

AWARD NUMBER: W81XWH-20-2-0036

TITLE: The Implementation of Psychologically Informed Physical Therapy to Prevent Chronification in Service Members with Musculoskeletal Disorders

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13. SUPPLEMENTARY NOTES					
14. ABSTRACT This study responds to the FY 19 CPMRP Congressional appropriation focus area of implementation science for evidence-based, efficacious interventions to manage chronic pain as well as comparative effectiveness incorporating a biopsychosocial model of assessment that includes pain interference in emotional and physical functioning. CPMRP defines chronic pain as pain that occurs on at least half the days for six months or more. This study is a hybrid type 3 design, which tests an implementation/strategy while observing/gathering information on the clinical intervention and related outcomes. In 2019, The Navy Surgeon General prioritized the advancement of capable medical personnel, and healthy, deployment-ready Sailors and Marines as a focus area. We propose to implement and assess an evidence-based psychologically informed training program for Navy physical therapy (PT) staff aimed at improving physical health and preventing attrition in active duty service members (ADSM) with musculoskeletal disorders (MSD).					
15. SUBJECT TERMS None listed.					
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1. INTRODUCTION:

Disability due to musculoskeletal disorders (MSD) poses a major problem for the Navy. Research has shown that once a Service member has been injured, negative thoughts and feelings about the injury can increase the likelihood of disability. There is evidence that early treatment may be more successful at reducing disability and that perhaps this type of treatment should be provided by physical therapists who have early and prolonged access to patients. We have developed a course to train physical therapists to identify and address psychological factors that increase the likelihood of disability in patients with MSD called Psychologically-informed Physical Therapy (PiPT). In a pilot study, we demonstrated successful implementation of training physical therapists onboard an aircraft carrier. The long-term objective of our research is to implement this training program in different settings and for different patients with MSD throughout the military. In the proposed study, we aim to establish the feasibility of implementing psychologically-informed PT in a US Navy shore-based health care facility. We will also assess the impact of PiPT on ADSM with MSD in comparison to usual physical therapy.

2. KEYWORDS:

Psychologically informed Physical Therapy (PiPT), Chronic Pain, Musculoskeletal Disorders, Biopsychosocial Intervention, Rehabilitation.

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Major Task 1: Submit Administrative Aspects to start the study	Target Date April 15, 2021
Subtask 1: Obtain CRADA and subcontract agreement	100% completed
Subtask 2: Prepare documentation for IRB submission, including research protocol, training material and protection of human subjects	100% completed
Subtask 3: Modify protocol as per IRB requirements	100% completed
Subtask 4: Hire, credential and train research team stationed at NMCP.	95% completed
Subtask 5: Submit IRB approval and other documentation required for HRPO approval.	90% completed

What was accomplished under these goals?

Q1 Accomplishments:

- Subcontract agreement finalized
- IRB documentation in preparation
- Training material completed and is in draft form to be reviewed after IRB submission and comments return to PI

Q2 Accomplishments:

- CRADA signed.
- FT research assistant and research coordinator hired and credentialed at NMCP.

Q3 Accomplishments:

- IRB documentation submitted
- Research Psychologist hired at NYUGSOM
- Transposed data collection forms into REDCap.
- Set up survey distribution automation in REDCap.

Q4 Accomplishments:

- DHA DSA application is in process
- Applied for CEUs for the PiPT training program.
- Established office space and recruiting areas at NMCP for the study.
- PT research assistant hired at NMCP; credentialing in progress.
- Received approval from the NMCP IRB

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

FT research assistant has learned how to develop data collection tools and surveys in REDCap. The NYU team received training on foreign influence.

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?

Since the NMCP IRB has approved the protocol, we will submit a DSA application to the DHA and continue preparation of the approved study materials. We will submit a IRB Reliance Agreement form to be signed between NYUGSOM and NMCP. We will also submit our documentation to HRPO for approval. Once HRPO approval and the DSA is acquired, we will begin recruiting and data collection for the control arm of the study.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

What was the impact on other disciplines?

Nothing to Report

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

Nothing to Report

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

The delay continued for the submission of IRB materials. We had to clarify some questions asked from IRB pre-screening personnel at NMCP. The Scientific Review Committee had questions and recommended modifications that further delayed our protocol's review by the actual IRB. Also a few technical issues caused a recent update to the EIRB program that caused an additional brief delay.

One potential problem we anticipate in executing the protocol is the potential for low enrollment. Although, it seems that the target clinics have sufficient census to justify our target recruitment and COVID-19 related restrictions have become more flexible, we are not discounting the possibility of a future lockdown or the refusal of ADSMs to attend in-person treatment. In that case we may have to extend the enrollment period. There is also a possible delay in subject recruitment due to the required onboarding period of our second research associate at NMCP. It is possible that subject recruitment will begin before this process is complete. Our full time research associate will monitor recruitment rates and make every effort to stay on schedule.

Changes that had a significant impact on expenditures

Delays in signing the subcontract award triggered delays in hiring staff resulting in pushing some funding to the next year period.
Delay of IRB approval has resulted in forestalling the purchase of some study supplies, particularly printed materials which require IRB approval to be used in the study.

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

Not Applicable

Significant changes in use of biohazards and/or select agents

Not Applicable

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(s) or other Internet site(s)**

Nothing to Report

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Marco Campello, Ph.D.

Project Role: Principal Investigator

Researcher Identifier (e.g. ORCID ID): 2-8340-8313

Nearest person month worked: 10.5

Contribution to Project: Dr. Campello has worked on conducting the weekly research meetings. He has been in contact with HJF (sub contracted vehicle) for hiring research personnel. He reviewed CV of potential candidates and interview a couple of them. He has worked together with the team in the preparation of the IRB documentation.

Name: Sherri Weiser, Ph.D

Project Role: Co-Principal Investigator

Researcher Identifier (e.g. ORCID ID): 2-0743-7059

Nearest person month worked: 10.5

Contribution to Project: Dr. Weiser has participated in the weekly research meetings. She has also been involved in the interview of potential research candidates for the NMCP site as well as the NYUSOM. Dr. Weiser is currently assisting in the preparation of the IRB documentation.

Name: CAPT Leslie Hair.

Project Role: Principal Investigator

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 9

Contribution to Project: CAPT Hair has participated in the weekly research meetings. He has also been involved in the interview of potential research candidates for the NMCP site. He has been instrumental in having the research staff credentialed at NMCP and he is also assisting in the preparation of the IRB documentation.

Name: CAPT ret. Gregg Ziemke
Project Role: Research Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 8.5
Contribution to Project: CAPT Ziemke has participated in the weekly research meetings. He is working with the research assistant in the preparation of the IRB documentation as well as the training logistics for the research personnel at NMCP, and attended weekly study team meetings.

Name: Timothy Hope
Project Role: Research Assistant
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 6
Contribution to Project: Timothy Hope has participated in the weekly research meetings, and has worked on preparation of the IRB and DSA documentation as well as development of the web-based version of the data collection tools.

Name: Dr. Cheongeun Oh
Project Role: Statistician
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Dr. Cheongeun Oh has participated in the weekly research meetings. She has designed the statistical analysis for this study, consulted with the research assistant and coordinator on how to represent the statistical terminology in lay terms, aided the research assistant in designing the Excel spreadsheet, and attended weekly study team meetings.
Funding Support: DOD; NIDA; Horizon Pharma; NINDS; NCI; NCCIH; NCATS; Genentech; NIH; NMSS

Name: Dr. Hope Mowery
Project Role: Associate Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1.5
Contribution to Project: Dr. Hope Mowery has participated in the weekly research meetings. She has also assisted in development of training materials for CEU approval, and facilitated development and maintenance of relevant literature base.

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

Nothing to Report

What other organizations were involved as partners?

Organization Name: Naval Medical Center, Portsmouth
Location of Organization: Portsmouth, Virginia
Partner's contribution to the project: Facilities and Collaboration

Organization Name: Henry Jackson Foundation
Location of Organization: Bethesda, Maryland
Partner's contribution to the project: Contract Personnel

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES: