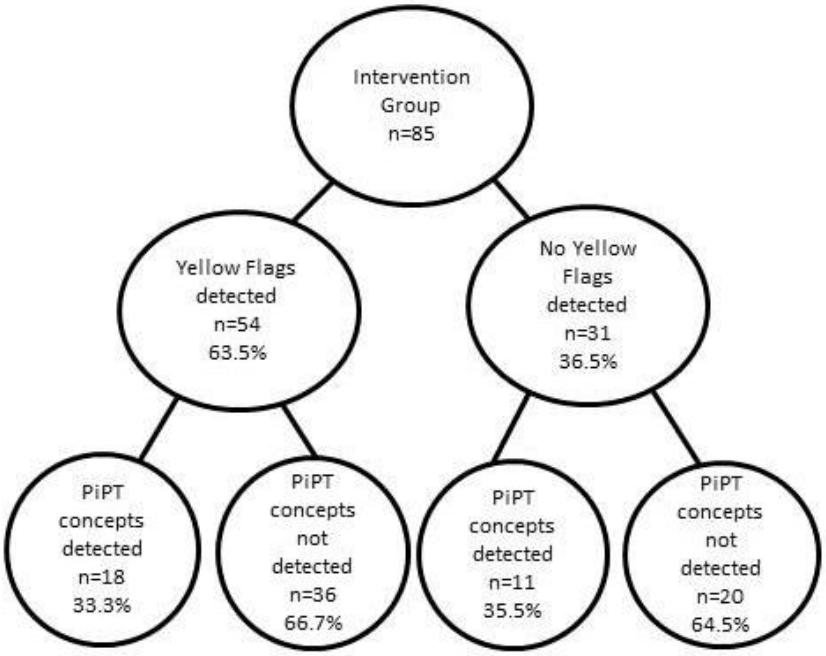
Statement	PiPT detected	PiPT not detected
1	*Why I felt the way I did how to prevent it. Pain management.*	*How to successfully stretch. How to work out and stretch other areas, to take the strain off of my knee.Taught me that some pain is good, my body is just recognizing me working it out again.Taught me that I have to continuously stay active in order for my knee to keep getting better and stronger.*
2	*Stress and physical pain have a connection. Stretching is good to relieve pain. Exercises that help my condition*	*How vital stretching is to strengthening the muscles.*
3	*I have learned what is causing my pain and that it can be treated without surgery. Some small lifestyle changes to improve my condition. Attitude is everything to improve treatment.*	*I learned what was causing my back pain, and how to stretch and exercise my back muscles properly to help correct the problem and improve my posture/back so that I won't have problems in the future.*
4	*Spinal stretches, how to stay active and manage the pain while reaching full range of motion. Building the core to help support the lower back. Most important not to be afraid of the motion but to use correct form, listen to my body and stretch/walk the muscles to build back and core strength.*	*Exercises.*
5	*I have learned correct posture, stretching, exercises, how to cope with my uncomfortness on a day to day basis.*	*Follow on exercises to relieve pain*
6	*Stress and pain go hand in hand. My body will respond to*	*Stretching help keep you limber. Being or maintaining flexibility*

	my stress by tensing up the muscles and creating pain as well as discomfort.	*will always help you maintain a healthy life style*
7	*The stretches help the most, knowing better ways to stretch changes the level of pain. Stress plays a larger role than I had thought and finding stress relievers.*	*Stretching is key, muscles don't like to be tight, treat your body as an important vessel take care of it.*
8	*More exercises to reduce the pain by strengthening the muscles. The link between stress and the muscles. Learned how to spot the symptoms before it becomes a major issues.*	*The exercises/ workouts, what my actual problem is how my stance/posture affects it, more knowledge about how the back and neck work together.*
9	*Learned what my condition is. Learned what causes my condition. Learned how to cope with flare ups to stay loose and prevent further pain.*	*Spinal alignment and management. Physical therapy and stretching. Body Posture.*
10	*I learned how to practice proper posture and strengths that will help me to deal with my pain levels. I also learned various techniques on how to trick the brain to defeat pain. Through my stretches, posture, and breathing techniques I feel a tremendous difference in my body and my pain has lowered a lot.*	*Stretches to help improve my back and knee pain.*

Both study groups had a comparable number of subjects who exceeded at least one SBST item cut-off (63.5% of the intervention group and 68% of the control group). Thirty-three percent (n=18) of those who exceeded at least one SBST item cut-off, indicated that they had learned PiPT concepts versus 35% of those who did not meet any SBST item cut-offs (see Figure 1). Therefore, subjects were equally likely to state that they learned PiPT concepts regardless of

whether they were at risk for poor outcome. Since zero statements reflected PiPT concepts in the control group, it was not possible to analyze a similar comparison within this group.

Figure 1.



Discussion and Conclusion

This study confirmed our hypotheses that intervention subjects would retain more PiPT messages than control subjects. One third of the subjects exposed to PiPT reported learning PiPT concepts compared to zero control subjects. This indicates that for at least a third of the patients who received PIPT, the message was received. There are some possibilities as to why this percentage wasn't higher. First, the patient was asked the question; "Please list the most important thing(s) you learned in physical therapy?". If we had asked the subjects to list all the messages they received, we may have found a higher percentage of PIPT messages. Another reason that more

patients didn't express more PIPT messages may be because of the open-ended question format. A questionnaire such as the FAB-Q or the one used by Overmeer et al do not rely on self-generated ideas and may have found a different level of accord with PIPT messages[25]. It should be noted that the analysis of the rater responses was conservative. If there was any doubt that a response contained a PiPT concept, it was excluded. For example, one subject responded "The most important things I have learned in physical therapy is how to manage my pain and how to help prevent it." A large part of PiPT involves educating patients about their injury and how to manage it. However, this approach involves managing thoughts, feelings and behaviors that perpetuate pain. From this subject's response it is not clear if the message was purely biomedical or contained a biopsychosocial component. Therefore it was not designated as a PiPT response. A lower number of PiPT messages would be expected by applying the stringent criteria used in this study. In any case, the fact that no patients in the control group reported learning any concepts consistent with PIPT indicates that the treatments were in fact, different and that some retention of these messages occurred in the intervention group.

Although some authors have suggested that PiPT may not be a useful approach for those who are not at risk for poor outcome, our findings suggest that those at risk of poor outcome as assessed using the SBST are just as likely as those not at risk for poor outcome to demonstrate learning of PiPT-related constructs [43-45]. Further research is required to determine whether this comparable propensity for learning is related to comparable treatment outcomes.

Bunzli et al (2016) found that the therapist-patient alliance was important in facilitating the patients shift from a biomedical to a biopsychosocial understanding of their pain [29]. We did not directly test that. However, only 6% of the subjects in the treatment arm failed to answer the open-ended question compared to 26% in the control arm. The higher compliance rate in the

intervention group may indicate a stronger investment in study participation possibly due to a stronger alliance with the PT. Future studies are needed to confirm this theory. However, PiPT requires more communication with patients and therefore, should improve the therapist-patient alliance.

Since this was a quasi-experimental design, subjects were not randomly assigned to carriers. This suggests that some systematic difference between carrier personnel could account for the findings. For example, the intervention group may have been exposed to PiPT concepts through various forms of media available before deployment, since they were deployed later than the control group. This is unlikely however, since deployment times for the carriers were within a year of each other and the PTs on the intervention carrier were not familiar with PiPT concepts prior to training. Also, since both groups had a similar number of subjects who exceeded the cut-off for psychological risk factors, the difference in outcome cannot be explained by variations in baseline psychological status either. In addition, the fact that none of the subjects in the control group reported learning PiPT concepts is strong support for the effectiveness of the intervention.

This is the first study to examine the transfer of specific PiPT knowledge from the PTto the patient. It is important to note that this study provides a description of patient open-ended responses. As part of a larger study, these findings are useful to validate the potency of the intervention and the efficacy of the PiPT approach. Our results are not based on a formal qualitative study and should not be taken as such. Future well-designed qualitative and mixed method studies may shed greater light on this topic. We intend these findings to be the start of a discussion about how PiPT messages are transmitted from provider to patient. It is important to understand the circumstances under which PiPT training results in changes to patients'

understanding of their condition. Studies suggest that patients who are treated by PTs trained in a biopsychosocial approach may be more willing to adopt associated beliefs when the physical therapist-patient therapeutic alliance is strong, the patient experiences a sense of control over pain and has the capacity to adopt new pain beliefs [29].

Equally important, is understanding how PIPT messages translate into cognitive and behavioral changes on the part of patients and if this change results in better outcomes. Learning PiPT messages through a short duration of treatment may not be enough to completely replace long-held beliefs about pain [46]. Also, a change in beliefs is a precursor to but not necessarily sufficient for behavior change. Other intrinsic and extrinsic factors such as motivation and external rewards affect behaviors as well [47]. We are currently in the process of evaluating these questions in a larger ongoing study. Future studies should also seek to identify patients who will benefit the most from this approach and determine if those patients are more or less likely to retain PIPT messages.

PiPT aimed at improving outcomes for patients with MSI shows promise. However, the mechanism by which it works is unknown. One important aspect of understanding the process of PiPT message transference from practitioner to patient is to verify that PiPT messages are retained by patients. This study demonstrates that a sizable proportion of subjects who received PiPT learned the messages they were taught compared to usual care controls. This suggests that PIPT may be effective in modifying patient beliefs, at least in the short run. Future studies are needed to determine if patient learning results in a change in patient beliefs that are retained over time and if they are associated with adaptive behaviors and patient-centered outcomes.

Keywords

Psychologically-informed Physical Therapy, Patient Education, Musculoskeletal Injuries.

Acknowledgements

The authors thank Danielle Southerst DC, FCCS(C), Elizabeth Plowman, PT, DPT, OCSLT, MSC, USN, Nicholas Azzaro HM2(FMF/EXW/IDW/SW), and Tahney C. Johnston, Psy.D LT/MSC/USN for their contribution to this study

Funding

This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs, through the Peer Reviewed Orthopedic Research Program under Award No. W81XWH-14-2-0146.

Disclaimers

The views expressed in this publication reflect the results of research conducted by the author(s) and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the United States Government

Human Subjects Statement

Research data derived from an approved Naval Medical Center, Portsmouth, Virginia Institutional Review Board (Institutional Animal Care and Use Committee) protocol number NMCP2014.0058

1. Chou R, Huffman LH. Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. *Annals of internal medicine*. 2007;147(7):492-504.
2. Mafi JN, McCarthy EP, Davis RB, Landon BE. Worsening trends in the management and treatment of back pain. *JAMA internal medicine*. 2013;173(17):1573-1581.
3. Bostick GP. Effectiveness of psychological interventions delivered by non-psychologists on low back pain and disability: a qualitative systematic review. *Spine J*. 2017;17(11):1722-1728.
4. Keefe FJ, Main CJ, George SZ. Advancing psychologically informed practice for patients with persistent musculoskeletal pain: promise, pitfalls, and solutions. *Physical therapy*. 2018;98(5):398-407.
5. Main CJ, George SZ. Psychologically informed practice for management of low back pain: future directions in practice and research. *Phys Ther*. 2011;91(5):820-824.
6. George SZ, Beneciuk JM. Psychological predictors of recovery from low back pain: a prospective study. *BMC Musculoskelet Disord*. 2015;16:49.
7. Waddell G. *The Back Pain Revolution*. New York: Churchill Livingstone; 1999.
8. Nicholas MK, Linton SJ, Watson PJ, Main CJ. Early identification and management of psychological risk factors ("yellow flags") in patients with low back pain: a reappraisal. *Phys Ther*. 2011;91(5):737-753.
9. Dupeyron A, Ribinik P, Gélis A, et al. Education in the management of low back pain. Literature review and recall of key recommendations for practice. *Annals of physical and rehabilitation medicine*. 2011;54(5):319-335.

10. Kendall N. Guide to assessing psychosocial yellow flags in acute low back pain. *Risk factors for long-term disability and work loss*. 1997.
11. Vlaeyen JW, Morley S. Cognitive-behavioral treatments for chronic pain: what works for whom? : LWW; 2005.
12. Hoffman BM, Papas RK, Chatkoff DK, Kerns RD. Meta-analysis of psychological interventions for chronic low back pain. *Health psychology*. 2007;26(1):1.
13. Williams ACdC, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. *The cochrane library*. 2012.
14. McCracken LM, Turk DC. Behavioral and cognitive–behavioral treatment for chronic pain: outcome, predictors of outcome, and treatment process. *Spine*. 2002;27(22):2564-2573.
15. Singla M, Jones M, Edwards I, Kumar S. Physiotherapists' assessment of patients' psychosocial status: are we standing on thin ice? A qualitative descriptive study. *Manual therapy*. 2015;20(2):328-334.
16. Synnott A, O'Keeffe M, Bunzli S, Dankaerts W, O'Sullivan P, O'Sullivan K. Physiotherapists may stigmatise or feel unprepared to treat people with low back pain and psychosocial factors that influence recovery: a systematic review. *Journal of physiotherapy*. 2015;61(2):68-76.
17. Darlow B, Fullen BM, Dean S, Hurley DA, Baxter GD, Dowell A. The association between health care professional attitudes and beliefs and the attitudes and beliefs, clinical management, and outcomes of patients with low back pain: a systematic review. *European Journal of Pain*. 2012;16(1):3-17.

18. Main CJ, Buchbinder R, Porcheret M, Foster N. Addressing patient beliefs and expectations in the consultation. *Best Practice & Research Clinical Rheumatology*. 2010;24(2):219-225.

19. Buchbinder R, Pransky G, Hayden J. Recent advances in the evaluation and management of nonspecific low back pain and related disorders. *Best Practice & Research Clinical Rheumatology*. 2010;24(2):147-153.

20. Jette AM, Delitto A. Physical Therapy Treatment Choices for Musculoskeletal Impairments. *Physical Therapy*. 1997;77(2):145-154.

21. Geffen SJ. 3: Rehabilitation principles for treating chronic musculoskeletal injuries. *The Medical journal of Australia*. 2003;178(5):238-242.

22. Linton SJ, Hellsing AL, Andersson D. A controlled study of the effects of an early intervention on acute musculoskeletal pain problems. *Pain*. 1993;54(3):353-359.

23. Gatchel RJ, Polatin PB, Noe C, Gardea M, Pulliam C, Thompson J. Treatment- and cost-effectiveness of early intervention for acute low-back pain patients: a one-year prospective study. *J Occup Rehabil*. 2003;13(1):1-9.

24. Weiser-Horwitz S, Campello M, Lis A, et al. *A Pilot Study to Test the Efficacy of Psychologically Based Physical Therapy Training for Treating Deployed US Sailors and Marines with Musculoskeletal Injuries*. New York University New York United States;2015.

25. Overmeer T, Boersma K, Denison E, Linton SJ. Does Teaching Physical Therapists to Deliver a Biopsychosocial Treatment Program Result in Better Patient Outcomes? A Randomized Controlled Trial. *Physical Therapy*. 2011;91(5):804-819.

26. Jacobs CM, Guildford BJ, Travers W, Davies M, McCracken LM. Brief psychologically informed physiotherapy training is associated with changes in physiotherapists' attitudes and beliefs towards working with people with chronic pain. *British journal of pain*. 2016;10(1):38-45.

27. Bryant C, Lewis P, Bennell KL, et al. Can physical therapists deliver a pain coping skills program? An examination of training processes and outcomes. *Physical therapy*. 2014;94(10):1443-1454.

28. Frederiksen P, Indahl A, Andersen LL, Burton K, Hertzum-Larsen R, Bendix T. Can group-based reassuring information alter low back pain behavior? A cluster-randomized controlled trial. *PLOS ONE*. 2017;12(3):e0172003.

29. Bunzli S, McEvoy S, Dankaerts W, O'Sullivan P, O'Sullivan K. Patient Perspectives on Participation in Cognitive Functional Therapy for Chronic Low Back Pain. *Phys Ther*. 2016;96(9):1397-1407.

30. Moseley GL, Butler DS. Fifteen Years of Explaining Pain: The Past, Present, and Future. *The journal of pain : official journal of the American Pain Society*. 2015;16(9):807-813.

31. Zimney K, Louw A, Puentedura EJ. Use of Therapeutic Neuroscience Education to address psychosocial factors associated with acute low back pain: a case report. *Physiotherapy theory and practice*. 2014;30(3):202-209.

32. Louw A, Diener I, Butler DS, Puentedura EJ. The effect of neuroscience education on pain, disability, anxiety, and stress in chronic musculoskeletal pain. *Arch Phys Med Rehabil*. 2011;92(12):2041-2056.

33. O'Sullivan K, Dankaerts W, O'Sullivan L, O'Sullivan PB. Cognitive Functional Therapy for Disabling Nonspecific Chronic Low Back Pain: Multiple Case-Cohort Study. *Phys Ther*. 2015;95(11):1478-1488.

34. Foster NE, Delitto A. Embedding psychosocial perspectives within clinical management of low back pain: integration of psychosocially informed management principles into physical therapist practice--challenges and opportunities. *Phys Ther*. 2011;91(5):790-803.

35. Sanders T, Foster NE, Bishop A, Ong BN. Biopsychosocial care and the physiotherapy encounter: physiotherapists' accounts of back pain consultations. *BMC Musculoskeletal Disorders*. 2013;14(1):65.

36. Alexa Knuth LRS, Corinne Brent1 and Ryan Salerno. Psychological Aspects of Rehabilitation as Perceived by Physical Therapists. *Journal of Physical Fitness, Medicine & Treatment in Sports*. 2018;2(1).

37. Overmeer T, Boersma K. What messages do patients remember? Relationships among Patients' perceptions of physical Therapists' messages, patient characteristics, satisfaction, and outcome. *Physical therapy*. 2016;96(3):275-283.

38. Weiser S, Lis A, Ziemke G, et al. Feasibility of Training Physical Therapists to Implement a Psychologically Informed Physical Therapy Program for Deployed U.S. Sailors and Marines with Musculoskeletal Injuries. *Mil Med*. 2018;183(suppl_1):503-509.

39. Cohen SP, Nguyen C, Kapoor SG, et al. Back pain during war: an analysis of factors affecting outcome. *Archives of internal medicine*. 2009;169(20):1916-1923.

40. Goodman GP, DeZee KJ, Burks R, Waterman BR, Belmont PJ. Epidemiology of psychiatric disorders sustained by a US Army brigade combat team during the Iraq War. *General hospital psychiatry*. 2011;33(1):51-57.

41. Huang GD. Back and upper extremity disorders among enlisted US Marines: burden and individual risk factors. *Military medicine*. 2001;166(11):1007.

42. Patzkowski JC, Rivera JC, Ficke JR, Wenke JC. The changing face of disability in the US Army: the Operation Enduring Freedom and Operation Iraqi Freedom effect. *Journal of the American Academy of Orthopaedic Surgeons*. 2012;20:S23-S30.

43. Foster NE, Mullis R, Hill JC, et al. Effect of stratified care for low back pain in family practice (IMPaCT Back): a prospective population-based sequential comparison. *Annals of family medicine*. 2014;12(2):102-111.

44. Hill JC, Whitehurst DG, Lewis M, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. *The Lancet*. 2011;378(9802):1560-1571.

45. Archer KR, Coronado RA, Wegener ST. The Role of Psychologically Informed Physical Therapy for Musculoskeletal Pain. *Current Physical Medicine and Rehabilitation Reports*. 2018;6(1):15-25.

46. Kamper SJ, Apeldoorn AT, Chiarotto A, et al. Multidisciplinary biopsychosocial rehabilitation for chronic low back pain: Cochrane systematic review and meta-analysis. *BMJ (Clinical research ed)*. 2015;350:h444.

47. Ryan P. Integrated Theory of Health Behavior Change: background and intervention development. *Clinical nurse specialist CNS*. 2009;23(3):161-170; quiz 171-162.

Mr. Lashbaugh,

Thank you for submitting Continuing Review 03 for your protocol NMCP.2014.0058 "A Pilot Study to Test the Efficacy of Psychologically Based Physical Therapy Training for Treating Deployed U.S. Sailors and Marines with Musculoskeletal Injuries", which expires on 26 July 2017.

IRB-2 reviewed the Continuing Review during the convened meeting on 28 June 2017 and recommended approval to the CO.

Your new study expiration date is 27 June 2018. Please note your study is now eligible for Expedited Category 8 review.

This continuing review includes:

Continuing review report

- Research Plan Version #5 appr 22Dec16
- Patient Information Questionnaire- Baseline
- Patient Information Questionnaire- Follow-up

As the study is closed to enrollment, no consent forms were reviewed or approved by the IRB at this time.

Please note that the agreement associated with this protocol is currently in good standing.

Should you complete all study activities and wish to close the protocol, you may do so by submitting a final report and a manuscript, abstract, or summary of your study results.

With best regards,

Melvina Queen, CIP, CCRP
IRB-2 Administrator

28 Jun 17

Full Board Continuing Review 03
Human Subjects Research
Naval Medical Center Portsmouth, VA
Contact Clinical Investigation Department at (757) 953-5939

STUDY TITLE
NMCP.2014.0058 "A Pilot Study to Test the Efficacy of Psychologically Based Physical Therapy Training for Treating Deployed U.S. Sailors and Marines with Musculoskeletal Injuries"

PRINCPAL INVESTIGATOR		
Name (Rank Name Degree): Michael Lashbaugh, MPT		PRD (MM/YY): N/A
Command: NMCP	Department: Physical Therapy	CITI (MM/DD/YY): 08/10/15
Phone/Pager: 757-953-1366		CV (MM/DD/YY): 11/07/16
Email: Michael.s.lashbaugh.civ@mail.mil		RIT (MM/DD/YY): 08/15/15
☐ **AD** ☒ Staff ☐ Intern ☐ Resident ☐ Other:____ ☒ **CIV** ☐ **CTR**: Company _____		

RESEARCH TEAM MEMBERS		
Name (Rank Name Degree): Sherri Weiser Horowitz PhD		PRD (MM/YY): N/A
Command:	Department:	CITI (MM/DD/YY): 06/30/2014
Phone/Pager: 212-255-6690		CV (MM/DD/YY): 03/02/2016
Email: sherri.weiser@nyumc.org		RIT (MM/DD/YY): 05/20/2016
☐ **AD** ☐ Staff ☐ Intern ☐ Resident ☐ Other:____ ☒ **CIV** ☒ **CTR**: Company NYU SOM		

Name (Rank Name Degree): Marco Campello PT PhD		PRD (MM/YY): N/A
Command:	Department:	CITI (MM/DD/YY): 04/16/2015
Phone/Pager: 212-255-6690		CV (MM/DD/YY): 03/02/2016
Email: marco.campello@nyumc.org		RIT (MM/DD/YY): 05/24/2016
☐ **AD** ☐ Staff ☐ Intern ☐ Resident ☐ Other:____ ☒ **CIV** ☒ **CTR**: Company NYU SOM		

Name (Rank Name Degree): Rudi Hiebert ScM		PRD (MM/YY): N/A
Command:	Department:	CITI (MM/DD/YY): 05/13/2015
Phone/Pager: 718-722-4421		CV (MM/DD/YY): 03/07/2016
Email: rhiebert@udel.edu		RIT (MM/DD/YY): 05/24/2016
☐ **AD** ☐ Staff ☐ Intern ☐ Resident ☐ Other:____ ☒ **CIV** ☒ **CTR**: Company Univ of Delaware		

Name (Rank Name Degree): Christopher Rennix ScD		PRD (MM/YY): N/A
Command: NMCP	Department: NMCPHC	CITI (MM/DD/YY): 07/22/2014
Phone/Pager: 757-953-5940		CV (MM/DD/YY): 03/02/2016

Email: christopher.p.rennix.civ@mail.mil	RIT (MM/DD/YY): 10/29/2014
☐ **AD** ☐ Staff ☐ Intern ☐ Resident ☐ Other:____ **X CIV** ☐ **CTR**: Company _____	

Name (Rank Name Degree): Tara Brennan MSc		PRD (MM/YY): N/A
Command:	Department:	CITI (MM/DD/YY): 07/07/2015
Phone/Pager: 212-255-6690		CV (MM/DD/YY): 07/09/2015
Email: tara.brennan@nyu.edu		RIT (MM/DD/YY): 07/09/2015
☐ **AD** ☐ Staff ☐ Intern ☐ Resident ☐ Other:____ **X CIV** **X CTR**: Company NYU SOM		

Name (Rank Name Degree): Lt Colleen Hopkins DPT		PRD (MM/YY): 11/2017
Command: CVN 71	Department: Physical Therapy	CITI (MM/DD/YY): 122/09/2014
Phone/Pager: 757-443-7415		CV (MM/DD/YY): 02/12/2015
Email: colleen.hopkins@cvn72.navy.mil		RIT (MM/DD/YY): 01/22/2015
X AD **X** Staff ☐ Intern ☐ Resident ☐ Other:____ ☐ **CIV** ☐ **CTR**: Company _____		

Name (Rank Name Degree): Lt Elizabeth Plowman, DPT		PRD (MM/YY): 08/2016
Command: CVN 71	Department: Physical Therapy	CITI (MM/DD/YY): 10/21/2015
Phone/Pager: 757-443-7415		CV (MM/DD/YY): 10/21/2015
Email: colleen.hopkins@cvn72.navy.mil		RIT (MM/DD/YY): 10/21/2015
X AD **X** Staff ☐ Intern ☐ Resident ☐ Other:____ ☐ **CIV** ☐ **CTR**: Company _____		

Name (Rank Name Degree): HM2 Nicholas Azzaro		PRD (MM/YY): 04/2017
Command: CVN 71	Department: Physical Therapy	CITI (MM/DD/YY): 10/21/2015
Phone/Pager: 757-443-7415		CV (MM/DD/YY): 10/21/2015
Email: colleen.hopkins@cvn72.navy.mil		RIT (MM/DD/YY): 10/21/2015
X AD **X** Staff ☐ Intern ☐ Resident ☐ Other:____ ☐ **CIV** ☐ **CTR**: Company _____		

RESEARCH MONITOR		
Name (Rank Name Degree): CAPT Geoffrey Wright		PRD (MM/YY): 06/2017
Command: NMCP	Department: Orthopedics	CITI (MM/DD/YY): 10/24/2016
Phone/Pager: 757-953-1868		CV (MM/DD/YY): 10/24/2016
Email: Geoffrey.A.Wright2.mil@mail.mil		RIT (MM/DD/YY): 04/14/2016
X AD **X** Staff ☐ Intern ☐ Resident ☐ Other:_____ ☐ **CIV** ☐ **CTR**: Company _____		

- *If available, the current Delegation of Duties Log should be submitted to explain the duties, responsibilities, and role for each member of the Research Team. The PI may, for example, identify some AIs as able to perform consent, but assign different responsibilities, be they clinical, regulatory, or administrative, to others.*

APPROVAL / EXPIRATION INFORMATION	
(3) Period Covered by this Continuing Review *[Date of most recent annual approval] to[date this CR was completed]*	From: 27 July 2016 To: 20 June 2017
(4) Initial IRB Protocol Approval Date	22 October 2014
(5) Initial Command Protocol Approval Date	06 November 2014
(6) Current Expiration Date	26 July 2017
(7) Review Cycle Periodicity	**X** Annual *(364 Days)* ☐ Other: _____

DISCLOSURES			
(9) Funding:		**Yes**	**No**
a. Does this study receive funding for resources, personnel, materials, or equipment, etc.) by: • An internal source such as BUMED-DSG, BUMED-WII, or the Commander's Fund?			**X**
• An external source such as NIH, NSF, RDT&E P6, academia, or industry?		**X**	
b. Is there a Cooperative Research and Development Agreement (CRADA), Memorandum of Understanding (MOU), Interagency Agreement (IAA), Educational Partnership Agreement (EPA) or ANY other collaborative agreement associated with this study?		**X**	
If yes, provide the identifier for this agreement:	CRADA 14-272 & 14-264		
Please list collaborating institutions: *Indicate what activities are occurring at each location:* *(For example, EVMS is collaborating, and Data Collection occurs at that location)*			
University of Delaware BADER consortium	☐ Subject Recruitment ☐ Subject Consenting ☐ Data Collection **X** Data Analysis ☐ Other: _____		
New York University School of Medicine Hospital for Joint Diseases Occupational and Industrial Orthopedics Ctr	☐ Subject Recruitment ☐ Subject Consenting ☐ Data Collection **X** Data Analysis ☐ Other: _____		

(10) Conflict of Interest:		
Do you or any other person responsible for the design, conduct or reporting of this research have an economic interest in or act as an officer or director of any outside entity whose financial interests would reasonably appear to be affected by this research? *If "yes", provide a written justification for continued association with this study.*		**X**
(11) Monitoring / Auditing Visits:		
d. Have any internal or external audits, reviews or evaluations been conducted on this study or the overall program, if this study is part of a sponsored trial, since the last continuing review?		**X**
e. Will any internal or external audits, reviews or evaluations be conducted before the next continuing review? *If "yes", please provide the scheduled dates and copies of any correspondence relating to the events.*		**X**

(12) Brief Progress Summary:
The study was closed for enrollment on 13 July 2016. The date of last subject enrollment was on 16 June 2016. Currently the study is in data analysis only. No interim analysis has been conducted because no adverse events have been detected. Funding for the study will end 30 September 2017 at which time the research team will have completed its technical report and distributed the study deliverables to the contracting agency (CDMRP).

STUDY CHARACTERISTICS		
(12) Risk Assessment:		
X Minimal Risk	☐ Greater than Minimal Risk	
(13) FDA IND / IDE / HDE?	☐ YES #_____	X NO
Single Patient Compassionate Use?	☐ YES	☐ NO
(14) Vulnerable Population ☐ YES X NO	☐ Newborns ☐ Minors ☐ Pregnant Women/Fetuses ☐ Decisionally Impaired ☐ Other: _____	
(15) Population	X Military ☐ Civilian ☐ Both	
(16) Active Subject Recruitment ☐ Yes X No	Are subjects recruited and consented in a group setting? ☐ YES X NO If yes, is an Ombudsman* present? ☐ YES Name: _____ ☐ NO * required for greater than minimal risk protocols	

(17) Study Status:		
Has the study been initiated?	X YES	☐ NO
Records (Chart Review) or Specimens ONLY		
Record / data collection is:	☐ Ongoing	X Completed
Are remaining research activities limited to data analysis?	X YES	☐ NO
Interactions with Active Subject Participation ONLY		
Enrollment is:	☐ Open	X Closed
Are remaining research activities limited to data analysis?	X YES	☐ NO

(18) Waiver of Authorization for the Use of PHI / Waiver or Alteration of Consent	**Yes**	**No**
Does your study include a Waiver of Authorization for the Use of PHI? *If yes, do you believe that the justifications for Waiver of Authorization continue to be appropriate?* ☐ YES ☐ NO		X
Does your study include a Waiver of Consent or Waiver of Documentation of Consent? *If yes, do you believe that the justifications for Waiver of Consent continue to be appropriate?* ☐ YES ☐ NO		X

(19) Multi-Site Enrollment Characteristics			
Is this a Multi-Center Trial ☐ YES X NO			
Primary Site:	NMCP	Affiliates:	
Total Approved at all Sites :	600		
Total Enrolled at all Sites:*	198		
**Most current multi-center summary report attached?* ☐ YES ☐ NO X N/A			

RECORD / SUBJECT ENROLLMENT INFORMATION	
(20) *Does this project involve Records (Chart Review) or Specimens **ONLY*** ☐ YES X NO	
Total Records/Specimens IRB Approved this Site	
Total Records/Specimens Collected this Site Since Initiation	
Total Records/Specimens Collected this Site during this Reporting Period	
Total Records/Specimens Withdrawn/Lost to Follow-Up Since Initiation ** *This includes incomplete or damaged records/specimens* ** *Provide reasons for Records/Specimen withdrawal:* _____	
Total Records/Specimens Withdrawn/Lost to Follow-Up during this Reporting Period ** ** *Provide reasons for Records/Specimen withdrawal:* _____	
Total Records/Specimens Completed	

(21) *Does this project involve Interactions with Active Subject Participants* **X** YES ☐ NO	
Total Subjects IRB Approved this Site: *Remember that the total number approved should account for loss due to screen failure or failure to fully qualify for inclusion.*	**600**
Number of Subjects Consented for Participation Since Initiation:	**198**
Number of Subjects Consented for Participation during this Reporting Period: *** Complete Appendix A: Subject Identifier Form*	**0**
Total Subjects Active during this reporting period: *This includes interactions with and interventions by research team members*	**0**
Total Subjects on Long Term Follow-Up for Outcomes Data during the reporting period	**0**
Total Subjects Withdrawn/Lost to Follow-Up Since Initiation ** *This includes screen failures, subjects who failed to reach intervention or study completion, and incomplete or damaged data.* *** Provide reasons for local subject(s)' withdrawal:* _____	**0**
Total Subjects Withdrawn/Lost to Follow-Up during this Reporting Period ** *** Provide reasons for local subject(s)' withdrawal:* _____	**0**
Total Subjects Completed & Off Study Protocol	**198**

SUBJECT INFORMATION

(22) Were subjects enrolled during this reporting period?

X NO (*skip to #24*) ☐ YES Is subject demographic information collected?

☐ NO (*skip to #24*)

☐ YES (*complete the table below*)

Females:		Males:	

Children (≤ 7 Yr)		Children (8-17 Yr)		Adults (18-89 Yr)		Adults (>90 Yr)	

Caucasian:		Black:		Hispanic:		Asian:		Other Ethnicity:	

ADVERSE EVENTS	**Yes**	**No**
(23) Any serious adverse events during this review period? *If "yes", have they been submitted to the IRB?* ☐ YES ☐ NO		**X**
(24) Any adverse events during this review period? *If "yes", please complete Appendix B "Summary of Adverse Events (AE) and Protocol Deviations to be Reported at the Time of Continuing Review"*		**X**

PROTOCOL DEVIATIONS / VIOLATIONS		
(25) Any protocol deviations during this review period? *If "yes", have they been submitted to the IRB?* ☐ YES ☐ NO *If NOT, please complete Appendix B "Summary of Adverse Events (AE) and Protocol Deviations to be Reported at the Time of Continuing Review*		**X**
(26) Any protocol violations during this review period? *If "yes", have they been submitted to the IRB?* ☐ YES ☐ NO		**X**

MODIFICATIONS		
(28) Were any changes made to the approved protocol, consent form or other study materials during the reporting period? *If "yes", indicate the identifier (AM01, etc.):* **2014.0058 AM09**	X	
(28) If a treatment protocol, has the standard of care changed since the last review? *If "yes", please attach a copy of all altered documents with the changes highlighted.*		X
(29) Is there any new information that affects the conduct of this study protocol? *If "yes", please attach a description of the new information's impact, especially where it may affect a subject's willingness to continue participation or may change the level of risk.*		X
(30) Has the risk/benefit assessment changed based on your study progress/results? *If "yes", please attach an explanation of the change.*		X

FINDINGS		
(31) Are there any interim findings? *If "yes", please attach an interim report.*		X

PUBLICATIONS / PRESENTATIONS		
(32) Have any data from this study been submitted for publication or presented? *If "yes", please attach a list detailing the author(s), title, date of submission or presentation and the journal, book or society in which the manuscripts or presentations appear.*	X	

SUBJECT CONSENT OBTAINED DURING THIS REPORTING PERIOD		
(33) Copies of consent forms signed this reporting period submitted to Compliance Advisor?		X

UPDATED LITERATURE SEARCH and ASSESSMENT OF IMPACT ON CURRENT PROJECT

(34) *Instructions: This section should demonstrate a literature search for articles published since the most recent IRB approval. Please contact the NMCP Library for assistance with the search but note that it is not sufficient to only submit the results of a search. The PI is expected to review the results of the search, identify relevant articles, and briefly comment upon how the new literature impacts this project. Do any articles present information that suggests a need to modify the existing project? Does this protocol unnecessarily duplicate newly published research? This is intended to be a thoughtful search – the IRB is interested in the PIs interpretation of the literature and its relationship to the protocol under review.*

A literature search is required for investigator initiated research, but is not mandatory for sponsored, multi-center research, as sponsor-generated protocols and annual reports generally satisfy this need.

Is a literature search and commentary required? X YES ☐ NO

Insert literature search and commentary here:

Literature review

The searches from NMCP.2014.0058 CR02 submission were re-run, and findings limited to 2016 – 2017. The following electronic databases were used:

MEDLINE/Pubmed
OVID/PsycInfo
The filters used were:
Filters: published in the last year (2016- current) AND English language AND Humans.
Search terms: cognitive therapy AND physical therapy AND musculoskeletal/pain.

Strategy:

```
((((pain[Title/Abstract] OR back pain[Title/Abstract]) OR musculoskeletal
pain[Title/Abstract]) OR musculoskeletal injury[Title/Abstract]) AND "2016/01/01"[PDAT] :
"2017/05/01"[PDAT]) AND ((((((yellow flags[Title/Abstract] OR psychosocial[Title/Abstract])
OR psychological[Title/Abstract]) OR biopsychosocial[Title/Abstract]) OR pain coping
skills[Title/Abstract]) OR cognitive therapy[Title/Abstract]) AND ("2016/01/01"[PDAT] :
"2017/05/01"[PDAT])) AND ((("physical therapy modalities"[MeSH Major Topic] OR "physical
therapists"[MeSH Major Topic]) AND "2016/01/01"[PDAT] : "2017/05/01"[PDAT]) AND "humans"[MeSH
Terms] AND English[lang]) (((((("physical therapy"[All Fields] OR "physiotherapy"[All Fields])
OR "intervention"[All Fields]) OR "treatment"[All Fields]) AND "2016/01/01"[PDAT] :
"2017/05/01"[PDAT]) AND ((("psychosocial"[All Fields] OR "yellow flags"[All Fields]) OR
"psychological"[All Fields]) AND "2016/01/01"[PDAT] : "2017/05/01"[PDAT])) AND
((("musculoskeletal"[All Fields] OR "back pain"[All Fields]) OR "musculoskeletal disease"[All
Fields]) OR "musculoskeletal injury"[All Fields]) AND "2015/05/20"[PDAT] : "2017/05/01"[PDAT]
AND "humans"[MeSH Terms] AND C2016/01/011PDAT]: "2017/05/01"[PDAT] AND English[lang])
```

This search yielded sixteen potential articles.

Searching other resources

We also searched reference lists of previously eligible papers as well as relevant authors in the field of "Psychologically Informed Physical Therapy"
Search concepts: by relevant authors Resource: MEDLINE/PUBMED

Strategy:

```
[Full Author Name] AND ("2016/01/01"[PDat]: "2017/05/01"[PDat])
```

Author	Search Term
J. Fritz.	Fritz, Julie[Full Author Name) AND ("2016/01/01"[PDat]: "2017/05/01"[PDat])
CJ. Main.	Main, Chris J[Full Author Name] AND ("2016/01/01"[PDat]: "2017/05/01"[PDat])
T. Pincus.	Pincus, Tamar [Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
WS. Shaw.	Shaw, William S[Full Author Name] AND ("2016/01/01"[PDat]: "2017/05/01"[PDat])
G. Sowden.	Sowden, Gail[Full Author Name] AND ("2016/01/01"[PDatj : "2016/05/20"[PDatl)
SZ. George.	George, Steven Z[Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
D. Serbic.	Serbic, Danijela[Full Author Name] AND ("2016/01/01"[PDat]: "2017/05/01"[PDat])
J. Hill.	Hill, Jonathan C[Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
MK. Nicholas.	Nicholas, Michael K[Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
JM. Beneciuk.	Beneciuk, Jason M[Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
N. Foster.	Foster, Nadine[Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
MJ. Sullivan.	Sullivan, Michael J[Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
FJ. Keefe.	Keefe, Francis J[Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
S. Linton.	Linton, Steven[Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
DC, Turk.	Turk, Dennis C[Full Author Name] AND ("2016/01/01"[PDat]: "2017/05/01"[PDat])

A. Delitto,	Delitto, Anthony[Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
R. Gatchel.	Gatchel, Robert J[Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
D. Butler.	Butler, David[Fuil Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
L. Moseley.	Moseley, Lorimer[Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
DL. Riddle.	Riddle, Daniel L[Full Author Name] AND ("2016/01/01"[PDat] : "2016/05/20"[PDat])
S. Bergbom.	Bergbom, Sophia [Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
C. Maher.	Maher, Chris[Full Author Name] AND ("2016/01/01"[PDat] : "2017/05/01"[PDat])
JW. Vlaeyen.	Vlaeyen, Johan W[Full Author Name] AND ("2016/01/01" [PDat] : "2017/05/01"[PDat])

Limiting these author searches to terms involving "musculoskeletal" and "psychological" yielded an additional two candidate studies. Combining these two search strategies yielded 18 candidate articles for review.

Of the eighteen candidate studies, six were thought to be most relevant. Of the six selected articles, one addressed issues of the *impact of psychological variables on the risk of musculoskeletal disability*, three articles addressed *screening for psychological risk factors ('yellow flags')* in the primary care setting, and two articles discussed the *feasibility and implementation of psychologically informed physical therapy*.

Impact of psychosocial variables on the risk of musculoskeletal disability

Melton et al (2015)[1] analyzed work disability related to low back pain using structural equation modeling. 156 subjects were included in the study, factors found to be predictive included female gender, full-time employment, depression, and fear avoidance beliefs as significant predictors. Full time employment reduced risk of work disability, the other significant predictors increased the likelihood of disability.

Screening for psychological risk factors ('yellow flags')

The STarT Back screening tool was evaluated to determine utility across a variety of musculoskeletal conditions (Butera et al 2016).[2] This study is important because NMCP.2014.0058 utilizes elements of the STarT Back Screening tool, and the question of whether STarT Back can be used across various musculoskeletal conditions is highly relevant. Participants included those with low back (n=118), neck (n=92), shoulder (n=106), or knee (n=111) pain. Logistic regression analysis showed that pain location did not appear as a significant factor, either as an independent factor or as an interaction term. This suggests that the STarT Back tool may have utility for multiple musculoskeletal conditions, but the authors caution that the tool requires more study before routine clinical implementation.

The utility of screening for yellow flags during the acute phase was studied by Ailliet et al (2016)[3] in a prospective, multicenter, chiropractic, practice-based cohort study in Belgium and the Netherlands. 917 participants, 326 with neck pain and 591 with low back pain were included in the study. Ailliet et al found that baseline psychological were weak predictors of subsequent disability. However, only a small percentage of the subjects scored highly on baseline psychosocial variables, so the authors caution that a fair evaluation of the importance of psychological variables as baseline predictors of recovery may not be possible, and that the findings may be subject to possible selection bias.

Rhon et al (2017)[4] evaluated how body diagram score (pain diagrams) could augment and enhance findings and interpretation of psychosocial scores among patients with musculoskeletal pain. In their study, military subjects with musculoskeletal pain were asked to complete pain diagrams along with

psychosocial questionnaires. Body pain scores contributed a statistically significant, additional 5% of explanation of variance in concurrent disability and pain intensity in addition to measures of pain catastrophizing and fear avoidance beliefs. Pain catastrophizing was observed as moderating the relationship between body diagram score and pain intensity. The authors conclude that the clinical utility of body diagrams with low symptom distribution may be improved by concomitant assessment of pain catastrophizing.

Feasibility and implementation of psychologically informed physical therapy

Andronis et al (2017)[5] conducted a systematic review of the cost-effectiveness of Non-Invasive and Non-Pharmacological Interventions for Low Back Pain. Thirty three studies were identified and reviewed. Study interventions were categorized as: (1) combined physical exercise and psychological therapy, (2) physical exercise therapy only, (3) information and education, and (4) manual therapy. Interventions assessed within each category varied in terms of their components and delivery. The authors found that that combined physical and psychological treatments, medical yoga, information and education programs, spinal manipulation and acupuncture are likely to be cost-effective options for low back pain.

Synnott et al (2016)[6] investigated the training of physical therapists in Cognitive Functional Therapy (CFT) training. In depth, semi structured interviews were conducted with 13 physiotherapists from four countries who had received specific CFT. The results of the qualitative study found that four main themes emerged: self-reported changes in understanding and attitudes; self-reported changes in professional practice; altered scope of practice; and increased confidence and satisfaction. Participants described increased understanding of the nature of pain, the role of patient beliefs, and a new appreciation of the therapeutic alliance. Changes in practice included use of new assessments, changes in communication, and adoption of a functional approach. The authors conclude that the physiotherapist participants expressed confidence in their capacity and skill set to manage the biopsychosocial dimensions of chronic low back pain after CFT training, and identified a clear role for including these skills within the physiotherapy profession. This study is important because NMCP.2014.0058 trained physical therapists in the implementation of psychologically informed physical therapy, and Synnot et al (2016) CFT appears similar to that of the training used in our protocol, and lends evidence to the idea that physical therapists can be trained to practice principles of psychologically informed physical therapy.

Summary and conclusion

Of the papers reviewed, the following observations can be made: there is additional literature evaluating the relationship between psychological variables and musculoskeletal disability. Additional work has been almost exclusively in the civilian sector. There is growing evidence of the relationship between psychological factors and risk of musculoskeletal disability, but the specific measurement instruments in use predict only a portion of variance in disability risk, and the low predictive nature of these instruments is due possibly to the specifics of the study populations themselves. The question of whether psychologically informed physical therapy, forward deployed in a military setting, has not been addressed by other authors and continues to be a compelling research question that motivates the completion of our protocol. Literature published since the last continuing review does not document instances of adverse events or side effects of the treatment protocol.

# # #

References cited

1. Melton BL, Moqbel M, Kanaan S, Sharma NK. Structural Equation Model of Disability in Low Back Pain. *Spine (Phila Pa 1976).* Oct 15 2016;41(20):1621-1627.
2. Butera KA, Lentz TA, Beneciuk JM, George SZ. Preliminary Evaluation of a Modified STarT Back Screening Tool Across Different Musculoskeletal Pain Conditions. *Phys Ther.* Aug 2016;96(8):1251-1261.
3. Ailliet L, Rubinstein SM, Hoekstra T, van Tulder MW, de Vet HC. Adding Psychosocial Factors Does Not Improve Predictive Models for People With Spinal Pain Enough to Warrant Extensive Screening for Them at Baseline. *Phys Ther.* Aug 2016;96(8):1179-1189.
4. Rhon DI, Lentz TA, George SZ. Unique Contributions of Body Diagram Scores and Psychosocial Factors to Pain Intensity and Disability in Patients With Musculoskeletal Pain. *J Orthop Sports Phys Ther.* Feb 2017;47(2):88-96.
5. Andronis L, Kinghorn P, Qiao S, Whitehurst DG, Durrell S, McLeod H. Cost-Effectiveness of Non-Invasive and Non-Pharmacological Interventions for Low Back Pain: a Systematic Literature Review. *Appl Health Econ Health Policy.* Apr 2017;15(2):173-201.
6. Synnott A, O'Keeffe M, Bunzli S, et al. Physiotherapists report improved understanding of and attitude toward the cognitive, psychological and social dimensions of chronic low back pain after Cognitive Functional Therapy training: a qualitative study. *J Physiother.* Oct 2016;62(4):215-221.

ELECTRONIC SUBMISSION CHECKLIST		
Please confirm that all relevant documents are attached to your submission. Missing documents will cause your submission to be returned for revisions.	**Yes**	**N/A**
WORD Version of Continuing Review form	X	
PDF of Signature Pages	X	
CITI / CV / RIT for Research Team *(if existing credentials are expiring ONLY)*	N/A	
Approved Research Plan	X	
Updated Literature Search and Assessment of Impact on Current Project	X	
Approved Waiver of Authorization for the Use of PHI (if applicable)		X
Approved Waiver or Alteration of Consent (if applicable)		X
Approved Consent Form(s) to be re-versioned for continued use		X
Approved Data Collection Tool(s) for continued use		X
Approved Instrument / Subject ID Key/ Questionnaire / Diary, etc. for continued use		X
Approved Recruitment Materials for continued use		X
Other: List of abstracts submitted	X	

Investigator Requests: **X** Continuation *To request Completion or Closure-Not Completed of your study, please submit a Final Report form.*		
Rudi Hiebert ScM Printed Name of PI or AI	Signature	10-June-2017 Date

IRB Action:		
☑ Full Board Review ☐ Expedited Review		
Date Reviewed: 28 Jun 17	Review Cycle: annual	Risk Level: ☑ Minimal Risk ☐ Greater than Minimal Risk
Was Appendix B *Summary of AEs/UPs* submitted with this report? ☐ YES ☑ NO All events/problems are acknowledged? ☐ YES ☐ NO ☑ N/A		
☑ Approval for Continuation ☐ Administrative Hold ☐ Suspension		
Christopher S. Ennen, MD CDR MC USN 9218 Maternal-Fetal Medicine Chair, IRB-2 Printed Name of IRB Chair/Vice Chair	Signature	28 Jun 17 Date

HRPO Review ☐ N/A		
Kersten Wheeler, M.S.	Kersten Wheeler	30 June 17
Printed Name	Signature	Date

Commanding Officer, NMCP
Approval given in the minutes of the IRB 2 - 28 June 17 meeting on 11 July 17. Meeting Date CO/XO Signature Date

APPENDIX B: SUMMARY OF ADVERSE EVENTS (AE) AND PROTOCOL DEVIATIONS TO BE REPORTED AT THE TIME OF CONTINUING REVIEW

Summarize events not identified as *Serious*, *Unexpected* **and** *Related* which occurred during the reporting period.

Subject Identifier	I/FU	L/NL	Date of Event	Date PI Notified	Summary of Event	Serious Y/N	Unexpected Y/N	Related Y/N
			00/00/00	00/00/00				

I/FU: Initial or Follow-Up L/NL: Local or Non-Local
Add more rows as needed.

Serious:
An adverse event is any undesirable experience associated with the use of a medical product in a patient.
The event is defined as serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability or Permanent Damage
- Congenital Anomaly/Birth Defect

Unanticipated / Unexpected:
An unanticipated or unexpected event/problem is an event/problem that was not foreseen or expected at the time of the occurrence. For example, an event or information that is not consistent given the nature or research protocol/procedures and subject population or the risks as described in the research protocol.

Related:
A related event/problem is an event/problem that is more likely than not to have been related to the research

NOTE:
*Events identified as Serious, Unexpected, **and** Related are defined as **Serious Adverse Events / Unanticipated Problems** and require submission to the IRB within one (1) business day of discovery. Please contact CID for guidance.*

List of abstracts submitted

1. World "What do patients learn from psychologically based physical therapy?" Submitted to World Confederation for Physical Therapy, 2-4 July 2017, Cape Town South Africa. Accepted.

2. "What do patients with spine pain learn from psychologically informed physical therapy?" Submitted to Eurospine, 11-13 October 2017, Dublin Irelane. In review for acceptance.

3. "Mental Disorders In Deployed Navy Active Duty Service Members Reporting Musculoskeletal Injuries Aboard Two United States Air Craft Carriers." Submitted to Military Health System Research Symposium, 27 – 30 August 2017 Kissimmee Fl. In review for acceptance.

4. "How does psychologically informed physical therapy affect treatment satisfaction in active duty service members with musculoskeletal injuries aboard a United States Air Craft Carrier?" Submitted to Military Health System Research Symposium, 27 – 30 August 2017 Kissimmee Fl. In review for acceptance.

Version: 5
Date: 22Dec16
CID: MAQ

APPENDIX A: RESEARCH PLAN

PI:	Michael Lashbaugh MPT
Study Title:	"A Pilot Study to Test the Efficacy of Psychologically Based Physical Therapy Training for Treating Deployed U.S. Sailors and Marines with Musculoskeletal Injuries"

RESEARCH PLAN

1. OBJECTIVES/SPECIFIC AIMS

The main objective of this project is to demonstrate the effectiveness of a PBPT intervention for the prevention of disability in ADSM who sustained an MSI during deployment in support of combat operations on a carrier. This intervention is intended to optimize recovery and restore function in injured ADSM.

Specific Aims

The three aims necessary to accomplish the main objective are:

1. Demonstrate the feasibility of implementing PBPT on board a carrier;
2. Document and compare risk factors related to disability from MSI aboard two carriers;
3. Demonstrate the effectiveness of the PBPT intervention in a comparative effectiveness trial.

Specific Aim 1: Demonstrate the feasibility of implementing PBPT on board a carrier

We intend to show that a carrier is a unique and ideal environment in which to implement this study to assure feasibility of a physical therapy intervention. The carrier is a self-contained community of approximately 6000 ADSM, allowing for a sample size suitable to assess an effect of the intervention. One hundred percent of all ADSM aboard the carrier who experience MSI will have the opportunity to enroll in the study, increasing the likelihood that the sample will represent the population. Because ADSM live on the carrier we have an opportunity to obtain a complete data set including follow-up. Based on our experience of recruiting subjects in other studies, we conclude that participation will be high. In a previous non-carrier based RCT study conducted by the present's investigators ADSM cited a reluctance to leave their command as a reason not to participate.(1) This will not affect treatment in the present study.

PBPT implemented in this setting has the potential to have a dramatic impact on the study outcomes. ADSM who seek care for MSI on a carrier will benefit from early care by a trained physical therapist staff, which will reduce the likelihood of the formation or maintenance of maladaptive beliefs about injury previously found to be associated with disability. The fact that there is a psychologist aboard the carrier also permits early referrals when needed. In addition, the lack of communication between carriers allows us to rule out any contamination of training effect on the control physical therapist. In addition, the carrier environment controls for organizational risk factors. For example, the ability to travel to a health care provider, which in a civilian setting may require a car or public transportation, is not an issue on board a ship. The ability to pay for treatment is also not an issue because treatment on board a ship does not require reimbursement. That is not to say that risk factors represented by these 'organizational flags' are absent; just that they are different from what has been found in the literature to date and are consistent on the two study carriers. Because we will be comparing two carriers with similar environments, we expect the internal validity of this study to be high.

We are assured access to the carrier study population from the key US Navy personnel (see letters of support in attachments 2 and 13) so that feasibility can be demonstrated in this environment. We plan to evaluate the success of our training through means described in attachment 7. Our access will continue during deployment which will permit us to reinforce the principles of the training and assess sustainability of the training also described in attachment 7.

Deliverable: A Manual of Operations and Procedures (MOOP) based on NIH recommendations, and a technical report that will outline the purpose, methods, findings and interpretation of the proposed pilot clinical study.

Specific Aim 2: Document and compare risk factors related to disability from MSI aboard two carriers

A flag system has been proposed to distinguish risk factors for disability -Table 1-. Two studies were conducted by the present investigators involving psychological risk factors (yellow flags). In one, fear of movement predicted work status twelve weeks after a reported MSI and in the second an intervention aimed at modifying yellow flags was successful in reducing three; fear of movement, perceived disability and catastrophizing.(1, 2) These findings and those of other studies in ADSM have informed our selection of flags to be assessed in this population shown in Table 1.

The proposed study provides an opportunity to enhance our understanding of how yellow flags affect ADSM with MSI as well as simultaneously assess other risk factors (flags) related to outcome. Furthermore, the data we collect will allow us to describe the characteristics of ADSM with MSI and their perceptions of their environment on two carriers. We will then be able to compare this data across carriers and ultimately evaluate the generalizability of our findings. This will also allow us to learn about the distinct environment of a carrier. This project is innovative in that it takes advantage of a unique research opportunity by studying MSI aboard a carrier and considerably strengthens the internal validity of this study should the two carriers have similar populations and characteristics.

Deliverable: Description of the risk factors for MSI affecting ADSM on two carriers.

Table 1: Definitions of flags and study variables

Flag	Definition	Study Variables
Red Flags	Medical - biomedical signs and symptoms that indicate a serious spinal pathology and referral to a specialist	Number of ADSM excluded from study based on screening
Orange Flags	Significant psychiatric disorders that can delay recovery from MSI	Clinical Depression, Anxiety Disorder and Post Traumatic Stress Disorder (PTSD)
Yellow Flags	Modifiable psychological responses to MSI that are associated with unfavorable clinical outcomes	MSI-related distress, expectations of recovery, self-efficacy, fear of work activity, perceived disability and pain interference
Blue Flags	Perceptions of the workplace that are associated with unfavorable clinical outcomes.	Job satisfaction, work stress, organizational commitment and job social support
Black Flags	Factors associated with the context in which a person functions, and include relevant systems and policies that may block helpful health care and/or workplace actions	Phase of deployment when injury occurred, number of previous deployments and perception of barriers aboard carrier for receiving the care

Specific Aim 3: Demonstrate the effectiveness of the PBPT intervention in a comparative effectiveness trial

We expect that an intervention of PBPT targeting the common psychological risk factors (yellow flags) based on the literature; fear of activity including work, psychological distress, and perceived disability will be effective in reducing these risk factors and optimizing recovery and restoring function in the intervention group. Pain and disability have been shown to be independent constructs.(3) While we will measure pain intensity, we do not expect that PBPT will impact this construct because its focus is not on pain reduction, but on increasing function. Therefore, we expect that the intervention group will show a difference in change of pain interference but not pain intensity. Because PBPT emphasizes self-care and independence, we also expect an increase in positive coping mechanisms such as self-efficacy and positive outcome expectations as a result of the intervention treatment as compared to the control treatment. Furthermore, we expect that subjects who received PBPT will show greater satisfaction with care and outcome and a higher quality of life than the control group because psychological factors, ignored in standard care, are addressed. This we believe, will result in different patterns of health care utilization and ultimately reduce the assignment of LIMDU in the treatment group thereby optimizing recovery and restoration of function for ADSM with MSI. We plan to test this on two carriers in a quasi-experimental, pre-post- test design with a non-concurrent control group.

Deliverable: A Manual of Operations and Procedures (MOOP) based on NIH recommendations, and a technical report that will outline the purpose, methods, findings and interpretation of the proposed pilot clinical study.

2. BACKGROUND AND SIGNIFICANCE

Musculoskeletal injuries pose a significant problem for ADSM and are the main reason for separation and long-term disability.(4-7) Little is known about determinants of disability and seeking care patterns in Sailors and Marines who experience MSI during deployment in support of combat operations, despite the fact that these branches of the armed services have the highest level of attrition from these disorders of all branches.(8-10) In a recent study conducted on two deployed United States Navy Aircraft Carriers (carriers), Herbert and Pasque found that MSI comprised 40% to 43% of all sick call visits during deployment.(11) ADSM with spine-related MSI sustained during deployment are unlikely to return to duty(4); they comprise 54% of limited duty (LIMDU) assignments.(12)

Carriers provide an optimal environment in which to study this problem as the environment avoids some of the previously mentioned pitfalls. In this proposed study, ADSM who seek care for MSI on a carrier will benefit from early care by a trained physical therapist staff, which will reduce the likelihood of the formation or maintenance of maladaptive beliefs about injury know to be associated with poor outcome. ADSM will not have to leave their command to be treated. The lack of communication between carriers allows us to rule out any contamination of training effect on the control physical therapist. The fact that there is a psychologist aboard the carrier permits referrals when needed. Finally, since the carrier is self-contained treatment cannot be sought elsewhere. We have the potential of a very high enrollment rate and a complete data set, including follow-up. Therefore, we plan to implement a comparative study on two carriers; one where the physical therapy staff is trained in PBPT and the other where the physical therapy staff has not been trained.

3. RESEARCH DESIGN/METHODS/SUBJECT JUSTIFICATION

a. General Approach

The proposed study design is a quasi-experimental, pre-post- test with a non-concurrent control group to test the effectiveness of PBPT. This approach will consist of a study with one deployed carrier serving as the intervention and a second carrier serving as a control. The two carriers (intervention and equivalent control) will be chosen based on deployment schedules. Both carriers will have similar deployment

characteristics to include; length of deployment, crew size and deployed health care team. For the purposes of this project, measurements will be done during deployment (pre physical therapy intervention and one month after enrollment) .Thus, two different endpoints will be used, a post treatment endpoint (one month after enrollment), and a second which takes place after the carrier returns from deployment. Note, for purposes of the study we will close case accrual 3 months after the carrier docks and follow subjects up an additional 6 months. Health care utilization post-deployment for MSI and LIMDU assignment will be analyzed.

The PT subjects on the control carrier will be blinded by using a separate consent form that does not reveal the purpose of the study. They will be informed that the study intends to assess predictors of outcome of MSIs. We are blinding the subjects to preserve the internal validity of this study. The internal validity (degree to which we can attribute the differences between groups on outcome to the intervention and not some external factor) depends on maximizing the power of the intervention. Subjects from the control carrier will be "debriefed" once the study is closed via a mailed letter. This letter will explain the two interventions used in the study as well as the background and purpose of the study described in more detail.

Subjects will be identified and recruited consecutively by the PT staff as they present to medical with an MSI complaint. The physical therapy staff will be trained to conduct informed consent following US Navy requirements and administer the data collection forms. The data collection forms are completed by the candidate subject. There are five points of data collection: subject screening for enrollment, informed consent, pre-treatment baseline data questionnaire, post-treatment questionnaire, and long-term follow-up.

We plan to do 6 months of follow-up following case accrual to obtain our secondary outcomes post deployment (this follow up period allows the detection of a deployment related injury claim within 3 months post-deployment, plus 6 months follow up to detect LIMDU assignments) to evaluate for the effect of carrier incurred MSI on subsequent, shore based health seeking behavior, disability and attrition.

A CRADA is in progress between NYU, NMCP, and UD. Therefore, this protocol will be submitted to the NMCP IRB for a scientific review and the NMCP IRB will serve as the IRB of record for this study.

(1) Research Objective

The purpose of the proposed study is to test the effectiveness of a psychologically-based physical therapy (PBPT) intervention for musculoskeletal injuries (MSI) in active duty service members (ADSM) aboard a US Navy Aircraft Carrier (carrier). This proposal responds to the FY 13 Clinical Trial Award Focus Area "Physical or occupational therapy (PT/OT) interventions, such as studies that establish optimal strategies for weight bearing progression or studies that examine the comparative effectiveness of different PT/OT regimens" and the Peer Reviewed Orthopedic Research Program (PRORP) goal of "optimizing recovery and restoration of function for military personnel with orthopedic injuries sustained in combat or combat-related duties."

(2) Detail how many groups or arms are in the study and what each receives

There are two arms to the study: an intervention arm, consisting of one carrier group deployment from Naval Station Norfolk, and a control arm, consisting of a second carrier group deployment from Naval Station Norfolk. The deployments could be overlapping, but two different carrier groups will be compared.

(3) Randomization Procedures

Intervention and control carriers will be randomly allocated using a random number table from a pool of available carriers based at Naval Station Norfolk. Norfolk is home to five carrier strike groups.

b. Methods and Materials

(1) Experimental Procedure

The study will take place on deployed carriers. One carrier will serve as the control arm, and a second carrier will serve as the intervention arm. Deployments last approximately six to nine months. To avoid contamination of the intervention between carriers, we will start the training with the control physical therapy staff, and once that carrier has deployed, we will train the intervention physical therapy staff.

The investigators will be notified of upcoming carrier deployments from members of the study advisory board, who are in a position to be notified of upcoming deployments, and relay that information to the study investigators. At that point the study investigators will approach the carrier's Senior Medical Officer (SMO) to engage the carrier's medical team and train them in the study protocols.

(2) Research Material To Be Collected

Data collected include paper and pencil, self-administered questionnaires and electronic medical and personnel records.

(3) Data Collection Tools

The study will use eight clinical measures of psychological risk factors, and one administrative metric, to evaluate the effect of the intervention. The clinical measures include: psychological distress, expectations of recovery, self-efficacy, fear of work, quality of life, perceived disability, pain interference, satisfaction with process of care and satisfaction with treatment outcome. Psychological distress, expectations of recovery, self-efficacy, and fear of work, perceived disability and pain interference will be measured at the start of treatment and one month after enrollment. The quality of life and satisfaction with care metrics will be measured at one month after enrollment. The administrative outcomes will be health care utilization and the assignment of limited duty or a physical evaluation board during the post deployment follow-up portion of the study.

<u>Outcome measures – psychological responses to treatment</u>

Psychological distress: Measured by the 5-item STarT Back Generic Screening Tool (SBT) which was originally intended for primary care providers to permit identification of patients at risk for poor outcome using the yellow flags with the highest prognostic values in this patient population.(13, 14) Scores range from 0 to 5 with patients scoring 4 or 5 being classified as "at risk". It is composed of five items: fear, anxiety, catastrophizing, depression and bothersomeness.(14)

In addition to the STarT Back Generic Tool, single item questions will be used to test the remaining psychological variables. They are:

Expectations of recovery: "I believe that my condition is going to get better". This item was constructed by the research team and included based on the evidence that associates expectations with recovery.(15-17)

Self Efficacy: adapted from the Core Outcome Measurements Index (COMI)(18): "I am confident I can cope with my condition" Self-efficacy has been associated with outcomes in military and civilian populations.(19)

Fear of work activity: "It's really not safe for a person with a condition like mine to work." This item was adapted from the STarT Back Screening Tool.(13) This construct appears relevant to the carrier environment, which is physically demanding and hazardous.

Quality of Life: "Compared to your quality of life before your injury, please rate your quality of life now". This item was adapted from the SF-12.(20) Quality of life is a recommended outcome measure for studies involving patients with MSI.(21)

Perceived Disability: "How much does your condition interfere with your usual activities, including work?" This item was adapted from COMI(18). Perceived disability is a recommended outcome measure for studies involving patients with MSI.(21)

These variables will be measured at the time the subject enrolls in the study, and again one month after enrollment. In addition to the psychological measures described above, the variables of pain interference and process of care satisfaction and an outcome satisfaction will be measured as follows:

Pain interference: Defense and Veterans Pain rating Scale (DVPRS) is an instrument designed to assess pain in military populations. Preliminary validation studies have found acceptable reliability and validity in the military and veterans population (Cronbach's alpha >0.8 and Pearson's r ranging from 0.6 to 0.9).(22)

Satisfaction with process of care: Measured by the "process of care" subscale of The MedRisk Instrument for Measuring Patient Satisfaction (MRPS).This subscale measures the patient's assessment of the interaction with the therapist which is relevant to the study. This subscale has been shown to have good reliability and validity.(23, 24) The rating scale of each item goes from 1 to 5 where 1 is 'strongly disagree' and 5 is 'strongly agree.' The score is calculated as the sum of the item scores where a higher score represents higher satisfaction.

Outcome satisfaction: 'If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it? This is derived from the COMI questionnaire (18) Outcome satisfaction is a recommended outcome measure for studies involving patients with MSI.(25)

The study outcomes of quality of life, satisfaction with the process of care and satisfaction with condition change score will be assessed at one month after enrollment into the study. A PTSD screening tool will be used to triage patients for psychological evaluation. This instrument will be completed only at baseline.

Outcome measures - administrative outcomes

Health care utilization: will be assessed through the Armed Forces Health Longitudinal Technology Application (AHLTA) for long-term, post-deployment health care utilization follow-up: Armed Forces Health Longitudinal Technology Application (AHLTA) is the military's unified electronic medical record system. The investigators plan to request an extract of administratively-releasable medical records of subjects enrolled in the study to count the number of MSI-related clinical treatment encounters.

Data elements requested

Data requested from the AHLTA system include the following:

- Subject demographics: birth date (required to calculate age at index visit), gender, marital status, rate and rank, military occupational code, race and ethnicity
- Encounter diagnosis and injury codes, used to characterize the nature of the MSI
- Encounter procedure codes, used to characterize the treatment provided
- Referrals to specialty care at the time of the encounter, to characterize referrals to specialty services
- Provider specialty, to characterize the nature of the service line providing care at the encounter.

Data will be requested from AHLTA Theater (AHLTA-T) (to capture clinic visit encounters related to the index MSI on board the carrier) and AHLTA (to capture shore based visits made by the subject.) Direct care and purchased care encounter data will be requested from AHLTA.

Limited duty (LIMDU): is an administrative designation that relieves a person from their assigned duty in order to allow time for rehabilitation. The authority to assign LIMDU to an ADSM rests with a shore-based specialty provider. LIMDU can be assigned for any relevant medical reason permitted by US Navy regulations. Generally, LIMDU is assigned for a period of six months.

Navy regulations allow two LIMDU periods for the same condition during an ADSM's career. If an ADSM requires more than two LIMDU periods, the ADSM will be referred to a Physical Evaluation Board (PEB). A PEB is also an administrative action that evaluates an ADSM for physical, mental and emotional fitness for continued service in the Navy. The PEB serves as the Navy's mechanism by which individuals' fitness to continue military service is evaluated. Because LIMDU is a gateway for subsequent PEB, there can be a disincentive to go on or accept a LIMDU assignment. The investigators recognize that persistent dysfunction and / or pain associated with an MSI may have a role as a risk factor for LIMDU. Because attrition (defined as separation from service before the end of an ADSM's service contract or obligation) has been identified by the Department of Defense (DoD) as an important problem affecting force readiness,(26) the investigators wish to follow-up MSI cases, identified in this proposed study, for this important administrative outcome.

LIMDU assignment will be obtained by querying a specific database (MEDBOLTT), where the information about all LIMDU and PEB cases are stored, at the end of the study follow-up period. The study follow-up period is discussed next.

Timing of data requests

The study's Principal Investigator, will make the data request to the Epidemiology Data Center for the AHLTA data extracts required for the study's statistical analysis. Requests will be made periodically by the study PI to test procedures for the retrieval, linking with questionnaire data, removal of personal identifiers and statistical analysis. A final data request will be made within one year of the return of the carrier, to allow six months of follow-up to pass, and to allow for the time necessary for data entry and processing into AHLTA of both direct care encounters and purchased care encounters by the study subjects. Requests will be made for the enrolled subjects for the control carrier, and again separately for the enrolled subjects for the intervention carrier.

Data request procedures

The study Principal Investigator will prepare a list of the enrolled subjects. That list will contain the following information: subject name, DoD ID number, date of the enrollment into the study (equivalent to the date the baseline questionnaire was completed by the subject), and the ship on which the subject was deployed. This information is needed by the Epi Data Center to formulate and execute the query necessary to retrieve clinical encounter records from AHLTA. The Epi Data Center will return the clinic visit data back to the Study PI via AMERDEC SAFE. An identical procedure will be used to return records from MEDBOLTT.

Data use agreement

A data use agreement has been submitted and is in the approval process that outlines the specifics of the data being requested.

Computerization and maintenance of subject questionnaire data

Subject questionnaire data will be computerized by the study Associate Investigators. The system used for computerization will be the University of Delaware BADER Consortium Clinical Trials Database system (BADER CTDB). The BADER CTDB is a web-based tool used for the maintenance of clinical research data. It was established through a partnership with the National Institutes of Health to host the first extramural research version of the NIH Clinical Trials Database (CTDB) housed inside the firewall of the NIH. The system is 21 CFR 11 compliant, and the design and data entry and validation procedures have been vetted by National Institutes of Health Information Security Officers, and features a secure HTTP(S) user interface that enables FISMA compliance. The system's internal security measures prevent one researcher from seeing another researcher's data (role/privilege model). Only pre-authorized users can access the BADER CTDB.

By agreement with the United States government, the BADER CTDB does not store protected health information (PII). Instead, each individual subject is assigned a unique identifier number, called a Globally Unique Identifier (GUID). The generated GUID is a string of 40 letters and numbers that is then assigned as the participant's Patient ID. There is no practical way to reverse the GUID-generation process -- that is, to determine the PII such as last name or birthplace from the GUID. The GUID is designed to be unique for each patient. The probability that two patients would be assigned the same GUID is extremely small, less than 1 in 10,000,000,000.

Eight PII items are necessary to generate the GUID. They are:

- First Name
- Middle Name
- Last Name

- Birth Month
- Birth Day of Month
- Birth Year
- Sex on Birth Certificate
- City/Municipality of Birthplace

These data will be collected from the subject demographic questionnaire. Computerization of subject responses on questionnaires will involve generation of the GUID, assigning the GUID to the questionnaire data, and recording the questionnaire responses. No PII are computerized during the process. The study's Associate Investigators will maintain a separate password protected electronic log that lists the GUID and subject name for purposes of linking AHLTA and MEDBOLTT records with subject questionnaire data.

Linking AHLTA and MEDBOLLT data to subject questionnaire data

The study's associate investigators will be responsible for linking AHLTA and MEDBOLLT data received from the Epi Data Center to subject questionnaire data.

To link the data, the AIs will first replace subject PII on the AHLTA and MEDBOLTT data with the subject's GUID that was generated during the process for computerizing subject questionnaire data. The study AIs will then link subject questionnaire data with AHLTA and MEDBOLTT records on the basis of matching subject GUID.

Linking the subject questionnaire data and AHLTA and MEDBOLTT records completes the preparation of the data for statistical analysis. The linking of the data will be accomplished using a US Navy desktop computer located at the Physical Therapy Department, Naval Medical Center Portsmouth that has been dedicated specifically to this study.

(4) Protection and security of data and identifying information

The following procedures will be used to protect the confidentiality of the subjects and the safety of the data:

1. Disposition of paper self-administered questionnaires on board the carrier: the carrier's PT will print out a blank copy of the informed consent form and questionnaires for a candidate subject. That copy will have on it the DoD ID number assigned to the candidate subject, so each page of the questionnaire will be 'branded' so to speak with the DoD ID number. This will help the research assistants ensure that paper records do not get mixed between subjects or out of order
2. The carrier's PT tech will scan the documents after they are completed by the subject: This ensures that the responses and ancillary markings of the subject are accurately recorded
3. The carrier's PT tech will destroy the documents after they have been successfully scanned into the computer on board the carrier: The PT will be equipped with a paper shredder, so that there is no paper record left lying around Medical. The PT's SOAP notes and subjects medical records used for treatment, however, will be handled as usual on board the carrier
4. The computer used for the study on board the carrier will use TrueCrypt 128 bit encrypted portion of the hard drive for storing the research records. The encrypted portion of the hard drive will be password protected using a password known only to the carrier's PT and the shore based research assistants, Sherri Weiser, Michael Lashbaugh, and Marco Campello. TrueCrypt offers a feature to wipe unused portions of the disk to a DoD standard and the carrier's PT will be taught to perform this 'wiping' function on a weekly basis. Doing so

removes any trace of deleted files, for example, scanned images that have been copied to the encrypted portion of the disk and then subsequently deleted.

5. We plan not to advertise the study on board the carrier, and instead use a recruitment method by having the carrier PT approach each candidate subject and describe the study in a standard way (refer to the informed consent form, Attachment 6). The reason for doing so is to limit the opportunity for crew members not to self-disclose their own participation in the research study. The investigators are sensitive to the notion that crew members want to appear physically fit and capable at all times, in order to maintain good working relationships with their peers and to ensure that their career opportunities are not limited by the perception of others of physical incapacity. Participation in a medical research study, however benign, may be viewed as a threat that challenges the image of physical fitness. For this reason we wish not to advertise, to limit the possibility that crewmembers may discuss the research project casually and thereby create a situation where a crewmember may feel compelled, against their wishes, to self-disclose their own participation status.
6. Data transmission between the carrier and NMCP will be done via a secure internet connection. Working together with Navy Information Technology specialists and the Epi Data Center personnel, the study investigators will utilize a method of posting the encrypted data file to a secure US government File Transfer Protocol (FTP) site, to which only the study investigators will have password access. This limits the possibility that data files may be inadvertently distributed to a person not associated with the study.
7. Data downloaded from the secure FTP site will be stored only on a US Navy desktop computer located at the Physical Therapy Department, Naval Medical Center Portsmouth. This computer, too, will be equipped with TrueCrypt and data files will be stored on the encrypted portion of the disk. The sole purpose of this computer will be for the research study, and access to the computer will password protected.
8. The subject enrollment log will be maintained by the NMCP research staff and kept as a password protected file located in the Physical Therapy Department, Naval Medical Center Portsmouth. This log will be used to link a subjects DoD ID to their SSN which is needed for the NMCPHC to link a patients MSI related treatment encounters.
9. The carrier's PT and the shore based research assistants will be trained to 'wipe' the unused portions of their respective computer disks to remove any trace of deleted files. A personal computer uses a file allocation table that serves as index to the physical location of the data stored on the disk. When an operating system deletes a file, it only removes the entry in the file allocation table, leaving open the possibility of data recovery. Deleted files and temporary files, potentially, can be easily recovered. Wiping a disk means that the portions of the disk where the actual data are stored get replaced with null values, so that the data are physically destroyed, and recovery of deleted and temporary files becomes impossible.
10. Access to data files will be limited to the study investigators. Only the research assistants, study monitor, principal and co-principal investigators, authorized representatives of USAMRMC and members of institutional research oversight committees will have access to data that contain PHI. All technical reports and interim reports will be presented using statistical summaries. Adverse events will require the disclosure of PHI.

(5) Disposition of data and identifying information at end of project

At the conclusion of the data collection period, all paper data collection forms, logs and notes will be scanned, and the digitalized images will encrypted and stored separately on DVD and NMCPHC Epi Data Center secure servers.

At the end of the study, all computerized data analysis files, manuscript drafts will be reviewed to ensure that PHI or any identifying information is removed, and stored on DVD and a separate copy stored on NMCPHC Epi Data Center secure servers for archival purposes. All paper records associated with the study, including any paper data collection instruments and data collection logs will be shredded. The investigators will confirm that paper records are destroyed and electronic records are stored in archival electronic format at the time the investigators close the study with the Institutional Review Board.

(6) Gender and Ethnicity

There are no restrictions required by the study to limit to specific gender or ethnicity groups. The demographics of the study population are expected to reflect that of the sampling pool, and the target population is Sailors and Marines seeking care at a military treatment facility for MSIs during or following their most recent deployment.

The study population is the carrier crew home ported at the Naval Station Norfolk, Norfolk, Virginia. The crew consists of a ship's company of 3,200 and an air wing of 2,480. We are unable to offer specific age, gender and ethnicity breakdown for upcoming deployments, because the US Navy does not release that information prior to deployment.

The study findings are intended to be generalized to ADSM serving on future carrier deployments. However, there is the possibility that the strength of the findings will motivate implementation of PBPT for other, forward deployed military units, such as Army units in theater abroad. In addition, the idea of addressing psychological risk factors for MSI-related disability by a physical therapist is sufficiently general that it could be implemented at other military medical treatment facilities. For this reason, we consider all active duty personnel to potentially benefit from the findings of the study. Therefore, age, race and gender characteristics of active duty personnel are presented below. Gender, race and age tables are reproduced from 2011 Demographics: Profile of the military community, Office of the Deputy Under Secretary of Defense (Military Community and Family Policy), Washington DC 2011:

Number and Ratio of Active Duty Officers and Enlisted Members by Service Branch and Gender, 2011

Service Branch	Officers		Enlisted		Total		Ratio of Officers to Enlisted	
	Male	Female	Male	Female	Male	Female	Male	Female
Army	81,791	15,760	403,631	60,255	**485,422**	**76,015**	1 to 4.9	1 to 3.8
Navy	44,689	8,520	223,036	43,896	**267,725**	**52,416**	1 to 5.0	1 to 5.2
Marine Corps	20,537	1,328	166,798	12,363	**187,335**	**13,691**	1 to 8.1	1 to 9.3
Air Force	53,187	12,291	213,042	50,301	**266,229**	**62,592**	1 to 4.0	1 to 4.1
Total DoD	**200,204**	**37,899**	**1,006,507**	**166,815**	**1,206,711**	**204,714**	**1 to 5.0**	**1 to 4.4**
	238,103		1,173,322		1,411,425		1 to 4.9	

Source: DMDC Active Duty Military Personnel Master File (September 2011)

c. Subject Population

The study population consists of ADSM serving aboard a carrier home ported at the US Naval Station Norfolk, Norfolk, VA. Combined, the ship's company and airwing on board a carrier comes to approximately 6000 individuals. The carrier ships company is responsible for running the ship, while the air wing is responsible for force projection. For the purposes of this study proposal, we will refer to the entire body of the carrier's personnel (carrier ship's company and air wing) as the crew. Based on previous data collected aboard carriers we can reasonably expect 300 members to report to the carrier medical department (Medical) with a MSI requiring physical therapy and being eligible for the study (5% of the crew).(11)

(1) Subject Inclusion and Selection Criteria

Subjects presenting to medical for a primary complaint of a new MSI will be considered for the study. A new MSI is considered in this study when the subject has not sought treatment, or has been under treatment, for the MSI complaint, for a period of 30 days or less prior to presenting to medical.

(2) Subject Exclusion

Subjects not eligible for a physical therapy treatment for a primary complaint of MSI including those who required medical evacuation, or have a trauma/ comorbidities that may prevent them from receiving physical therapy treatment (i.e. amputations, fractures, contusions and other 'Red Flags' that required specialized medical care) will be excluded from the study. ADSM who exceed cut-offs for orange flags (i.e. PTSD) will be referred for psychological evaluation.

(3) Subject Recruiting Methods

Recruitment into the study is done in person by the treating physical therapy staff. Recruitment is done when an eligible candidate presents to the physical therapy staff for treatment for a new MSI episode for the first time.

The physical therapy staff will evaluate whether the candidate is eligible for the study. The PT will determine: 1) that the candidate is seeking care for a primary complaint of MSI, 2) that the candidate was prescribed a course of physical therapy for the MSI.

An MSI is one where the potential subject presents to the carrier's medical with for a complaint of pain or dysfunction of a specific body part related to the musculoskeletal system. The definition of an MSI case is not limited to a single body part, but can involve multiple

body parts simultaneously. For example a candidate can present to medical with a complaint of knee and neck pain, and that person would be eligible for the study.

The PT will evaluate for exclusion criteria. Exclusion criteria are those MSI for which PBPT would not be indicated; these include amputations and fractures.

The PT will then advise the subject about the study and conduct informed consent in a closed area separate from treatment or waiting areas. The individuals handling research records are required to complete CITI human subjects training prior to taking on research responsibilities.

(4) Informed Consent Procedures

The informed consent statement will formatted on five pages. Subjects will be offered a copy of the consent for their records, the consent form will be scanned into the study's computer, and then shredded. A copy of the proposed informed consent form is included at the end of this attachment.

Space will be allocated for Informed consent in a private space. This will be the same area where the research records will be computerized and the study's shredder will be located. The space will have a lockable cabinet where the study's paper recruitment log will be stored. Only the research physical therapy staff will have a key to the study storage cabinet. The cabinet will contain all of the supplies required for data collection, including paper for printing out the questionnaires, extra printer toner cartridges, pens, kneeboards, and external drives for backing up the study's computer.

The physical therapy staff conducting informed consent will verbally review the form. The physical therapy staff will allow the subject enough time privately to consider the informed consent and agree or refuse. The subject will also have the ability to defer a decision on participating. However, since the objective of the study is to get a baseline measure of condition at or near the onset of the complaint, the physical therapy staff will ask the candidate to take no more than 10 days to make a decision, and ask permission to follow-up with the subject. The physical therapy staff administering informed consent will be available to answer questions and also offer to refer questions to the study principal investigator. A set of possible questions the investigators anticipate may be asked will be documented in the study's Manual of Operations and Procedures (MOOP) and will be elaborated on as the study progresses by means of exchanges between the study investigators and the deployed physical therapy staff during the course of the study.

(5) Justification of Subject Population

US Sailors and Marines as part of the carrier crew complement will be the immediate beneficiaries of the intervention, and as such, are the most suitable population in which to test the intervention.

(6) Vulnerable Populations

US Sailors and Marines, because of the closed environment of the carrier, can be by definition considered a vulnerable population and subject to the potential for coercion. However, the informed consent process will note that the participation in the study is voluntary and the choice to participate or not will have no bearing on the individual's relationships with peers or supervisors on board the carrier.

d. Risks

(1) List and document risks

The principal risk of participation in the study is unintended loss of confidentiality. Loss of confidentiality could foreseeably happen in a number of different ways: 1) compromise of questionnaire data, 2) Loss of subject identification and recruitment logs, 3) loss of digital recording device(s) used for the qualitative interviews. The impact of how this release of information on the participant's well-being depends on the individual's own circumstances. For some, there is no impact; for others, the impact may be noticeable. In accordance with requirements of the respective IRB, the informed consent statement will indicate to the potential volunteer who could potentially have access the data collected as part of the study.

(2) Justification of Risks

The investigators feel that this study can be considered a minimal risk study. No blood samples are drawn or tissue collected, and there are no invasive or radiographic tests required by the data collection protocol. The risks encountered by the subject are exactly the same as what would be encountered during a course of physical therapy otherwise available on board the carrier. The only additional risk from participating in the study comes from completing questionnaires and the possibility of loss of confidentiality from unauthorized release of research data. The risk of loss of confidentiality, however, is low (see next section) and there is considerable benefit from the knowledge gained from the study. The investigators feel that the risk to the individual subject is outweighed by the potential benefit for the study population as a whole.

(3) Minimization of Risks

The investigators plan to computerize all data collected from the protocol. Technical limitations prevent online computerization via a secure internet connection when the carrier is at sea. To work around this limitation, the investigators will print out informed consent forms and questionnaires at the point of data collection, scan the completed paper forms, and then destroy the paper records using a shredder.

The computer used for data collection and storage will have its entire drive encrypted using publically available TrueCrypt software. This software provides for 128 bit encryption and is password protected. The study investigators will create a unique password for each computer used in the study (intervention and control carrier), and passwords will be recorded in the study's MOP. Only the study investigators and onboard physical therapy staff will have access to the password.

Daily, the physical therapy staff will back up the contents of the research computer to a separate, external hard drive. The process of making a backup involves simply copying the encrypted partition of the hard drive to the backup drive. Weekly, the encrypted drive will be compressed and uploaded to a secure FPT site when an internet connection can be established. The investigators will then access and download the data file from the FTP site to a military computer located at the Physical Therapy Department at the Naval Medical Center Portsmouth. Each iteration of the uploaded data file will be retained in an archive located on the NMCP research computer. This serves as an additional layer of protection of the data collected and serves as a means to create an audit trail to maintain the integrity of the data.

e. Benefits

Subjects enrolled in the intervention arm could experience improved recovery from MSI while on board ship, experience a reduction in shore based follow-up treatment for the index MSI while on board ship, and express greater satisfaction with care as compared to those in the control arm.

All subjects who participate may experience benefits from completing questionnaires, which if detecting those in need of psychological care because of PTSD, will be able to referred for treatment.

f. Costs to Subjects

There are no direct costs to the subject. Indirect cost is 30 minutes at physical therapy encounters on board ship to complete written questionnaires.

4. RESEARCH MONITOR

CAPT Geoffrey Wright, MC, USN will be serving as research monitor on this protocol. If the shipboard physical therapist detects an adverse event, the PT will alert a member of the research team, the PI, and the medical monitor. The medical monitor will be responsible for determining whether the adverse event meets the criteria of a serious adverse event or not. All adverse events will be reported to the IRB according to the local IRB guidelines.

5. ADVERSE EVENT MANAGEMENT AND REPORTING

Adverse event reporting will be done via IRBNet. If the shipboard physical therapist detects an adverse event, the PT will alert a member of the research team, the medical monitor, and local research staff members. That person in term will ensure that that PI is notified of the adverse event as soon as possible. The PI will then make a report of the adverse event via IRBNet.

6. STATISTICAL ANALYSIS

An electronic relational database will be developed to reflect the longitudinal design of the study. It will include basic subject demographic data, enrollment data, pre-intervention questionnaire data and one month post enrollment data. Each case will represent a discrete treatment episode for a main MSI complaint. For example if a subject presents to medical with a main complaint of low back pain, that subject's data would be entered into the database as a case. If the same subject returned back to medical with a separate, unrelated, but eligible complaint, that subject's data for the second complaint would be entered into the database as a separate, distinct case. The analysis will make provision for coding and analyzing subjects with multiple, eligible MSI complaints. If the carrier is in port and the follow-up period requires administration when the subject is ashore, the carrier's physical therapist will ensure that the subject will report for follow-up questionnaire administration. This same procedure will apply if the subject fails to present to a prescribed follow-up treatment visit.

For purposes of statistical analysis cases will be categorized into 'complicated' and 'uncomplicated'. An 'uncomplicated' case is one where one body part is the subject of the MSI complaint. Affected body parts will be described using terminology adopted from Barrel matrix. A 'complicated' case is one where the MSI complaint involves multiple, affected body parts and treatment involves simultaneous or contiguous treatment encounters. A recurrent episode will be defined as at least a 30 day pain-free period between candidate MSI episodes.(27) A treatment episode will be coded as involving a comorbidity where a subject is being treated simultaneously for a non-MSI condition during the period of time the subject is being treated for the index MSI.

Specific Aim 1: Demonstrate feasibility of a carrier-based model for implementing PBPT

We will consider that feasibility of the carrier-based model of PBPT is demonstrated when the following tasks have been accomplished:

1) conduct training for the intervention and control physical therapy staff;

2) document the degree to which the participating physical therapy staffs have successfully learned and implemented their respective protocols;

3) assure protocol compliance and sustainability.

Conduct training for the intervention and control physical therapy staff:

Study protocol training for the intervention and control PTs: PBPT includes the early identification and management of psychological obstacles to recovery in order to modify maladaptive responses previously found to be associated with chronicity and disability. This is accomplished through patient education, an emphasis on functional goals rather than pain reduction goals and encouraging self-care techniques as described in evidence-based guidelines so as to reduce dependency on the health care system. Another important objective of this intervention is to teach the intervention physical therapy staff to triage patients who require psychological intervention in a timely manner so that those who need it get the necessary care.

Training includes didactic and practical portions. The training will take place within three months of deployment and is described in detail in Attachment 7. Training for the intervention physical therapy staff includes specific information on PBPT and methods to implement it and interpretation of questionnaires to assess yellow flags shown in Attachment 10. Common training for the intervention and the control PT focus on data collection, data management and protection of human subjects, identification of orange flags through questionnaires found in Attachment 10 and information on documenting practice in a standardized fashion for research purposes through the use of a SOAP note (Attachment 7). The intervention and the control carrier PT will complete Collaborative Institutional Training Initiative (CITI) training for Biomedical Research, Basic Course specific to the US Navy, and all other required US Navy CITI tutorials for conducting minimal-risk, human subjects clinical research.

Training in the intervention protocols requires 12 contact hours (three days) to complete. Training for the control physical therapist requires 2 contact hours to complete. CITI tutorial training requires completion of an online course requiring 6 hours. CITI certification is a prerequisite for the intervention / control arm training programs. The Advisory Board members will review the training program to best tailor the content and procedures to the carrier environment.

Document the degree to which the participating physical therapy staffs have successfully learned and implemented their respective protocols

PBPT trained physical therapy staff only:

Knowledge: The staff will receive a knowledge quiz at the end of the training.

Skill development: The staff will be evaluated on the accurate identification and management of yellow flags using case studies (Attachment 7). Training will continue until competency is reached.

Participant Feedback: At the end of the training we will solicit feedback in paper format from the PT staff in the form of two open-ended questions:

1) what aspects of the training do you feel were most successful?

2) What aspects of the training would you change, and how?

PBPT trained physical therapy staff and control physical therapy staff:

Questionnaires administration: Both staffs will be trained and evaluated in how and when to administer the study questionnaires and apply inclusion and exclusion criteria.

Protocol compliance and sustainability

Both PBPT trained and control physical therapy staff will be evaluated in protocol compliance and sustainability. Two methods will be used for this purpose. First we will use the patient's perception of the intervention as a proxy measure. Patients will be asked to list the most important things learned in physical therapy. The goal is to detect the main elements of the training. Second, we will review physical therapy progress notes in the subjective, objective, assessment, plan (SOAP) note format to assure that the content is in compliance with the training. This content is shown in Attachment 7. As part the regular feedback meetings during deployment between the trained physical therapy staff and the research trainers/clinicians, the SOAP notes will be reviewed and corrected. This will help to reinforce the training and ensure sustainability.

Analysis

Knowledge of main concepts, skill development and sustainability of the training will be assessed in the treatment group (see Attachment 7) .Knowledge will be tested using a quiz where the passing score is 85%. The skills development portion of the training will be evaluated using case studies and role playing to detect and address yellow flags. A scored of pass or fail will be given. An inter-rater agreement of 100% is required to obtain a passing score. We will also compare SOAP notes and the patient proxy measure of the two study groups by using a systematic analysis searching for keywords we expect to find only in the intervention group, shown in attachment 7. In addition, PT staff feedback will be described.

Specific Aim 2: Document and compare risk factors related to disability from MSI aboard two carriers

This aim will be demonstrated when the following tasks have been accomplished: 1)Document anticipated risk factors (flags) in the study population on each carrier 2)Compare the study populations on risk factors and to identify factors that may confound the findings of the proposed clinical effectiveness trial. For purposes of this study the investigators have identified potential variables representative of each risk factor (flag) category. In this section we discuss the instruments used to collect data on variables representative of red, orange, blue and black flags. Yellow flag instruments, the focus of the intervention, are discussed in the next section.

Red flags

We will collect the number of subjects in each group excluded from the study due to red flags.

Orange flags

Clinical Depression: The Center for Epidemiologic Studies Depression Scale (CES-D) is a 20-item self-administered scale that measures the major components of depressive symptomatology, including depressive mood, feelings of guilt and worthlessness, psychomotor retardation, loss of appetite, and sleep disturbance using a 4-point Likert scale. The item scores are summed to obtain the total scale score between 0 and 60. A score of 16 or greater indicates clinically significant distress and was used as a criterion for exclusion in the RCT and referral for treatment.(28, 29)

Anxiety Disorder: General Anxiety Disorder Screener (GAD-7) which is a 7 item screening tool and severity measure for generalized anxiety disorder that can detected mild, moderate and severe anxiety.(30)

Post Traumatic Stress Disorder (PTSD): measured using the PCL-M: The PCL-M is a 17-item self-report measure of the 17 DSM-IV symptoms of Post Traumatic Stress Disorder (PTSD). Items are rated on a 5-point scale ranging from 1 ("not at all") – 5 ("extremely") with a total score range of 17– 85. A score of 50 or greater indicates clinically significant symptoms.(31, 32)

Blue flags

Job satisfaction: Job satisfaction has been shown to be a relevant risk factor for disability in the civilian setting, and appears to be relevant to a carrier setting as well. The investigators plan to use the following question to assess job satisfaction, taken from Dolbier et al (2005)(33): "Taking everything into consideration, how do you feel about your job as a whole?" The item is presented as a five point Likert scale, 1 (i.e. very dissatisfied) to 5 (i.e. very satisfied).

Work stress: The negative perception of work has been shown to be a risk factor for MSI-related disability in the civilian setting, and appears relevant to a carrier setting as well, because of the long work hours, dangerous work setting, high noise, and cramped quarters. We will formulate an item that reflects work stress that is similar to the job satisfaction question, i.e.: "Taking everything into consideration, how stressful is your job as a whole?" The item will also be presented as a five point Guttmann scale, 1 (i.e. extremely stressful) to 5 (i.e. not stressful at all).

Organizational commitment: Commitment will be assessed by the affective dimension of the Commitment Scale (Porter and Smith (1970)(34) and Gade et al (2003)(35)). Previous studies have shown the affective commitment dimension to be associated with important military outcomes. Of particular relevance to this study is its high association with retention intentions.(36, 37) All items are scored on a 5-point Likert scale ranging from strongly agree to strongly disagree, with a midpoint of neither agree nor disagree. The Commitment scale is determined by summing the scores of the four items.

Job social support: Information about the subject's relationships with co-workers and social environment at their job will come from questions drawn from the Deployment Risk and Resilience Inventory-2 (DRRI) unit support subscale.(38) That subscale consists of 12 questions about working relationships with other military personnel. We will modify the items to reflect the present, rather than the past tense, as originally written. The items are scored as Likert scale, from "1 = strong disagree" to "5 = strongly agree" and are combined in an additive fashion to form a unit support score.

Black flags

Number and timing of previous deployment(s): We anticipate the number of timing of previous deployments may create physical and emotional stress on the research subject. Our query will be made via the Epi Data Center. The process of querying and linking data sets is described in the Data Collection section of this Attachment.

Phase of deployment when injury occurred: The investigators anticipate that the frequency, severity and type of musculoskeletal injury will be correlated with the phase of the deployment. We will categorize the deployment into three phases: leaving for a mission, during mission, and return from a mission. This datum will be obtained from the PTs log of clinical encounters, which records the date of the encounter. We will obtain the date of deployment, the date of arrival on station, and the date that the ship begins its return back from deployment from the carrier's PT.

Perception of barriers aboard carrier for receiving the care needed: this will be measured using an open-ended question: "Please list any barriers aboard carrier that prevent you from receiving the care that you think you need" Responses will be reviewed using a systematic analysis searching for key words in the patient responses; these key words will represent the four categories of working conditions (ie. gym not adequate, job demands, lack of time), health care conditions (ie. don't give preferred treatment, don't give enough treatment), policies and procedures (ie. no time off, lack of modified duty) and supervisor/unit attitudes to the sick worker (ie. lack of support for treatment, lack of understanding of injured)"

Other variables

General demographic and injury related information will be collected at baseline to characterize the population. Individual characteristics such as gender, age, marital status, race, education, length of service military rate, MOS and rank will be collected as well as injury related information such as body part affected, time since onset, other MSI comorbidities, episode recurrence, previous MSI injuries and pain intensity.

Analysis

Descriptive statistics for the interventions and control carrier will be presented. Note that distributions include the reporting of the mean, median, minimum, maximum, standard deviation, quartiles and histogram, and that frequency tables include the frequency and percentage. We will compare demographic characteristics of the enrolled, study sample population with the demographics of the carrier as a whole. Table 2 shows the descriptive analysis of each carrier's respective study sample population.

Identification of possible confounding factors

Distributions of these variables will be compared between the intervention and the control carrier to determine if there are important differences in the distributions that will require statistical adjustment in subsequent analyses. Non-parametric and exact methods will be used to compare distributions of continuous variables. Chi-square tests will be used for categorical variables. Items that are found to have differences in distributions by an amount greater than chance variation alone will be retained for possible inclusion as covariate in the analysis of treatment effect, described next.

Specific aim 3: Demonstrate the effectiveness of the PBPT intervention in a comparative effectiveness trial

Effectiveness of the PBPT intervention will be demonstrated by comparing the intervention and control group in five domains: psychological risk factors, satisfaction with care, quality of life, health care utilization for MSI and limited duty assignment (LIMDU). We hypothesize the following:

Hypotheses:

- Among those exposed to PBPT, the psychological distress score (most common risk factors) will show a greater improvement pre-post treatment as compared to those exposed to physical therapy treatment aboard the control carrier;

- Among those exposed to PBPT, the pain interference score will show a greater improvement pre-post treatment as compared to those exposed to physical therapy treatment aboard the control carrier;

- Among those exposed to PBPT, the expectations of recovery will show greater improvement pre-post treatment as compared to those exposed to physical therapy treatment aboard the control carrier;

- Among those exposed to PBPT, the self-efficacy will show greater improvement pre-post treatment as compared to those exposed to physical therapy treatment aboard the control carrier;

Table 2: Proposed descriptive analysis of the enrolled sample

Factor		Univariate, descriptive analysis
Demographics		Frequency table by gender
		Age distribution
		Frequency table by race
		Length of service distribution
		Frequency table by rate
		Frequency table by military occupational specialty (MOS)
Clinical		Frequency table by Primary MSI Complaint
		Pain intensity distribution
		Comorbidity distribution
Study recruitment		Primary complaint x treatment encounters
		Temporal distribution of encounters
Disability risk factors ('Flags')	Red	Frequency table by 'Red Flag' exclusion
	Orange	Frequency table by CES-D cutoff
		Frequency table by GAD-7 cutoff
		Frequency table by PCL-M cutoff
	Blue	Job satisfaction distribution
		Work stress distribution
		Commitment Scale distribution
		Job Social Support Scale distribution
	Black	Average number of previous deployments
		Average time elapsed since previous deployment
		Frequency table of phase of deployment when injury occurred
		Frequency table of perceived barriers to receiving care needed aboard the carrier

• Among those exposed to PBPT, the fear of work will show greater reduction pre-post treatment as compared to those exposed to physical therapy treatment aboard the control carrier;

• Among those exposed to PBPT, the perceived disability will show greater improvement pre-post treatment as compared to those exposed to physical therapy treatment aboard the control carrier;

• Among those exposed to PBPT, satisfaction with process of care score will on average show greater (better) satisfaction with care one month after enrollment as compared to those exposed to physical therapy treatment aboard the control carrier;

• Among those exposed to PBPT, satisfaction with condition change scores will on average show greater (better) satisfaction one month after enrollment as compared to those exposed to physical therapy treatment aboard the control carrier

• Among those exposed to PBPT, the quality of life score will be greater as compared to those exposed to physical therapy treatment aboard the control carrier;

• Health care utilization for MSI following deployment will differ among those subjects treated by the intervention physical therapy staff as compared to the control physical therapy staff;

• The rate of MSI-related limited duty assignment will be lower among intervention subjects as compared to controls.

Analyses

Sample size estimate

Estimates of required sample size are reproduced from G*Power. The analysis for sample size hold constant Type I error (alpha) to 0.05 and Type II error to 0.20. Table 4 shows sample size estimates required to detect an effect size ranging from 0.1 to 0.2 (small to a moderate effect size). Table 3 is calculated for a fixed effect ANCOVA for between group effect with 1 covariate, holding Type II error to 0.2 and Type I error to 0.05. This sample size estimates the total number of cases required to demonstrate an improvement in average yellow flag scores within each ship. Table 4shows that a total of 574 cases would be required to demonstrate an improvement of yellow flag scores with an effect size of 0.13 (small effect size), requiring 286 cases per carrier for the study. The bigger the effect being evaluated, the smaller the required number of subjects. The investigators anticipate, based on prior published reports, to capture at least 300 eligible cases. Consequently, a single carrier would likely be sufficient to demonstrate an improvement in psychological factors related to MSI disability as a result of exposure to PBPT.

Table 3: Sample size estimates by effect size

ANCOVA, testing for main effect of between 2-level group
1 covariate, Type I error = 0.05, Type II error = 0.80

Effect size	Total sample
0.10	967
0.11	800
0.12	673
0.13	574
0.14	495
0.15	432
0.16	380
0.17	337
0.18	301
0.19	270
0.20	244

Descriptive statistics will be presented for all variables in this section in the same manner used to describe the variables in aim two.

Psychological distress

The approach to the evaluation of treatment effect will be that of assessing differential changes of the STarT Back Generic Screening Tool pre-post intervention between the intervention and control carriers. We plan to use Analysis of Covariance (ANCOVA) for this purpose. Because treatment allocation is not randomized, there is a possibility that baseline psychological scores will be different between the intervention and control carrier. If one group is substantially higher than the other, there can be the possibility of over or underestimating treatment effect due to regression to the mean, a phenomenon whereby subjects showing an extreme score show scores closer to the group mean on subsequent measurements. ANCOVA will allow the investigators to parse out variance due to maturation and evaluate

if there is residual variance that is associated with group membership. This differential change will be interpreted by the investigators as evidence for a treatment effect. In our analysis we will evaluate change in pre-post STarT generic tool scores, controlling for intervention/control carrier as the principal covariate.

The investigators will treat the subscale as a continuous variable for purposes of this study. Patients scoring 4 or 5 will be classified as at high psychosocial risk.(13) Our study anticipates that those in the low risk category at baseline will not regress into the 'High' category; and that those classified in the 'High' risk category in the intervention carrier at baseline will exhibit a differential reduction greater than that observed in the control carrier after PT treatments.

The principal confounding variable the authors consider important is the phase of the cruise (in transit to station, on station, or in transit from station). Self-reported psychological risk factors for disability may change based on the phase of the cruise and associated operational tempo. The investigators will record the date of the index encounter and categorize the time during the cruise at which the index visit took place. We will use ANCOVA to evaluate differential reduction in pre-post scores between the intervention and the control carriers for each of these separate psychological measures. Separate ANCOVA analyses will be performed for two other, continuously-scaled yellow flag outcome variables: pain interference (measured using the DVPRS) and perceived disability score. We theorize that PBPT will produce a differential improvement from the beginning to the end of the treatment episode as compared to those on the control carrier beyond chance variation alone. The remaining 'Yellow flag' variables are continuous and will be treated in the same manner as the STarT Back Generic Screening Tool.

Patient satisfaction

The MedRisk instrument produces a single score, measured continuously. We will evaluate differences in satisfaction using two-way analysis of variance, using part of body injured and carrier as the main effects and satisfaction scores as the outcome.

Differences in the percentage of subjects expressing satisfaction will be assessed using a chi-square test statistic.

Quality of Life

We will evaluate differences in quality of life using two-way analysis of variance, using part of body injured and carrier as the main effects and satisfaction scores as the outcome.

Health care utilization

We plan to construct a rate of health care treatment encounters that reflect the total number of treatment visits, post deployment, for subjects with MSI. The numerator consists of treatment visits (post deployment), extracted from AHLTA related to the index MSI, and the denominator will be the total number of subjects with an MSI. We will calculate this metric for the intervention carrier and for the control carrier. We will compare these two rates using a chi-square test.

LIMDU

This will be assessed using a chi-square test. Two percentages will be compared. The percentage reflects the percentage of all individuals reporting an eligible MSI event on board the intervention carrier during the accrual period divided by the total number of individuals serving on the carrier during the deployment. The percentage of calculated for the intervention carrier will compared against the percentage calculated for the control carrier.

7. SIGNIFICANCE TO NAVY MEDICINE

This proposal will evaluate the efficacy of incorporating psychologically-based techniques into an established physical therapy clinical practice for ADSM deployed aboard a carrier in support of combat. By implementing this study, fitness for duty may be enhanced due to the following objectives:

• Provide physical therapists that are currently assigned to combat- based operational platforms and closest to ADSM at the onset of the original MSI, with additional skills and expertise to care for them.

• Identify ADSM who require mental health intervention to process sooner to the specialist. As a result, timely care for ADSM with significant mental health conditions may be expedited, problems may be averted, and potentially the command's combat readiness will be increased.

• Decrease chronicity in MSI conditions by providing early care. As a result, health outcomes as well as quality of life for ADSM experiencing musculoskeletal injuries will improve and attrition may be reduced.

The mission of Navy Medicine is to enable readiness to ADSM during peacetime and war. As of March 2013, more than 2.2 million troops have been sent to battle in support of military operations in southwest Asia resulting in more than 6,000 deaths.(39) Statistics as of November/December 2012 indicate that 50,291 service members have been medically evacuated from theater and sent to a fixed medical treatment facility for definitive care.(40) A recent report prepared by Navy and Marine Corps Public Health Center, November 2012, showed that from January 2010 until October 2012, 13,394 service members received care for an injury sustained during their deployment or within 90 days after returning. The majority of injuries were musculoskeletal with the most often being: sprains and strains (33%), followed by fractures (17%) and contusions/superficial (11%). Furthermore, contrary to previous psychoanalytic views that physical injury is protective for PTSD, the opposite has been shown to be true. Physical injury is a major risk factor for subsequent PTSD.(41)

Service members with MSI have been identified as the highest group of combat related injuries who are separated from active duty.(4) Several studies have been conducted on specific combat related injuries such as TBI, amputees, and limb savage; however, very little is known about MSI sustained during combat and deployment and the psychological aftermath. In addition, a literature search revealed that most of the studies were conducted within the Army while little information is available for the Navy and Marine Corps, despite the fact that they have the highest rate of attrition from MSI when compared to the Army and Air Force.(9)

In August, 2010, Navy Medicine set up multi-disciplinary Concussion Restoration Care Center at Camp Leatherneck, Helmand Province, Afghanistan. The purpose of this clinic was to provide a prototype for screening, evaluating, and treating service members with suspected concussion, mild TBI, and other psychological issues as well as musculoskeletal injuries in a multidisciplinary team approach.(42) The investigators of the proposed study will explore the efficacy of this type of program aboard a carrier. If successful in reducing the burden of MSI, this study will advance a model for sustainability in a tri-service operation platform.

This project supports Navy Medicine's Goals and Objectives 2010-2015 on quality of care which states: "Navy Medicine will promote healthy Naval (and Marine Corps) Forces and ensure Warfighters are medically prepared to meet their mission." Successful project implementation and outcome will foster the development of a treatment model that could be used in other military settings and ultimately reduce attrition due to MSI. Changes in treatment and policy that result from this study ensure sustainability of the project.

8. PATENT DISCLOSURES/INVENTIONS

There are no patents or inventions associated with this protocol

9. HAZARDS

There are no hazards to the subject related to any of the intervention procedures.

10. ANTICIPATED ENROLLMENT TIMELINE

	Number of Subjects
Year 1:	225
Year 2:	375
Year 3:	

Anticipated study enrollment by calendar quarter

	Year 1				Year 2				Year 3		Total
Target Enrollment Pilot Study	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	
Control Carrier	-	-	100	125	75	0	0	0	0	0	300
Intervention Carrier	-	-	0	0	100	125	75	0	0	0	300
Target Enrollment (cumulative)	-	-	100	225	175	125	75	0	0	0	600

11. BIBLIOGRAPHY FOR RESEARCH PLAN

1. Campello M, Ziemke G, Hiebert R, Weiser S, Brinkmeyer M, Fox B, et al. Implementation of a multidisciplinary program for active duty personnel seeking care for low back pain in a U.S. Navy Medical Center: a feasibility study. Military Medicine 2012;177(9):1075-80.

2. Hiebert R, Campello MA, Weiser S, Ziemke GW, Fox BA, Nordin M. Predictors of short-term work-related disability among active duty US Navy personnel: a cohort study in patients with acute and subacute low back pain. The spine journal : official journal of the North American Spine Society 2012;12(9):806-16.

3. Linton SJ, Shaw WS. Impact of psychological factors in the experience of pain. Physical therapy 2011;91(5):700-11.

4. Cohen SP, Nguyen C, Kapoor SG, Anderson-Barnes VC, Foster L, Shields C, et al. Back pain during war: an analysis of factors affecting outcome. Archives of internal medicine 2009;169(20):1916-23.

5. Goodman GP, DeZee KJ, Burks R, Waterman BR, Belmont PJ, Jr. Epidemiology of psychiatric disorders sustained by a U.S. Army brigade combat team during the Iraq War. General hospital psychiatry 2011;33(1):51-7.

6. Huang GD, Feuerstein M, Arroyo F. Back and upper extremity disorders among enlisted U.S. Marines: burden and individual risk factors. Military medicine 2001;166(11):1007-17.

7. Patzkowski JC, Rivera JC, Ficke JR, Wenke JC. The changing face of disability in the US Army: the Operation Enduring Freedom and Operation Iraqi Freedom effect. The Journal of the American Academy of Orthopaedic Surgeons 2012;20 Suppl 1:S23-30.

8. Bohnker BK, Telfair T, McGinnis JA, Malakooti MA, Sack DM. Analysis of Navy Physical Evaluation Board diagnoses (1998-2000). Military medicine 2003;168(6):482-5.

9. Cohen SP, Brown C, Kurihara C, Plunkett A, Nguyen C, Strassels SA. Diagnoses and factors associated with medical evacuation and return to duty for service members participating in Operation Iraqi Freedom or Operation Enduring Freedom: a prospective cohort study. Lancet 2010;375(9711):301-9.

10. Shaffer RA, Brodine SK, Ito SI, Le AT. Epidemiology of illness and injury among U.S. Navy and Marine Corps female training populations. Military medicine 1999;164(1):17-21.

11. Hebert DJ, Pasque CB. Orthopedic injuries during carrier battle group deployments. Military medicine 2004;169(3):176-80.

12. Ziemke GW, Campello M, Rennix CP, Keer S, Zook J, Nordin M, et al. Retrospective Administrative Limited Duty Outcome Review Lovelace Respiratory Research Institute; 2012. Report No.: Contract Number 2011.029.

13. Hill JC, Dunn KM, Lewis M, Mullis R, Main CJ, Foster NE, et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. Arthritis and rheumatism 2008;59(5):632-41.

14. Main CJ, Sowden G, Hill JC, Watson PJ, Hay EM. Integrating physical and psychological approaches to treatment in low back pain: the development and content of the STarT Back trial's 'high-risk' intervention (StarT Back; ISRCTN 37113406). Physiotherapy 2012;98(2):110-6.

15. Foster N. Beliefs and preferences: Do they help determine the outcome of musculoskeletal problems? Physical Therapy 2007;12:199-206.

16. Gunstad J, Suhr JA. "Expectation as etiology" versus "the good old days": postconcussion syndrome symptom reporting in athletes, headache sufferers, and depressed individuals. Journal of the International Neuropsychological Society : JINS 2001;7(3):323-33.

17. Mondloch MV, Cole DC, Frank JW. Does how you do depend on how you think you'll do? A systematic review of the evidence for a relation between patients' recovery expectations and health outcomes. CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne 2001;165(2):174-9.

18. Mannion AF, Elfering A, Staerkle R, Junge A, Grob D, Semmer NK, et al. Outcome assessment in low back pain: how low can you go? European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society 2005;14(10):1014-26.

19. Booth-Kewley S, Larson GE, Highfill-McRoy RM. Psychosocial predictors of return to duty among marine recruits with musculoskeletal injuries. Military medicine 2009;174(2):139-52.

20. Selim AJ, Rogers W, Fleishman JA, Qian SX, Fincke BG, Rothendler JA, et al. Updated U.S. population standard for the Veterans RAND 12-item Health Survey (VR-12). Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation 2009;18(1):43-52.

21. Pincus T, Santos R, Breen A, Burton AK, Underwood M. A review and proposal for a core set of factors for prospective cohorts in low back pain: a consensus statement. Arthritis and rheumatism 2008;59(1):14-24.

22. Buckenmaier CC, 3rd, Galloway KT, Polomano RC, McDuffie M, Kwon N, Gallagher RM. Preliminary validation of the Defense and Veterans Pain Rating Scale (DVPRS) in a military population. Pain medicine 2013;14(1):110-23.

23. Beattie P, Turner C, Dowda M, Michener L, Nelson R. The MedRisk Instrument for Measuring Patient Satisfaction With Physical Therapy Care: a psychometric analysis. The Journal of orthopaedic and sports physical therapy 2005;35(1):24-32.

24. Beattie PF, Pinto MB, Nelson MK, Nelson R. Patient satisfaction with outpatient physical therapy: instrument validation. Physical therapy 2002;82(6):557-65.

25. Bombardier C. Outcome assessments in the evaluation of treatment of spinal disorders: summary and general recommendations. Spine 2000;25(24):3100-3.

26. Yancosek KE, Roy T, Erickson M. Rehabilitation programs for musculoskeletal injuries in military personnel. Current opinion in rheumatology 2012;24(2):232-6.

27. Stanton TR, Latimer J, Maher CG, Hancock MJ. A modified Delphi approach to standardize low back pain recurrence terminology. European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society 2011;20(5):744-52.

28. Radloff LS. The CES-D Scale: A self-report depression scale for research in the general population. Applied Psychological Measurement 1977;1:385-401.

29. Radloff LS, Locke B. The community mental health assessment survey and the CES-D scale In: Weissman M, Myers J, Ross C, editors. Community surveys of psychiatric disorders. New Brunswick (NJ): Rutgers University Press; 1986.

30. Lowe B, Decker O, Muller S, Brahler E, Schellberg D, Herzog W, et al. Validation and standardization of the Generalized Anxiety Disorder Screener (GAD-7) in the general population. Medical care 2008;46(3):266-74.

31. Bliese PD, Wright KM, Adler AB, Cabrera O, Castro CA, Hoge CW. Validating the primary care posttraumatic stress disorder screen and the posttraumatic stress disorder checklist with soldiers returning from combat. Journal of consulting and clinical psychology 2008;76(2):272-81.

32. Weathers FW, Huska JA, Keane TM. PCL-M for DSM-IV. In: Division NCfPBS, editor. Boston; 1991.

33. Dolbier CL, Webster JA, McCalister KT, Mallon MW, Steinhardt MA. Reliability and validity of a single-item measure of job satisfaction. American journal of health promotion : AJHP 2005;19(3):194-8.

34. Porter L, Smith F. The etiology of organizational commitment: A longitudinal study of the initial stages of employee-organization reactions. In: University of California at Irvine; 1970.

35. Gade PA, Tiggle RB, W.R. S. The measurement and consequences of military organizational commitment in soldiers and spouses. Military Psychology 2003;14(3):191-207.

36. Martin TN, O'Laughlin MS. Predictors of organizational commitment: The study of part-time Army reservists. Journal of Vocational Behavior 1984;25:270-283.

37. Rosen LN, Martin L. Childhood antecedents of psychological adaptation to military life. Military medicine 1996;161(11):665-8.

38. Vogt DS, Proctor SP, King DW, King LA, Vasterling JJ. Validation of scales from the Deployment Risk and Resilience Inventory in a sample of Operation Iraqi Freedom veterans. Assessment 2008;15(4):391-403.

39. Institute of Medicine (IOM). Returning home from Iraq and Afghanistan: Assessment of readjustment needs of veterans, service members, and their families. Washington DC: The National Academies Press; 2013.

40. Fischer H. U.S. Military Casualty Statistics: Operation New Dawn, Operation Iraqi Freedom, and Operation Enduring Freedom Washington D.C.: Congressional Research Service; 2013.

41. Koren D, Norman D, Cohen A, Berman J, Klein EM. Increased PTSD risk with combat-related injury: a matched comparison study of injured and uninjured soldiers experiencing the same combat events. The American journal of psychiatry 2005;162(2):276-82.

42. Keleher K. Care for Concussions in Afghanistan. In: America's North Shore Journal; 2011.

43. Feuerstein M, Berkowitz SM, Peck CA, Jr. Musculoskeletal-related disability in US Army personnel: prevalence, gender, and military occupational specialties. Journal of occupational and environmental medicine / American College of Occupational and Environmental Medicine 1997;39(1):68-78.

44. Berkowitz SM, Feuerstein M, Lopez MS, Peck CA, Jr. Occupational back disability in U.S. Army personnel. Military medicine 1999;164(6):412-8.

45. Lincoln AE, Smith GS, Amoroso PJ, Bell NS. The natural history and risk factors of musculoskeletal conditions resulting in disability among US Army personnel. Work 2002;18(2):99-113.

46. Packnett ER, Gubata ME, Cowan DN, Niebuhr DW. Temporal trends in the epidemiology of disabilities related to posttraumatic stress disorder in the U.S. Army and Marine Corps from 2005-2010. Journal of traumatic stress 2012;25(5):485-93.

47. Ferreira PH, Ferreira ML, Maher CG, Refshauge K, Herbert RD, Hodges PW. Changes in recruitment of transversus abdominis correlate with disability in people with chronic low back pain. British journal of sports medicine 2010;44(16):1166-72.

48. Hodges PW, Richardson CA. Inefficient muscular stabilization of the lumbar spine associated with low back pain. A motor control evaluation of transversus abdominis. Spine 1996;21(22):2640-50.

49. Sudhaus S, Mollenberg T, Plaas H, Willburger R, Schmieder K, Hasenbring M. Cortisol awakening response and pain-related fear-avoidance versus endurance in patients six months after lumbar disc surgery. Applied psychophysiology and biofeedback 2012;37(2):121-30.

50. Dawson AP, Schluter PJ, Hodges PW, Stewart S, Turner C. Fear of movement, passive coping, manual handling, and severe or radiating pain increase the likelihood of sick leave due to low back pain. Pain 2011;152(7):1517-24.

51. Kendall NAS, Linton SJ, Main CJ. Guide to Assessing Psychosocial Yellow Flags in Acute Low Back Pain: Risk Factors for Long-Term Disability and Work Loss. In. Wellington, New Zealand: Accident Rehabilitation & Compensation Insurance Corporation of New Zealand, and the National Health Committee, Ministry of Health; 1997.

52. Nicholas MK, Linton SJ, Watson PJ, Main CJ. Early identification and management of psychological risk factors ("yellow flags") in patients with low back pain: a reappraisal. Physical therapy 2011;91(5):737-53.

53. Foster NE, Delitto A. Embedding psychosocial perspectives within clinical management of low back pain: integration of psychosocially informed management principles into physical therapist practice--challenges and opportunities. Physical therapy 2011;91(5):790-803.

54. Keefe FJ, Beaupre PM, Gil KM, Rumble ME, Aspnes AK, editors. Group Therapy for Patients with Chronic Pain. 2nd ed. New York, NY: The Guilford Press; 2002.

55. Main CJ, Foster N, Buchbinder R. How important are back pain beliefs and expectations for satisfactory recovery from back pain? Best practice & research. Clinical rheumatology 2010;24(2):205-17.

56. Turk DC, Meichenbaum D, Genest M. Pain and Behavioral Medicine: A Cognitive-Behavioral Perspective. New York, NY: The Guilford Press; 1987.

57. Hofmann SG. An introduction to modern CBT : psychological solutions to mental health problems Chichester, West Sussex, U.K. ; Malden, MA: Wiley-Blackwell; 2012.

58. Nicholas MK, George SZ. Psychologically informed interventions for low back pain: an update for physical therapists. Physical therapy 2011;91(5):765-76.

59. Shaw WS, van der Windt DA, Main CJ, Loisel P, Linton SJ. Early patient screening and intervention to address individual-level occupational factors ("blue flags") in back disability. Journal of occupational rehabilitation 2009;19(1):64-80.

60. Foster NE, Mullis R, Young J, Doyle C, Lewis M, Whitehurst D, et al. IMPaCT Back study protocol. Implementation of subgrouping for targeted treatment systems for low back pain patients in primary care: a prospective population-based sequential comparison. BMC musculoskeletal disorders 2010;11:186.

61. Hayden JA, van Tulder MW, Malmivaara AV, Koes BW. Meta-analysis: exercise therapy for nonspecific low back pain. Annals of internal medicine 2005;142(9):765-75.

62. Karjalainen K, Malmivaara A, van Tulder M, Roine R, Jauhiainen M, Hurri H, et al. Multidisciplinary biopsychosocial rehabilitation for subacute low back pain among working age adults. Cochrane Database of Systematic Reviews 2003(2):CD002193.

63. Keller A, Hayden J, Bombardier C, van Tulder M. Effect sizes of non-surgical treatments of non-specific low-back pain. European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society 2007;16(11):1776-88.

64. Chou R, Loeser JD, Owens DK, Rosenquist RW, Atlas SJ, Baisden J, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine 2009;34(10):1066-77.

65. Lamb SE, Hansen Z, Lall R, Castelnuovo E, Withers EJ, Nichols V, et al. Group cognitive behavioural treatment for low-back pain in primary care: a randomised controlled trial and cost-effectiveness analysis. Lancet 2010;375(9718):916-23.

66. Burton AK, Balague F, Cardon G, Eriksen HR, Henrotin Y, Lahad A, et al. Chapter 2. European guidelines for prevention in low back pain : November 2004. European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society 2006;15 Suppl 2:S136-68.

67. van der Windt D, Hay E, Jellema P, Main C. Psychosocial interventions for low back pain in primary care: lessons learned from recent trials. Spine 2008;33(1):81-9.

68. Main CJ, George SZ. Psychologically informed practice for management of low back pain: future directions in practice and research. Physical therapy 2011;91(5):820-4.

69. Goertz C, Marriott BP, Finch MD, Bray RM, Williams TV, Hourani LL, et al. Military report more complementary and alternative medicine use than civilians. Journal of alternative and complementary medicine 2013;19(6):509-17.

70. Overmeer T, Boersma K, Denison E, Linton SJ. Does teaching physical therapists to deliver a biopsychosocial treatment program result in better patient outcomes? A randomized controlled trial. Physical therapy 2011;91(5):804-19.

12. DATABASE/LITERATURE SEARCHED

	Source	Date	Key Words
a.	PUBMED	01/01/2013	BACK PAIN, MILITARY, MUSCULOSKELETAL, COGNITIVE BEHAVIORAL THERAPY, OUTCOME, RANDOMIZED CONTROLLED TRIAL, RISK FACTOR, DISABILITY, ATTRITION

13. SUMMARY OF LITERATURE SEARCH

Risk factors associated with MSI-related disability

Several factors have been shown to have a strong relationship to disability from MSI. Studies that look specifically at work outcomes in military populations emphasize a multidimensional perspective that includes clinical, individual and social factors. Feuerstein et al (1997)(43) and Berkowitz et al (1999)(44) identified factors associated with disability in ADSM, that included younger age, lower rank, poor aerobic conditioning, high work stress, worries and low social support. Lincoln et al (2002)(45) also found a variety of factors to be associated with disability from MSI in ADSM such as pay grade, diagnosis, length of service, age, military occupational specialty, job satisfaction, previous history of MSI, smoking, work stress and job demands. Booth-Kewley et al (19) explored a variety of psychosocial factors contributing to attrition from basic training due to MSI in Marine Corps recruits. Using a mixed-method format of questionnaires and structured interviews, they found only two factors that were retained in the final regression analysis: expectations about graduation and career intentions. In a study of ADSM from 2005-2010 who were diagnosed with post-traumatic stress disorder (PTSD) previously found as a major cause of disability, MSI were a frequent comorbidity.(46) The author speculates that this is due to the traumatic etiology of both conditions simultaneously. A longitudinal study conducted by the present investigators examined the relationship between known modifiable psychological risk factors and work outcomes among ADSM who were not deployed and found that fear of activity was predictive of work status twelve weeks after a reported back injury.(2) Therefore, we see clear scientific evidence linking psychosocial factors with increased risk of disability following MSI in ADSM.

The biopsychosocial model of pain and disability explains the multidimensional nature of MSI. This model emphasizes the interplay of physiological, psychological (cognitive, affective, and behavioral) responses to pain and how they interact with the social environment to ameliorate or maintain pain and dysfunction. For example, when there is prolonged pain, cortical changes result in altered muscle response patterns such as abnormal dynamic muscle control.(47, 48) In addition, stress hormones that accompany these painful conditions enhance pain transmission.(49) These changes result in cognitive appraisals of pain as unremitting and individuals often express anxiety about their future and suffer depression from feelings of helplessness and

hopelessness. Many develop a fear of movement that is reflected in the social dimension as restriction of social activities including work and social activities.(50) This pattern decreases the likelihood of recovery as it is self-sustaining.

This model is applied to clinical practice by identifying various elements as risk factor categories, or 'flags'.(51) Red flags are clinical indicators of serious underlying conditions that warrant further medical intervention such as the presence of systemic diseases. Orange flags can be considered the psychiatric equivalent of red flags and include serious psychiatric pathology that may interfere with recovery such as clinical depression and PTSD.(52) Yellow flags are modifiable psychological or behavioral risk factors associated with unfavorable clinical outcomes. Common yellow flags are negative beliefs about recovery, feelings of distress and inability to cope with pain. Blue flags are the workers' perceptions of the work environment such as perceived work stress or lack of social support. Finally, black flags are more objective characteristics of the system or the environment in which a person functions such as the nature of the work or the insurance and compensation system of the workplace.(52)

Evidence of effectiveness of Cognitive Behavioral Therapy (CBT) in modifying psychological risk factors

Yellow flags are considered modifiable through clinical intervention. CBT, derived from a well-established mode of psychotherapy, has been developed to address modifiable psychological risk factors in patients with MSI.(53-56) CBT is rooted in the work of Aron Beck, who identified automatic thoughts or responses to stimuli that result in affective states that may interfere with adaptive behaviors and proposed techniques to alter these thoughts.(57) The emphasis on factors that could be altered was of critical importance to the development of effective interventions for treating MSI. It has been shown that there is a clear relationship between the presence of modifiable yellow flags and future clinical and occupational outcomes. Indeed, fear-avoidance beliefs, distress, somatization and pain catastrophizing are associated with high risk of a poor outcome in patients with low back pain (LBP).(52, 55, 58, 59)

Using CBT to target yellow flags, especially when they are at high levels, leads to more positive outcomes.(52, 60) Best evidence reviews show moderate levels of evidence that treatments that address psychological issues with cognitive-behavioral techniques in conjunction with physical therapy are effective in reducing symptoms and limiting disability among individuals with sub-acute MSI.(61-63) It has also been shown that patients who have psychological risk factors do not benefit from a biomedical approach alone but do benefit from a combined approach.(63-65) It has been shown that patients with LBP who express fear of activity can be treated successfully only when these fears are addressed.(63-65)

The present investigators designed an education and training program for an interdisciplinary team at the Navy Medical Center in Portsmouth.(1) Team members were trained in the biopsychosocial model as a group and then individually by experts in their field. The purpose of this training was to teach physical therapists, psychologists and physicians how to work in an interdisciplinary team and not specifically to train physical therapists in PBPT. In a pilot randomized controlled trial, the present authors tested the feasibility of implementing an interdisciplinary work restoration program based on this training called "Backs to Work" in a Navy and Marine Corps setting for ADSM with work limiting MSI. Findings showed preliminary evidence that those randomized to CBT and physical therapy had improved perception of function as compared to the control arm and there was a trend in decrease in fear of activity and pain catastrophizing in the intervention group as compared to the control arm (usual care).(1) Our experience with this study has informed the development of the present proposal.

Benefits of PBPT

Identification and modification of yellow flags has been shown to be more effective in reducing or preventing chronic or recurrent disability when they are addressed early in an episode.(64, 66, 67) Recently, it has been proposed that this should be done by physical therapists (PTs) who have early and prolonged access to patients. Other advantages of having PTs address yellow flags are that CBT administered by a psychologist is

expensive and may not be readily available and patients may be reluctant to seek psychotherapy due to stigma concerns.

PBPT, sometimes called psychologically informed physical therapy, is an approach designed to incorporate the concepts of CBT for pain management into routine clinical practice in order to modify maladaptive responses that are associated with chronicity.(58, 68) The goal of PBPT is to promote a fast and optimal recovery by removing psychological obstacles, obviating the need for referral to a psychologist in patients at risk and to facilitate triage to other health professionals when needed in a timely manner. A recent study reports that ADSM are more likely than civilians to seek complementary and alternative care that is outside the biomedical model. Yet this type of care is not available in the military and members seek care elsewhere.(69) Currently, physical therapy training is based in the biomedical model which posits a direct relationship between the nature and severity of the injury and the symptoms reported by the patient. In this model, the objective of treatment is to address the physical cause of pain or disability in an effort to improve outcomes without taking into account the psychosocial nature of the risk factors of disability. A shift in treatment from the biomedical paradigm to a biopsychosocial paradigm requires education and training.

Overmeer et al have developed an eight day training course for physical therapists in PBPT, this training included questionnaire administration, the biopsychosocial model, yellow flags, behavioral principles, communication, addressing fear of movement, and role playing.(70) In a recent and significant large scale randomized clinical trial (RCT) examining the effectiveness of this training, the investigators found mixed results. While attitudes and knowledge of the physical therapists shifted in the expected direction, their behavior did not. Furthermore, the training did not improve outcomes in patients overall. However patients in the screening and referral arm of the study high in catastrophizing and depression benefited differentially as compared to a regimen of active physical therapy alone when the attitudes of therapists changed from purely biomedical to psychologically-based.(70) The authors point out that a onetime course is insufficient for changing behaviors, even if attitudes are altered. Ongoing education and reinforcement is needed. Secondly, they speculate that their topics were too broad and did not focus on specific ways to address yellow flags. Finally, they posit a possible selection bias in that participants were interested in learning about yellow flags, so they may have already been exhibiting different behaviors than other physical therapists. In our interdisciplinary training for the RCT described above(1), we avoided some of these weaknesses by giving specific examples of how to implement guideline-based care for each discipline and by providing weekly teleconferences to discuss questions and difficult cases and reinforce training. In addition, we encouraged the use of self-care techniques to reduce patient reliance on health care professionals. This further distinguished our approach from Overmeer's.

Patient Information Questionnaire-BASELINE

Name: _____ **D.O.B:**_____ **DoD ID#**_____
Job Title/Rate: _____ **City/Municipality of Birthplace**_____

Current Tobacco Smoking Status

1. Do you currently smoke tobacco on a daily basis, less than daily, or not at all?
   - Daily.....□ Continue with question 3
   - Less than daily.....□ Continue with question 2a
   - Not at all.....□ Continue with question 2b
   - Don't know.....□ Continue with question 3

Past Daily Tobacco Smoking Status

2. a. Have you smoked tobacco daily in the past?
   - Yes.....□ Continue with question 3
   - No.....□ Continue with question 3
   - Don't know.....□ Continue with question 3

Past Smoking Status

b. In the past have you smoked tobacco on a daily basis, less than daily or not at all?
   - Daily.....□ Continue with question 3
   - Less than daily.....□ Continue with question 3
   - Not at all.....□ Continue with question 3
   - Don't know.....□ Continue with question 3

Current Level of education

3. What is the highest level of formal education that you have completed? Please choose only **ONE** of the following options:
   - ☐ Doctoral or professional degree
   - ☐ Master's degree
   - ☐ Bachelor's degree
   - ☐ Associate's degree
   - ☐ Postsecondary non-degree award
   - ☐ Some college, no degree
   - ☐ High school diploma or equivalent
   - ☐ Less than high school

Patient's Initials: ☐

Pain Description

4. What is the main reason for which you are seeking care?
   Please choose only **ONE** of the following options:

- ☐ None
- ☐ Low back pain problem
- ☐ Neck problem
- ☐ Mid-back problem
- ☐ Shoulder problem
- ☐ Arm or hand problem
- ☐ Hip problem
- ☐ Knee problem
- ☐ Ankle or foot problem
- ☐ Other (specify):

5. For how long have you had this current complaint?

- ☐ Less than 4 weeks
- ☐ 4 weeks to 12 weeks
- ☐ More than 12 weeks

6. How often do you have pain?

- ☐ Never
- ☐ On some days
- ☐ On most days
- ☐ Every day

7. Prior to this visit, have you sought care for this complaint within the past 30 days?

- ☐ Yes
- ☐ No

8. Have you ever had this complaint before?

- ☐ Yes,
  If yes, were you pain free for 30 days prior to the onset of this current episode?
  - O Yes
  - O No
- ☐ No

Patient's Initials: ☐

9. Please indicate the intensity of the pain of your main complaint on a scale of 0 to 10, where 0 means "no pain" and 10 means "the worst pain imaginable"

0	1	2	3	4	5	6	7	8	9	10

No pain — Worst pain Imaginable

10. Aside from your main complaint, please mark any other complaints. Choose **ALL** that apply:

- ☐ None
- ☐ Low back pain problem
- ☐ Neck problem
- ☐ Mid-back problem
- ☐ Shoulder problem
- ☐ Arm or hand problem
- ☐ Hip problem
- ☐ Knee problem
- ☐ Ankle or foot problem
- ☐ Other (specify):

Attitudes about Pain

Thinking about your **MAIN** complaint. Please answer the following questions.

11. Circle the one number that describes how, during the past 24 hours, pain has interfered with your usual ACTIVITY:

Does not interfere — Completely interferes

0	1	2	3	4	5	6	7	8	9	10

12. Circle the one number that describes how, during the past 24 hours, pain has interfered with your SLEEP:

Does not interfere — Completely interferes

0	1	2	3	4	5	6	7	8	9	10

Patient's Initials: ____

13. Circle the one number that describes how, during the past 24 hours, pain has affected with your MOOD:

Does not affect										Completely affects
0	1	2	3	4	5	6	7	8	9	10

14. Circle the one number that describes how, during the past 24 hours, pain has contributed to your STRESS:

Does not contribute										Contributes a great deal
0	1	2	3	4	5	6	7	8	9	10

For each of the following, thinking about the **last few days**, **circle** the number that indicates how much you agree or disagree with the following statements.

15. I believe that my condition is going to get better.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

16. I am confident I can cope with my condition.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

17. It's really not safe for a person with a condition like mine to work.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

18. It's **really not safe** for a person with a condition like mine to be **physically active**.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

Patient's Initials: [ ]

19. **Worrying thoughts** have been going through my mind a lot of the time in the last **few days**.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

20. I feel that **my condition is terrible** and that **it is never going to get any better**.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

21. In general, in last **few days**, I have **not enjoyed** all the things I used to enjoy.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

Please circle the number that corresponds to your answer in the table below:

	Not at all	**Slightly**	**Moderately**	**Very much**	**Extremely**
22. Overall, how **bothersome** has your **condition** been in the **last few days**?	1	2	3	4	5
23. How much does your condition interfere with your usual activities, including work	1	2	3	4	5

Patient's Initials: [ ]

Questions about your job

Circle the answer that indicates how much you agree or disagree with the following statements:

24. I feel like "part of the family" in the military	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
25. The military has a great deal of personal meaning for me.	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
26. I feel a strong sense of belonging to the military.	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
27. I feel emotionally attached to the military.	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**

The statements below are about your relationships with other military personnel while you have been deployed. Please read each statement and describe how much you agree or disagree by **circling** the number that best fits your answer

	Strongly Disagree	**Somewhat Disagree**	**Neither agree nor disagree**	**Somewhat agree**	**Strongly agree**
28. My unit is like family to me.	1	2	3	4	5
29. I feel a sense of camaderie between myself and other soldiers in my unit.	1	2	3	4	5
30. Members of my unit understand me.	1	2	3	4	5

Patient's Initials: ____

	Strongly Disagree	Somewhat Disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
31. Most people in my unit are trustworthy.	1	2	3	4	5
32. I can go to most people in my unit for help when I have a personal problem.	1	2	3	4	5
33. My supervisors (s) are interested in how I think and how I feel about things.	1	2	3	4	5
34. I am impressed by the quality of leadership in my unit.	1	2	3	4	5
35. My superiors make a real attempt to treat me as a person.	1	2	3	4	5
36. The supervisor (s) in my unit are supportive of my efforts.	1	2	3	4	5
37. I feel like my efforts really count to the military.	1	2	3	4	5
38. The military appreciates my service.	1	2	3	4	5
39. I am supported by the military.	1	2	3	4	5

Patient's Initials: ____

Stress Symptoms

Below is a list of problems and complaints that veterans sometimes have in response to stressful life experiences. Please read each one carefully, **circle** the answer to indicate how much you have been bothered by that problem in the **last month**.

DURING THE LAST MONTH:	**Not at all**	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
40. Repeated, disturbing memories, thoughts, or images of a stressful military experience from the past?	1	2	3	4	5
41. Repeated, disturbing dreams of a stressful military experience from the past?	1	2	3	4	5
42. Suddenly acting or feeling as if a stressful military experience were happening again (as if you were reliving it)?	1	2	3	4	5
43. Feeling very upset when something reminded you of a stressful military experience from the past?	1	2	3	4	5
44. Having physical reactions (e.g., heart pounding, trouble breathing, or sweating) when something reminded you of a stressful military experience from the past?	1	2	3	4	5
45. Avoiding thinking about or talking about a stressful military experience from the past or avoid having feelings related to it?	1	2	3	4	5

Patient's Initials: ____

DURING THE LAST MONTH:	**Not at all**	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
46. Avoid activities or situations because they remind you of a stressful military experience from the past?	1	2	3	4	5
47. Trouble remembering important parts of a stressful military experience from the past?	1	2	3	4	5
48. Loss of interest in things that you used to enjoy?	1	2	3	4	5
49. Feeling distant or cut off from other people?	1	2	3	4	5
50. Feeling emotionally numb or being unable to have loving feelings for those close to you?	1	2	3	4	5
51. Feeling as if your future will somehow be cut short?	1	2	3	4	5
52. Trouble falling or staying asleep?	1	2	3	4	5
53. Feeling irritable or having angry outbursts?	1	2	3	4	5
54. Having difficulty concentrating?	1	2	3	4	5
55. Being "super alert" or watchful on guard?	1	2	3	4	5
56. Feeling jumpy or easily startled?	1	2	3	4	5

Patient's Initials: ____

Below is a list of the ways you might have felt or behaved. Please indicate how often you have felt this way **during the past week.**

DURING THE PAST WEEK:	**Rarely or none of the time (less than 1 day)**	**Some or a little of the time (1-2 days)**	**Occasionally or a moderate amount of time (3-4 days)**	**Most or all of the time (5-7 days)**
57. I was bothered by things that usually don't bother me.	0	1	2	3
58. I did not feel like eating; my appetite was poor.	0	1	2	3
59. I felt that I could not shake off the blues even with help from my family or friends.	0	1	2	3
60. I felt that I was just as good as other people.	3	2	1	0
61. I had trouble keeping my mind on what I was doing.	0	1	2	3
62. I felt depressed.	0	1	2	3
63. I felt that everything I did was an effort.	0	1	2	3
64. I felt hopeful about the future.	3	2	1	0
65. I thought my life had been a failure.	0	1	2	3
66. I felt fearful.	0	1	2	3
67. My sleep was restless.	0	1	2	3
68. I was happy.	3	2	1	0
69. I talked less than usual.	0	1	2	3
70. I felt lonely.	0	1	2	3
71. People were unfriendly.	0	1	2	3
72. I enjoyed life.	3	2	1	0
73. I had crying spells.	0	1	2	3
74. I felt sad.	0	1	2	3
75. I felt that people disliked me.	0	1	2	3
76. I could not get "going."	0	1	2	3

Patient's Initials: ____

Over the last **2 weeks**, how often have you been bothered by the following problems? Please read each statement and **circle** the number that best fits your answer.

	Not at all	Several days	More than half the days	Nearly every day
77. Feeling nervous, anxious or on edge	0	1	2	3
78. Not being able to stop or control worrying	0	1	2	3
79. Worrying too much about different things	0	1	2	3
80. Trouble relaxing	0	1	2	3
81. Being so restless that it is hard to sit still	0	1	2	3
82. Becoming easily annoyed or irritable	0	1	2	3
83. Feeling afraid as if something awful might happen	0	1	2	3

84. Taking everything into consideration, how do you feel about your job as a whole?

☐ Very satisfied
☐ Somewhat satisfied
☐ Mixed (About equally satisfied & dissatisfied)
☐ Somewhat dissatisfied
☐ Very dissatisfied

Patient's Initials: ☐

85. Taking everything into consideration, how stressful is your job as a whole?

☐ Extremely stressful
☐ Stressful
☐ Moderately stressful
☐ Slightly stressful
☐ Not stressful at all

Treatment concerns

86. Please list any barriers aboard the carrier that you think may prevent you from receiving the care that you think you need:

Patient Information Questionnaire-FOLLOW UP

Name: _____ **D.O.B:**_____ **DoD ID#**_____

Job Title/Rate: _____ **City/Municipality of Birthplace**_____

Pain Description

1. What is the main reason for which you are seeking care?

Please choose only **ONE** of the following options:

- ☐ None
- ☐ Low back pain problem
- ☐ Neck problem
- ☐ Mid-back problem
- ☐ Shoulder problem
- ☐ Arm or hand problem
- ☐ Hip problem
- ☐ Knee problem
- ☐ Ankle or foot problem
- ☐ Other (specify):

2. Please indicate the intensity of the pain of your main complaint on a scale of 0 to 10, where 0 means "no pain" and 10 means "the worst pain imaginable"

0	1	2	3	4	5	6	7	8	9	10

No pain — Worst pain imaginable

Attitudes about Pain

Thinking about your **MAIN** complaint. Please answer the following questions.

3. **Circle** the one number that describes how, during the past 24 hours, pain has interfered with your usual ACTIVITY:

Does not interfere — Completely interferes

0	1	2	3	4	5	6	7	8	9	10

Patient's Initials: [ ]

4. **Circle** the one number that describes how, during the past 24 hours, pain has interfered with your SLEEP:

Does not interfere										Completely interferes
0	1	2	3	4	5	6	7	8	9	10

5. **Circle** the one number that describes how, during the past 24 hours, pain has affected with your MOOD:

Does not affect										Completely affects
0	1	2	3	4	5	6	7	8	9	10

6. **Circle** the one number that describes how, during the past 24 hours, pain has contributed to your STRESS:

Does not contribute										Contributes a great deal
0	1	2	3	4	5	6	7	8	9	10

For each of the following, thinking about the last few days, **circle** the number that indicates how much you agree or disagree with the following statements.

7. I believe that my condition is going to get better.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

8. I am confident I can cope with my condition.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

9. It's really not safe for a person with a condition like mine to work.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

Patient's Initials: [ ]

10. It's **really not safe** for a person with a condition like mine to be **physically active**.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

11. **Worrying thoughts** have been going through my mind a lot of the time in the last **few days**.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

12. I feel that **my condition is terrible** and that **it is never going to get any better**.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

13. In general, in last **few days**, I have **not enjoyed** all the things I used to enjoy.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

14. Overall, how **bothersome** has your **condition** been in the **last few days**?

Not at all	Slightly	Moderately	Very much	Extremely
[ ]	[ ]	[ ]	[ ]	[ ]

15. How much does your condition interfere with your usual activities, including work?

Not at all	Slightly	Moderately	Very much	Extremely
[ ]	[ ]	[ ]	[ ]	[ ]

16. Compared to your quality of life before your injury, please rate your quality of life now.

Very Good	Good	Fair	Poor	Very poor
[ ]	[ ]	[ ]	[ ]	[ ]

Patient's Initials: ☐

Information about satisfaction with care

Please answer the questions below by ***circling*** the response which best describes your opinions about your treatment.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
17. My therapist spent enough time with me.	1	2	3	4	5
18. My therapist thoroughly explained the treatment(s) I received.	1	2	3	4	5
19. My therapist was respectful.	1	2	3	4	5
20. The therapist's assistant/aide was respectful (if applicable).	1	2	3	4	5
21. My therapist did not listen to my concerns.	1	2	3	4	5
22. My therapist answered all my questions.	1	2	3	4	5
23. My therapist advised me on ways to stay healthy and avoid future problems.	1	2	3	4	5
24. My therapist gave me detailed instructions regarding my home exercise program.	1	2	3	4	5

25. If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it?

Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied
☐	☐	☐	☐	☐

Patient's Initials: ☐

26. Please list the most important things you learned in physical therapy:

Manual of Operating Procedures (MOOP): Final Version

Data Management and Statistical Analysis

Introduction

This document describes the procedures used for the management of administratively collected data and the statistical analysis of the Psychologically Informed Physical Therapy protocol.

The protocol analyzes subject self-administered questionnaire data and administratively collected health care utilization and work disability data. This document first describes the procedures for computerization of the self-administered subject questionnaire, and then describes the procedures used for accessing, preparing and analyzing administratively collected health care utilization and work disability data.

Approvals

Institutional Review Board (IRB)

Copies of US Navy Institutional Review Board approvals can be found in the appendix

Data use agreement

A copy of the submitted data use agreement can be found in the appendix.

The organizational entity that handles data use agreements is the Navy Medicine Office of the Chief Information Officer. The person who is handling our data use agreement (DSA) is:

Barbara Hazzard
Barbara.hazzard.ctr@med.navy.mil
703-681-2475

Documents relating to the submission and management of a data use agreement can be found at:

http://health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/Submit-a-Data-Sharing-Application

Sources of data

Data for this study come from three sources: subject self-administered questionnaires, medical records maintained by the treating physical therapist on board ship (Subjective, Objective, Assessment and Plan – SOAP notes) and subject's electronic medical and personnel records.

Subject self-administered questionnaires

Two subject self-administered questionnaires are used for this study: an enrollment questionnaire, and a questionnaire that is administered at the end of treatment or at 4 weeks if an end-of-treatment encounter with the PT is not kept. Copies of these two questionnaires can be found in the appendix.

Electronic personal and medical records

The request asks for clinical encounter data made by enrolled subjects relating to the index MSI, starting with the index encounter and for a period of six months following return from deployment. Note that our study protocol enrolls new cases for a period of up to three months after the ship docks from deployment. For these cases, the end of follow-up will occur nine months after the ship docks. This allows for a period of three months of additional case accrual that the investigators consider related to the deployment, and a follow-up period of six months to evaluate for health care utilization.

Data will be requested from AHLTA-Theater for shipboard visits, and AHLTA for shore based encounters following return from deployment.

Data will be drawn from the following M-2 tables:

DEERS Person Detail	required for subject demographics
Direct Care Professional Encounter (CAPER) detail	captures MTF encounters (ship and shore)
Purchased Care Non-Institutional detail	captures out of network encounters

The data request will specify the following:

1. Subject name;
2. Name of the ship the subject was on board during deployment;
3. Date of baseline questionnaire;
4. A date representing the close of data capture;

The date representing the close of data capture is calculated by the study investigator, and is specific to each study subject. For those subjects who enrolled in the study while the ship was at sea, the end of follow-up will be calculated as 180 days after the subject's ship has returned back from deployment. For those subjects enrolling in the three month period following return from deployment, the end of follow-up will be calculated as 270 days following the return of the ship from deployment.

The Epi Data Center staff will take the data request and run three queries: 1) a query will be run on DEERS person detail to return subject demographics; 2) a query will be run on Direct Care Professional Encounter table data to return all encounters made by the subject to MTF starting on the date of the baseline questionnaire through to the date of close of data capture calculated for that subject; 3) a query will be run on Purchased Care Non-Institutional Detail table starting on the date of the baseline questionnaire through to the date of close of data capture calculated for that subject. Note that because the subject was deployed at the time of study enrollment, there should be no records returned from the Purchased Care table from the date of the subject's baseline questionnaire to the time the subject returns shoreside from deployment.

Four flat, ASCII formatted data files will be returned from the Epi Data Center. The first flat file will contain the direct care ambulatory records and associated DEERS fields, the second flat file will be the purchased care and associated DEERS fields, the third MTF admissions records and associated DEERS fields, and the last file non-MTF admissions and associated DEERS fields.

Physical Therapist SOAP notes

Copies of SOAP notes maintained by the treating ship board physical therapist will be scanned and transferred to the researchers via a secure data transfer mechanism. A copy of a sample SOAP note can be found in the appendix.

Preparation of analysis data sets

Transfer

Electronic data files from the Epi Data Center, scans of subject questionnaires and scans of PT SOAP notes will be transferred to the study associate investigators, Danielle Faulkner and Rudi Hiebert, via AMERDEC SAFE.

These files are downloaded and stored on a US Navy CAC-card secured computer located in the Spine Research office at the Physical Therapy Department Naval Medical Center Portsmouth.

Computerization of subject questionnaire data

Subject self-administered questionnaire data will be computerized using the BADER Consortium Clinical Trials Database (CTDB). The study's Associate Investigators Danielle Faulkner and Rudi Hiebert are responsible for computerizing subject questionnaire data.

CTDB Point of Contact:
Michelle Mattera Keon, MBE
University of Delaware
STAR Annex
101 Discovery Blvd.
Newark, DE 19713
(cell) 718-564-3894
mattera@udel.edu

Personnel with CTDB access include:

Sherri Weiser PhD	sherri.weiser-horwitz@nyumc.org; sw20@nyu.edu	View only	PI	Login Password
Gregg Ziemke PT	gwz1@cox.net	View only	Co-PI	
Marco Campello PhD	marco.campello@nyu.edu; marco.campello@nyumc.org	View only	Investigator	
Angela Lis PT PhD	angela.lis@nyumc.org	QA privileges only	Investigator	
Danielle Faulkner	faulkner@udel.edu	Data entry; QA privileges (full access required) -	Danielle will be doing reports and statistical analysis together with Rudi	
Rudi Hiebert	rhiebert@udel.edu	Data entry; QA privileges; export capability (full access required)	I will be doing reports and statistical analysis on the data	Hiebertr !Bruno123#
Chris Rennix ScD	christopher.p.rennix.civ@mail.mil	View only	Investigator	

Purging data of PII (Safe Harbor)

Purging of identifiable data will be done by the University of Delaware research staff according to DHHS 'Safe Harbor' specification. The following data are to be purged from data sets before analysis. Purging of the data take place on site at the Naval Medical Center, Portsmouth VA, Department of Occupational Therapy. The following fields are to be removed (https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#protected):

(A) Names;

(B) All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:

> (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
>
> (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000;

(C) All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(E) Fax numbers;

(M) Device identifiers and serial numbers;

(F) Email addresses;

(N) Web Universal Resource Locators (URLs);

(G) Social security numbers;

(O) Internet Protocol (IP) addresses;

(H) Medical record numbers;

(P) Biometric identifiers, including finger and voice prints;

(I) Health plan beneficiary numbers;

(Q) Full-face photographs and any comparable images;

(J) Account numbers;

(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section [Paragraph (c) is presented below in the section "Re-identification"]; and

(K) Certificate/license numbers.

Analysis data set design

The analysis data set is set up with where each row represents a subject, and columns represent the variables. The total number of rows in the data set equal the total number of subjects enrolled in the study. A separate variable serves as an allocator indicator (0=control carrier (USS Roosevelt) and 1 = intervention carrier (USS Truman))

A data dictionary for the analysis data set is in appendix XX.

Software packages used for the statistical analysis include: StatSoft, Inc. (2011). STATISTICA (data analysis software system), version 10. www.statsoft.com, and IBM Corp, SPSS, version 23. www. https://www.ibm.com

Calculation of scale scores

Outcomes

Expectations of recovery

"I believe that my condition is going to get better". This item was constructed by the research team and included based on the evidence that associates expectations with recovery.(15-17)

This is a *psychological* outcomes measure. This item appears in the baseline and the end-of-treatment questionnaire.

"I believe that my condition is going to get better." Q15 baseline

Q15 is a single item scored on an 11 point LIKERT scale from 0 – 10 where 0 = completely disagree and 10 = strongly agree.

Self efficacy

This item is adapted from the Core Outcome Measurements Index (COMI)(18): "I am confident I can cope with my condition" Self-efficacy has been associated with outcomes in military and civilian populations.(19)

This is a *psychological* outcomes measure. This item appears in the baseline and the end-of-treatment questionnaire.

"I am confident I can cope with my condition" Q16 baseline

Q16 is a single item scored on an 11 point LIKERT scale from 0 – 10 where 0 = completely disagree and 10 = strongly agree.

Fear of work activity

"It's really not safe for a person with a condition like mine to work." This item was adapted from the STarT Back Screening Tool.(13) This construct appears relevant to the carrier environment, which is physically demanding and hazardous.

This is a *psychological* outcomes measure. This item appears in the baseline and the end-of-treatment questionnaire.

"It's really not safe for a person with a condition like mine to work" Q17 baseline

Q17 is a single item scored on an 11 point LIKERT scale from 0 – 10 where 0 = completely disagree and 10 = strongly agree.

STarT Back Screen

the 5-item STarT Back Generic Screening Tool (SBT) which was originally intended for primary care providers to permit identification of patients at risk for poor outcome using the yellow flags with the highest prognostic values in this patient population.(13,14){Hill, 2008 #3621;Main, 2012 #3973} Scores range from 0 to 5 with patients scoring 4 or 5 being classified as "at risk". It is composed of five items: fear, anxiety, catastrophizing, depression and bothersomeness.

This is a *psychological* outcomes measure. This item appears in the baseline and the end-of-treatment questionnaire.

The PBPT study uses 5 item psychosocial subscale from the instrument

Item 18: It's **really not safe** for a person with a condition like mine to be **physically active**.
Item 19: **Worrying thoughts** have been going through my mind a lot of the time in the last **few days**.
Item 20: I feel that **my condition is terrible** and that **it is never going to get any better**.
Item 21: In general, in last **few days**, I have **not enjoyed** all the things I used to enjoy.
Item 22: Overall, how **bothersome** has your **condition** been in the **last few days**?

The items are scaled differently from the original instrument. Instead of a dichotomous agree- disagree we scale the items on an 11 point scale:

0 = completely disagree ---------- 10 = completely agree

They're collapsed just the same into a dichotomous scale, so the overall subscale scoring is still the same:

Item 18 It's **really not safe** for a person with a condition like mine to be **physically active**
Score as 0 if answer from 0 to 6 and 1 if answer from 7 to 10
= item 5 original

Item 19 **Worrying thoughts** have been going through my mind … in the last **few days**
Score as 0 if answer from 0-2 and 1 if answer 3 to 10
= item 6 original

Item 20 I feel that **my condition is terrible** and that **it is never going to get any better**
Score as 0 if answer 0-5 and 1 if answer 6 to 10
= item 7 original

Item 21 In general, in last **few days**, I have **not enjoyed** all the things I used to enjoy.
Score as 0 if answer 0-6 and 1 if answer 7 to 10
= item 8 original

Item 22 Overall, how **bothersome** has your **condition** been in the **last few days**?
Score as 0 if a little bit, slightly or moderately and as 1 if very much or extremely
= item 9 original

The total score then for the 5 items of the sTarT tool is the addition of the scores as rated 0 or 1, being 0 the minimum score and 5 the maximum score.

Reference: Beneciuk, J. M., Bishop, M. D., Fritz, J. M., Robinson, M. E., Asal, N. R., Nisenzon, A. N. and George, S. Z. (2012) 'The STarT Back Screening Tool and individual psychological measures: evaluation of prognostic capabilities for low back pain clinical outcomes in outpatient physical therapy settings' Physical Therapy

Reference: Main, C. J., G. Sowden, et al. (2012). "Integrating physical and psychological approaches to treatment in low back pain: the development and content of the STarT Back trial's 'high-risk' intervention (StarT Back; ISRCTN 37113406)." Physiotherapy 98(2): 110-116.

Appendix A. The Keele STarT Back Screening Tool

Patient name: _____ Date: _____

Thinking about the **last 2 weeks,** tick your response to the following questions:

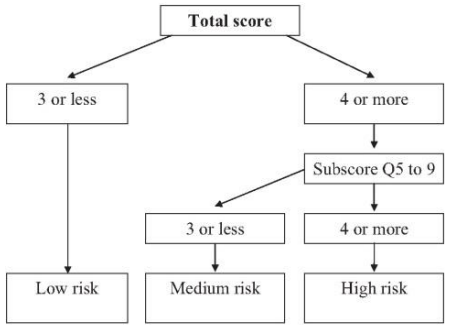
		Disagree 0	Agree 1
1	My back pain has **spread down my leg(s)** at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It is not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible** and **it is never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
☐ 0	☐ 0	☐ 0	☐ 1	☐ 1

Total score (all 9): _____ **Subscore (Q5 to 9):**_____

The STarT Back Tool Scoring System



Quality of Life

"Compared to your quality of life before your injury, please rate your quality of life now". This item was adapted from the SF-12.(20) Quality of life is a recommended outcome measure for studies involving patients with MSI.(21)

This is a *psychological* outcomes measure. This item appears does not appear in the baseline questionnaire

Perceived disability

"How much does your condition interfere with your usual activities, including work?" This item was adapted from COMI(18). Perceived disability is a recommended outcome measure for studies involving patients with MSI.(21)

This is a *psychological* outcomes measure. This item appears in the baseline and the end-of-treatment questionnaire.

"How much does your condition interfere with your usual activities, including work?" " Q23 baseline

Q23 is a single item scored on an 11 point LIKERT scale from 0 – 10 where 0 = completely disagree and 10 = strongly agree.

Pain interference (DVPRS)

Defense and Veterans Pain rating Scale (DVPRS) is an instrument designed to assess pain in military populations. Preliminary validation studies have found acceptable reliability and validity in the military and veterans population (Cronbach's alpha >0.8 and Pearson's r ranging from 0.6 to 0.9).(22)"

This is a *pain interference* outcomes measure.

Questions 11 to 14: DVPRS supplemental questions.

Score system: The supplemental scales are score as a "mean summary score".

Reference: Buckenmaier CC, 3rd, Galloway KT, Polomano RC, McDuffie M, Kwon N, Gallagher RM. Preliminary validation of the Defense and Veterans Pain Rating Scale (DVPRS) in a military population. Pain medicine 2013;14(1):110-23.

Satisfaction with process of care

This is a *process* outcomes measure. This item does not appear in the baseline questionnaire.

Measured by the "process of care" subscale of The MedRisk Instrument for Measuring Patient Satisfaction (MRPS).This subscale measures the patient's assessment of the interaction with the therapist which is relevant to the study. The rating scale of each item goes from 1 to 5 where 1 is 'strongly disagree' and 5 is 'strongly agree.' The score is calculated as the sum of the item scores where a higher score represents higher satisfaction.

Reference: Beattie P, Turner C, Dowda M, et al. The MedRisk instrument for measuring patient satisfaction with physical therapy care: A psychometric analysis. J Orthop Sports Phys Ther. 2005;35:24-32.

Outcome satisfaction

This is an outcomes measure of patient satisfaction with their condition. This item does not appear in the baseline questionnaire.

'If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it? This is derived from the COMI questionnaire (18) Outcome satisfaction is a recommended outcome measure for studies involving patients with MSI.(25)

Potential Confounders

Organizational Commitment

Question B24 - B27- Organizational Commitment (affective subscale), developed from Gade, Tiggle and Schumm.

Scoring: 5-point rating scale ranging from 1 (*Strongly Disagree*) to 5 (*Strongly Agree*).
Higher scores on the affective commitment scale are indicative of higher levels of attachment to the military.

Total score= The Commitment scale is determined by summing the scores of the four items.

Reference: Gade , P. A. Tiggle , R. B. Schumm , W. (2003 /this issue). The measurement and consequences of military organizational commitment in soldiers and spouses. Military Psychology, 15, 191-207.

Unit Support

Question B28 - B39 – DRRI, Section F, Unit Support.

Scoring: The items are scored as Likert scale, from "1 = strong disagree" to "5 = strongly agree" and are combined in an additive fashion to form a unit support score.

DEPLOYMENT SOCIAL SUPPORT [Section F: Unit Support]	5-point Likert scale (1 = Strongly disagree; 5 = Strongly agree). Sum item scores. Possible range is 12 to 60; higher scores are indicative of greater perceived support and cohesion with regard to the military in general, leaders, and fellow unit members.

Reference: King, D. W., King, L. A., & Vogt, D. S. (2003). Manual for the Deployment Risk and Resilience Inventory (DRRI): A Collection of Measures for Studying Deployment-Related Experiences of Military Veterans. Boston, MA: National Center for PTSD.

PTSD

Questions 40-56: PCLM measuring Post-Traumatic Stress Disorder.

Scoring: Add up all the items for a total severity score

Items are rated on a 5-point scale ranging from 1 ("not at all") – 5 ("extremely") with a total score range of 17– 85. A score of 50 or greater indicates clinically significant symptoms.

Reference: Weathers, F. W., Litz, B. T., Herman, D. S., Huska, J. A., & Keane, T. M. (1993). The PTSD Checklist (PCL): Reliability, validity, and diagnostic utility. Paper presented at the Annual Meeting of the International Society for Traumatic Stress Studies, San Antonio, TX.

Depression

Questions 57-76: CES-D measuring Depression.

Scoring: Each of the 20 items in this instrument is assigned one value of 0, 1, 2 or 3. The values are assigned as follows:

Rarely or none of the time (less than 1 day) = 0
Some or a little of the time (1-2 days) = 1
Occasionally or a more moderate amount of the time (3-4 days) = 2
More or all of the time (5-7 days) = 3

There are four items with reversed scoring –
60. I felt that I was just as good as other people.
64. I felt hopeful about the future.
68. I was happy.
72. I enjoyed life.

For the four items with reversed scoring, the values should be assigned as follows:
Rarely or none of the time (less than 1 day) = 3
Some or a little of the time (1-2 days) = 2
Occasionally or a more moderate amount of the time (3-4 days) = 1
More or all of the time (5-7 days) = 0

Once you have assigned a value for each item, compute a total, adding the values for each of the 20 items. The resulting score should range between 0 and 60. Do not compute a total if there is more than one answer missing.

High scores on the CES-D indicate high levels of distress. A score ≥ 16 suggests a clinically significant level of psychological distress. A score of 16 or greater indicates clinically significant distress and was used as a criterion for exclusion in the RCT and referral for treatment.

References:
Hann, D., Winter, K., & Jacobsen, P. (1999) Measurement of depressive symptoms in cancer patients. Evaluation of the Center for Epidemiological Studies Depression Scale (CES-D). Journal of Psychosomatic Research, 46, 437-443.

Radloff, L.S. (1977). The CED-D scale: A self-report depression scale for research in the general population. Applied Psychological Measurement, 1, 385-401.

Anxiety: GAD-7

Questions 77-83: GAD-7 measuring anxiety.

Each item is scaled:
0 = Not at all; 1 = Several days; 2 = More than half the days; 3 = Nearly every day

Scoring: The total score is simply the sum of question items one through seven. Scores of 5, 10 and 15 are taken as the cut off points for mild, moderate, and severe anxiety respectively. When used as a screening tool, further evaluation is recommended should the score be ten or greater.

The maximum score of the GAD-7 is 21, lower scores are better. Scores are assigned in the following manner:

Normal	Mild	Moderate	Severe
0 - 4	5 - 9	10 - 14	15 - 21

References: Spitzer, R.L, Kroenke, K. & Williams, J.B. *et al.* A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch. Intern. Med.* 2006: 166:1092-7.

Job Satisfaction

Five point Likert scale, 1 (i.e. very dissatisfied) to 5 (i.e. very satisfied)

Job Stress

Score: Five point Guttmann scale, 1 (i.e. extremely stressful) to 5 (i.e. not stressful at all).

Issues encountered during the study

1. The investigators were unable to retrieve race/ethnicity, rate and rank information, job title, information from the US Navy. The investigators were relying on extracting these data from AHLTA; however, electronic medical and personnel records from the intervention and control carriers could not be uploaded from the ships before the end of the study approvals. Furthermore, these data were not captured by the subject questionnaires administered on board the respective ships. These data are not available for analysis.

2. The investigators were unable to retrieve diagnosis and procedure codes (ICD and CPT codes) from the ship's medical electronic records, again, because of a fault in transferring these data from the two respective ships to onshore AHLTA system. Verification of the main complaint of the enrolled subject by means of electronic ICD coding could not take place, and analysis of the data by ICD diagnosis code could not take place.

3. US Navy Institutional Review Board required the investigators to change the protocol to reflect two different informed consent forms, one tailored for each carrier. This revision was not approved until the Control carrier had departed and was already on station. Therefore, an analysis of the phase of deployment on outcomes in this study is not possible. The control

carrier collected data only when it was on station; the intervention carrier collected data during the outbound transit and on station. Neither carrier collected new cases during the return transit.

4. 'Black Flags' that is, workplace and work environment factors that may affect risk of subsequent disability, could not be collected, again, because of the fault in transferring electronic medical records from the ship back to shore after deployment.

5. The control carrier physical therapist maintained a completed study log; however, notes of encounters by sailors and marines that did not meet the inclusion criteria were not recorded. The intervention carrier PT maintained a study log of all encounters for a MSI complaint; therefore a comparison between the control and intervention carrier of all subjects making an initial visit to PT and those enrolling in the study cannot be made.

Subject self-administered questionnaire, enrollment

Name: _____D.O.B:_____ SSN#_____
Job Title/Rate: _____

Current Tobacco Smoking Status

1. Do you currently smoke tobacco on a daily basis, less than daily, or not at all?
   Daily…….□ Continue with question 3
   Less than daily……..□ Continue with question 2a
   Not at all……..…….□ Continue with question 2b
   Don't know…… ……..□ Continue with question 3

Past Daily Tobacco Smoking Status

2. a. Have you smoked tobacco daily in the past?
   Yes……...…….…….□ Continue with question 3
   No……...…..……..□ Continue with question 3
   Don't know.……..……□ Continue with question 3

Past Smoking Status

b. In the past have you smoked tobacco on a daily basis, less than daily or not at all?
   Daily…….□ Continue with question 3
   Less than daily……..□ Continue with question 3
   Not at all……..…….□ Continue with question 3
   Don't know…… ……..□ Continue with question 3

Current Level of education

3. What is the highest level of formal education that you have completed? Please choose only **ONE** of the following options:

☐ Doctoral or professional degree

☐ Master's degree

☐ Bachelor's degree

☐ Associate's degree

☐ Postsecondary non-degree award

☐ Some college, no degree

☐ High school diploma or equivalent

☐ Less than high school

Pain Description

4. What is the main reason for which you are seeking care?

Please choose only **ONE** of the following options:

- ☐ None
- ☐ Low back pain problem
- ☐ Neck problem
- ☐ Mid-back problem
- ☐ Shoulder problem
- ☐ Arm or hand problem
- ☐ Hip problem
- ☐ Knee problem
- ☐ Ankle or foot problem
- ☐ Other (specify):

5. For how long have you had this current complaint?

- ☐ Less than 4 weeks
- ☐ 4 weeks to 12 weeks
- ☐ More than 12 weeks

6. How often do you have pain?

- ☐ Never
- ☐ On some days
- ☐ On most days
- ☐ Every day

7. Prior to this visit, have you sought care for this complaint within the past 30 days?

- ☐ Yes
- ☐ No

8. Have you ever had this same complaint before?

- ☐ Yes,

No

- ☐ B.If yes to 8A were you pain free for 30 days prior to the onset of this current episode?

9. Please indicate the intensity of the pain of your main complaint on a scale of 0 to 10, where 0 means "no pain" and 10 means "the worst pain imaginable"

0	1	2	3	4	5	6	7	8	9	10

No pain Worst pain Imaginable

10. Aside from your main complaint, please mark any other complaints. Choose **ALL** that apply:

- ☐ None
- ☐ Low back pain problem
- ☐ Neck problem
- ☐ Mid-back problem
- ☐ Shoulder problem
- ☐ Arm or hand problem
- ☐ Hip problem
- ☐ Knee problem
- ☐ Ankle or foot problem
- ☐ Other (specify):

Attitudes about Pain

Thinking about your **MAIN** complaint. Please answer the following questions.

11. Circle the one number that describes how, during the past 24 hours, pain has interfered with your usual ACTIVITY:

Does not interfere Completely interferes

0	1	2	3	4	5	6	7	8	9	10

12. Circle the one number that describes how, during the past 24 hours, pain has interfered with your SLEEP:

Does not interfere Completely interferes

0	1	2	3	4	5	6	7	8	9	10

13. Circle the one number that describes how, during the past 24 hours, pain has affected with your MOOD:

Does not affect										Completely affects
0	1	2	3	4	5	6	7	8	9	10

14. Circle the one number that describes how, during the past 24 hours, pain has contributed to your STRESS:

Does not contribute										Contributes a great deal
0	1	2	3	4	5	6	7	8	9	10

For each of the following, thinking about the last few days, **circle** the number that indicates how much you agree or disagree with the following statements.

15. I believe that my condition is going to get better.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

16. I am confident I can cope with my condition.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

17. It's really not safe for a person with a condition like mine to work.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

18. It's **really not safe** for a person with a condition like mine to be **physically active**.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

19. **Worrying thoughts** have been going through my mind a lot of the time in the last **few days**.

Completely disagree — Strongly agree

0	1	2	3	4	5	6	7	8	9	10

20. I feel that **my condition is terrible** and that **it is never going to get any better**.

Completely disagree — Strongly agree

0	1	2	3	4	5	6	7	8	9	10

21. In general, in last **few days**, I have **not enjoyed** all the things I used to enjoy.

Completely disagree — Strongly agree

0	1	2	3	4	5	6	7	8	9	10

22. Overall, how **bothersome** has your **condition** been in the **last few days**?

Not at all ☐ Slightly ☐ Moderately ☐ Very much ☐ Extremely ☐

23. How much does your condition interfere with your usual activities, including work?

Not at all ☐ Slightly ☐ Moderately ☐ Very much ☐ Extremely ☐

Questions about your job

Check the box that indicates how much you agree or disagree with the following statements:

24. I feel like "part of the family" in the military.

Strongly Agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly Disagree ☐

25. The military has a great deal of personal meaning for me.

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
☐	☐	☐	☐	☐

26. I feel a strong sense of belonging to the military.

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
☐	☐	☐	☐	☐

27. I feel emotionally attached to the military.

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
☐	☐	☐	☐	☐

The statements below are about your relationships with other military personnel while you have been deployed. Please read each statement and describe how much you agree or disagree by **circling** the number that best fits your answer

28. My unit is like family to me.

Strongly Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
1	2	3	4	5

29. I feel a sense of camaderie between myself and other soldiers in my unit.

Strongly Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
1	2	3	4	5

30. Members of my unit understand me.

Strongly Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
1	2	3	4	5

31. Most people in my unit are trustworthy.

Strongly Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
1	2	3	4	5

32. I can go to most people in my unit for help when I have a personal problem.

Strongly Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
1	2	3	4	5

33. My supervisors (s) are interested in how I think and how I feel about things.

Strongly Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
1	2	3	4	5

34. I am impressed by the quality of leadership in my unit.

Strongly Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
1	2	3	4	5

35. My superiors make a real attempt to treat me as a person.

Strongly Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
1	2	3	4	5

36. The supervisor (s) in my unit are supportive of my efforts.

Strongly Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
1	2	3	4	5

37. I feel like my efforts really count to the military.

Strongly Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
1	2	3	4	5

38. The military appreciates my service.

Strongly Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
1	2	3	4	5

39. I am supported by the military.

Strongly Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
1	2	3	4	5

Stress Symptoms

Below is a list of problems and complaints that veterans sometimes have in response to stressful life experiences. Please read each one carefully, mark the answer to indicate how much you have been bothered by that problem in the **last month**.

DURING THE LAST MONTH:	**Not at all**	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
37. Repeated, disturbing memories, thoughts, or images of a stressful military experience from the past?	1	2	3	4	5
38. Repeated, disturbing dreams of a stressful military experience from the past?	1	2	3	4	5
39. Suddenly acting or feeling as if a stressful military experience were happening again (as if you were reliving it)?	1	2	3	4	5
40. Feeling very upset when something reminded you of a stressful military experience from the past?	1	2	3	4	5
41. Having physical reactions (e.g., heart pounding, trouble breathing, or sweating) when something	1	2	3	4	5

reminded you of a stressful military experience from the past?					
DURING THE LAST MONTH:	**Not at all**	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
42. Avoiding thinking about or talking about a stressful military experience from the past or avoid having feelings related to it?	1	2	3	4	5
43. Avoid activities or situations because they remind you of a stressful military experience from the past?	1	2	3	4	5
44. Trouble remembering important parts of a stressful military experience from the past?	1	2	3	4	5
45. Loss of interest in things that you used to enjoy?	1	2	3	4	5
46. Feeling distant or cut off from other people?	1	2	3	4	5
47. Feeling emotionally numb or being unable to have loving feelings for those close to you?	1	2	3	4	5
48. Feeling as if your future will somehow be cut short?	1	2	3	4	5
49. Trouble falling or staying asleep?	1	2	3	4	5
50. Feeling irritable or having angry outbursts?	1	2	3	4	5
51. Having difficulty concentrating?	1	2	3	4	5
52. Being “super alert” or watchful on guard?	1	2	3	4	5

53. Feeling jumpy or easily startled?	1	2	3	4	5

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way **during the past week**.

DURING THE PAST WEEK:	**Rarely or none of the time (less than 1 day)**	**Some or a little of the time (1-2 days)**	**Occasionally or a moderate amount of time (3-4 days)**	**Most or all of the time (5-7 days)**
54. I was bothered by things that usually don't bother me.	0	1	2	3
55. I did not feel like eating; my appetite was poor.	0	1	2	3
56. I felt that I could not shake off the blues even with help from my family or friends.	0	1	2	3
57. I felt that I was just as good as other people.	3	2	1	0
58. I had trouble keeping my mind on what I was doing.	0	1	2	3
59. I felt depressed.	0	1	2	3
60. I felt that everything I did was an effort.	0	1	2	3
61. I felt hopeful about the future.	3	2	1	0
62. I thought my life had been a failure.	0	1	2	3
63. I felt fearful.	0	1	2	3
64. My sleep was restless.	0	1	2	3
65. I was happy.	3	2	1	0
66. I talked less than usual.	0	1	2	3
67. I felt lonely.	0	1	2	3
68. People were unfriendly.	0	1	2	3
69. I enjoyed life.	3	2	1	0
70. I had crying spells.	0	1	2	3
71. I felt sad.	0	1	2	3
72. I felt that people disliked me.	0	1	2	3

73. I could not get "going."	0	1	2	3

Over the last **2 weeks**, how often have you been bothered by the following problems? Please read each statement and **circle** the number that best fits your answer.

	Not at all	Several days	More than half the days	Nearly every day
74. Feeling nervous, anxious or on edge	0	1	2	3
75. Not being able to stop or control worrying	0	1	2	3
76. Worrying too much about different things	0	1	2	3
77. Trouble relaxing	0	1	2	3
78. Being so restless that it is hard to sit still	0	1	2	3
79. Becoming easily annoyed or irritable	0	1	2	3
80. Feeling afraid as if something awful might happen	0	1	2	3

81. Taking everything into consideration, how do you feel about your job as a whole?

- ☐ Very satisfied
- ☐ Somewhat satisfied
- ☐ Mixed (About equally satisfied & dissatisfied)
- ☐ Somewhat dissatisfied
- ☐ Very dissatisfied

82. Taking everything into consideration, how stressful is your job as a whole?

☐ Extremely stressful
☐ Stressful
☐ Moderately stressful
☐ Slightly stressful
☐ Not stressful at all

Treatment concerns

83. Please list any barriers aboard the carrier that you think may prevent you from receiving the care that you think you need:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Subject self-administered questionnaire, end of treatment

Name: _____D.O.B:_____ SSN#_____

Job Title/Rate: _____

Pain Description

25. What is the main reason for which you are seeking care?

Please choose only **ONE** of the following options:

- ☐ None
- ☐ Low back pain problem
- ☐ Neck problem
- ☐ Mid-back problem
- ☐ Shoulder problem
- ☐ Arm or hand problem
- ☐ Hip problem
- ☐ Knee problem
- ☐ Ankle or foot problem
- ☐ Other (specify):

26. Please indicate the intensity of the pain of your main complaint on a scale of 0 to 10, where 0 means "no pain" and 10 means "the worst pain imaginable"

0	1	2	3	4	5	6	7	8	9	10

No pain — Worst pain imaginable

Attitudes about Pain

Thinking about your **MAIN** complaint. Please answer the following questions.

27. **Circle** the one number that describes how, during the past 24 hours, pain has interfered with your usual ACTIVITY:

Does not interfere — Completely interferes

0	1	2	3	4	5	6	7	8	9	10

28. **Circle** the one number that describes how, during the past 24 hours, pain has interfered with your SLEEP:

Does not interfere										Completely interferes
0	1	2	3	4	5	6	7	8	9	10

5. **Circle** the one number that describes how, during the past 24 hours, pain has affected with your MOOD:

Does not affect										Completely affects
0	1	2	3	4	5	6	7	8	9	10

6. **Circle** the one number that describes how, during the past 24 hours, pain has contributed to your STRESS:

Does not contribute										Contributes a great deal
0	1	2	3	4	5	6	7	8	9	10

For each of the following, thinking about the last few days, **circle** the number that indicates how much you agree or disagree with the following statements.

7. I believe that my condition is going to get better.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

8. I am confident I can cope with my condition.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

9. It's really not safe for a person with a condition like mine to work.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

10. It's **really not safe** for a person with a condition like mine to be **physically active**.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

11. **Worrying thoughts** have been going through my mind a lot of the time in the last **few days**.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

12. I feel that **my condition is terrible** and that **it is never going to get any better**.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

13. In general, in last **few days**, I have **not enjoyed** all the things I used to enjoy.

Completely disagree										Strongly agree
0	1	2	3	4	5	6	7	8	9	10

14. Overall, how **bothersome** has your **condition** been in the **last few days**?

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐

15. How much does your condition interfere with your usual activities, including work?

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐

16. Compared to your quality of life before your injury, please rate your quality of life now.

Very Good	Good	Fair	Poor	Very poor
☐	☐	☐	☐	☐

<u>Information about satisfaction with care</u>

Please answer the questions below by ***circling*** the response which best describes your opinions about your treatment.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
17. My therapist spent enough time with me.	1	2	3	4	5
18. My therapist thoroughly explained the treatment(s) I received.	1	2	3	4	5
19. My therapist was respectful.	1	2	3	4	5

20. The therapist's assistant/aide was respectful (if applicable).	1	2	3	4	5
21. My therapist did not listen to my concerns.	1	2	3	4	5
22. My therapist answered all my questions.	1	2	3	4	5
23. My therapist advised me on ways to stay healthy and avoid future problems.	1	2	3	4	5
24. My therapist gave me detailed instructions regarding my home exercise program.	1	2	3	4	5

25. If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it?

Very satisfied	Somewhat dissatisfied	Neither satisfied nor dissatisfied	Somewhat satisfied	Very dissatisfied
☐	☐	☐	☐	☐

26. Please list the most important things you learned in physical therapy:

_____

_____

_____

_____

_____

_____

_____

_____

Procedures for computerizing subject self-administered questionnaires into BADER CTDB

Subject questionnaire data entry procedures

Accessing CTDB

Point your internet browser to: https://ctdb.nichd.nih.gov/bader/welcome.jsp

If you have an existing login and password, enter those now

If you do not have a login and password, one will need to be assigned to you by the NIH

The point of contact for requesting login and password credentials is Michelle Mattera Keon, MBE. Her colleague and the NIH responsible for login credential management is

Frank Velez
NIH/NICHD Contractor
Technical Frontiers Inc.
315-222-4433

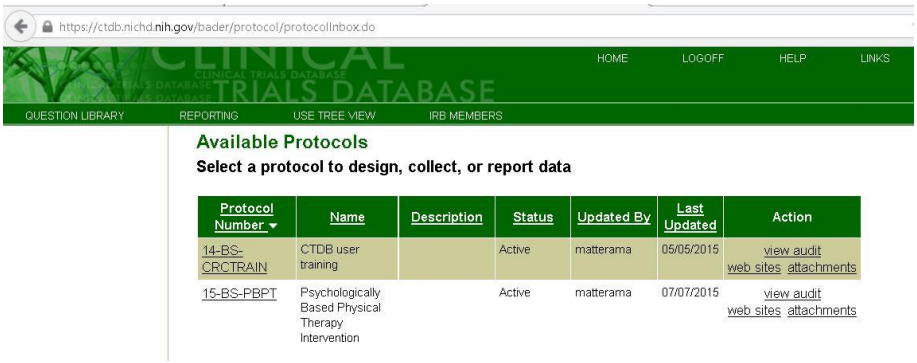
Once assigned a username and a temporary password, access the site. You will be asked to create a new password, and select and provide answers to 3 security questions, e.g. for Rudi Hiebert:

Adding a new subject

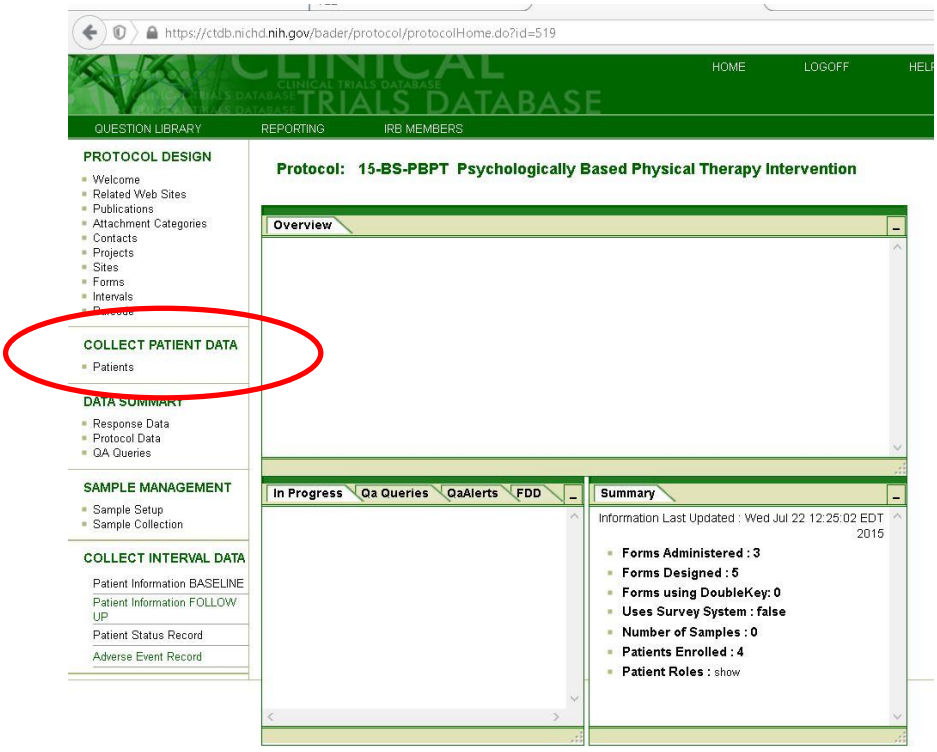
Use the following steps to add a new subject to the CTDB:

1. Login in to the CTDB

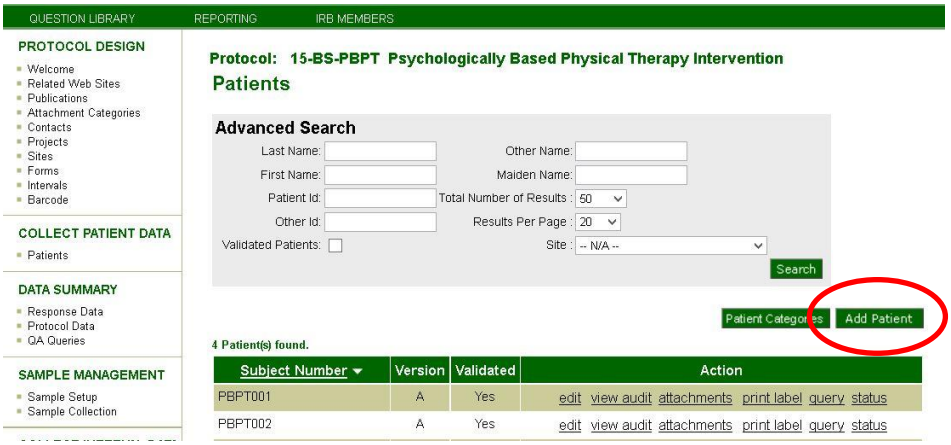
2. Select PBPT protocol.



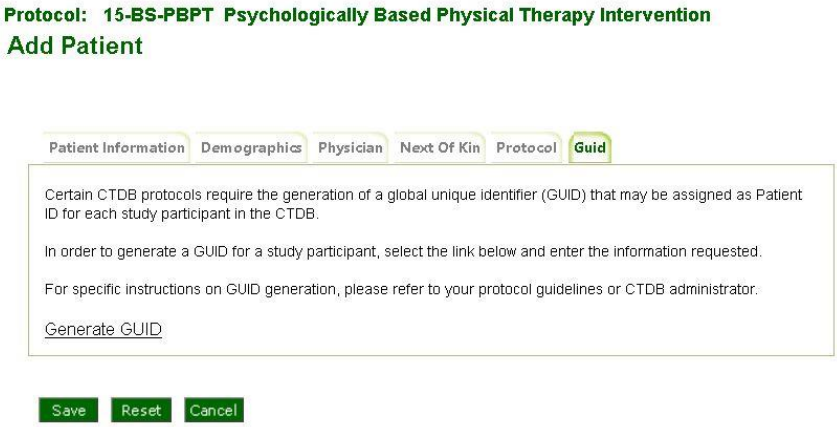
3. Under the left hand column, section “Collect Patient Data”, click ‘Patients’



4. Click the ‘Add Patient’ button



5. Click the 'Generate GUID' link on the GUID tab

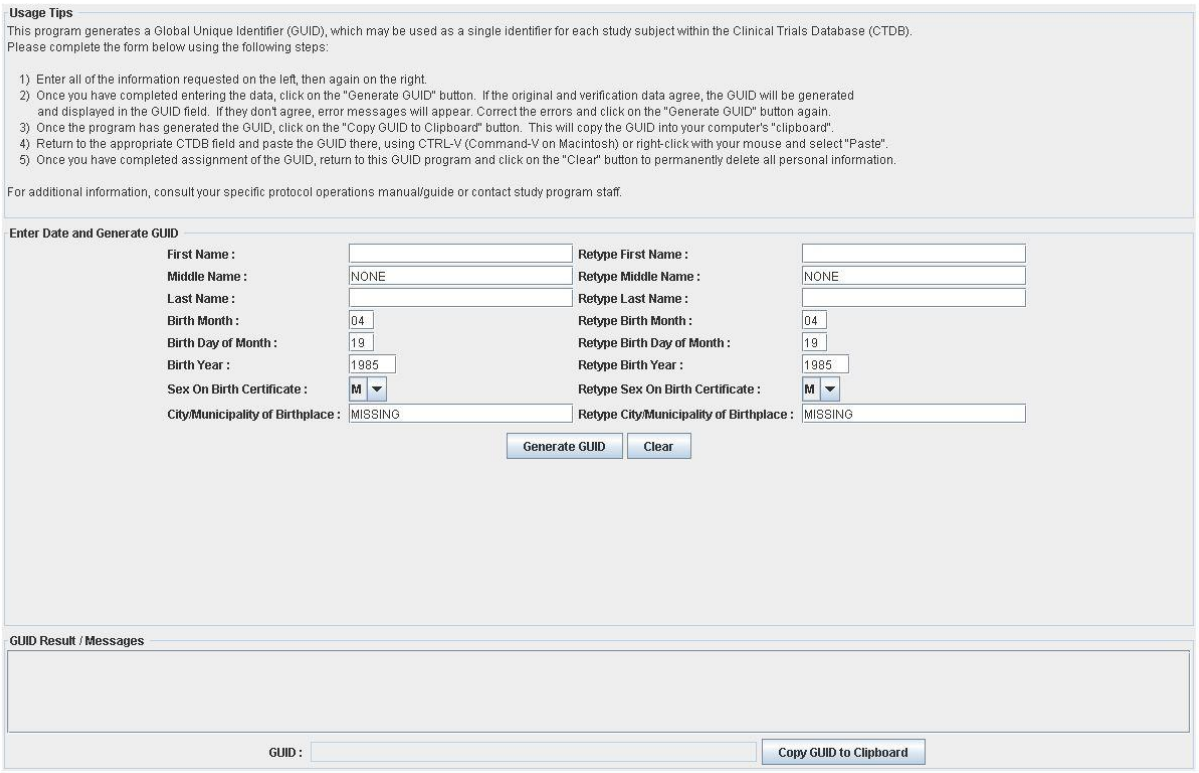


Input subject first name, last name, month of birth, year of birth, and place of birth. These data are collected on the self-administered questionnaire forms approved for the intervention carrier.

The web page will generate a GUID for the subject. Highlight and copy the GUID.
Note that the questionnaires for the subjects on board the control carrier do not capture date and place of birth. For these subjects a temporary GUID will be required to be entered.

Steps to Creating a Temporary GUID

- Type MISSING into each field for which the PII is missing.



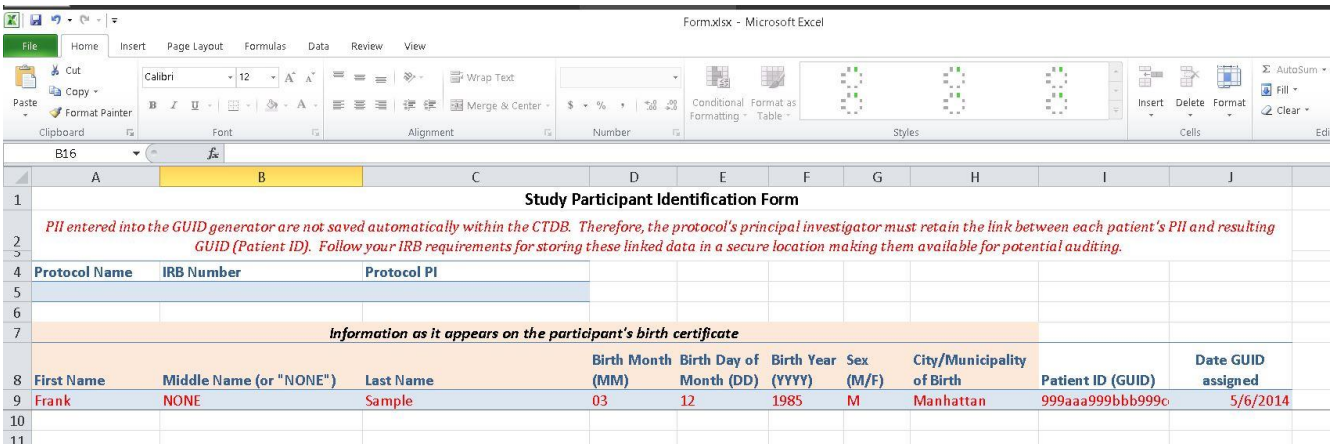
- After the GUID is generated and copied to the Patient ID field, add a T to the end of the generated GUID. For example, a temporary GUID might look like:

  d9327ca6acff9bb40064ed9d6554ba5b27a07b85 T

6. Add data to the study participant identification log
   Open “Study Participant Identification Form.xlsx” This form serves as the separate log that links GUIDs with PHI data. This form is a protected form. It is stored on the desktop on a US Navy computer at the Spine Research office in the Department of Physical Therapy (a locked office).

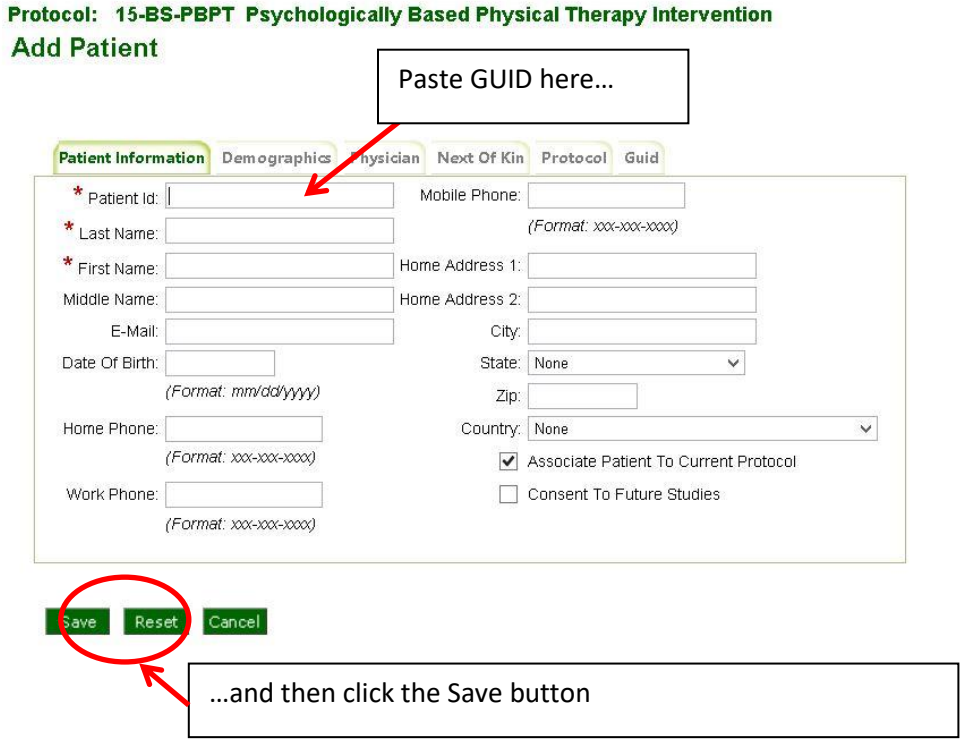
   Fill in the first and last name columns, birth month, birth day and year, gender. Replace subject middle name with “NONE”.

   Replace City/Municipality of Birth column with “MISSING” in the case of a subject being assigned a temporary GUID. Fill in the date GUID assigned column.

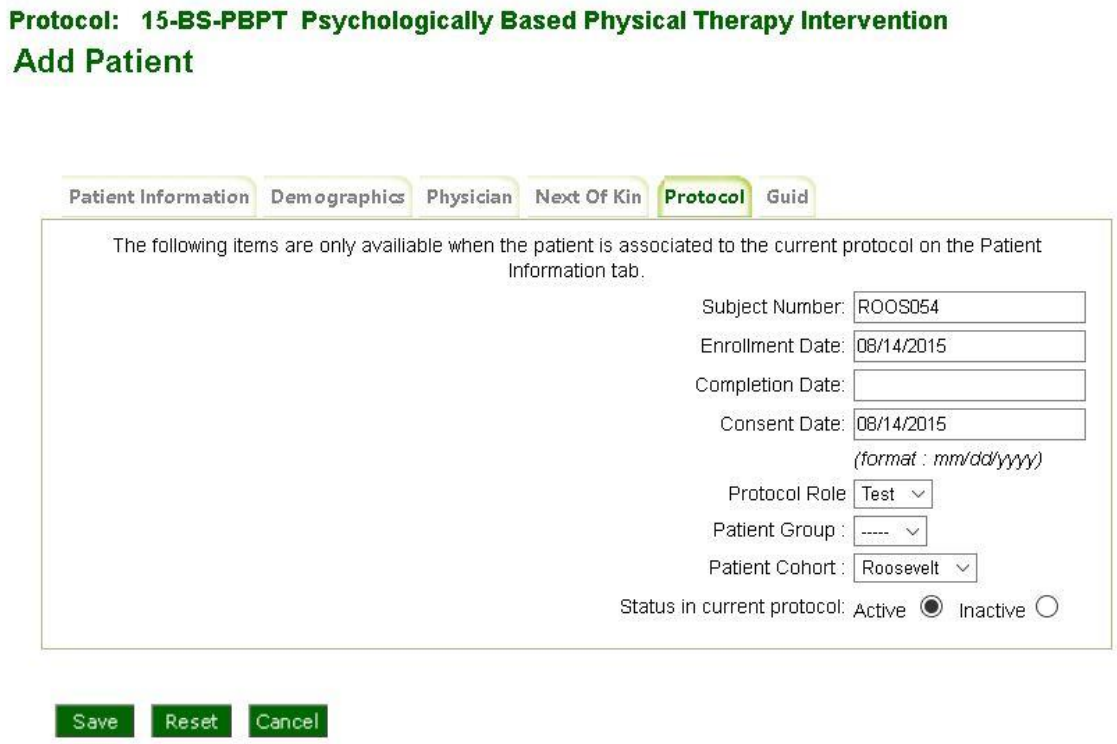


	A	B	C	D	E	F	G	H	I	J
1	Study Participant Identification Form									
2	*PII entered into the GUID generator are not saved automatically within the CTDB. Therefore, the protocol's principal investigator must retain the link between each patient's PII and resulting GUID (Patient ID). Follow your IRB requirements for storing these linked data in a secure location making them available for potential auditing.*									
4	**Protocol Name**	**IRB Number**	**Protocol PI**							
5										
6										
7			***Information as it appears on the participant's birth certificate***							
8	**First Name**	**Middle Name (or "NONE")**	**Last Name**	**Birth Month (MM)**	**Birth Day of Month (DD)**	**Birth Year (YYYY)**	**Sex (M/F)**	**City/Municipality of Birth**	**Patient ID (GUID)**	**Date GUID assigned**
9	Frank	NONE	Sample	03	12	1985	M	Manhattan	999aaa999bbb999c	5/6/2014
10										
11										

7. Return back to the CTDB. Click on the Patient Information tab. Paste the GUID into the Patient ID field. Replace “last name” with “LAST” and “First name” with “FIRST”. Ensure the “Associate patient to current protocol” is checked. Click Save.



8 . Click on the Protocol tab. Replace the subject number field with subject number assigned by the researcher on board ship. The subject number is preceded by “ROOS” if the data were collected on board the USS Roosevelt (control carrier) and “TRUM” if the data were collected on board the USS Truman (intervention carrier):

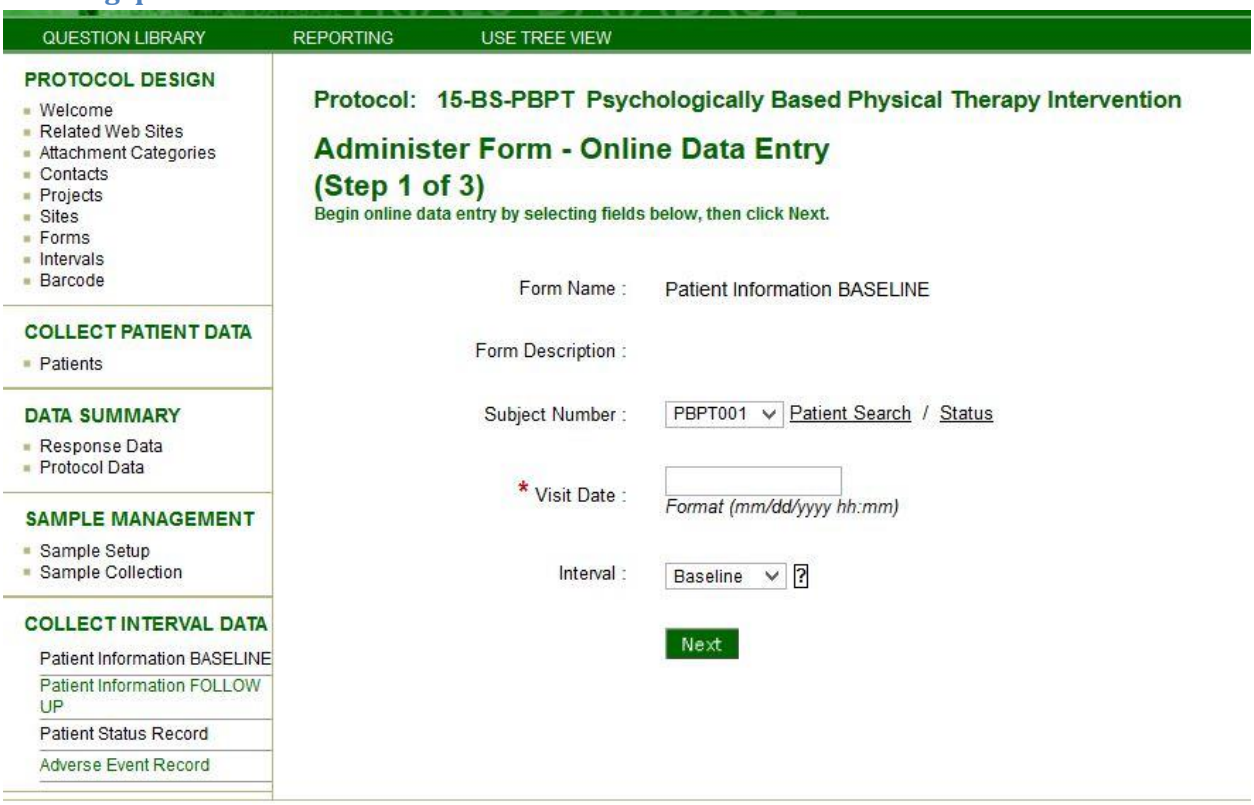


Fill in the enrollment date and the consent date. For this study the enrollment date is the same as the date of consent. The date of consent is the date the informed consent form was completed, and is found on the informed consent form. The protocol role is "Test" and the patient cohort should be set to the ship where the data were collected for the subject.

Replacing the temporary GUID

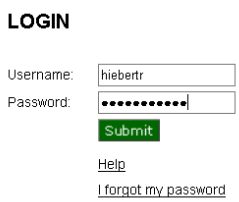
When you have obtained all of the PII, you will replace the temporary GUID with the permanent GUID. Do not create a new patient record. In the CTDB patient module, find and open the patient record whose GUID you wish to change. Use the GUID applet to generate a permanent GUID and paste it into the Patient ID field to replace the temporary GUID. A pop-up window will request a reason for the change. Type Replaced temporary GUID with permanent GUID and click Save.

Entering questionnaire data

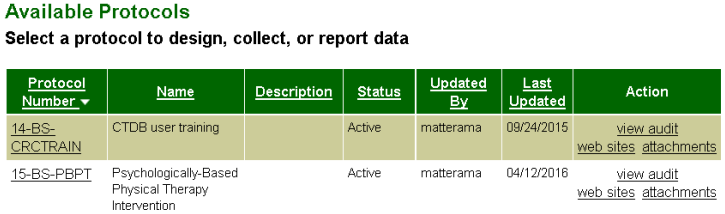


Extracting subject questionnaire data

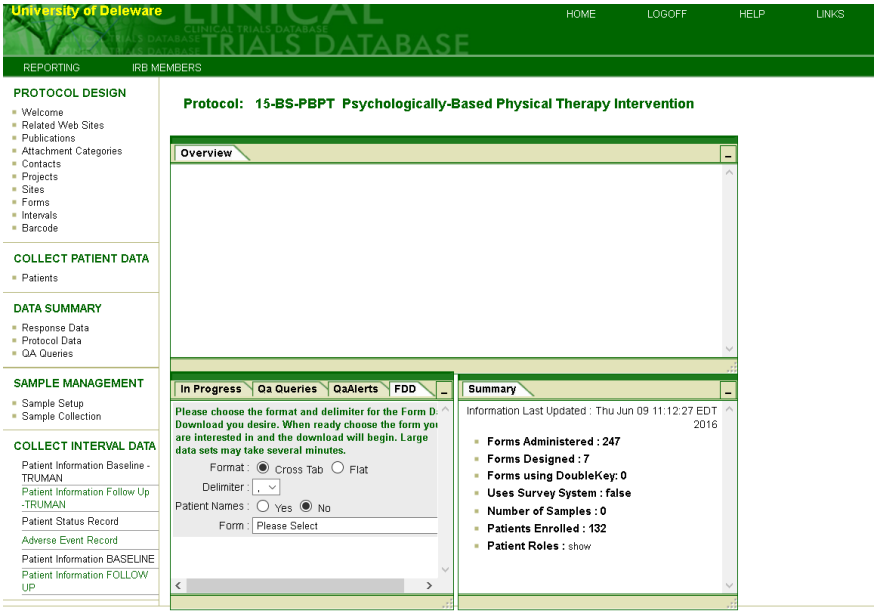
Step 1: Log into the system



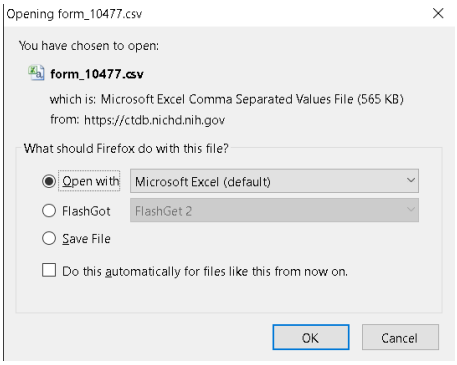
Step 2: Select PBPT



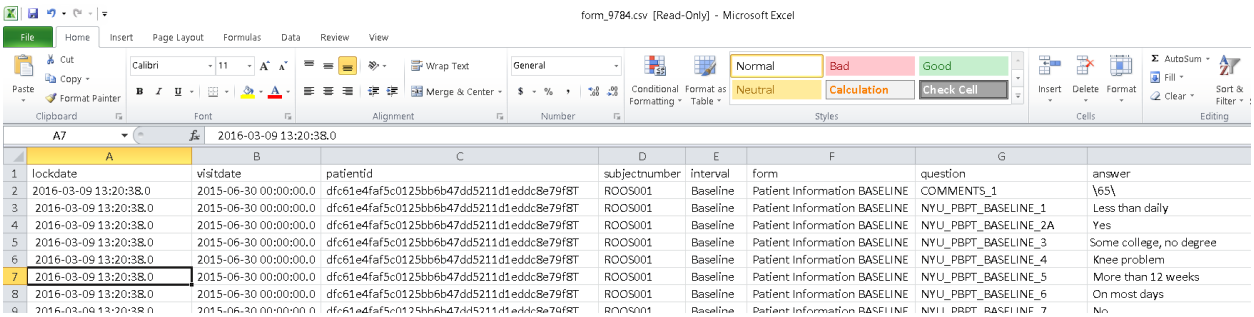
Step 3: Select FDD from the Protocol summary page



On the FDD tab, chose Format: “Flat”; Delimiter “,”; Patient names: “Yes” (this gives the scrambled ID number, not the actual identifier); and select form (e.g. “patient information baseline” – this is for the Roosevelt)Step 4: Open the file or save it locally



This is the resultant file



	A	B	C	D	E	F	G	
1	lockdate	visitdate	patientid	subjectnumber	interval	form	question	answer
2	2016-03-09 13:20:38.0	2015-06-30 00:00:00.0	dfc61e4faf5c0125bb6b47dd5211d1eddc8e79f8T	ROOS001	Baseline	Patient Information BASELINE	COMMENTS_1	\65\
3	2016-03-09 13:20:38.0	2015-06-30 00:00:00.0	dfc61e4faf5c0125bb6b47dd5211d1eddc8e79f8T	ROOS001	Baseline	Patient Information BASELINE	NYU_PBPT_BASELINE_1	Less than daily
4	2016-03-09 13:20:38.0	2015-06-30 00:00:00.0	dfc61e4faf5c0125bb6b47dd5211d1eddc8e79f8T	ROOS001	Baseline	Patient Information BASELINE	NYU_PBPT_BASELINE_2A	Yes
5	2016-03-09 13:20:38.0	2015-06-30 00:00:00.0	dfc61e4faf5c0125bb6b47dd5211d1eddc8e79f8T	ROOS001	Baseline	Patient Information BASELINE	NYU_PBPT_BASELINE_3	Some college, no degree
6	2016-03-09 13:20:38.0	2015-06-30 00:00:00.0	dfc61e4faf5c0125bb6b47dd5211d1eddc8e79f8T	ROOS001	Baseline	Patient Information BASELINE	NYU_PBPT_BASELINE_4	Knee problem
7	2016-03-09 13:20:38.0	2015-06-30 00:00:00.0	dfc61e4faf5c0125bb6b47dd5211d1eddc8e79f8T	ROOS001	Baseline	Patient Information BASELINE	NYU_PBPT_BASELINE_5	More than 12 weeks
8	2016-03-09 13:20:38.0	2015-06-30 00:00:00.0	dfc61e4faf5c0125bb6b47dd5211d1eddc8e79f8T	ROOS001	Baseline	Patient Information BASELINE	NYU_PBPT_BASELINE_6	On most days

Step 5: Note the date of data retrieval and cross check the QA log to ensure that this is the most recent file and double checked