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

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CONTRACTING ORGANIZATION: NYU Grossman School of Medicine
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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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TABLE OF CONTENTS

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

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 ADMS 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. | 100% completed |
| Subtask 5: Submit IRB approval and other documentation required for HRPO approval. | 100% completed |
| Major Task 2: Study Phase 1 | Target Date July 15, 2022 |
| Subtask 1: Control cohort subject accrual | 100% completed |
| Subtask 2: Completed follow-up assessments of control cohort | 30% completed |
| Milestone 1: control cohort subjects' recruitment complete (target 200 subjects) | 100% completed |
| Milestone 2: Data collection completed | 30% completed |
| Major Task 3: Study Phase 2 | Target Date Feb 15, 2022 |
| Subtask 1: Training of physical therapy staff personnel | 20% completed |
| Subtask 2: Evaluate training | 20% completed |

What was accomplished under these goals?

Q1 Accomplishments:

- approval to award CEUs to PT staff for PiPT training
- DHA DSA agreement submitted and approved
- HRPO approval received
- Part-time research staff at NMCP hired, received security clearance, and credentialed
- Completed preparation of research materials and related resources for control cohort data collection
- IRB Reliance Agreement form signed between NYUGSOM and NMCP
- Completed development of REDCap project for data

Q2 Accomplishments:

- Part-time research staff at NMCP completed credentialing, training
- Began recruitment of control cohort
- Data collection from control cohort underway
- Troubleshooting and refining protocol for collecting follow-up data from control cohort
- Submitted protocol as abstract for presentation at MHSRS

Q3 Accomplishments:

- Part-time research staff at NMCP added to protocol
- Continued recruitment of control cohort
- Data collection from control cohort underway
- Baseline data collection close to complete
- Began follow-up data collection (T2 and T3)
- Abstract accepted for presentation at MHSRS
- Optimized recruitment procedures and follow-up engagement
- Development of logistics for training program to optimize engagement
- .

Q4 Accomplishments:

- Completed recruitment of control cohort
- Presented protocol at MHSRS 22
- Adapted training protocol for Major Task 3: Phase 2 of study to accommodate logistical restrictions at Site 2 as well as larger training class than anticipated
- Began implementation of Phase 3
- Candidate search and hire of new Research Associate at Site 2 as previous RA left for personal reasons
- Successfully completed Annual Continuing Review with NMCP IRB

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

Abstract on the protocol was submitted and accepted by MHSRS and presented by the research coordinator at MHSRS 22 in September.

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?

We are scheduled and on track to complete the training and evaluation of all relevant PT staff over the next few weeks (Major Task 3). We will also begin recruiting intervention cohort subjects for Study Phase 3 as soon as training has been completed. We will continue collecting follow-up data from the control cohort. One of our Research Assistants at NMCP resigned for personal reasons; thus, we have begun the process of recruiting a new full-time RA to assist with recruitment, data collection, and administration.

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

Changes to the approach to training are required. The training class will be larger than anticipated (approximately 45 PT staff) as the flow of patients from the Site 2 clinic extends to several branch clinics for treatment following evaluation. Changes in logistics of training are required due to restrictions associated with COVID, increased class size, and Site 2 logistical restrictions.

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

There was a change of site PI. CAPT Leslie Hair was transferred and CDR Brittany Jansen replaced him as site PI. There was a slight delay in the recruitment as we needed to resubmit the paperwork to IRB, HRPO and DSA, It was necessary to adapt the training program to accommodate several restrictions due to COVID and operations of the Site 2 clinic, as well as the larger than anticipated training class. The training course was adapted in 3 ways: 1) program was compressed from 2 full days to 1.25 days, 2) program was divided into a didactic portion (self-administered) and an interactive portion, and 3) the trainers were not all present on site during (some were virtual, via Microsoft Teams). We are planning to hold additional "Office Hours" for the trainees with the trainers to insure universal competency.

In addition, one of our RAs at Site 2 resigned for personal reasons. We are actively recruiting to hire a new full-time RA. We have been informed that several PT staff will likely be deployed away from the NMCP network; this may affect recruitment numbers in the next quarter. We will monitor and troubleshoot as necessary.

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

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.

- **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: CAPT(ret). Gregg Ziemke Project Role: Research Coordinator. Researcher Identifier (e.g. ORCID ID): Nearest person month worked: 10 Contribution to Project: CAPT Ziemke has participated in the weekly research meetings. He worked with the research assistants in recruitment and data collection for the control arm. He has also been involved in planning the logistics of the training for the PTs for Phase 2 to optimize engagement. He has also been engaged in a search for a new Research Assistant.

Name: Timothy Hope Project Role: Research Assistant. Researcher Identifier (e.g. ORCID ID): Nearest person month worked: 12 Contribution to Project: Timothy Hope has participated in the weekly research meetings, and recruiting and collecting data for the control arm. He has also been maintaining relevant documentation, preparation and submission of documents to change the PI, and other reports.

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: 6 Contribution to Project: Dr. Hope Mowery has participated in the weekly research meetings. She was also involved in troubleshooting recruitment and data collection for the control arm. She has also assisted in preparation of reports to sponsor, submission of IRB materials, and facilitated development and maintenance of relevant literature base. She has also been involved in planning the logistics of the training for the PTs for Phase 2 to optimize engagement, as well as in development of the training materials and program. She prepared and delivered a talk at MHSRS 2022 on the study.

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 worked together with the team to troubleshoot recruitment and data collection for the control arm. Reported and oversaw change of PI at NMCP/NYU CRADA. He has also been involved in troubleshooting the logistics of and development of the training for the PTs for Phase 2 to optimize engagement. He assisted in development of the materials for the initial phase of training for the PTs.

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 troubleshooting recruitment and data collection for the control arm. She has also been involved in troubleshooting the logistics and development of the training for the PTs for Phase 2 to optimize engagement. She developed the materials for the initial phase of training of the PTs (didactics).

Name: CAPT Leslie Hair. Project Role: Principal Investigator (through May 31, 2022) Researcher Identifier (e.g. ORCID ID): Nearest person month worked: 6 Contribution to Project: CAPT Hair has participated in the weekly research meetings.

Name: CDR Brittany Jansen. Project Role: Principal Investigator (since June 1, 2022) Researcher Identifier (e.g. ORCID ID): Nearest person month worked: 2 Contribution to Project: CDR Jansen replaced CAPT Hair in June and has been participating in the weekly meeting and taken the lead on monitoring the clinical flow and staff turnover, as well as formulating training plan to optimize engagement and minimize disruption to clinic operations. She has also been involved in planning the logistics of the training for the PTs for Phase 2 to optimize engagement. She ensured administration of the initial phase of training for the PTs (didactics) and has worked with the team to schedule the rest of the training so that all relevant PT staff can be trained.

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: