

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

CONTRACTING ORGANIZATION: New York University School of Medicine
New York, NY 10016

REPORT DATE: October 2017

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 2017	2. REPORT TYPE Annual	3. DATES COVERED 30SEPT2016 - 29SEPT2017
---------------------------------------	---------------------------------	--

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, Michael Lashbaugh. 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 28	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

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 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

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.

Scope of Work (SOW) Major Goals and Milestones – Months 24-36

- Conduct short-term data analysis and report the results. Complete.2/3/2017
- Conduct long-term data analysis and report the results (Limited Duty assignments and health care utilization 6-months post enrollment). Ongoing.
- Study findings will be disseminated in the form of abstracts, scientific papers and lectures. Ongoing.
- Prepare a Manual of Operations and Procedures (MOOP) The MOOP will describe a model of care and the finalized PBPT protocol and will be prepared for Triservice review. Ongoing.
- Evaluation of physical therapy notes was completed in order to confirm implementation of the intervention by coding notes based on predetermined categories that correspond to the training. Complete. 08-01-2017.
- Subjects were asked to indicate the most important things they learned in physical therapy and answers were assessed based on a priori categories corresponding to the intervention and control conditions. This allowed further assessment of intervention implementation. Complete.10/12/2016.
- Submit protocol for United States Army Medical Research and Materiel Command Human Research Protection Office (USAMRMC HRPO) for continuation. August 2017. Complete.

What was accomplished under these goals?

- 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 patients 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.

Goals not met as of this period are:

Due to delays in retrieving long-term follow up data (healthcare utilization and LIMDU designation) data analysis was not completed within this annual period as expected. In addition the MOOP is in its final stages due to these delays.

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?

Five abstracts based on the study and its findings were submitted and accepted in this annual period. Four of these abstracts have already been presented at annual conferences nationally and internationally. The final abstract is due to be presented in February 2018. In addition based on an abstract presentation we were invited to submit a manuscript to the Journal of Military Medicine. This is currently pending approval and publication. The research team is currently working on two additional manuscripts.

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

We plan finalize follow-up data retrieval, quality control and begin analysis in order to report final results. Baseline descriptive data will be analyzed while controlling for demographic s.

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 PB 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

We have had difficulties obtaining follow-up administrative data from the Navy database due to changes in data storage procedures. Therefore, the final report and MOOP has been delayed.

Action Plan:

We are working with the administrator to obtain this data and believe we will be able to access the data in the next quarter.

We have requested a no cost extension for this award to complete these tasks.

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 submitted to The Journal of Military Medicine and is pending approval and publication. Feasibility of Training Physical Therapists to Implement a Psychologically-Informed Physical Therapy Program for Deployed US Sailors and Marines with Musculoskeletal Injuries (Journal of Military Health- Submitted)

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

Nothing to report

-Other publications, conference papers, and presentations

Abstracts

1. What do patients learn from psychologically based physical therapy? (World Congress of Physical Therapy – Accepted and Presented 2017)
2. 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)
3. 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)
4. What do patients with spine pain learn from psychologically informed physical therapy? (EUROSPINE-Accepted and Presented 2017)
5. 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 2017)

Manuscripts

1. Feasibility of Training Physical Therapists to Implement a Psychologically-Informed Physical Therapy Program for Deployed US Sailors and Marines with Musculoskeletal Injuries
2. What do patients learn from psychologically based physical therapy? (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

Short-term data results.

7. 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>Michael Lashbaugh MS PT</i>
Project Role:	<i>Co-Principal Investigator (Navy)</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	<i>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.</i>
Funding Support:	NA

Name:	<i>Angela Lis</i>
Project Role:	<i>Research Coordinator</i>
Researcher Identifier (e.g. ORCID ID):	

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:	No change
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>Rudi Hiebert</i>
Project Role:	<i>Associate Investigator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person	No change

month worked:	
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), Volunteer</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?

The Navy PI CDR Brian Iveson left his Navy 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:

- Short-term outcomes
- Qualitative results of assessment of intervention implementation
- Quad Chart (final quarter of the third annual period);
- Abstracts

Appendices

Short-Term Outcomes

Short-term outcome	Comparison and Direction	Significance
Psychological Distress	Both carriers improved. Adjusted OR= 0.938.	p = 0.8877
Pain Intensity	Both carriers improved. Intervention carrier showed greater likelihood of improving. Adjusted OR=1.367	p = 0.536
Outcome Expectation	Both carriers improved. Intervention carrier showed greater likelihood of improvement. Adjusted OR=1.177.	p= 0.698
Self-Efficacy	Both carriers improved. Intervention carrier showed greater likelihood of improvement. Adjusted OR=1.129	p = 0.780
Fear of Work	Both carriers improved. Intervention carrier showed a greater likelihood of improvement. Adjusted OR=1.189	p = 0.687
Pain Interference (DVPRS)	Both carriers improved. Intervention carrier showed a greater likelihood of improvement. Adjusted OR=0.894	p = 0.739
Perceived Disability	Both carriers improved. Intervention carrier showed a greater likelihood of improvement. Adjusted OR=1.230	p = 0.664
Satisfaction with process of care	Both carriers improved. Intervention carrier showed a greater likelihood of improvement. Adjusted OR=2.780	p = 0.015
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=1.902	p = 0.740

Qualitative results of 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 were 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 taught me the tolerance levels of damaged tissues, the slow road to recovering, learning how to strengthen other muscles to help support a weaker more damaged/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 ease 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 how 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 uncomforness 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/stretchers. 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:

	<u>No of Statements identified reflecting PBPT "keywords"</u>	<u>Total No of follow-ups completed</u>	<u>Percentage showing PBPT "keywords"</u>	<u>Total no of subjects who completed follow-up questionnaires but left the open ended questionnaire "blank"</u>	<u>Spine Only Blank</u>
Control Carrier	0	84	0%	22 (26%)	6 (23) 26.09%
Intervention Carrier	29	86	33.7%	5 (5.8%)	2 (47) 4.26%

Abstracts

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.

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.

Wilcoxon 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.

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, PTSD 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 10 were 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.

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.

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 Brenan, 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 Psychological Measures: 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_I 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.