Official Title:	The Implementation of Psychologically Informed Physical Therapy to Prevent Chronification in Service Members With Musculoskeletal Disorders
NCT Number:	NCT05132400
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SUBJECT ID: _____

NAVAL MEDICAL CENTER PORTSMOUTH
CONSENT TO PARTICIPATE IN RESEARCH

Research Title: Factors associated with physical therapy outcomes in active duty service members with musculoskeletal disorders

Local Principal Investigator: CDR Brittany Jansen, PT, DPT, SCS, ATC
Lead NYU Investigator: Marco Campello, P.T., PhD

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions that you have. You may also wish to talk to others (for example, your friends, family, or your personal doctor) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without any consequence.

Please tell the researchers if you are taking part in another research study.

1. KEY INFORMATION:

Voluntary Participation	You do not have to take part in this research. It is your decision. You can also choose to stop participating at any time during the study. Your decision will not affect your current or future care at Naval Medical Center Portsmouth. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.
Purpose	This study seeks to investigate the effect of attitudes, beliefs and social circumstances on the outcome of your physical therapy treatment.
Duration	This study is estimated to continue for four years. Your participation will include four questionnaire packets completed over a period of twelve months.
Procedures	During study visits participants will: • Complete a total of four (4) questionnaire packets on the status of your injury and treatment. • Leave contact information for follow-up.

Why might you want to participate in this research (benefits)?	Participation will not directly benefit you but may improve physical therapy treatment for future patients.
Why might you choose not to participate in this research (risk)?	All efforts are made to protect your research study records. However, there is always a small risk that someone could get access to your personal information. There is a chance you may find some questions upsetting
What are the alternatives to participating?	Participation in this study will not affect your treatment. The alternative is not to participate in this research.

2. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The influence of attitudes, beliefs and social circumstances on physical therapy outcomes has not been well-studied in the military. The purpose of this research study is to learn about how these factors affect the outcome of physical therapy.

3. WHY ARE YOU BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you are an active duty service member (ADSM) beginning physical therapy treatment.

4. HOW LONG IS THE RESEARCH STUDY?

There will be about 600 ADSMs taking part in the study at Naval Medical Center Portsmouth, and its branch clinics over a 4 year period.

Your participation in this study consists of completing four questionnaire packets over the course of twelve months. Each packet will take less than one hour to complete. You will not need to return to the clinic to complete the follow-up questionnaire packets.

5. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to have some tests and provide some information so that the study team can confirm if you qualify for the study. This is the "screening process." The information and tests may have been part of your regular care.

The researcher will ask you to verify that you are:
- An active duty service member in the DoD.
- Beginning physical therapy for your current injury.
- NOT pregnant.
- NOT here for post-surgical follow-up.
- NOT currently scheduled or in a Physical Evaluation Board.

6. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will be asked to complete a questionnaire packet that measures attitudes and beliefs about your injury at four points: before treatment, at your 4th treatment session, and 6, and 12 months after your treatment began. These questionnaire packets should take no more than one hour each. Nothing else is required from you to participate in this study. We may extract information from your physical therapy records related to the current treatment period. We will ask for your contact information for follow-up only.

7. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

All efforts are made to protect your research study records. However, there is always a small risk that someone could get access to your personal information.

The questionnaires used in this study include some standard questions about your beliefs and feelings which some participants may find upsetting. If you become upset, please let the researcher know; you may stop participation and/or request medical assistance if necessary.

8. ARE THERE BENEFITS TO TAKING PART IN THIS RESEARCH STUDY?

There are no direct benefits to you for taking part in this research study. However, others may benefit in the future from the information learned. The possible benefits to others are changes in physical therapy treatment that may reduce pain and disability for other service members.

9. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Your alternative is not to take part in this research study.

10. WILL YOU GET PAID FOR TAKING PART IN THIS RESEARCH STUDY?

No, you will not receive any compensation for participating in this study.

11. ARE THERE COSTS FOR TAKING PART IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

12. WHO IS THE STUDY SPONSOR?

The study sponsor is the Department of Defense.

As the sponsor of this research, Department of Defense may have access to your research data in accordance with DoD Instruction 3216.02.

13. IS THERE A SOURCE OF FUNDING?

This study is funded by the Department of Defense office of the Congressionally Directed Medical Research Programs (CDMRP), under the 2019 Chronic Pain Management Research Program (CPMRP) Translational Research Award for four years.

14. WHAT IS THE LOCATION OF THE RESEARCH?

Naval Medical Center Portsmouth, Portsmouth, VA and its branch medical clinics.

15. ARE THERE ANY DISCLOSURES OF FINANCIAL INTERESTS OR OTHER COMMERCIAL RELATIONSHIPS?

The research study team has no financial interests or commercial relationships related to this research study.

16. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Your records related to this research study may only be shared in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read online at: https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf

The research team will keep your research records. These records will be stripped of any identifiers that can be linked to you. These records may be accessed by the research staff at NMCP Physical Therapy Department, NYUSOM and the DoD for research purposes only. The committee responsible for protecting research participants, called the Institutional Review Board (IRB), may also look at your records as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to:

Signed informed consent documents and data will be housed separately in locked cabinets to prevent linking of participant identifying information and responses. Data will be de-identified (meaning your name and identifying information will be removed immediately), coded and maintained per current requirements on password protected servers. As part of the de-identification process participants will be assigned a subject study ID number. In addition, the investigators plan to computerize as much data as possible during the data collection procedures. If you complete any questionnaire packets on a paper copy, investigators will scan the completed paper forms and then destroy the paper records using a shredder. Signed consent forms will be maintained for six years after completion of the study, then destroyed using a shredder.

DoD
IRB NUMBER: NMCP.2021.0116
IRB APPROVAL DATE: 12/22/2022
IRB EXPIRATION DATE: 08/09/2023

Researchers will make every effort to protect your privacy and confidentiality. However, there are risks of breach of information security and information lost.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

The researchers will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

17. <u>WILL YOUR INFORMATION OR SPECIMENS BE USED IN THE FUTURE?</u>

The information from this study will not be used in the future.

HIPAA AUTHORIZATION

I. Purpose

An Authorization is your signed permission to use or reveal your health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or reveal your health information with a valid Authorization. The 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.

Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information.

II. Authorization

The following describes the purposes of the requested use and disclosure of your health information:

The title of the research study is *Factors associated with physical therapy outcomes in active duty service members with musculoskeletal disorders.* The influence of attitudes, beliefs and social circumstances on patient outcomes <u>has not</u> been well-studied in the military. The purpose of this research study is to learn about how these factors affect the outcome of physical therapy.

A. What health information will be used or disclosed?

For this study we will review your diagnosis, physical therapy treatment plan and treatment, demographics and self-reported questionnaires.

B. Who will be authorized to use or disclose (release) your health information?

The MTF you are receiving physical therapy from will be authorized to use or disclose health information to the research team.

C. Who may receive your health information

NMCP physical therapy research staff will receive the PHI. IRBs or Data Safety and Monitoring Boards may also view your information.

D. What if you decide not to sign this Authorization?

The MHS **will not** refuse treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this Authorization.

E. Is your health information requested for future research studies?

No, your health information *is not* requested for future research studies.

F. Can you access your health information during the study?

You may have access to your health information at any time, unless your identifiers are permanently removed from the data.

G. Can you take back this authorization?

- You may change your mind and take back your Authorization at any time. However, if you take back this Authorization, any person listed above may still use or share any already obtained health information as necessary to maintain the integrity or reliability of this research.
- If you take back this Authorization, you may no longer be allowed to take part in this research study.
- If you want to take back your Authorization, you must write to:

CDR Brittany Jansen, Naval Medical Center Portsmouth, Department Head of Physical Therapy, 620 John Paul Jones Cir, Portsmouth VA 23708

H. Does this Authorization expire?

Yes, it expires at the end of the research study.

I. What else may you want to consider?

- No publication or public presentation about the research described above will reveal your identity without another signed Authorization from you
- If all the information that does or can identify you is removed from your health information, the remaining de-identified information will no longer be subject to this Authorization and may be used or shared for other purposes
- In the event your health information is disclosed to an organization that is not covered by HIPAA, the privacy of your health information cannot be guaranteed.

18. WHAT HAPPENS IF THE RESEARCHERS SEE AN INCINDENTAL FINDING?

There is a possibility that while reviewing your test results, the researchers may see an abnormality that they did not expect to see in this study. This is what is called an "incidental finding."

They will let you know if they see such an incidental finding. Depending on the type of incidental finding, they may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

The researchers will also give information about this incidental finding to your primary doctor or will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

19. WHAT HAPPENS IF YOU WITHDRAW FROM THIS RESEARCH?

If you do not want to continue taking part in the research study, you must simply notify a member of the research team. All the information collected to date will be destroyed.

Please note that taking back your consent to take part in this research does not take back your HIPAA Authorization to use or reveal your protected health information. To take back your authorization, please send a letter to the Principal Investigator as discussed above.

The Principal Investigator of this research study may stop you from taking part in this research study at any time if the investigator thinks it is in your best interest, if you can't complete the research study procedures, or if you no longer qualify to take part.

DoD
IRB NUMBER: NMCP.2021.0116
IRB APPROVAL DATE: 12/22/2022
IRB EXPIRATION DATE: 08/09/2023

20. WHO DO YOU CONTACT IF YOU HAVE QUESTIONS?

Principal Investigator (PI)
The Principal Investigator or a member of the research study team will be available to answer any questions throughout this study.

Local Principal Investigator: CDR Brittany Jansen
Phone: (757)-953-1497
Email: Brittany.j.jansen.mil@health.mil
Mailing Address: Naval Medical Center Portsmouth
Physical Therapy Department
620 John Paul Jones Cir
Portsmouth, VA 23708

Lead NYU Investigator: Marco Campello, P.T., PhD
Phone: (212)-255-6690
Email: marco.campello@nyulangone.org
Mailing Address:
New York University School of Medicine
63 Downing Street Cellar
New York, NY 10014

Clinical Research Coordinator: Timothy Hope
Phone: (757) 953-5488
Email: timothy.g.hope.ctr@health.mil
Mailing Address:
Naval Medical Center Portsmouth
Physical Therapy Department
620 John Paul Jones Cir
Portsmouth, VA 23708

NMCP Human Research Protection Program (HRPP) Office
The Human Protections Director (HPD) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Director: Kersten Wheeler, MS
Phone: 757-953-5939

DoD
IRB NUMBER: NMCP.2021.0116
IRB APPROVAL DATE: 12/22/2022
IRB EXPIRATION DATE: 08/09/2023

Institutional Review Board (IRB) Office

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, you can contact the office of the committee responsible for ensuring research participant protection, the Institutional Review Board (IRB).

Naval Medical Center Portsmouth
620 John Paul Jones Circle
ATTN: CID
Portsmouth, VA 23708
(757) 953-5939
usn.hampton-roads.navhospporsva.list.nmcp-irboffice@health.mil

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE RESEARCHER BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL DOCTOR OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

21. SIGNATURES

SIGNATURE OF PARTICIPANT

Your signature below indicates that:

- You authorize the Military Health System to use and reveal your health information for the research purposes stated above;
- You have read (or someone has read to you) the information in this consent including the HIPAA Authorization;
- You agree that you have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to you. You have been provided with the opportunity to ask questions
- You voluntarily consent to take part in this research study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date (DDMMMYYYY)

SIGNATURE OF INDIVIDUAL ADMINSTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date (DDMMMYYYY)