

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

CONTRACTING ORGANIZATION: New York University
New York, NY 10016-6402

REPORT DATE: OCT-2016

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE October 2016		2. REPORT TYPE Annual		3. DATES COVERED 30 SEPT 2015-29 SEPT 2016	
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) Dr Sherri Weiser, Dr Marco Campello, Dr Angela Lis, CDR Brian Iveson, Rudi Hiebert, Danielle Faulkner, CAPT MSC USN (Ret) Greg Ziemke, Tara Brennan. 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 is 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: Unclassified			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 26	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

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

Table of Contents

	<u>Page</u>
1. Introduction.....	4
2. Keywords.....	4
3. Accomplishments.....	4
4. Impact.....	6
5. Changes/Problems.....	7
6. Products.....	8
7. Participants & Other Collaborating Organizations.....	9
8. Special Reporting Requirements.....	14
9. Appendices.....	15

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 will result 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. If the pilot is successful, it will serve as the 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

3. Accomplishments

What were the major goals of the project?

- Demonstrate the feasibility of implementing psychologically 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.

Scope of Work (SOW) Major Goals and Milestones – Months 12-24

- Train and certify the physical therapy staff including the certification in the Collaborative Institutional Training Initiative tutorial as required by IRB, training in the PBPT study protocol and questionnaire administration and data collection on the intervention carrier. October 19th-October 21st 2015. Complete.
- Implement the pilot study. June 2015- July 2016. Complete.
- Submit protocol for United States Army Medical Research and Material Command Human Research Protection Office (USAMRMC HRPO) for continuation. August 2016. Complete.

What was accomplished under these goals?

- 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 were completed for the control carrier and intervention carrier questionnaire data. If discrepancies were found between baseline and follow-up main complaints SOAP notes were 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.

Goals not met as of this period are:

- Due to a delay in accessing the MEDBOLTT database we have not retrieved Limited duty assignments 6 months after enrollment for the control carrier.

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

- The PT personnel within the intervention carrier have been trained in a psychologically based physical therapy approach.
- Training of the intervention carrier resulted in the creation of an evidence based PBPT training protocol and physical therapist and patient educational materials.

How were the results disseminated to communities of interest?

An abstract describing the PBPT intervention carrier training was successfully presented as a poster at the Military Health System Research Symposium (MHSRS) annual conference.

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

Within the next quarter we plan to:

- Start data analysis;
- Assess limited duty assignments 6 months after enrollment as a secondary outcome for both carriers.
- Begin evaluation of physical therapy notes to document the implementation of the intervention by coding notes based on predetermined categories that correspond to the training.

Within the next year we plan to:

- Complete and integrate data analysis;
- Produce Manual of Operations and Procedures (MOOP).
- Prepare abstracts and publication from the study;
- Publish results within the clinical trials database.

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 indicates 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.

What was the impact on other disciplines?

The protocol is likely to make an 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?

Nothing to report

4. Changes /Problems

Changes in approach and reasons for change

In the original protocol we aimed to exclude those participants from the study who exceeded cut-off scores for orange flags. However, a high number of participants with orange flags were found within the control carrier. Therefore, it was decided that those exceeding cut-off scores would be included in the study and advised to seek consultation with the psychology personnel on board. Those in the intervention carrier with orange flags were also advised to seek psychological consultation in addition to starting the psychologically based physical therapy treatment. This change was previously reported to the IRB.

When completing data quality control procedures within the control carrier questionnaire discrepancies regarding patient's main complaints were identified in several patients. Corresponding SOAP notes were used to resolve discrepancies based on consensus among all researchers. Those for which no consensus could be reached were excluded.

Data quality rules were established to ensure a systematic process (see below).

- If patient rates in the middle of two answers round up.
- If patient marks two pain ratings use the highest pain rating.
- If a patient indicates a main complaint at baseline and indicates no main complaint or "none" at follow up, the main complaint for follow-up is that reported at baseline.
- If a patient marks a different main complaint at baseline and at follow-up (new main complaint), SOAP notes are reviewed and a decision is made based on the complaint treated by the physical therapist as indicated in the SOAP notes.
- If the patient marks a different complaint at baseline and at follow-up and the SOAP notes do not clarify the complaint they were treated for the patient is excluded.

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

Problem

Our participant enrollment was projected to be 600 for both carriers. Upon completion of the pilot study recruitment we have enrolled a total of 84 participants in the control carrier and 86 participants in the intervention carrier with full data sets. A lower than expected recruitment number within the control carrier was previously discussed within the last annual period.

As the intervention carrier recruitment occurred for the full deployment period we expected a substantially higher enrollment in comparison to the control carrier. However, similar numbers were recruited in the intervention carrier and the control carrier despite the fact that the intervention carrier recruitment period was several months longer. It is unclear why we did not reach higher enrollment in the intervention carrier. One reason may be that the deployment experience differed between the two carriers. The intervention carrier was deployed during a period of conflict.

Action Plan

Based on the recalculation done for the control sample we reached the revised subject accrual number on the intervention carrier to ensure that the study will have 80% statistical power to demonstrate that improvement as distinguishable from chance variation.

With respect to the STarT Back Screening tool, the less-than-anticipated enrollment means that the intervention carrier must show a minimum of a 13% differential improvement as compared to the control carrier among those MSI cases categorized as 'High psychological risk' over the course of the 4 week treatment period. With respect to the DVPRS, the less than anticipated case accrual in the both arm means the study will be able to detect a differential change from baseline to four week follow-up of as little as 1.5 points.

Problem

We have had difficulty accessing the MEDBOLT data for the control carrier follow-up. The individual in charge of this data has been out of the office.

Action Plan

A new person has been assigned to this task and we expect resolution in the next quarter.

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.

Nothing to report.

5. Products

Publications, conference papers, and presentations

-Journal Publications

Nothing to report

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

Nothing to report

-Other publications, conference papers, and presentations

Poster abstract titled “Feasibility of Training Physical Therapists to Implement a Psychologically-Based Physical Therapy Program for Deployed US Sailors and Marines with Musculoskeletal Injuries” was presented at the annual Military Health System Research Symposium (MHSRS). See within the appendix.

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

Nothing to report

6. Participant’s & other collaborating organizations

What individuals have worked on the project?

Name:	<i>Sherri Weiser-Horwitz</i>
Project Role:	<i>Principal Investigator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	No change
Contribution to Project:	<i>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.</i>
Funding Support:	NA

Name:	<i>Marco Campello</i>
Project Role:	<i>Co- Principal Investigator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	No change
Contribution to Project:	<i>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.</i>
Funding Support:	N/A

Name:	<i>Brian Iveson</i>
Project Role:	<i>Co-Principal Investigator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	No change
Contribution to Project:	<i>CDR Iveson participated in weekly research meetings, assisted in IRB preparations and amendments and assisted with advisory board material preparation. CDR Iveson has also been instrumental in explaining the unique circumstances of a deployment and how to solve problems that arise on board of ship as it relates to this study. He has been working very closely with the Navy IRB to get the amendments approval. CDR Iveson has assumed the Co-PI role here months ago.</i>
Funding Support:	NA

Name:	<i>Angela Lis</i>
Project Role:	<i>Research Coordinator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	No change
Contribution to Project:	<i>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.</i>
Funding Support:	NA

Name:	<i>Tara Brennan</i>
Project Role:	<i>Research Associate</i>
Researcher	

Identifier (e.g. ORCID ID):	
Nearest person month worked:	12
Contribution to Project:	<i>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.</i>
Funding Support:	NA

Name:	<i>Danielle Faulkner</i>
Project Role:	<i>Protocol and Data Management Co-Coordinator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	No change
Contribution to Project:	<i>Ms. Faulkner assisted in the preparation of IRB material and HRPO documentation, participated in weekly research meetings and completed the advisory board materials and literature review. She assisted with piloting data collection procedures.</i>
Funding Support:	NA

Name:	<i>Rudi Hiebert</i>
Project Role:	<i>Associate Investigator</i>

Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	No change
Contribution to Project:	<i>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</i>
Funding Support:	NA

Name:	<i>Gregg Ziemke</i>
Project Role:	<i>Co-Principal Investigator (SEPT 2014- JUNE 2015)</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	No change
Contribution to Project:	<i>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.</i>
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.

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).

7. Special reporting requirements

Collaborative Awards

N/A

Quad Charts

Please see appendices for updated Quad Chart.

8. Appendices

Appendices attached below include:

- Quad Chart 8 (final quarter of the second annual period);
- Intervention training syllabus;
- MHSRS Abstract .

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



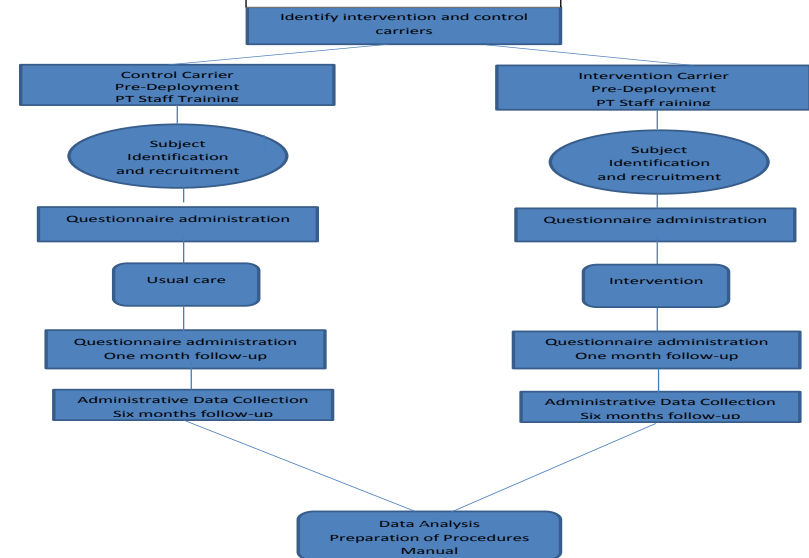
Study/Product Aim(s)

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 ADMS 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.

STUDY FLOW CHART



Timeline and Cost

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

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

Participant enrollment, data entry and data quality control procedures have been completed for the intervention carrier 86 subjects where enrolled in the intervention carrier in comparison to 84 in the control carrier. Based on the previous recalculation done for the control sample we will still have 80% statistical power to detect outcome differences. Data analysis is expected to begin in the next quarter. Our budget expenditure is on target.

Updated: (New York 30/09/2016)

Sherri Weiser-Horwitz, 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***

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.

Disclaimer

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.

Ethics statement

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

For more information or media:

Marco Campello PhD

Director, Occupational and Industrial Orthopedics Center (OIOC),
Hospital for Joint Diseases, NYU Langone Medical Center
63 Downing Street New York NY 10014

Marco.Campello@nyumc.org

Intervention Group

Training Syllabus

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

You will be assisting with a study to determine how psychological factors may be associated with outcomes in ADSM with musculoskeletal injuries. On behalf of the study investigators, thank you for your effort towards this objective.

The following syllabus will outline the training content for the following three days. Each session has a specific goal designed to enhance your knowledge and skills as a researcher and health care provider in the field of Psychologically Based Physical Therapy.

The training will consist on 5 sessions as follows:

Session 1

Main Topics:

The goal of this session is for you to understand the operating procedures required for recruiting and consenting participants and associated data collection protocols.

Goals:

To become knowledgeable of all Standard Operating Procedures related to the intervention group (SOP) and skillful in the specific research-related tasks.

Skills to achieve:

Identifying candidate patients

Consenting and enrolling subjects in the study

Tracking refusal rate

Collecting research data

Overseeing the data collection process to ensure integrity, completeness and accuracy of data collection

Handling, storing and transferring research data

Reporting of adverse events

Participation in periodic meetings with investigators

Session 2

Psychologically Based Physical Therapy (PBPT) is an approach designed to incorporate the concepts of cognitive behavioral therapy (CBT) for pain management into routine physical therapist practice in order to modify maladaptive responses that are associated with chronicity. PBPT has been defined as “an approach with a focus on the identification and management of psychological and psychosocial obstacles to recovery of optimal function. The goal of PBPT is to promote a fast recovery by modifying psychological obstacles, to obviate or facilitate when needed appropriate referral to a psychologist in patients at risk of poor outcome/chronicity/disability and to facilitate triage to other health professionals in a timely manner. Standard physical therapy relies on biomedical principles, PBPT goes beyond to recognize and address the role of psychological factors in the development of pain and disability. It integrates and applies psychological principles into physical therapy treatment to enhance functional outcomes and prevent disability by addressing the risk factors.

Main Topics

Basic Concepts of Psychologically Based Physical Therapy

- Models of pain and disability
- Pain pathways
- Evidence based predictors of disability and delayed recovery
- Evidence based treatments for the prevention of disability
- Principles of cognitive behavioral pain management in physical therapy practice

Goals

Understand the biopsychosocial model of pain and disability

Understand the concept of Psychologically Based Physical Therapy

Skills to achieve

Exhibit understanding of the topic by utilizing examples from the rehabilitation setting

Tools and References

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

Main, C. J., & George, S. Z. (2011). Psychologically informed practice for management of low back pain: future directions in practice and research. *Physical Therapy*, 91(5), 820-824.

Nicholas, M. K., Linton, S. J., Watson, P. J., Main, C. J., & "Decade of the Flags" Working Group. Early identification and management of psychological risk factors ("yellow flags") in patients with low back pain: A reappraisal. *Physical Therapy*, 91(5), 737-753. (2011).

Further Optional Reading

Kendall, N. A. S., Burton, A. K., Main, C. J., & Watson, P. J. (2009). On behalf of the Flags Think-Tank: Tackling Musculoskeletal Problems: a Guide for the Clinic and Workplace—Identifying Obstacles Using the Psychosocial Flags Framework. London: The Stationery Office. The Stationery Office.

Schabrun, S. M., Jones, E., Kloster, J., & Hodges, P. W. (2013). Temporal association between changes in primary sensory cortex and corticomotor output during muscle pain. *Neuroscience*, 235, 159-164.

Waddell, G., McCULLOCH, J. A., Kummel, E. D., & VENNOR, R. M. (1980). Nonorganic physical signs in low-back pain. *Spine*, 5(2), 117-125.

Moseley, G. L., & Butler, D. S. (2015). 15 Years of Explaining Pain-The Past, Present and Future. *The Journal of Pain*.

Overmeer, T., Boersma, K., Denison, E., & Linton, S. J. (2011). Does teaching physical therapists to deliver a biopsychosocial treatment program result in better patient outcomes? A randomized controlled trial. *Physical therapy*, 91(5), 804-819.

Assessment

Knowledge test

Session 3

Main Topics

Identifying yellow flags and other risk factors associated with delayed recovery.

- Use of questionnaires to assess yellow flags and other risk factors associated with disability
- Assessing risk factors using the clinical interview
- Use of risk factors to develop a plan of care

Goals

To learn how to use study assessment tools to identify patients at risk

To learn how to use the clinical interview and patient based questionnaires to identify patients at risk

To develop a plan of care based on the presence of psychological risk factors and their modification

Skills to achieve

Learn how to identify obstacles to recovery

Learn how to assess the need for a psychological evaluation

Learn communication skills necessary to elicit risk factors for delayed recovery during the clinical evaluation

Learn how to develop a psychologically based physical therapy plan of care

Tools and References

Hill, J.C., Dunn, K. M., Lewis, M., Mullis, R., Main, C. J., Foster, N. E., & Hay, E. M. A primary care back pain screening tool: Identifying patient subgroups for initial treatment. *Arthritis and Rheumatism*, 59(5), 632-641. (2008)

Further Optional Reading

Fritz, J. M., Beneciuk, J. M., & George, S. Z. Relationship between categorization with the STarT back screening tool and prognosis for people receiving physical therapy for low back pain. *Physical Therapy*, 91(5), 722-732. (2011).

Assessment

Role playing and case studies

Session 4

Main Topics

How to address yellow flags to prevent delayed recovery

- How to communicate with the patient at risk
- How to educate the patient at risk
- How to implement a plan of care
- How to use CBT techniques in practice
- How to combine CBT with a behavioral approach to treatment

Goals

To train physical therapists in how to communicate with and educate patients at risk of delayed recovery

To train physical therapists in how to implement a plan of care based on the principles of Psychologically Based Physical Therapy.

Skills to achieve

- Patient Education Skills :
 - Cognitive reassurance (models, pain and movement, self-care)
 - Modifying mal-adaptive beliefs
 - Replacing negative thoughts
- Behavioral Modification Skills:
 - Graded activity
 - Exposure approach
 - Able to identify, address and promote functional goals
 - Able to break down into short-term goals or daily quota if needed
 - Activity pacing

- Pain Coping Skills:
 - Relaxation techniques
 - Breathing techniques

Tools and References

Main, C. J., Sowden, G., Hill, J. C., Watson, P. J., & Hay, E. M. Integrating physical and psychological approaches to treatment in low back pain: The development and content of the STarT back trial's 'high-risk' intervention. *Physiotherapy*, 98(2), 110-116. (2012)

Nicholas, M. K., & George, S. Z. (2011). Psychologically informed interventions for low back pain: an update for physical therapists. *Physical therapy*, 91(5), 765-776.

Further Optional Reading

Hasenbring, M. I., & Pincus, T. (2015). Effective Reassurance in Primary Care of Low Back Pain: What Messages From Clinicians are Most Beneficial at Early Stages?. *The Clinical journal of pain*, 31(2), 133-136.

Foster, Nadine E., and Anthony Delitto. "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* 91.5 (2011): 790-803.

Bryant, C., Lewis, P., Bennell, K. L., Ahamed, Y., Crough, D., Jull, G. A., & Keefe, F. J. (2014). Can physical therapists deliver a pain coping skills program? An examination of training processes and outcomes. *Physical therapy*, 94(10), 1443-1454.

Hunt, M. A., Keefe, F. J., Bryant, C., Metcalf, B. R., Ahamed, Y., Nicholas, M. K., & Bennell, K. L. (2013). A physiotherapist-delivered, combined exercise and pain coping skills training intervention for individuals with knee osteoarthritis: a pilot study. *The knee*, 20(2), 106-112.

Sanders, T., Foster, N. E., Bishop, A., & Ong, B. N. (2013). Biopsychosocial care and the physiotherapy encounter: physiotherapists' accounts of back pain consultations. *BMC musculoskeletal disorders*, 14(1), 65.

Nielsen, M., Keefe, F. J., Bennell, K., & Jull, G. A. (2014). Physical Therapist–Delivered Cognitive-Behavioral Therapy: A Qualitative Study of Physical Therapists' Perceptions and Experiences. *Physical therapy*, 94(2), 197-209.

Assessment

Role playing and case studies

Session 5

Main Topics

Physical therapy documentation

- Standardizing evaluation and progress notes that reflect the use of PBPT

Goals

To standardize evaluation and progress notes to ensure high quality data

Skills to achieve

To learn how to document evaluation and implementation of a plan of care based on PBPT

To learn how to document changes in attitudes, beliefs and behaviors through observation and communication during treatment.

To learn how to document changes in yellow flags or standardize questionnaires at the end of treatment.

Assessment

Role playing and SOAP notes analysis