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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

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6. AUTHOR(S)
Dr Sherri Weiser, Dr Marco Campello, Dr Angela Lis, CDR Brian Iveson, Rudi Hiebert, Danielle Faulkner, Greg Ziemke, Tara Brennan.

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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)

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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.

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Table of Contents

1. Introduction

This is a pilot study to test the efficacy of a psychologically based physical therapy (PBPT) training for treating deployed U.S. sailors and marines with musculoskeletal injuries (MSI). The study 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 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 1-12

- Finalize consent form and human subjects' protocol: 11/5/2014. Completed.
- Refine and finalize eligibility/exclusion criteria: 11/05/14. Completed.
- Prepare control carrier training material: 12/16/2014. Completed.
- Finalize assessment measures: 07/1/2015. Completed.
- Finalize Navy Observational Clinical Cooperative Research and Development Agreement (NCRADA) between Naval Medical Center Portsmouth (NMCP), New York University (NYU) and University of Delaware -03/16/2015. Completed.
- Prepare and submit protocol to NMCP Internal Review Board (IRB) and revise as required – approved 06/19/15. Completed.
- Submit protocol for United States Army Medical Research and Material Command Human Research Protection Office and gain approval (USAMRMC HRPO) - Approved 05/27/15. Completed.
- Hire research associate, credential him/her according to Navy regulations. Train research assistant in the study protocol including the preparation of training and study materials, data collection and quality assurance of study data, coding physical therapy notes for analysis, and recording minutes of clinical meetings with carrier physical therapy staff-. Research Associate start date including training: 05/27/2015. Completed.
- Identify a carrier to act as a control site and train and certify the physical therapy staff including the certification in the Collaborative Institutional Training Initiative tutorial as required by IRB, training in the study protocol and questionnaire administration and data collection- 01/06/2015 & 03/05/2015. Completed.
- Identify a carrier to act as the intervention site -11/5/14. Completed.
- Train physical therapists and psychologist on intervention carrier in PBPT Protocol and CITI tutorial- 0%.

What was accomplished under these goals?

- NYU and NYUMC IRB approval;
- IRB protocol submitted to HRPO and approved;
- Site visit to carrier by three study personnel;
- Establishment of study advisory board;
- Establishment of weekly research conference call meetings;
- Preparation of training materials for control carrier;
- Control carrier training package passed by advisory board;
- Pilot control carrier training;
- Training of control carrier physical therapy staff;
- UDEL IRB approved;
- NCRADA signed for both carriers;

- Lesson plans and Standard Operating Procedures Manual specific to the control carrier;
- Established data recording procedures with data base administrator from BADER;
- Study registered in the clinical trials data base;
- Start of the recruitment of control carrier participants;
- Intervention training protocol and materials completed;
- Intervention training package passed by advisory board;
- Operations Procedures manual created for the intervention carrier;
- Intervention carrier training dates scheduled;
- Data sharing agreement application completed and submitted.

Goals not met as of this period are:

1. Signed data sharing agreement. The data sharing agreement application has been submitted and we expect a response shortly.
2. Sample size: reaching the total projected enrollment of 250 within the control carrier was not possible due to a delay in IRB approvals and thus, a delay of recruitment.
3. Training of the intervention carrier was not completed within the first annual period because the departure date is expected to occur in the fall of 2015. The training however has been scheduled for October 19th 2015 to October 21st 2015.

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.
- The research associate, Tara Brennan, is attending a biostatistics course which will assist in the statistical analysis and interpretation of study data.

How were the results disseminated to communities of interest?

Nothing to Report.

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

***Within the next quarter we plan to*:**

- Train and certify the intervention carrier physical therapy staff and psychologist in PBPT and the study protocol;
- Recruit and begin data collection in intervention carrier subjects;
- Finalize data sharing agreement;
- Complete data collection for the control carrier.

Within the next year we plan to:

- Complete data collection for the intervention carrier;
- Complete data entry for both carriers;
- Start data analysis and interpretation;
- Update clinical trials data base.

4. Impact

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

As part of the protocol implementation on the control carrier, the PT personnel is suggesting psychological consultation to those with elevated distress scores on the CES-D, GAD, and PCL-M. This may change the physical therapists' clinical practice.

What was the impact on other disciplines?

The protocol is likely to make an impact on the psychology discipline as it is facilitating referrals from physical therapy.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report

5. Changes /Problems

Changes in approach and reasons for change

As stated within our initial IRB approved protocol we planned to exclude those participants who exceeded cut-off scores for orange flags (at risk for psychiatric disorders). Upon reviewing the control carrier's baseline questionnaires it was found that a large number of potential participants exceeded these cut-off scores. The advisory board psychologist informed us that elevated distress scores are to be expected due to the nature and environment of deployment. Under his advisement, we therefore decided to include such participants in the study. All participants exceeding cut-off scores were advised to seek consultation with the psychology personnel on board the carrier in addition to starting the physical therapy treatment. This change has been reported to the IRB.

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

Our participant enrollment was projected to be 250 for the first annual period, allowing for a 50% refusal rate. As of this date we have enrolled a total of 83 participants out of 98 eligible subjects who were approached, which is significantly lower than anticipated (It is important to note, however, that

this represents a 15% refusal rate which is low and indicates a sample that is representative of the population). There are two main reasons why the planned and actual case accrual differed significantly. The first reason involves the Navy IRB. Although we had an approved IRB prior to deployment of the control carrier, we submitted an amendment for minor changes to the questionnaire that resulted in approval delays of four months. This resulted in a significantly shorter recruitment period for the control carrier. These delays were reported in the quarterly reports.

In addition, the control carrier PT reported difficulties in recruiting at times when the ship's medical department experienced high caseloads, and there was insufficient staffing to provide medical care and administer informed consent.

Action Plan

The less than anticipated study enrollment in the control carrier arm requires a change in the effect size that the investigators must find in order to detect the effect of the intervention on the study's primary outcomes. The psychological outcomes, and the ones that are the most sensitive to and reflective of the intervention, are the Defense and Veterans Pain Rating Scale (DVPRS) and STarT Back screening tool. The investigators initially anticipated enrolling all (or nearly all) candidate musculoskeletal injury (MSI) cases on board the carrier. The investigators anticipated approximately 300 MSI during the course of a 9 month deployment on the control carrier. The original sample size estimate presented to CDMRP showed that, with 300 MSI cases in the control arm, and a similar enrollment in the intervention carrier, the study had 80% power to detect 'small' to 'moderate' effect sizes. The investigators ran a series of sample size and power calculations to evaluate the change in effect size as a result of the less-than-anticipated enrollment in the control carrier. With respect to the STarT Back Screening tool, the less-than-anticipated enrollment means that the intervention carrier now must show a minimum of a 13% differential improvement in the intervention carrier as compared to the control carrier among those MSI cases categorized as 'High psychological risk' over the course of the 4 week treatment period. If the study had met its originally anticipated case accrual, the study would have had to demonstrate only a 10% differential improvement to show that the PBPT intervention effective beyond chance variation. With respect to the DVPRS, the less than anticipated case accrual in the control 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. Even with the less than anticipated case accrual, the study will still have 80% statistical power to demonstrate that improvement as distinguishable from chance variation. Training of intervention carrier personnel will include a problem-solving session to facilitate recruitment and data collection based on lessons learned from the control carrier.

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.

Due to a change in the study inclusion criteria we are now including those participants that exceeded cut-off scores for orange flags on the baseline questionnaire. These subjects are now included as potential participants in addition to being referred for a psychological consultation to address their elevated distress scores in accordance with the protocol. The IRB amendment has been submitted.

6. 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

Nothing to report

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

7. Participant's & other collaborating organizations

What individuals have worked on the project?

Name:	*Sherri Weiser-Horwitz*
Project Role:	*Principal Investigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to Project:	*Dr Weiser oversaw all research activities, including preparation of documentation to IRB, preparation of training material for control group, preparation of material for HRPO application, weekly research meetings, preparation of intervention training program, training the research associate, monitoring data collection, registering the study through clinical trials and preparing quarterly reports.*
Funding Support:	NA

Name:	*Marco Campello*
Project Role:	*Co- Principal Investigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	*Dr Campello assisted the PI in all aspects of the study and in particular, prepared study procedure training materials for the control group and trained control carrier physical therapists and oversaw preparation of study procedures and training materials for the intervention group. He prepared documentation for NCRADA and participated in weekly research meetings.*

Funding Support:	N/A

Name:	*Brian Iveson*
Project Role:	*Co-Principal Investigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	*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.*
Funding Support:	*NA*

Name:	*Angela Lis*
Project Role:	*Research Coordinator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	*Dr Lis supervised the preparation of training materials for the control group, participated in weekly research meetings, participated in the development of the intervention group training program and training tools. Assisted with ongoing literature searches and trained the research associate.*

Funding Support:	*NA*

Name:	*Tara Brennan*
Project Role:	*Research Associate*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	4
Contribution to Project:	*Ms. Brennan has completed ongoing literature searches to update the investigators and assisted in the creation of training materials and tools for the intervention group. She assisted with registering the trial at Clinical Trials.Gov and preparing quarterly and year end reports. She participated in weekly research meetings and assisted in piloting data collection.*
Funding Support:	NA

Name:	*Danielle Faulkner*
Project Role:	*Protocol and Data Management Co-Coordinator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	5
Contribution to Project:	*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.*
Funding Support:	*NA*

Name:	*Rudi Hiebert*
Project Role:	*Associate Investigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	5
Contribution to Project:	*Mr. Hiebert assisted in the preparation of IRB material and study procedure training material, prepared data collection materials, data recording procedures and data use agreement, participated in weekly research meetings and assisted in control carrier training. He piloted data collection procedures.*
Funding Support:	NA

Name:	*Gregg Ziemke*
Project Role:	*Co-Principal Investigator (SEPT 2014- JUNE 2015)*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	*CAPT Ziemke prepared study procedure training material for the control group, prepared documentation for NCRADA, participated in weekly research meetings and assisted in the IRB preparation. He also took part on the training of the control carrier personnel. As Co-PI, he also helped in the identification of the control and intervention carriers. CAPT Ziemke was instrumental in reaching out the Physical Therapy teams of both carriers as well as their respective commanders.*
Funding Support:	NA

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

- CDR Iveson replaced CAPT Ziemke who retired as the study's Navy PI.

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.

9. Appendices

Appendices attached below include:

- Study baseline questionnaire;
- Study follow-up questionnaire;
- Control carrier training protocol;
- Quad Chart 4 (final quarter of the first annual period).

Patient Information Questionnaire-BASELINE

Name: _____D.O.B:_____ DoD ID#_____
Job Title/Rate: _____

Current Tobacco Smoking Status

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

Past Daily Tobacco Smoking Status

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

Past Smoking Status

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

Current Level of education

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

Patient's Initials: ☐

Pain Description

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

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

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

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

6. How often do you have pain?

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

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

   ☐ Yes
   ☐ No

8. Have you ever had this complaint before?

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

   ☐ No

Patient's Initials: ____

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

0	1	2	3	4	5	6	7	8	9	10

No pain — Worst pain Imaginable

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

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

Attitudes about Pain

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

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

Does not interfere — Completely interferes

0	1	2	3	4	5	6	7	8	9	10

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

Does not interfere — Completely interferes

0	1	2	3	4	5	6	7	8	9	10

Patient's Initials: ____

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

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

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

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

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

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

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

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

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

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

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

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

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

Patient's Initials: ____

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

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

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

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

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

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

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

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

Patient's Initials: ____

Questions about your job

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

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

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

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

Patient's Initials: ____

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

Patient's Initials: ____

Stress Symptoms

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

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

Patient's Initials: ____

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

Patient's Initials: ____

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

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

Patient's Initials: ____

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

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

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

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

Patient's Initials:

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

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

Treatment concerns

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

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Patient Information Questionnaire-FOLLOW UP

Name: _____D.O.B:_____ DoD ID#_____

Job Title/Rate: _____

Pain Description

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

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

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

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

0	1	2	3	4	5	6	7	8	9	10

No pain — Worst pain imaginable

Attitudes about Pain

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

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

Does not interfere — Completely interferes

0	1	2	3	4	5	6	7	8	9	10

Patient's Initials: ____

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

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

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

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

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

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

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

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

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

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

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

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

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

Patient's Initials: ☐

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

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

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

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

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

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

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

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

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

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐

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

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐

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

Very Good	Good	Fair	Poor	Very poor
☐	☐	☐	☐	☐

Patient's Initials: ☐

Information about satisfaction with care

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

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

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

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

Patient's Initials: ☐

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

_____

_____

_____

_____

_____

_____

_____

_____

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Research Study

Lesson plans

and

Standard Operating Procedures (SOP)

specific to the USS Theodore Roosevelt (CVN 71)

Contents

Introduction

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.

You play a central role in the execution of this study. You will be directly responsible for the collection of valuable research data. Your specific research-related tasks are:

a. Identifying candidate patients;
b. Consenting and enrolling subjects in the study;
c. Tracking refusal rate;
d. Collecting research data;
e. Overseeing the data collection process to ensure integrity, completeness and accuracy of data collection;
f. Completion of SOAP notes;
g. Handling, storing and transferring research data;
h. Reporting of adverse events;
i. Participation in periodic meetings with investigators.

The attached lesson plans address these various tasks.

Lesson Plans

Lesson 1: Completing study contact log

Time required: 1 hour

Objectives: In this lesson the study staff will learn how to complete and maintain the study contact log

Topics

1. Role of the study contact log
    a. Used for generating statistics on contacts, for purposes of assessing recruitment bias
    b. Used for tracking visits for the index medical condition
    c. Used to identify visits to medical by an enrolled subject for possible complicating or comorbid conditions
    d. Used by the researchers for internal monitoring of data collection efforts and for generating data for the methods section of the technical report
    e. Used to report problems related to data collection including issues discussed in Lesson 3, topic 2.
2. Construction of the study contact log
    a. Number of people approached to participate
    b. Number of people that met inclusion criteria
    c. Number of people excluded
    d. Number of people who refused to participate
    e. Number of people consented
    f. Number of people who withdraw
    g. Number of people that completed four week follow up
    h. Number of adverse events reported
    i. Number of people that drop out

3. Completing the study contact log
    a. Scenarios: initial contact for an index MSD; revisit for index MSD; contact by non-eligible subject; refusal to enroll; withdrawal of consent; visit by eligible subject for a complicating or comorbid condition
4. Storage and computerization of the study contact log

Exercises

1. Practice completing entries for a sample study contact log for the following scenarios: initial contact for an index MSD; revisit for index MSD; contact with non-eligible subject; refusal to enroll; withdrawal of consent; visit by eligible subject for a complicating or comorbid condition, logging follow up data
2. Practice

Competency criteria

1. Staff successfully completes entries for the following scenarios: initial contact for an index MSD; revisit for index MSD; contact with non-eligible subject; refusal to enroll; withdrawal of consent; visit by eligible subject for a complicating or comorbid condition, logging follow up data
2. Staff recalls guidelines for maintaining confidentiality of the study contact log
3. Staff computerizes study contact log entries successfully

Lesson 2: Obtaining informed consent

Objective: In this lesson study staff will learn how to obtain the informed consent agreement

Time required: 1 hour

Topics

1. Role and purpose of informed consent
2. IRB requirements for informed consent (content, organization, required signatures)
3. Examples of a properly completed informed consent and an improperly completed informed consent form.

Exercise

1. Create a brief, semi-structured script that reviews the following required elements of the informed consent process: study purpose, why subject is being solicited, study procedures, risks, benefits and the voluntary nature of participation. Practice the script to enable a smooth, consistent delivery in a relaxed and pleasant manner.

   Example "The Navy is conducting a study for research purposes and we are asking you to voluntarily participate in it. The name of the study is "A Pilot study to Assess Factors Associated with Musculoskeletal Injuries in Deployed US Sailors and Marines" and it is being conducted at the Naval Medical Center Portsmouth, Virginia by medical researchers from the Orthopedic and Physical Therapy Departments along with researchers from New York University.

   You will be required to fill out a questionnaire at the time you accept to participate, on how you feel about your musculoskeletal condition; participate in physical therapy treatment; fill out a second questionnaire one month from the time you are evaluated or agree to participate; and grant permission to the research scientists to view your medical records as they relate to your present musculoskeletal condition. Your permission would extend from time you agree to participate and expire nine months after the ship returns back from deployment. This study does not bring any direct benefit to your current care. However, the results may be used to help us improving future care. You may withdraw from the study at any time. "

2. Administer, collect and review informed consent form for proper completion.

Performance criteria

1. Using their own words, study staff will be able to verbally review the following required elements of the informed consent process in 5 minutes or less: study purpose, why subject is being solicited, study procedures, risks, benefits and the voluntary nature of participation.
2. The study staff will convey the elements of the informed consent in a pleasant and relaxed manner

3. The study staff will administer, collect and review an informed consent form as instructed.

Lesson 3: Collecting study data

Time required: 1.5 hour

Objectives: In this lesson the study staff will learn the procedures for administering the study questionnaire, reviewing the questionnaire for completeness, and preparing the SOAP note according to the template.

Topics

1. Study questionnaire – role, purpose and extent of information gathered
2. Issues in study questionnaire administration
    a. Sources of response bias:
        i. Question ambiguity
        ii. Failure to respond (absence of perceived relevance, sensitive or delicate topic)
        iii. Missed items
    b. Please advise any patient that if they have any psychological concerns, they should contact the carrier psychologist.
3. Review SOAP note template
4. Quality check
    a. Completeness, clarity, labeling

Exercises

1. Practice completing a sample study questionnaire for baseline and discharge
2. Practice completing a sample SOAP note from a scenario
3. Create a FAQ for sample questions reasonably imagined to be posed by subjects
4. How to handle missing data

Lesson 4: Computerization, storage and transfer of research data

Objectives: In this lesson the study staff will learn the procedures for computerizing, storing and transferring research data

Time required: 1 hour

Materials required: study computer, study scanner, study printer, electronic files for the informed consent, questionnaire and SOAP note template.

Topics

1. Overview: Data must be organized in a way that each data element recorded is accurate, traceable and unambiguous. It should be stored in a way that allows auditing
2. Scanning documents
    a. Steps for scanning research material specific to the equipment on board ship
    b. If unable to use primary scanner in medical, consider using scanner from other areas, eg. main medical area.
3. Storage
    a. Content of a subject's research folder
        i. Signed, dated informed consent form
        ii. Baseline subject questionnaire
        iii. Four-week follow up subject questionnaire
    b. Locked file box organization
    c. Computer file directory organization
4. Data transfer
    a. Procedures for combining and transferring research data
    b. In case data transfer is not possible, save the electronic file to the research folder in the physical therapy department computer.
5. Procedure for transmission problems

Exercises

1. Practice compiling a study folder for a scenario
2. Practice completing scanning and computerizing data
3. Practice combining electronic study folders, encrypting and transferring research data via established DoD FTP transfer methods
4. Problem solving

Competency criteria

1. Staff compiles a sample paper subject research data folder
2. Staff scans research data, computerizes and organizes electronic copies of research data
3. Staff demonstrates ability to answer reasonably anticipated questions about completing questionnaire items
4. Staff demonstrates the ability to combine, encrypt and transfer research data
5. Staff demonstrate appropriate problem solving solutions

Standard Operating Procedures

Procedures for subject identification as a possible candidate for the study

1. Identify the person presenting: Name and DoD ID#
2. Determine main complaint and the reason for the visit: If the main complaint is for a musculoskeletal issue AND the reason for the visit is for evaluation AND treatment and has patient has not sought care for this injury in the last 30 days, go to step 3, otherwise exit the procedure.
3. Cross check the name and DoD ID with the study contact log (Figure 1): if the name and DoD ID DO NOT already appear on the study contact log, go to step 4.
4. Apply study exclusion criteria to the subject. If the subject meets one or more exclusion criteria, update the contact log noting the exclusion criteria met and exit the procedure. If the subject does not meet any exclusion criteria, proceed to step 5.
5. Enter the date, name and DoD ID, main complaint and reason for visit in the contact log.

Procedures for administering informed consent

1. Provide the potential subject with information about the study Ask the candidate if they are willing to participate. If the subject says yes, proceed to step 2. If the subject says no, go to step 4. If the subject does not volunteer right away but wants to think about it, go to step 5.
2. Print out a copy of the informed consent form. Label the informed consent form with the candidate's name, subject ID, and date.
3. Review the informed consent form and obtain signature. Update the contact log with a notation that the subject volunteered for the study. Go to step 6.
4. Update the contact log with a notation that subject declined to volunteer for the study. .
5. Update the contact log with a notation that subject declined to volunteer for the study initially, and set a follow-up time together with the candidate to enquire about volunteering for the study. Go to step 4.
6. Proceed with data collection.
7. Initiate treatment.

Procedures for administering baseline questionnaires

1. Print out a blank copy of the baseline questionnaire
2. Ensure that the first page of the questionnaire contains the subject's name, DoD ID#, D.O.B., and Job Title/Rate.
3. Ensure that pages two through thirteen of the questionnaire contain the subject's initials.
4. Review the questionnaire and instructions for completing together with the subject
5. Provide the subject with a clipboard, pen and a physical space to complete the questionnaire.
6. Be available to answer questions the subject may have while completing the form. Other clinical or research activities can be done while the subject is completing the questionnaire.

7. Monitor the subject. When the subject is done, review the questionnaire to ensure the following: a) no pages are missing, b) Ensure that each page is labeled with subject initials. Ensure that the first page of the questionnaire is labeled with the subject's name, DoD ID and date.
   c) that each question has a response, d) there are no ambiguous (such as double responses for items that require a single response) responses. This review needs to be done before the subject leaves the ship's medical department.
8. Update the study contact log noting that the baseline questionnaire was completed.

Procedures for collecting treatment data

1. Open SOAP note template on the computer in AHLTA-T
2. Complete the free text section using SOAP note sections shown in Appendix 1. Note that the SOAP note identifiers are not necessary when completing the free text form in AHLTA-T

If AHLTA-T is inoperative then

1. Proceed to handwritten SOAP utilizing the template format
2. Write the subject's name, subject's DoD ID#, encounter date and treating HCP name
3. Complete each section of the SOAP note.
4. Scan paper SOAP note into computer and upload it to authorized Sharepoint like data repository allocated for the study. Refer to "Procedures for transmitting electronic research data back to shore-based study investigators"
5. File the paper SOAP note in the subject's medical record.

Procedures for collecting 4 weeks follow-up data

1. You will be prompted to collect follow-up questionnaire from enrolled subjects approximately 4 weeks after their index (baseline) visit. This prompt will come from NMCP research personnel via an email prompt or by a prompt from your Excel study contact log
2. For enlisted personnel, direct your medical corpsman to contact the subject's supervisor with a request for the subject to come to physical therapy. For officers, direct your medical corpsman to contact the officer (as appropriate and consistent with military protocol) to relay a request and a reminder from the study PI to return to Medical for a brief follow-up visit.
3. Administer the follow-up questionnaire.
4. Review the questionnaire for completeness. Ensure that each page is labeled with subject initials. Ensure that the first page of the questionnaire is labeled with the subject's name, DoD ID, and date.
5. Scan the questionnaire into computer and upload it to authorized Sharepoint like data repository allocated for the study. Refer to "Procedures for transmitting electronic research data back to shore-based study investigators"
6. File the completed questionnaire along with the subject's informed consent form and baseline questionnaire.

Procedures for transmitting electronic research data back to shore-based study investigators

1. Documents should be grouped and scanned by subject and date of encounter. So, for example, a subject completed the informed consent form and the baseline questionnaire during a single encounter, those two documents should be grouped and scanned together into a single .pdf file. If only one document was collected, scan that document by itself. If a SOAP note was generated as a printed document instead of an AHLTA-T entry, then label the printed copy of the SOAP note with the subject's name, DoD ID and encounter date, and scan that document as a separate file.
2. Scan the pages as a single, adobe acrobat document. Label the scanned file in the following format: DoDID_YYYY-MM-DD_Consent.pdf, DoDID_YYYY-MM-DD_SOAP.pdf, DoDID_YYYY-MM-DD_Baseline.pdf or DoD ID_YYYY-MM-DD_followup.pdf as appropriate.
3. Using your computer, log onto an authorized, Sharepoint-like data repository designated for this study.The site URL is https://safe.amrdec.army.mil/safe/. Upload the scanned files. Upload a copy of the excel study contact log spreadsheet.
4. File the paper questionnaires in the designated, secure location.
   (NB: At the end of the study, the computerized data will be cross checked with the paper records. The paper records will then be destroyed by shredding after the data have been cross-checked for completeness and accuracy.)
5. After the transmission has been completed, log out of the secure FTP site.
6. In a separate email, notify the investigators the data file has been uploaded.
7. Upload will occur once in a weekly basis.

8. The investigators will access the secure FTP site, and confirm receipt of the encrypted data file in a response email. You should expect a response from the investigators within one day of the transmission of the encrypted data file.

Procedures for withdrawal of consent

1. Ask the subject to document withdrawal of consent to participate by completing a 'withdrawal of consent' form.
2. Make an entry in the Subject Contact log that notes the date, name, DoD ID. In the 'volunteered' column note "Consent withdrawn'
3. Communicate to the study PI the withdrawal of the subject within 3 days via receipt request e-mail which will serve as documentation of notification to the PI.
4. Wait until an approval to destroy the subject's data from the study PI. When approved, shred subject questionnaires and SOAP notes. Retain the subject's folder with the signed informed consent form and the signed withdrawal of consent form.
5. Delete from the computer scanned copies of the subject's questionnaire form and SOAP notes.
6. 'Wipe' the free space of the computer to permanently remove the subject's data

Procedures for adverse event

1. Verify that the subject has or is receiving care for the adverse event
2. Notify the PI of the adverse event as soon as practicable.
3. Complete an adverse event report form and forward to the study PI within 3 days of the event

Anticipated problems

1. ***Equipment malfunction***:
    a. If a scanner malfunctions: attempt to locate a replacement or substitute scanner on board ship. Notify the investigators. Continue data collection and store the completed paper records.
    b. If a printer malfunctions: attempt to locate a replacement or substitute printer on board ship. Notify the investigators. Have a set of 10, blank informed consent forms, questionnaires and SOAP note templates printed out at any given time in case it is inconvenient to print research forms out or if equipment malfunctions.
    c. If a study computer malfunctions: attempt to locate a replacement or substitute computer on board ship. Notify the investigators. The investigators will try to help: 1)

coordinate with shipboard IT to restore functionality to the study computer, or 2) coordinate to help locate a replacement or substitute computer on board ship or 3) coordinate to deliver a new, replacement study computer at the next COD delivery cycle.

2. ***Communications disruption with shore-based investigators***: Continue to collect data. Simply defer transfer of research records from the ship to shore to the next transmission cycle to be determined.

3. ***Supplies for the study run out***: Notify the investigators if materials and supplies for the study (such as pens, paper, clipboard, staples, printer cartridges, toner, etc.) are likely to run out. Attempt to locate replacement materials on board the ship. The study investigators will help coordinate resupply at the next COD delivery cycle.

Participation in periodic meetings with investigators.

The investigators will be available to clarify any questions the PT staff should have. The research coordinator will touch base monthly with the PT on board ship to check how the research project is going and gather any information that need to be convey to the PIs. If necessary, more frequent contacts will be schedule in order to make sure the study is being conducted as planned.

Figures

Figure 1: Suggested Study Contact Log

Encounter date	Name	DoD ID	Main complaint	Reason for visit	Eligible?	Consent	Baseline
02/12/15	Doe, John	1234567890	Back pain	Initial eval	Yes	Yes	2/12/15
02/15/15	Jones, Dave	0987654321	Back pain	Initial eval	Yes	Deferred until 2/11/15	
03/01/15	Clancey, T	1357986420	Knee problem	Initial eval	No	Declined	
02/13/15	Doe, John	1234567890	Back pain	Treatment			

Forms

1. Study Log
2. Informed Consent
3. Baseline Questionnaire
4. SOAP note
5. Follow-up Questionnaire

Terms and Definitions

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

Appendix 1

SOAP NOTE

TEMPLATE FOR TREATMENT VISITS

SOAP note identification (Subject name, DoD ID, subject date of encounter, therapist name)

Subjective: Contains ADSM main complaint(s), pain level, and general information about complaint, Duty status and job title. Evaluation: Report MOI, all treatments received for the condition (what helped and what did not), and what has ADSM done so far to control symptoms, including medication consumption and diagnostic tests. Report on functional limitations. Report ADSM goals for treatment. Follow-ups: Response to current treatment, report in any change of symptoms including new symptoms.

Objective: May include education about pathomechanics of the injury. Evaluation: Describe observation of involved sight, eg. Genu valgus or rectification of the spine, special tests to assess functional or discriminatory soft tissue involvement Manual muscle tests, laxity of joint, palpation results. Treatment: Describe treatment given. If Therex what type of exercise, joint mobilization, cardio which type of equipment and how long, strengthening machine versus free weights or resistive bands. Include any pain control modalities (ice or heat). Include use of electrotherapy (ultrasound or e-stim). Include use of trigger point dry needling.

Assessment: (Diagnosis) treatment codes: eval, re-eval, manual therapy, etc. Referral to consults (eg radiology, meds or other services) – this stuff normally goes in "today's tx" section. The assessment portion just has my assessment of "pain most consistent with xxx, deficits in x, y, z.". Response to treatment.

Plan: Treatment plan. What will be done at the next visit. Plan for return to full-duty status if applicable.

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

ERMS/Log Number: OR130160

Award Number: GRANT11452369

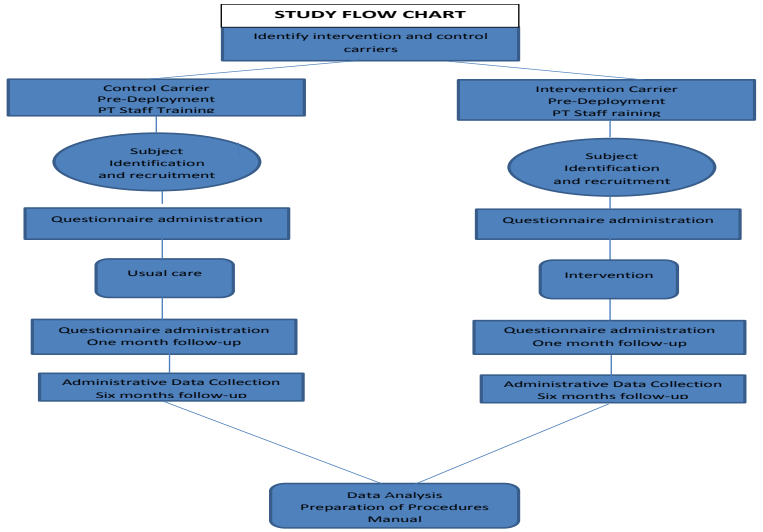
PI: Sherri Weiser, PhD **Org:** New York University School of Medicine **Award Amount:** $1,021,985

Study/Product Aim(s)

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

Approach

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



Timeline and Cost

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

Updated: (New York 30/09/2015)

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

Due to previous IRB delays we have not reached our annual recruitment target for the control carrier (250). However we are expected to surpass the minimum recruitment number required to identify statistical differences between both carriers on important outcome measures. Due to a high number of potential study participants exceeding orange flags cut-off scores we have decided to include these patients in the study. We are currently awaiting IRB approval for this amendment.