

AWARD NUMBER: W81XWH-20-2-0036

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

PRINCIPAL INVESTIGATOR: Dr. Marco Campello, PhD

CONTRACTING ORGANIZATION:
New York University 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					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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1. INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

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: *Provide a brief list of keywords (limit to 20 words).*

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

3. ACCOMPLISHMENTS: *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Major Task 1: Submit Administrative Aspects to start the study	Target Date April 15, 2021
Subtask 1: Obtain CRADA and subcontract agreement	Completed
Subtask 2: Prepare documentation for IRB submission, including research protocol, training material and protection of human subjects	Completed
Subtask 3: Modify protocol as per IRB requirements	Completed
Subtask 4: Hire, credential and train research team stationed at NMCP.	Completed
Subtask 5: Submit IRB approval and other documentation required for HRPO approval.	Completed
Major Task 2: Study Phase 1	Target Date July 15, 2022
Subtask 1: Control cohort subject accrual	Completed
Subtask 2: Completed follow-up assessments of control cohort	50% completed
Milestone 1: Control cohort subjects' recruitment complete (target 200 subjects)	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	Completed
Subtask 2: Evaluate training	80% completed
Subtask 3: Training reinforcement	90% completed
Milestone 1. PT staff training	Completed
Milestone 2. Training Evaluation	80% completed
Milestone 3. Training reinforcement	Ongoing
Milestone 4. Aim 1 Feasibility of recruiting subjects achieved	Completed
Milestone 5. Training manual finalized	Completed

Major Task 4: Study Phase 3	Target Date Feb 15, 2023
Subtask 1: Intervention cohort subject accrual	Completed
Subtask 2: Completed follow up assessments	25% completed
Milestone 1: Intervention subjects' recruitment completed (target 200 subjects)	Completed
Milestone 2: Data collection completed	Ongoing
Milestone 3: Aim 1 feasibility of recruiting intervention subjects completed	Completed
Major Task 5: Data Analysis	Target Date Oct 1, 2023
Subtask 1: Statistical analysis	20% completed
Subtask 2: Data synthesis	10% completed
Subtask 3: Report writing	10% completed

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Q1 Accomplishments:

Training of 45/47 of training class

- Initiated evaluation of training
- Continued data collection from control cohort
- Initiated recruitment of intervention cohort
- Initiated data collection from intervention cohort
- Accepted invitation to submit MHSRS presentation for publication in Supplement of Military Medicine
- Submitted article based on MHSRS presentation to Supplement of Military Medicine
- Scheduled to complete training with remaining 2 PT staff during next quarter

Q2 Accomplishments:

- Completed training of all personnel (47 staff)
- Continued evaluation and reinforcement of training
- Continued follow-up data collection from control cohort
- Continued recruitment of intervention cohort
- Continued data collection from intervention cohort
- Hired 2 new Research Associates at NMCP site for assistance in recruitment and data collection
- Updated DSA to reflect transition at NMCP site to new electronic medical record (Genesis)

Q3 Accomplishments:

- Continued recruitment of intervention cohort
- Continued follow-up data collection for control and intervention cohorts
- Onboarded and trained new Research Associates
- Delivered PiPT training to 11 new PT staff
- Article on study as presented at MHSRS 2022 accepted for publication in Military Medicine Supplement
- Abstracts on study accepted for presentation at MHSRS 2023

Q4 Accomplishments:

- Completed recruitment of intervention cohort
- Continued follow-up data collection for control and intervention cohorts
- Presented baseline data at MHSRS 2023
- Successfully completed Annual Continuing Review with NMCP IRB
- Submitted invited grant consistent with transition from current project
- Began analyzing baseline data
- Accepted invitation to submit manuscripts on baseline data based on MHSRS 2023 presentations
- Began preparation of above-mentioned manuscripts

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

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. “Training” activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. “Professional development” activities result in increased knowledge or skill in one’s area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Baseline data was submitted and accepted by MHSRS, and presented by the research coordinator at MHSRS 2023 in August. Research coordinator also worked with PI and Co-Is in reviewing data and the development of abstracts and manuscripts.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

During Year 3, the physical therapy staff at NMCP and some of the branch clinics were trained in psychologically-informed physical therapy. The new research staff was able to assist one of the training sessions.

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

If this is the final report, state “Nothing to Report.”

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

We will continue collecting follow-up data from both cohorts. We have begun and will continue to synthesize and analyze data. We are preparing manuscripts for invited articles on baseline data. We also plan to begin review of randomly selected SOAP notes from training class of PTs to assess implementation of PiPT. During the next and last period, we will also prepare a manual of operations containing the training program packet.

4. IMPACT: *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

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

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

We received feed-back from the participants that they thought the training was very helpful and they intended to incorporate the principles learned in their clinical practice.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report. We are yet to evaluate effectiveness of the knowledge transfer and how its results compare to the civilian population.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions;*
or
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:*

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Our overall training class was larger than anticipated (58 PT staff total). As anticipated and reported in previous annual report, we had to modify the training to take place in one day rather than the two-day previously planned. The Hospital was undergoing an implementation of a new electronic medical record system that requires the staff to be away from clinical duties for an extensive amount of time. We scheduled and completed 3 additional days of training for other new hires during the past year.

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

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

There were unanticipated delays in hiring of our two new RAs and their ability to be cleared and able to start working at NMCP. Both RAs were hired in February 2023. One of them was able to be clear and begin assisting with data collection in May, and the other RA in June. Collection of follow-up data has been challenging in that a smaller percentage of participants than anticipated are responding to the requests to complete the follow-up questionnaires. Our RAs have been contacting the participants with reminders via phone and email.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

The delay in hiring research staff and the delay in the overall process of starting the study forced us to push the recruitment timeline. We were able to extend the subcontractor for the last year without compromising the funds available.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

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:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume; year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Campello, M., Ziemke, G., Hair, L.C., Oh, C., Mowery, H.C., Hope, T., & Weiser, S. (in press). Protocol for the implementation of psychologically-informed physical therapy to prevent chronification in Service Members with musculoskeletal disorders (MSD). *Military Medicine*.

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

- 1) Campello, M, Ziemke, G, Hair, L.C., Oh, C., Mowery, H.C., Hope, T., Weiser, S. (2022). Protocol for the implementation of psychologically-informed physical therapy to prevent chronification in Service Members with musculoskeletal disorders (MSD). Military Health System Research Symposium, Orlando, FL. (presentation)
- 2) Campello, M., Mowery, H.C., Oh, C., Hope, T., Ziemke, G., Jansen, B. & Weiser, S. (2023) Musculoskeletal Injury Incidence in Active Duty Service Members (ADSM) Reporting to a Base Medical Clinic. Military Health System Research Symposium, Orlando, FL. (poster)
- 3) Mowery, H.C., Weiser, S., Oh, C., Hope, T., Ziemke, G., Jansen, B., Campello, M. (2023) Psychiatric Symptoms in Active Duty Service Members with Musculoskeletal Disorders Reporting to a naval medical facility for outpatient Physical Therapy care. Military Health System Research Symposium, Orlando, FL. (poster)
- 4) Weiser, S., Mowery, H.C., Hope, T., Oh, C., Ziemke, G., Jansen, B., Campello, M. (2023) Indicators of Delayed Recovery in Active Duty Service Members with Musculoskeletal Disorders Reporting to a Branch Medical Clinic. Military Health System Research Symposium, Orlando, FL. (poster)

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

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report

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

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

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 worked together with the team to troubleshoot recruitment and data collection. He helped in the development of the training

materials, traveled to the NMCP site for the training, and lead the trainings for Phase 2. He has been involved in evaluation of the training. He also assisted in preparation of the article in press at Military Medicine.

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 was involved in troubleshooting recruitment and data collection. She co-lead the trainings for Phase 2. She has assisted in the evaluation of the training. She also assisted in preparation of the article in press at Military Medicine.

Name: CDR Brittany Jansen. Project Role: Principal Investigator Researcher Identifier (e.g. ORCID ID): Nearest person month worked: 9 Contribution to Project: CDR Jansen has been participating in the weekly meeting and taken the lead on monitoring the clinical flow and staff turnover. She assisted in coordinating training of new PT staff. She also facilitated engagement and participation of the PT staff post-training.

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. He co-lead several of the trainings in Phase 2, and facilitated engagement and evaluation of PTs post-training. He also facilitated hiring of 2 Research Assistants. He also assisted in preparation of the article in press at Military Medicine.

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. He has also been maintaining relevant documentation, preparation and submission of documents to IRB, and other reports. He facilitated technology during the training at the NMCP site. He trained the most recently hired RAs.

Name: Danielle Leverich Project Role: Research Assistant. Researcher Identifier (e.g. ORCID ID): Nearest person month worked: 2.5 Contribution to Project: Danielle Leverich has participated in the weekly research meetings, and recruiting and collecting data for the intervention arm. She has also continued the follow-up data collection from the control arm.

Name: Deja Anderson Project Role: Research Assistant. Researcher Identifier (e.g. ORCID ID): Nearest person month worked: 1.5 Contribution to Project: Danielle Leverich has participated in the weekly research meetings, and recruiting and collecting data for the intervention arm. She has also continued the follow-up data collection from the control arm.

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. Delivered descriptive statistics for abstracts submitted to and ultimately presented at MHSRS 2023. Began synthesizing and analyzing of baseline data.

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 co-lead the trainings for Phase 2. She also assisted in preparation of the article in press at Military Medicine. She also prepared and presented 3 posters on the baseline data at MHSRS 2023.

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

If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to Report

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: *(if foreign location list country)*

Partner’s contribution to the project *(identify one or more)*

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner’s facilities for project activities);*
- *Collaboration (e.g., partner’s staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and*
- *Other.*

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: *N/A*

QUAD CHARTS: *N/A*

9. APPENDICES: *N/A*