NYU Langone Health

Official Title:	The Implementation of Psychologically Informed Physical Therapy to Prevent Chronification in Service Members With Musculoskeletal Disorders
NCT Number:	NCT05132400
Study Number:	s21-01351
Document Type:	Study Protocol and Statistical Analysis Plan
Date of the Document:	• October 12, 2021

EIRB Protocol Template (Version 1.4)

1.0 General Information

***Please enter the full title of your study:**

Factors associated with physical therapy outcomes in active duty service members with musculoskeletal disorders.

***Please enter the Protocol Number you would like to use to reference the protocol:**

PiPT Study
* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

Is this a multi-site study (i.e. Each site has their own Principal Investigator)?

No

Does this protocol involve the use of animals?

○ Yes ◉ No

2.0 Add Site(s)

2.1 List sites associated with this study:

Primary Dept?	Department Name
◆	**Navy** - Naval Medical Center Portsmouth (NMCP)

3.0 Assign project personnel access to the project

3.1 *Please add a Principal Investigator for the study:

Hair, Leslie Chris, DSc CAPT

Select if applicable

☐ Student ☐ Site Chair
☐ Resident ☐ Fellow

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Hope, Timothy Gilman, BS in Biomed. Sciences
Associate Investigator
Ziemke, Gregg W, CAPT

Associate Investigator

B) Research Support Staff

Stephens, Sam, Psy.D. LCDR
Monitor

3.3 *Please add a Protocol Contact:

Hair, Leslie Chris, DSc CAPT

The Protocol Contact(s) will receive all important system notifications along with the Principal Investigator. (i.e. The protocol contact(s) are typically either the Protocol Coordinator or the Principal Investigator themselves).

3.4 If applicable, please select the Designated Site Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Site (e.g. the Site Chair).

4.0 Project Information

4.1 * Has another IRB/HRPP reviewed this study or will another IRB/HRPP be reviewing this study? If Yes, answer the questions according to the IRB/HRPP Determination.

○ Yes ◉ No

IRB Name	Review Date	Determination
No records have been added		

4.2 * Is this a research study or a Compassionate Use/Emergency Use/HUD project?

◉ Yes ○ No

4.3 What type of research is this?

- ☐ Biomedical Research
- ☐ Clinical trial (FDA regulated)
- ☐ Behavioral Research
- ☐ Educational Research
- ☑ Psychosocial Research
- ☐ Oral History
- ☐ Other

4.4 Are you conducting this project in pursuit of a personal degree?

○ Yes ◉ No

4.6 * Is this human subjects research? (As defined by 32 CFR 219) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

(•) Yes ( ) No

4.7 * Do you believe this human subjects research is exempt from IRB review?

( ) Yes (•) No

5.0 Personnel Details

5.1 List any Research Team members without EIRB access that are not previously entered in the protocol:

Name: (Last, First, M.I.)	Phone Number:	Email Address:	Associated Institution:
Campello, Marco Role on Protocol: Co-PI	212-255-6690	marco.campello@nyulangone.org	New York University
Weiser, Sherri Role on Protocol: AI	212-255-6690	sherri.weiser-horwitz@nyulangone.org	New York University
Oh, Cheongeun Role on Protocol: Statician	212-263-3394	ohc03@nyumc.org	New York University
Mowery, Hope C. Role on Protocol: AI	212-255-6690	Hope.Mowery@nyulangone.org	New York University

5.2 Will you have a Research Monitor for this study?

(•) Yes
( ) No
( ) N/A

Research Monitor Qualifications
Ensure the individual has expertise consistent with the nature of risk(s) identified within your study and is independent of the team conducting the research.

Research Monitor Role:

We have identified a clinical psychologist at NMCP, LCDR Sam Stephens, to serve as our Research Monitor.

A primary focus of our study is the interaction between emotional wellbeing and physical therapy outcomes. Our participants will already be receiving treatment by a physical therapist, and participation in this study will not alter their course of treatment. Our research monitor will assist us in navigating any emotional distress-related adverse events, incidental findings, or unexpected problems that may emerge during the study.

If applicable, you may nominate an individual to serve as the Research Monitor:

Selected Users
Sam Stephens, Psy.D.

6.0 Data/Specimens

6.1 Does the study involve the use of existing data or specimens only (no interaction with human subjects)?

( ) Yes (•) No

7.0 Funding and Disclosures

7.1 Source of Funding:

Funding Source	Funding Type	Amount
: Congressionally Directed Medical Research Program (CDMRP)	: Research Development Testing and Evaluation (RDT&E) funds	1527509

Total amount of funding:

1527509

7.2 Do you or any other Investigator(s) have a disclosure of a personal interest or financial nature significant with sponsor(s), product(s), instrument(s) and/or company(ies) involved in this study?

( ) Yes (•) No

If Yes, complete and attach Conflict of Interest forms for all key personnel

8.0 Study Locations

8.1 Is this a collaborative or multi-site study? (e.g., are there any other institutions involved?)

(•) Yes ( ) No

8.2 Study Facilities and Locations:

Institution	Site Name	Site Role	FWA or DoD Assurance Number	Assurance Expiration Date	Is there an agreement?	IRB Reviewing for Site
No records have been added						

Other:

	Other Institution Site	Site Role	FWA or DoD Assurance Number	FWA or DoD Expiration Date	Is there an agreement?	IRB Reviewing for Site

8.3 Are there international sites?

Attach international approval documents, if applicable, when prompted. Note: Ensure local research context has been considered

( ) Yes (•) No

8.4 Is this an OCONUS (Outside Continental United States) study?

( ) Yes (•) No

Select the area of responsibility:

Have you obtained permission from that area of responsibility? (This is a requirement prior to study approval)

( ) Yes ( ) No

9.0 Study Details

9.1 Key Words:

Provide up to 5 key words that identify the broad topic(s) of your study

Psychologically informed Physical Therapy (PiPT)
Chronic Pain

Musculoskeletal Disorders
Biopsychosocial Intervention
Rehabilitation

9.2 Background and Significance:

Include a literature review that describes in detail the rationale for conducting the study. Include descriptions of any preliminary studies and findings that led to the development of the protocol. The background section should clearly support the choice of study variables and explain the basis for the research questions and/or study hypotheses. This section establishes the relevance of the study and explains the applicability of its findings

Chronic pain from Musculoskeletal Disorders (MSD) poses a significant problem for Active Duty Service Members (ADSM) and are the main reason for separation and long-term disability.[1-4] Overseas conflicts in the last decade have contributed to a rise in reported MSD among ADSM.[5] Sailors and Marines who experience MSD have the highest level of attrition from these disorders among all military branches.[6-8] In a study conducted on two deployed United States Navy aircraft carriers, Hebert et al. (2004)[9] found that MSD comprised 40% to 43% of all sick call visits during deployment. Lewis Shattuck et al. (2016)[10] found that 57.7% of ADSM aboard a Navy carrier reported MSD symptoms over the course of one year; twenty percent of whom had symptoms that interfered with their daily activities on board ship. The current investigators studied all Navy ADSM and found that the rate of conversion from first career limited duty assignments to the fitness for duty assessment or physical evaluation boards (PEB) was 15% for MSD cases. Only 28% of those referred to PEB return to full duty.[11,12] It is apparent that MSD deserve our attention. Despite this, there is little research into effective treatment approaches for MSD in Navy ADSM.

Risk factors associated with MSD-related disability in ADSM

Several factors have been shown to be strongly associated with disability from MSD. Studies looking at work outcomes in military populations emphasize a biopsychosocial perspective that includes a variety of factors. Feuerstein et al. (1997)[13] and Berkowitz (1999)[14] identified characteristics associated with disability in ADSM including younger age, lower rank, poor aerobic conditioning, high work stress, worries and low social support. Lincoln et al. (2002)[15] also found similar factors to be associated with disability from MSD in ADSM such as pay grade, diagnosis, length of service, age, military occupational specialty, job satisfaction, previous history of MSD, smoking, work stress and job demands. Schoenfeld et al. (2014)[16] found that MSD, psychiatric conditions, and lower rank accounted for 78% of the variance in unfavorable Physical Evaluation Board (PEB) outcomes in soldiers with a variety of health complaints.

Studies specific to Navy ADSM are few but echo some findings from studies of other military branches. Stephanie Booth-Kewley et al. (2009)[17] explored a variety of psychosocial factors contributing to attrition from basic training due to MSD in Marine Corps recruits but found only expectations about graduation and career intentions to be predictive in the final regression analysis. In a later study, the same researchers found similar results in a

one-year follow-up of injured marines. Individuals who had high recovery expectations at baseline were over five times as likely to be recovered at follow-up as individuals who had low expectations (OR = 5.18, $p \leq .01$).[18] A longitudinal study conducted by the present investigators examined the relationship between known modifiable psychological risk factors and work outcomes among ADSM who were not deployed and found that fear of activity was predictive of work status twelve weeks after a reported back injury.[19] Taken together, these studies provide clear scientific evidence linking psychosocial factors with increased risk of disability following MSD in ADSM and support additional investigation into Navy members.

The biopsychosocial model of pain and disability explains the multidimensional nature of MSD. This model emphasizes the interplay of physiological and psychological (cognitive, affective, and behavioral) responses to pain and how they interact with the social environment to ameliorate or maintain pain and dysfunction. For example, when there is prolonged pain, cortical changes result in altered muscle response patterns such as abnormal dynamic muscle control.[20,21] In addition, stress hormones that accompany these painful conditions enhance pain transmission.[22] These changes result in cognitive appraisals of pain as unremitting and individuals often express anxiety about their future and suffer depression from feelings of helplessness and hopelessness. Many develop a fear of movement that is reflected in the social dimension as restriction of work and social activities.[23] This pattern decreases the likelihood of recovery as it is self-sustaining.

This model is applied to clinical practice by identifying various elements as risk factor categories, or 'flags'.[24] Red flags are clinical indicators of serious underlying conditions that warrant further medical intervention such as the presence of systemic diseases. Orange flags can be considered the psychiatric equivalent of red flags and include serious psychiatric pathology that may interfere with recovery such as clinical depression and Post-traumatic Stress Disorder (PTSD).[25] Yellow flags are modifiable psychological or behavioral risk factors associated with unfavorable clinical outcomes. Common yellow flags are negative beliefs about recovery, feelings of distress and inability to cope with pain. Blue flags are the workers' perceptions of the work environment such as perceived work stress or lack of social support. Black flags are characteristics of the system or the environment in which a person functions such as the nature of the work or the insurance and compensation system of the workplace.[25] Recently pink flags, which are protective from poor outcome such as self-efficacy and positive outcome expectations, have also been identified and should be considered when assessing risk.[26]

Evidence of effectiveness of Cognitive Behavioral Therapy (CBT) in modifying psychological risk factors

Yellow flags are considered modifiable through clinical intervention. CBT, derived from a well-established mode of psychotherapy, has been developed to address modifiable psychological risk factors for chronicity and poor outcome in patients with MSD.[27-30] CBT is rooted in the work of Aron Beck, who identified automatic thoughts or responses to stimuli that result in affective states that may interfere with adaptive behaviors and proposed techniques to alter these thoughts.[31] The emphasis on modifiable factors is of critical importance to the development of effective interventions for treating MSD. It has been shown that there is a clear relationship between the presence of modifiable yellow flags and future clinical and occupational outcomes. Indeed, factors such as fear-avoidance beliefs, distress, somatization, and pain catastrophizing are associated with high risk of a poor outcome such as chronicity in patients with low back pain (LBP).[26,30,32-34]

Using CBT to target yellow flags, especially when they are at high levels, leads to more positive outcomes.[25,35,36] Systematic reviews show moderate evidence that treatments that address psychological factors using cognitive-behavioral techniques in conjunction with PT are effective in reducing symptoms and limiting disability among individuals with sub-acute MSD.[37-39] A recent study showed CBT to be cost-effective in treating chronic pain.[40] Furthermore, it has been shown that patients with psychological risk factors do not benefit from a biomedical approach alone but do benefit from a combined approach.[36,39,41,42] For example, patients with Low Back Pain (LBP) who express fear of activity can be treated successfully only when these fears are addressed.[30]

Benefits of Psychologically-informed Physical Therapy (PiPT)

Identification and modification of yellow flags has been shown to be effective in reducing or preventing chronic or recurrent disability in patients with MSD.[36,41,43,44] Recently, it has been proposed that this should be done by physical therapists who have early and prolonged access to patients. Other advantages of having physical therapists address yellow flags are that CBT administered by a psychologist is expensive, may not be readily available and patients may be reluctant to seek psychotherapy due to stigma.

PiPT, sometimes called psychologically based PT, is an approach designed to incorporate the concepts of CBT for pain management into routine clinical PT practice in order to modify maladaptive responses associated with chronicity.[32,45] The goal of PiPT is to promote a fast and optimal recovery by removing psychological obstacles, obviating the need for referral to a psychologist and facilitating triage to other health professionals in a timely manner when needed. PiPT training includes education about the neuropsychology of pain, patient communication skills, and identification of psychosocial risk factors for chronicity and treatment approaches that include reassurance, relaxation, and psycho-behavioral reactivation. Currently, PT training is based in the biomedical model, which posits a direct relationship between the nature and severity of the injury and the symptoms reported by the patient. In this model, the objective of treatment is to address the physical cause of pain or disability in an effort to improve outcomes without taking into account the psychosocial nature of the risk factors for chronicity and disability. A shift in treatment from the biomedical paradigm to a biopsychosocial paradigm requires education and training.

Studies have found that physical therapists who acknowledge the importance of addressing psychological risk factors in patient care often feel ill equipped to do so.[46,47] There is a growing body of literature suggesting that physical therapists have the potential to assimilate

biopsychosocial principles into their traditional biomedical training.[48-51] However, it is yet unknown how well such training translates into clinical application. Studies exploring the impact of this training on patient outcomes are promising but are limited by small sample sizes or low response rates.[52-54]

In one recent larger study, Overmeer et al developed an eight-day training course for physical therapists in PiPT including questionnaire administration, the biopsychosocial model, yellow flags, behavioral principles, communication, addressing fear of movement, and role playing.[45] In a randomized clinical trial (RCT) examining the effectiveness of this training, the investigators found that while attitudes and knowledge of the physical therapists shifted in the expected direction, their behavior did not. Furthermore, training did not improve patient outcomes. However, patients with high of levels catastrophizing and depression showed better outcome regarding disability when the attitudes of therapists changed from purely biomedical to psychologically-based.[55] The authors point out that a one-time course is insufficient for changing behaviors, even if attitudes are altered. Ongoing education and reinforcement is needed. This sentiment is echoed in a study by Nielsen et al. (2014)[49], where trained physical therapists stated a preference for more role-play experience prior to implementing treatment. Secondly, Overmeer et al. (2011)[55] speculate that their topics were too broad and did not focus on specific ways to address yellow flags. Finally, they posit a possible selection bias in that participants were interested in learning about yellow flags, so they may have already been exhibiting different behaviors than other physical therapists.

Our research group has experience in training Navy personnel to address psychological risk factors. We designed an education and training program for an interdisciplinary team at the Navy Medical Center Portsmouth (NMCP).[56] Team members were trained in the biopsychosocial model as a group and then individually by experts in their field. The purpose of this training was to teach physical therapists, psychologists, and physicians how to work in an interdisciplinary team. In a pilot randomized controlled trial, we tested the feasibility of implementing an interdisciplinary work restoration program based on this training called "Backs to Work" in a Navy and Marine Corps setting for ADSM with work-limiting low back pain. We found preliminary evidence that those randomized to CBT and PT had improved perception of function as compared to usual care and there was a trend of decreased fear of activity and pain catastrophizing in the intervention group as compared to usual care.[56]

Furthermore, we developed a PiPT course to train PT personnel aboard an aircraft carrier in a case-controlled cohort pilot study comparing PiPT to usual care. Results demonstrated the feasibility of implementing this intervention onboard US Navy aircraft carriers.[57] Trained PT personnel achieved a priori criteria for feasibility by obtaining passing knowledge scores following training, completing clinical notes indicating PiPT implementation and participating in regular case reviews in which they discussed their treatment plans via phone conference with the research team. Feedback from the PT staff who stated that their treatment paradigm and practice had changed from a biomedical to a biopsychosocial model after training also confirms successful transfer of PiPT training into clinical practice.

We found evidence for the effectiveness of PiPT in the carrier study as well. Subjects in the intervention arm reported learning coping strategies that are associated with good outcomes. Responses to the question "Please list the most important things you learned in physical therapy?" differed between the two groups. Among subjects on the intervention carrier, 33.7% indicated they had learned concepts consistent with PiPT treatment based on a priori analysis criteria developed by the investigators. For example, one intervention subject said, "Stress and physical pain have a connection". In contrast, none of the subjects from the control carrier responded in this manner.[11] Our experience with PiPT training has informed the development of the present proposal.

In our interdisciplinary training for the RCT described above, we avoided some of the weaknesses highlighted in previous studies by giving specific examples of how to implement guideline-based care for each discipline and by providing weekly teleconferences to answer questions, discuss difficult cases and reinforce training.[56] In addition, we encouraged the use of self-care techniques to reduce patient reliance on health care professionals. This further distinguished our approach from Overmeer's. In our training for US Navy PT staff aboard a carrier we replicated our original training while incorporating important aspects found to be effective in other studies, such as ongoing role-playing and case-examples once the PT staff was deployed through teleconference.[57]

The long-term objective of our research is to implement PiPT in different settings and for different cohorts of patients with MSD, throughout the Military. Therefore, we propose a full-scale study replicating the design and methods used in our pilot carrier study to test the feasibility and short- and long-term effectiveness of PiPT on psychological and functional outcomes in ADSM seeking care for MSD at a shore based rehabilitation setting; Navy Medical

Center Portsmouth (NMCP). ADSM who seek care for MSD at NMCP may differ from patients aboard a carrier in terms of type and duration of MSD, rank, deployment status and environment. For example, most of the MSD on the carrier were acute and unlikely to be severe. The NMCP sees all ADSM with MSD regardless of severity and duration. Therefore, we wish to establish feasibility and effectiveness of PiPT in this setting to augment the generalizability of our findings. The results of this study along with those from the carrier study will allow us to modify our rehabilitation strategy to address the needs of specific Navy cohorts across different phases of care in different health care settings. The ultimate goal is to decrease MSD-related chronicity leading to disability in ADSM in support of combat readiness.

9.3 Objectives/Specific Aims/Research Questions:

Describe the purpose and objective(s) of the study, specific aims, and/or research questions /hypotheses

Our study objective is to establish the feasibility of implementing a psychologically informed rehabilitation strategy while concurrently assessing its' effectiveness in ADSM with MSD seeking care in a US Navy shore-based health care setting. This intervention is intended to improve the management of chronic pain in order to optimize ADSM function.

Specific aims

1. Demonstrate the feasibility of implementing PiPT in a US Navy shore-based health care setting. We will analyze SOAP notes to assess whether the clinicians have applied aspects of the training in the treatment given to the patients and they are reflected in the notes.

2. Document and compare baseline risk factors related to pain interference in two cohorts of patients with MSD.

3. Demonstrate the effectiveness of a PiPT intervention on psychological and functional work outcomes in a comparative effectiveness trial through a relative increase in protective follow-up measures such as quality of life, self-efficacy, and satisfaction and a relative decrease in detrimental measures like pain catastrophizing, fear of movement, and distress.

9.4 Study Design:

Describe study design in one to two sentences (e.g., prospective, use of existing records/data /specimens, observational, cross-sectional, interventional, randomized, placebo-controlled, cohort, etc.). Specify the phase – Phase I, II, III, or IV – for FDA-regulated investigational drug research

We are proposing an observational prospective comparative cohort study. This study meets the criteria for a hybrid type 3 study; a hybrid type 3 study tests an implementation/strategy while observing/gathering information on the clinical intervention and related outcomes.[58]

9.5 Target Population:

Describe the population to whom the study findings will be generalized

Active duty service members receiving physical therapy for musculoskeletal disorders.

9.6 Benefit to the DoD:

State how this study will impact or be of benefit to the Department of Defense

This study will demonstrate the feasibility and efficacy of implementing PiPT training at a military treatment facility in improving outcomes of musculoskeletal disorders. The ultimate goal is to decrease MSD-related chronicity leading to separation and disability in ADSM in support of combat readiness.

10.0 Study Procedures, Data Management, and Privacy

10.1 Study Procedures:

Describe step-by-step how the study will be conducted from beginning to end

Phase I

Recruitment and Consenting

- Research staff will review the PT clinic's schedule for patients scheduled for initial evaluation, then request an introduction from the therapist if appropriate (patient must be scheduled for at least 4 physical therapy sessions).
- Research staff will brief the patient on the study.
- If the patient is interested, the researcher will show them to the private study room, screen them for eligibility, and then ask them to review the consent form. The researcher will remain in the room to answer any questions.

Treatment

- After signing the consent form, the participant will complete a paper form collecting contact information for follow-up and demographic information. At this point, the participant will be assigned a participant ID number. The researcher will verify the participant's diagnostic code and therapist using AHLTA afterward.
- Before the participant's next PT appointment, the participant will complete the baseline questionnaire battery, a 139 question survey battery. The participant may complete the battery immediately on paper, or at a later date online using a link to REDCap that will be sent via encrypted email. This battery must be completed before their next appointment.
- Participants will receive standard PT care as prescribed and scheduled by their therapist. Participation in the study will not alter their care plan.
- Participants will complete follow up questionnaire batteries after their 4^{th} PT appointment*, 6mo and 12mo post enrollment. The first follow-up questionnaire is a 77 question survey battery. The second and third follow-up points use a 68 question battery. All follow-up questionnaires will be completed remotely via REDCap.
- We will collect de-identified SOAP notes from randomly selected participants and review them for verbiage indicating that the therapist employed principles of PiPT. We will collect up to 30 SOAP notes, pertaining to various physical therapists and throughout various stages of treatment.

PT Training

Following the completion of Phase I recruitment, PT staff will be trained in PiPT by the NYU personnel. NYU personnel intend to deliver the training in person; however, they are prepared to deliver virtual, real-time training should COVID protocols make face-to-face training unfeasible.

- PT staff will receive a knowledge quiz at the end of their training sessions to document successful completion of training. PT staff must obtain a passing score (85% or above) on this quiz to be considered proficient.
- We will also assess the PT staff's confidence in implementing PiPT using a seven point Likert scale self-rating derived from a previous study.[86]
- Furthermore, staff will be evaluated on the accurate identification and management of yellow flags using case studies.
- Once the staff shows proficiency in delivering PiPT, the second study phase will begin. There will likely be some overlap between the follow-up data collection of Phase I and the training period.
- After initial training and as Phase II recruitment begins, staff will receive weekly reinforcement sessions for one month, after which they will receive further reinforcement sessions on a biweekly basis as needed.

During training, PT staff will be asked whether they have had previous experience with PiPT. If so, participants who saw these providers, whether during Phase 1 or 2, will be analyzed for a possible confounding effect.

Phase II

Recruitment and Consenting

- Recruitment for Phase II will largely proceed as with Phase I (pending unforeseen changes in the PT department's process). The only major change is that when researchers screen the schedule for evaluation appointments, they will also verify that the corresponding therapist completed the PiPT training.
- Research staff will brief the patient on the study.
- If the patient is interested, the researcher will show them to the private study room, screen them for eligibility, and then ask them to review the consent form. The researcher will remain in the room to answer any questions.

Treatment

- After signing the consent form, the participant will complete a paper form collecting contact information for follow-up and demographic information. At this point, the participant will be assigned a participant ID number. The researcher will verify the participant's diagnostic code and therapist using AHLTA afterward.
- Before the participant's next PT appointment, the participant will complete the baseline questionnaire battery, a 139 question survey battery. The participant may complete the battery immediately on paper, or at a later date online using a link to REDCap that will be sent via encrypted email. This battery must be completed before their next appointment.
- Participants will receive PT care as prescribed and scheduled by their therapist. Participation in the study will not directly alter their care plan.
    - During Phase II, we anticipate that therapists who completed PiPT training will incorporate the training into their standard care. We will not ask therapists to give differential treatment to patients who are enrolled in the study.
- Participants will complete follow up questionnaire battery after their 4th PT appointment, 6mo and 12mo post enrollment. The first follow-up questionnaire is a 77 question survey battery. The second and third follow-up points use a 68 question battery. All follow-up questionnaires will be completed remotely via REDCap.
- We will collect de-identified SOAP notes from randomly selected participants and review them for verbiage indicating that the therapist employed principles of PiPT. We will collect up to 30 SOAP notes, pertaining to various physical therapists and throughout various stages of treatment.

We chose to conduct this study in sequential cohorts rather than conducting the two cohorts (PiPT and non-PiPT) in parallel because there are no comparable sites with similar characteristics such as type of subjects, catchment area size and availability of the health care team in the Navy.

*We chose the 4th visit as the first follow-up point for two reasons. First, we expect to see a difference between groups on study outcomes at that point. Secondly, since according to the former head of the NMCP department of physical therapy (PI) the average number of visits at the outpatient PT clinic is 6, the 4th visit will allows us to capture complete data.

10.2 Data Collection:

Describe all the data variables, information to be collected, the source of the data, and how the data will be operationally measured.

Intake Form (Demographics)

VARIABLE	Collection Point	TOOL	Variables Tyepse	Rieasponse	Citation

Gender	Intake Form	Single Item	Demographics	Free Response	n/a
Age	Intake Form	Single Item	Demographics	Free Response	n/a
Marital Status	Intake Form	Single Item	Demographics	Free Response	n/a
Ethnicity	Intake Form	Single Item	Demographics	Yes/No	n/a
Race	Intake Form	Single Item	Demographics	Select from a List	n/a
Length of Service	Intake Form	Single Item	Demographics	Free Response	n/a

vice	orm		hics	e	
Rate/Rank	Intake Form	Single Item	Demographics	Free Response	n/a
Evaluation Date	Intake Form	Single Item	Demographics	Date (ddMONyy)	n/a
Therapist Name	Intake Form	AHLTA	Demographics	Last name, First	n/a
Diagnosis	Intake Form	AHLTA	Demographics	ICD-10 Code	n/a

Evaluation Date: Because participants will be consented and fill out the intake form on the day of their PT evaluation, the research staff member will simply record the current date that the form is completed.
We will require a DSA to harvest those last two variables.

Questionnaires/Outcomes

The self-report questionnaire batteries are largely composed of the validated survey tools and single-item questions.

1. The Pain Disability Index (PDI) will measure pain interference. [60]
2. Catastrophizing will be assessed by the Pain Catastrophizing Scale (PCS).[61]
3. Fear avoidance beliefs will be assessed using the Fear Avoidance Beliefs Questionnaire (FABQ).[62,63] (Excluding "I have a claim for compensation for my pain," no relevance).
4. Psychological distress will be measured using the Hospital Anxiety and Depression Scale (HADS).[64-66]
5. Self-efficacy will be assessed using the Pain Self-Efficacy Questionnaire (PSEQ).[67-70]
6. *Positive outcome expectations* will be assessed using a 5 point single item scale developed for the military population by Stephanie Booth-Kewley et al. (2009).[17]

7. Satisfaction with process of care will be measured by the "process of care" subscale of The MedRisk Instrument for Measuring Patient Satisfaction (MRPS).[71,72]
8. Outcome satisfaction (single item scale): 'If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it? This is derived from the Core Outcome Measures Index (COMI) questionnaire.[73]
9. Clinical Depression: The Center for Epidemiologic Studies Depression Scale (CES-D). [74,75]
10. Anxiety Disorder: General Anxiety Disorder Screener (GAD-7).[76]
11. Post-Traumatic Stress Disorder (PTSD) will be assessed using the PTSD Checklist – Military version (PCL-M).[77,78]
12. Job satisfaction (single item scale): "Taking everything into consideration, how do you feel about your job as a whole?" taken from Dolbier et al. (2005):[79]
13. Work stress (single item scale): "Taking everything into consideration, how stressful is your job as a whole?"
14. Organizational commitment (single item scale): Commitment will be assessed by the affective dimension of the Commitment Scale.[80-83]
15. Job social support: Subject's relationships with co-workers and social environment at their job, drawn from the Deployment Risk and Resilience Inventory-2 (DRRI) unit support subscale.[84]

Injury history: affected body part(terminology adopted from Barrel matrix.[85]), time since onset, other MSD comorbidities, episode recurrence, previous MSD and pain intensity.

Baseline Questionnaire Battery

- 139 questions charted below and one open field question on any barriers to treatment the participant perceives.

VARIABLE	**Collection Point**	**TOOL**	**Variable Type**	**Responses**	**Citation**
Tobacco Use	Baseline Survey	Three Item	Confounder	Select from List	n/a
Education	Baseline Survey	Single Item	Demographics	Select from List	n/a
	Bas				

primary Injury Location	eline Survey, Follow-Up 1, 2, 3	Single Item	Demographics	Select from List	85
Time since onset	Baseline Survey	Single Item	Demographics	>4 weeks, 4-12 weeks, <12 weeks	n/a
Episode Recurrence	Baseline Survey	Single Item	Demographics	Yes/No	n/a
pre	Baseli	Tw	Demo	Ye	

Quality of Life	Up 1 Baseline Survey, Follow-Up 1,2,3	Single Item	Dependent Variable	5pt scale	n/a
Pain Interference	Baseline Survey, Follow-Up 1,2,3	PDI	Dependent Variable	0-10 scale; 7 questions	60
Self-	Baseline Surv		Depend	0-6 sc	

efficacy	ey, Follow-Up 1,2,3	PSEQ	ent Variable	ale; 10 questions	67
Pain Catastrophizing	Baseline Survey, Follow-Up 1,2,3	PCS	Dependent Variable	0-4 scale; 13 questions	61
Fear of movement	Baseline Survey, Follow-Up 1,2,3	FABQ	Dependent Variable	0-6 scale; 15 questions	62

Distress	Baseline Survey, Follow-Up 1, 2, 3	HADS	Dependent Variable	4 pt scale; 14 questions	64
Org commitment	Baseline Survey	Affective commitment scale	Confounder	5 pt Likert; 4 questions	80
Job social support	Baseline Survey	DRRI	Confounder	5 pt Likert; 12 questions	84
	Base		Co	1-5 sc	

PTSD	line Survey	PCL-M	nfounder	ale; 17 questions 0-3	77
Depression	Baseline Survey	CES-D	Confounder	scale; 20 questions 0-3	74
Anxiety	Baseline Survey	GAD-7	Confounder	scale; 7 questions	76
Mental Health Care	Baseline Survey, Follow-up 1, 2	Three Item	Confounder	Yes/No	n/a

	, 3				
Job satisfaction	Baseline Survey	Single Site	Confounder	1-5 scale	79
Work stress	Baseline Survey	Single Site	Confounder	1-5 scale	n/a
Duty Status	Baseline Survey, Follow-up 1, 2, 3	Single Site	Confounder	Full Duty; Limited Duty; Med Board; Other	n/a
Perceived barr	Baseline	Single	Dependen	Free Re	

iers to care	Survey	Item	t Variable	sponse	11

Follow-up Questionnaire Batteries

- Post 4th treatment session- 77 items long, including one open field question
- 6 and 12mo – 68 items (excludes MRPS scale and outcome expectation)

VARIABLE	Collection Point	TOOL	Variable Type	Responses	Citation
Primary Injury Location	Baseline Survey, Follow-Up 1, 2, 3	Single Item	Demographics	Select from List	85
Pain inten	Baseline Survey, Fo	Single	Demograp	0-10 Sc	n/a

sity	llow-Up 1, 2, 3	Items	hi c	al e	
Outcome expectation	Baseline Survey, Follow-Up 1	Single item	Independent Variable	0-5 scale	17
Quality of Life	Baseline Survey, Follow-Up 1, 2, 3	Single Item	Dependent Variable	5 pts scale	n/a
Pai	Baseline Su		Dep	0-10	

	, 3				
Fear of movement	Baseline Survey, Follow-Up 1, 2, 3	FABQ	Dependent Variable	0-6 scale; 15 questions	62
Distress	Baseline Survey, Follow-Up 1, 2, 3	HADS	Dependent Variable	4 pt scale; 14 questions	64
Mental He	Baseline Survey,	Three	Confou	Yes	

alth Care	Follow-up 1, 2, 3	e Item	nder	/No	n/a
Satisfaction with process	Follow-up 1	MEDRISK	Dependent Variable	1-5 Likert; 8 questions	71
Satisfaction with Outcome	Follow-up 1, 2, 3	COMI Single item	Dependent Variable	5 pt scale	73
Duty Status	Baseline Survey, Follow	Single item	Confounder	Full Duty; Limited Duty; Med B	n/a

	-up 1, 2, 3			oard; Other	
Lessons learned from therapy	Follow-up 1, 2, 3	Single Item	Dependent Variable	Free Response	11

SOAP Note Review

Researchers will review the randomly selected, de-identified SOAP notes for verbiage indicating that the therapists identified and applied principles of PiPT, such as references to yellow flags like fear avoidance behavior. These SOAP notes and their reviews will not be assigned a Subject ID number or otherwise be associated with their corresponding demographic information or questionnaire responses.

10.3 At any point in the study, will you request, use, or access health information in any form, including verbal, hard copy and electronic?

(•) Yes ( ) No

10.4 Review the definitions below and respond to the following two questions. If you are not sure of the answers, email DHA.PrivacyBoard@mail.mil for assistance. The *Military Health System (MHS)* is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force *MHS workforce members* are employees, volunteers, trainees, and other persons whose conduct, in the performance of work for the MHS, is under the direct control of the MHS, whether or not they are paid by the MHS. *MHS business associates* are persons or entities that provide a service to the MHS and require protected health information (PHI) to provide the service.

Are you an MHS workforce member?

(•) Yes, I am an MHS workforce member
( ) No, I am not an MHS workforce member

Are you an MHS business associate?

( ) Yes, I am an MHS business associate

○ No, I am not an MHS business associate

10.5 Have you consulted with an MHS data expert to determine the data elements required for your study?

Consulting with a data expert often saves time later in the compliance process because the data expert can advise on the data available in the numerous MHS information systems, the quality of that data and the methods for encrypting and collapsing data. To schedule a consult with an MHS data expert, send an email to: (**DHA.PrivacyBoard@mail.mil**)

◉ Yes, then complete the questions below according to the data consult
○ No, then complete the questions below according to the best of your knowledge

10.6 Indicate how you will request data from the MHS. Select all that apply.

☐ Talking with MHS health care providers or MHS health plans about specific research participants
☐ Obtaining MHS hard copy records specific to research participants
☑ Obtaining data from an MHS information system(s)

10.7 If you are obtaining data from an MHS information system(s), indicate whether you plan to receive a data extract or whether you plan to access an MHS information system directly to create a data set.

A data extract is when the MHS or a contractor provides the data set directly to the researcher. When receiving a data set through data extract, the researcher may indicate whether the data elements should be provided as is, encrypted or collapsed. In contrast to a data extract, access to an information system means that the researcher may directly access an MHS information system and create a data set for the research study

☐ Data Extract
☑ Access

10.8 Do you intend to request de-identified data from the MHS in your research study?

There are different two methods for de-identifying data pursuant to HIPAA:
1) Safe Harbor Method: Removing all of the identifiers listed in Table 1 below, provided that the researcher does not have actual knowledge that the remaining data can be used alone or in combination with other information to identify the individual who is the subject of the information
2) Statistical Method: An expert, with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable, determines that the data is not individually identifiable

○ Yes ◉ No

10.9 Indicate the MHS information system(s) from which you will seek to obtain data

If you do not know which system(s) contains the data elements you need, refer to the Guide for DoD Researchers on Using MHS Data or request guidance from an MHS data expert at: **DHA.PrivacyBoard@mail.mil**.

Below is a list of commonly used MHS systems. If the system from which you seek to obtain data is not listed below, list the name of the system in the "Other MHS Systems" category below
PHI Systems:

MHS Information System	Requesting Data
: AHLTA	: Yes
: CHCS	: No

PII-Only Systems:

MHS Information System	Requesting Data
No records have been added	

De-Identified Data & Other Systems:

Information System	Requesting Data
No records have been added	

10.10 Do you intend to merge or otherwise associate the requested data with data from any sources outside of the MHS, including other DoD systems that are not part of the MHS?

- ○ Yes, will merge data
- ◉ No, will not merge data

10.11 Indicate the data elements about research participants or relatives, employers, or household members of the research participants that you will request from MHS hard copies or from MHS information systems.
If you will merge data, also indicate non-MHS data elements about research participants or relatives, employers, or household members of the research participants that you will have access to in any form or medium.

Data Element(s)	MHS	Non-MHS Systems	MHS Hard Copies
1. Names	☐	☑	☐
2. Postal address with only town, city, state and zip code	☐	☐	☐
3. Postal address with all geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of Census: 1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and 2) the initial three digits of a zip code for all such geographic	☐	☐	☐

units containing 20,000 or fewer people is changed to 000			
4. Dates including all elements (except year) directly related to an individual, including birth date, admission date, discharge date, and date of death	☐	☑	☐
5. Ages over 89 and all elements of dates (including year) indicative of such age, unless you will only request a single category of "age 90 or older"	☐	☐	☐
6. Telephone numbers	☐	☑	☐
7. Fax numbers	☐	☐	☐
8. Electronic mail addresses	☐	☑	☐
9. Social Security numbers (SSNs)	☐	☐	☐
10. Medical record numbers	☐	☐	☐
11. Health plan beneficiary numbers	☐	☐	☐
12. Account numbers	☐	☐	☐
13. Certificate /license numbers	☐	☐	☐
14. Vehicle identifiers and serial numbers, including license plate numbers	☐	☐	☐

15. Device identifiers and serial numbers	☐	☐	☐
16. Web Universal Resource Locators (URLs)	☐	☐	☐
17. Internet Protocol (IP) address numbers	☐	☐	☐
18. Biometric identifiers, including finger and voice prints	☐	☐	☐
19. Full-face photographic images and any comparable images	☐	☐	☐
20. Any other unique identifying number, characteristic, or code (Diagnosis, DEERS ID, EDI-PI, Rank)	☐	☑	☐

If you are obtaining SSNs, provide a justification as to why and explain why a substitute cannot be used

10.12 Do you believe it is possible for the MHS data to become identifiable because of triangulation, a small cell size, or any unique data element(s)?

Triangulation means using different data elements that are not themselves identifiable but that when combined can be used to identify an individual. For example, triangulation would use rank and race together to determine the identity of an individual with a particular health condition.

Small cell size means that there is only a small number of eligible individuals that satisfy the category description. Guidance for acceptable cell size is available from the Centers for Medicare and Medicaid Services. For example, the rank category of four star generals with a particular diagnosis may be less than 30, so the rank category may need to be expanded to include lower ranks.

A unique data element includes any unique features that are not explicitly enumerated in the categories of data in rows 1 – 20 of the table above (in Section 10.10), but that could be used to identify an individual. Unique data elements include characteristics that are not themselves identifying, such as the rank of general or admiral, or a race or gender, but within the context of other information could be identifiable.

- ○ Yes, I believe there is a reasonable possibility the MHS data will become identifiable
- ◉ No, I believe there is no reasonable possibility the MHS data will become identifiable

10.13 Have you completed and uploaded an appropriate HIPAA document (i.e. HIPAA Authorization will be obtained or Waiver/alteration of HIPAA Authorization is being requested)?

- (•) Yes
- ( ) No
- ( ) N/A

10.14 Managing Data (Data Management and/or Sharing Plan) and/or Human Biological Specimens for this Study:

Include in this section the plan for acquiring data (both electronic and hard copy), access during the study, data/specimen storage and length of time stored, shipment/transmission, and the plan for storage and final disposition at the conclusion of the study. Describe any data agreements in place for accessing data within and/or outside of your institution (e.g., Data Sharing Agreement, Data Use Agreement, Business Agreements, etc.)

Acquiring Data: The majority of participant data will be accrued via self-report questionnaire. We plan to retrieve diagnostic codes from their PT SOAP notes on AHLTA, and we will extract and de-identify whole SOAP notes from a subgroup of randomly selected participants. We will also use CHCS and AHLTA to determine when a participant has or will receive their fourth PT session, but this is merely for scheduling follow-up, and will not be retained as data.

Data Entry and Integrity: For data entered by participants into the REDCap surveys, we presume that participants responded correctly. All data collection tools completed on paper will be scanned and initially entered into REDCap by the proctoring research team member, who will mark the instrument as "Unverified" in REDCap. The scanned forms will be transmitted to CAPT Gregg Ziemke via SAFE, who will use them to verify the entered data, correct any inconsistencies, and then mark the instrument as "Complete."
Our Excel database has been designed to draw values directly from downloaded REDCap data reports, reducing the potential for human error. We have also employed Excel's conditional logic programming and formatting to alert us if a participant's records are incomplete or mismatched.

Access to Data: The PI and research contractors (Gregg Ziemke and Timothy Hope) will have access to all study data, electronic and hard copy. NYU collaborators (Dr. Marco Campello and Dr. Sherri Weiser) will not have access to the original data; de-identified data and de-identified SOAP notes (for training evaluation) will be securely transmitted to them using the SAFE computer app.

Data Storage: All physical data and consent forms will be maintained in locked cabinets within a locked office at NMCP; forms collected at branch clinics may be temporarily stored in a similar two-lock situation until they can be transferred to the NMCP office. All digital data will be originally generated or collected on GFE at NMCP and maintained on that network. De-identified digital data will be transmitted to the NYU collaborators.

Shipment/Transmission: Any physical data that needs to be transferred from branch clinics to the NMCP office will be transported by a member of the NMCP research personnel. Transmission of digital data to NYU collaborators will be through the SAFE program.

Conclusion: The investigators will end support of dissemination of research data at the end of the project's contract period. The investigators will maintain the de-identified data in a secure location for a period of six years after the end of the contract period. At the end of six years the de-identified subject questionnaire data will be destroyed. The PI will notify CDMRP, the NMCP regulatory facilities such as IRB of record of the fulfillment of the requirement to destroy the research data at the end of the four and a half year period.

Data Agreements: Once the protocol is approved, NYU will apply for a DHA Data Sharing Agreement, with NYU listed as the applicant/primary contractor and HJF staff listed as subcontractors.

10.15 Managing Data (Data Management and/or Sharing Plan) and/or Human Biological Specimens for Future Research:

If the study involves collecting, storing, or banking human specimens, data, or documents (either by the Investigator or through an established repository) for FUTURE research, address.

How the specimens/data will be used, where and how data/specimens will be stored (including shipping procedures, storage plan, etc.), whether and how consent will be obtained, procedures that will fulfill subjects' request as stated in the consent, whether subjects may withdraw their data/specimens from storage, whether and how subjects may be recontacted for future research and given the option to decline, whether there will be genetic testing on the specimens, who will have access to the data/specimens, and the linkage, the length of time that data/specimens will be stored and conditions under which data/specimens will be destroyed.

N/A

11.0 Statistical/Data Analysis Plan

11.1 Statistical Considerations:

List the statistical methods to be used to address the primary and secondary objectives, specific aims, and/or research hypotheses. Explain how missing data and outliers will be handled in the analysis. The analysis plan should be consistent with the study objectives. Include any sub-group analyses (e.g., gender or age group). Specify statistical methods and variables for each analysis. Describe how confounding variables will be controlled in the data analysis

The characteristics of subjects including demographics and questionnaire responses will be summarized using descriptive statistics (e.g. mean ± standard deviation for continuous variables, and counts (%) for categorical variables). Alternatively, response frequencies for the questionnaires will be determined and displayed in tabular and graphic formats. After examining the response frequencies, some variable categories will be collapsed in order to allow further analysis using them as dependent measures in subsequent analysis (chi-square and logistic regression analyses). For the continuous outcomes (quantitative measurements such as Pain Disability Index scale, self-efficacy, positive outcome expectations, catastrophizing, fear avoidance beliefs and distress in Aims 2 and 3), we will conduct the Kolmogorov-Smirnov or the Shapiro-Wilk test to confirm the normality prior to performing statistical analyses. We will detect outliers via histograms, box-plots, normal plots and summary statistics. Where appropriate, we will conduct logarithmic transformation on variables.

All analyses will be conducted using the principle of "intent-to-treat" in which every participant is assumed to have received his/her assigned intervention, regardless of adherence.

11.2 Sample Size:

600

11.3 Total number of subjects requested (including records and specimens):

600

11.4 If you are recruiting by study arm, please identify the arms of the study and how many subjects will be enrolled in each arm

300 in the pre-training arm (control arm)
300 in the post-training arm (intervention arm)

11.5 Please provide a justification for your sample size

In order to achieve a statistical power of greater than 80% at an effect size of 0.3, we require a minimum of 200 participants to complete all follow-up in each cohort of the study, as detailed in the power analysis in Section 11.6. In order to account for a roughly 30% rate of attrition, we are requesting a sample size of 300 participants per arm, for a total of 600. Based on previous longitudinal studies by team members Dr. Campello, Dr. Weiser, and CAPT Ziemke,[11,19,56,57] we believe that this is a conservative estimate considering the duration of each participant's involvement.

11.6 Data Analysis Plan: Complete description: Background, Objectives, Design, Step by Step how the project is going to be done, Data analysis plan:

In order to assess for significant differences between two cohorts of patients, bivariate comparisons will first be conducted using a Chi-squared (Fisher exact) test to compare proportions of categorical (dichotomous outcomes) and an unpaired t-test for mean changes of continuous outcomes (i.e. Pain Disability Index scale, self-efficacy, positive outcome expectation, catastrophizing, fear avoidance beliefs and distress).

Alternatively, Wilcoxon nonparametric counterpart will be used for continuous variables where there is deviation from normality. These univariate analyses will be followed by multivariable regression methods for an adjustment of all other potential confounding variables.We will also use longitudinal logistic models (i.e., mixed-effects regression models with a random subject effect and GEE with exchangeable and independent correlations) to analyze the changes of the outcome at baseline at all follow-up times (baseline, post-treatment, at 6 months, and 1 year). Psychological outcomes will be analyzed at baseline and at post-treatment (approximately 4 weeks of enrollment). The models will be specified with random intercepts and slopes such that a linear trajectory representing outcomes will be compared between two arms. For example, longitudinal changes in all available continuous psychological outcomes over time of follow-up will be displayed using locally weighted smoothing scatter (lowess) plots, identifying nonparametric mean trajectories over time.[86] Mean trajectories then will be modeled with mixed-effects linear regression models, and if necessary using segment-linear models to approximate non-linear mean trajectories for ease of interpretation. Group (arm)-specific (as well as individual-level) intercepts and slopes over the period of follow-up will be included as random effects, while other covariates such as other clinical or demographic confounders will be modeled as fixed effects. An interaction term will be also assessed to test group differences in outcomes over time. Residual-based diagnostics will be used to evaluate validity of model assumptions. Two sided p-values <0.05 will be considered to be statistically significant. All statistical procedures will be performed using R statistical package (**www.R-project.org**).

In order to determine the association of treatment effects among the subjects who endorse the mental care questions, we will further perform the sub-analysis using the regression analysis similarly stated as above. All covariates and their source are shown in the tables of variables found in Section 10.2. This analytic approach will be hypotheses generating and will be largely exploratory as the study may not be powered to detect significant effects. Therefore, we have not proposed any formal power calculation for the sub-analysis.

Assuming normality, we calculated the statistical power for various detectable effect sizes and sample sizes in a two-sided hypothesis test with a significance level of 0.05, where the ratio of sample size of 1:1 is assumed between cases (intervention arm) vs. controls. When outcomes are proportions, we calculated power based on rate differences. Table 2 shows that our sample size will have adequate power to detect listed effect sizes. For example, we will achieve 95.4% power to detect a difference of rate of 0.3 (i.e., achieving minimal clinically important difference of 80% in receiving therapy by PT staff "after training" group vs. 50% in receiving therapy by PT staff before training) between two arms of a size of 100 (117) for each with 30 (40) % of missingness. For continuous outcomes, the same size of n=100 (117) for each will have a 83.6% power to detect standardized mean difference of 0.5, which corresponds that the reduction in PDI (Pain Disability Index) score from baseline to follow-up would be 50% greater in the training group as compared to that before training. Note that for each domain outcome, the power is the same for each effect size since they are standardized, but the mean change corresponding to a given effect size differs.

Table 2. Sample size and power

Cohort size N (Total sample)	Loss to follow-up or noncompliance	Unpaired t-test		Fisher exact test	
		Effect size[1]	Power (%)	Effect size[2]	Power (%)
117 (234) 100 (200)	40% 30%	0.5	83.6	0.30 (p1=0.8, p2=0.50)	95.4
167 (334) 143 (286)	40% 30%	0.5	94	0.25 (p1=0.8, p2=0.55)	95.8
250 (500) 215 (430)	40% 30%	0.4	93.2	0.20 (p1=0.8, p2=0.6)	96
334 (668) 286 (572)	**40% 30%**	**0.3**	**84.9**	**0.15 (p1=0.8, p2=0.65)**	**96**

1 standardized mean difference of 2 groups
2 absolute proportion difference of 2 groups with proportions (p1=P(above MID in pre-training cohort), p2= p2=P(above MID in post-training cohort))

Missing data: We will make every effort to prevent and avoid missing data. Even with the most robust processes, however, some missing data is inevitable. We will assess the mechanism of missing data by comparing patients with and without missing values on baseline and other complete information, to detect any patterns in demographics or other characteristics associated with missing data. First, the various missingness assumptions (missing completely at random: MCAR, missing at random: MAR or missing not at random: MNAR) will be tested by comparing subjects with missing and non-missing data.87 In order to incorporate uncertainty in handling missing data, we will perform a multiple imputation, which begins with a prediction of the missing data using the existing data from other variables.88 The missing values will then be replaced with the predicted values, and a full data set called the imputed data set will be created. This process iterates the repeatability and makes multiple imputed data sets. Each multiple imputed data set produced will be then analyzed using the standard statistical analysis procedures for complete data, and give multiple analysis results. Subsequently, by combining these analysis results, a single overall analysis result will be produced.

12.0 Participant Information

12.1 Subject Population:

US active duty service members receiving physical therapy for musculoskeletal disorders at Naval Medical Center Portsmouth and its branch health clinics.

12.2 Age Range:

Check all the boxes that apply. if the age range of potential subjects (specimens, records) does not match the range(s) selected, please specify in the text box.

- [ ] 0-17
- [x] 18-24
- [x] 25-34
- [x] 35-44
- [x] 45-54
- [x] 55-64
- [ ] 65-74
- [ ] 75+

12.3 Gender:

- [x] Male
- [x] Female
- [x] Other

12.4 Special categories, check all that apply

- [ ] Minors /Children
- [ ] Students
- [ ] Employees - Civilian
- [ ] Employees - Contractor
- [ ] Resident/trainee
- [ ] Cadets /Midshipmen

- [x] Active Duty Military Personnel
- [ ] Wounded Warriors
- [ ] Economically Disadvantaged Persons
- [ ] Educationally Disadvantaged Persons
- [ ] Physically Challenged (Physical challenges include visual and/or auditory impairment)
- [ ] Persons with Impaired Decisional Capacity
- [ ] Prisoners
- [ ] Pregnant Women, Fetuses, and Neonates
- [ ] Non-English Speakers
- [ ] International Research involving Foreign Nationals - Headquarters Review is necessary

You must also consider the requirements of DoDI 3216.02, Enclosure 3, paragraph 7.e.

12.5 Inclusion Criteria:

Order Number	Criteria
1	Active duty service members (at baseline; separation from the military post-treatment will not be grounds for exclusion)
2	Patients presenting to an NMCP or branch clinic physical therapy department
3	Patients who have only received their evaluation appointment for their primary complaint
4	Patients presenting for a primary complaint of a MSD (The following ICD-10 codes will be included: M13,M14.8,M15-19,M21-25,M40-43,M46-48,M50- 54,M60-71, M73,M75-77)

12.6 Exclusion Criteria:

Order Number	Criteria
1	Patients not eligible to receive outpatient physical therapy.
2	Patients receiving fewer than four treatment sessions of physical therapy.
3	Patients who are pregnant
4	Patients receiving physical therapy for acute post-surgical recovery
5	Patients scheduled for or subject to a Physical Evaluation Board (PEB) at baseline
6	Coast Guard, as they are DoT rather than DoD

13.0 Recruitment and Consent

13.1 Please describe the recruitment process, including how subjects will be identified and selected for the study.

Research staff will approach pre-screened patients immediately after their evaluation appointment with their physical therapist, inform them of the study, and ask them if they are interested in participating. Interested patients will then be lead to a private study area nearby to begin the consenting process described in Section 13.4. Those who consent will leave us their contact information and may complete their baseline questionnaire immediately on location, or they may complete it remotely before their next appointment.

13.2 Compensation for Participation:

Participants will not be compensated for participation.

13.3 Please describe the pre-screening process. If no pre-screening, enter Not Applicable in the text editor

Physical therapy staff will be informed of the inclusion and exclusion criteria for our study. Researchers will use printouts of the clinic schedule received from the clinic manager to determine which patients are coming in for evaluation. In Phase II, we will also use the schedule to verify that the patient's therapist has completed PiPT training. We will let staff members conducting evaluations know that we are interested in approaching their patients after the evaluation if they are eligible. If the staff member assents, we will brief the patient on the study and ask them to verify that they are:

1. An active duty service member beginning physical therapy for their current musculoskeletal injury
2. NOT pregnant, receiving PT for post-surgical follow-up, or scheduled for or subject to a Physical Evaluation Board.

13.4 Consent Process: Revised Common Rule, Section 219.116: General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

Are you requesting a waiver or alteration of informed consent?

○ Yes ◉ No

Please explain the consent process:

Once patients have been prescreened and approached, patients will be shown to a private room to review the consent form with the researcher. The researcher will lead patients through the consent form using proper consenting procedures, then give patients time to further review the consent form privately and receive answers to any questions they may have regarding the study. Patients will be granted as much time as they need to make their decision in a private space. The patient will decide whether to participate, and will sign and date the consent form along with the researcher. The participant will also receive a duplicate copy of the consent form, signed and dated by the researcher.

13.5 DoDI 3216.02 requires an ombudsman to be present during recruitment briefings when research involves greater than minimal risk and recruitment of Service members occurs in a group setting. If applicable, you may nominate an individual to serve as the ombudsman.

◉ N/A
○ Propose ombudsman

13.6 Withdrawal from Study Participation:

Explain the process for withdrawal and specify whether or not the subjects will be given the opportunity to withdraw their data their data/specimens in the event they wish to withdraw from the study

Participants may contact a member of the research team using any of the contact methods on the ICF to let them know that they wish to withdraw. They will be prompted to revoke their HIPAA Authorization as well, and have instructions recapitulated.

Once we have received the participant's revocation of HIPAA Authorization, their data will be purged from the study.

14.0 Risks and Benefits

14.1 Risks of Harm:

Identify all research-related risks of harm to which the subject will be exposed for each research procedure or intervention as a result of participation in this study. Consider the risks of breach of confidentiality, psychological, legal, social, and economic risks as well as physical risks. Do not describe risks from standard care procedures; only describe risks from procedures done for research purposes

As with most studies, there is a risk of breaches of privacy and/or confidentiality.

Additionally, during our initial questionnaire we ask our participants to self-report on a number of psychological and social health measures, notably depression, anxiety, and PTSD. It is possible that some participants may become distressed while answering these questions. If a participant experiences an emergent mental health event, the researcher will immediately contact a clinician to transfer the patient to the Emergency Medicine Department (EMD).

14.2 Measures to Minimize Risks of Harm (Precautions, safeguards):

For each research procedure or intervention, describe all measures to minimize and/or eliminate risk of harms to subjects and study personnel

We will minimize risks of confidentiality and privacy breaches as described in Sections 14.3 and 14.5, respectively.

We will address the potential for distress by informing patients of the nature of the questionnaires during the consenting process. Additionally, the survey tools we use to measure aspects of mental health are established, validated clinical psychology measures. If a participant grows distressed while responding to the questionnaire, we will notify their physical therapist, who may refer them to the adult mental health department or the emergency department, depending on the severity and urgency of the incident.

14.3 Confidentiality Protections (for research records, data and/or specimens):

Describe in detail the plan to maintain confidentiality of the research data, specimens, and records throughout the study and at its conclusion (e.g., destruction, long term storage, or banking). Explain the plan for securing the data (e.g., use of passwords, encryption, secure servers, firewalls, and other appropriate methods). If data will be shared electronically with other team members/collaborators outside the institution, describe the method of transmission and safeguards to maintain confidentiality. Explain whether this study may collect information

that State or Federal law requires to be reported to other officials or ethically requires action, e. g., child or spouse abuse

Electronic study data will primarily be housed on government furnished equipment, and files containing PII will be password protected. All data transmitted to NYU personnel will be de-identified and transmitted via SAFE. Paper forms such as consent forms and questionnaires will be secured in locked cabinets behind at least one additional locked door. The consent forms and intake forms, which contain identifiers, will be stored in a separate cabinet from any paper questionnaires.

We will be collecting data on distress, depression, anxiety, and PTSD. While any one of these measures may not be reportable, if our team psychologist believes these indicate a dangerous situation, e.g. a suicide risk, we will report to the appropriate authorities.

14.4 Potential Benefits:

Describe any real and potential benefits of the research to the subject and any potential benefits to a specific community or society

If the individuals in the research are considered experimental subjects (per 10 USC 980), and they cannot provide their own consent, the protocol must describe the intent to directly benefit all subjects

Participants will not directly benefit, but we expect to improve physical therapy for ADSM with musculoskeletal disorders.

14.5 Privacy for Subjects:

Describe the measures to protect subject's privacy during recruitment, the consent process, and all research activities, etc.

Recruiting and consenting: We intend to rely on physical therapy staff to introduce us to eligible patients in their exam room after their evaluation session, so that participants can be briefed on the study in private. Interested patients will be provided a private space in the PT clinic to review the consent form and ask questions.
Participation: Participants may either complete their baseline questionnaire in person or online; all follow-up questionnaires will be completed remotely. If they choose to participate in person, they will complete the questionnaire in paper in the consenting area. The online method will consist of the research team sending a link to the online questionnaire via encrypted email to the address specified by the participant. The online questionnaire will be hosted on REDCap.

14.6 Incidental or Unexpected Findings:

Describe the plan to address incidental findings and unexpected findings about individuals from screening to the end of the subject's participation in the research. In cases where the subject could possibly benefit medically or otherwise from the information, state whether or not the results of screening, research participation, research tests, etc., will be shared with subjects or their primary care provider. State whether the researcher is obligated or mandated to report results to appropriate military or civilian authorities and explain the potential impact on the subject

While our study is observational and physical therapy is a lower-risk clinic, we will be viewing SOAP notes and administering mental health survey tools. Several members of our research team are physical therapists, and another is a psychologist. This puts us in a position to discover incidental findings of a two different natures.

Misdiagnosis or mistreatment of MSD: If the physical therapists on the research team conclude that a subject's MSD has been misdiagnosed or that their course of treatment is grossly inappropriate, they will pass that information along to the department head of physical therapy, so the matter can be brought to the attention of the participant's therapist. However, we only plan to do this if the patient is at risk of harm, not if the study team simply believes the course of treatment is sub-optimal.

Mental Health dangers: During our initial questionnaire, we ask our participants to self-report on a number of psychological and social health measures, notably PTSD, depression, and anxiety. If a participant scores >50 on the PCL-M scale for post-traumatic stress disorder, >16 on the CES-D scale for clinical depression, or >10 on the GAD-7 scale for anxiety disorder (the thresholds for severe psychiatric disorder) at baseline, we will notify the participant's physical therapist and our research monitor to make a referral for appropriate treatment. If we find evidence of an emergent mental health issue, a researcher will immediately contact the participant's physical therapist to transfer the patient to the Emergency Medicine Department (EMD).

15.0 Study Monitoring

15.1 Your study requires either Data and Safety Monitoring Plan (DSMP) or a Data and Safety Monitoring Board (DSMB).

- ○ DSMP
- ○ DSMB
- ○ Both
- ◉ Not Applicable

16.0 Reportable Events

16.1 Reportable Events: Consult with the research office at your institution to ensure requirements are met. Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event.

Consult with the research office at your institution to ensure requirements are met

• Describe plans for reporting expected adverse events. Identify what the expected adverse events will be for this study, describe the likelihood (frequency, severity, reversibility, short-term management and any long-term implications of each expected event)

• Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the research protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event

We believe that the most likely adverse events are already described under "Incidental Findings" (Section 14.6). Beyond those, the most plausible adverse events we foresee are possible breaches of privacy and/or confidentiality and the potential distress of answering questions regarding mental health, which are also previously explored in Section 14.1.

Any reportable events, expected or not, will result in our team submitting a Note to File to the IRB within 24 hours of discovery. Serious adverse events and unanticipated problems will be reported to the Research Subject Protection Division within 24 hours. Similarly, any protocol violations will be reported within five business days. Other events such as non-serious adverse events and protocol deviations will be reported with the next continuing review unless they require a protocol modification. In that instance, the event will be reported alongside the modification.
Research staff will inquire whether any adverse events (AEs) have occurred at each in-person encounter with participants, and REDCap surveys will include instructions for contacting the research coordinator or PI if an AE has occurred. All research staff interacting with participants will maintain blank AE Log forms. Due to the large sample size and low risk, an AE Log will not be maintained for every participant, only those involved in an AE.

17.0 Equipment/non-FDA Regulated Devices

17.1 Does the study involve the use of any unique non-medical devices/equipment?

- ○ Yes
- ◉ No

18.0 FDA-Regulated Products

18.1 Will any drugs, dietary supplements, biologics, or devices be utilized in this study?

- ☐ Drugs
- ☐ Dietary Supplements
- ☐ Biologics
- ☐ Devices
- ☑ N/A

18.5 Sponsor (organization/institution/company):

- ☑ N/A

If applicable, provide sponsor contact information:

19.0 Research Registration Requirements

19.1 ClinicalTrials.gov Registration:

- ○ Registration is not required
- ◉ Registration pending
- ○ Registration complete

19.2 Defense Technical Information Center Registration (Optional):

- ○ Registration is not required
- ◉ Registration pending
- ○ Registration complete

20.0 References and Glossary

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20.2 Abbreviations and Acronyms:

ADSM – Active Duty Service Members
AHLTA - Armed forces Health Longitudinal Technology Application
CBT – Cognitive Behavioral Therapy.
CES-D – Center for Epidemiologic Studies Depression Scale
CID – Clinical Investigations Department at NMCP
COMI – Core Outcome Measures Index
CDMRP - Congressionally Directed Medical Research Programs
CRADA – Cooperative Research and Development Agreement
DRRI - Deployment Risk and Resilience Inventory-2
FAB – Fear avoidance beliefs
FABQ – Fear Avoidance Beliefs Questionnaire
GAD-7 – General Anxiety Disorder Screener
HADS – Hospital Anxiety and Depression Scale
ICD – International Classification of Diseases
IFC – Informed Consent Form
IRB – Institutional Review Board
LBP – Low Back Pain
MRPS – MedRisk Instrument for Measuring Patient Satisfaction
MSD – Musculoskeletal Disorders
NMCP – Navy Medical Center Portsmouth
NYU – New York University
PCL-M – PTSD Checklist Military Version
PCS – Pain Catastrophizing Scale
PDI – Pain Disability Index
PEB – Physical Evaluation Board
PHI – Personal Health Information
PI – Principle Investigator
PiPT – Psychologically-informed Physical Therapy
PSEQ – Pain Self-efficacy Questionnaire
PT – Physical Therapy
PTSD – Post-traumatic Stress Disorder
RA – Research Assistant
RCT – Randomized Controlled Trial
SOAP note – Subjective, Objective, Assessment, and Plan note