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TITLE: “The Biopsychosocial Aspects of Chronic Pain Pre and Post Functional Restoration Program within the SAMMC Interdisciplinary Pain Management Clinic”

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5b. GRANT NUMBER
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5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Chronic pain often results in reduction of function, disability, and overall reduction in quality of life. Currently, assessment of pain intensity is 1) limited to pain scales which are largely subjective in manner, 2) do not reflect comorbidities associated with chronic pain, and 3) do not take into account the biopsychosocial aspects and complexity of the chronic pain experience; therefore lacking any individualized precision in assessing proper pain management strategies. In addition, opioid therapy continue to be the predominant pharmacologic treatment for most chronic pain diagnoses and are associated with increased risk of adverse clinical outcomes, including opioid-related accidents and overdoes; which are particularly elevated in veterans with PTSD. Fear avoidance behavior, and kinesiophobia are common in chronic pain patients and contribute to physical limitations patients place on themselves. While healthcare providers struggle to identify specific pathophysiological mechanisms responsible for persistent pain, rehabilitation may aid in re-training the mind and body of any functional limits that may not truly exist. An interdisciplinary, holistic approach utilizing the biopsychosocial aspects of chronic pain management seems advantageous, more precise than currently available measurements, and imperative in the understanding and optimization of pain management strategies. Functional Restoration Programs (FRPs) are an intensive interdisciplinary approach involving physical strengthening, psychological conditioning, and education of chronic pain in a group setting. It addresses the biopsychosocial aspects of chronic pain and has potential to minimize narcotic based pain management, decrease disability, and improve overall quality of life. In addition, FRP educates patients on pain while restoring function and offering confidence to self-manage pain in a group setting. Objective: This study will evaluate the impact of FRP on activity levels, sleep health, psychological health, body composition, pain scores, and analgesic use in active duty military and veterans with chronic pain. Data collection tools will monitor activity and sleep in patients prior to, during, and after FRP while assessment of physical/physiological measures, including body composition testing and stress/immune response molecules will be accomplished. The goal is to assess a few components of the biopsychosocial model throughout FRP intervention. This study will ultimately utilize clinical and rehabilitative principles as well as psychological/behavioral counseling in a group setting to reduce pain in active duty military and veterans with chronic pain by empowering and educating. Meanwhile, physiological markers often associated with chronic pain and chronic pain comorbidities, such as cortisol levels will be monitored. These outcomes which address the biological and psychological components of pain can be monitored, addresses, and applied in many, if not all pain management strategies including conventional and complimentary modalities (massage, acupuncture, yoga, meditation) with possibility of optimizing pain management from individual to individual. Functional Restoration Programs (FRPs) are an intensive interdisciplinary approach involving physical strengthening, psychological conditioning, and education of chronic pain in a group setting. It addresses the biopsychosocial aspects of chronic pain and has potential to minimize narcotic based pain management, decrease disability, and improve overall quality of life. This study will evaluate the impact of FRP on activity levels, sleep health, psychological health, body composition, pain scores, and analgesic use in active duty military and veterans with chronic pain.

15. SUBJECT TERMS
Functional restoration, chronic pain, biopsychosocial, rehabilitation, quality of life

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
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Unclassified	Unclassified	Unclassified	Unclassified		**19b. TELEPHONE NUMBER** *(include area code)*

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1. INTRODUCTION

Many service members experience injuries which induce chronic pain states during multiple phases of their active duty careers: including basic training, serving stateside, or while in theater. In 2007 alone, a Department of Defense survey reported musculoskeletal injuries accounted for 68% of all limited-duty days and medical profiles. Ultimately, chronic pain often results in reduction of function, disability, and overall reduction in quality of life. Currently, assessment of pain intensity is limited to uni-dimensional pain scales including the Visual Analogue Scales, Numeric Rating Scales, and Verbal Rating Scales which do not take into account the biopsychosocial aspects of the chronic pain experience and therefor lack any individualized precision in proper pain management strategies. These measurements contain a largely subjective component, are not quantitatively sound, and are difficult for use in assessing clinical practice methods. Moreover, a biomarker for assessing pain does not exist. Aside from the physical facet of chronic pain; psychosocial contributions to pain perception (aka- the pain experience) are often underestimated and undermanaged. The complexity of chronic pain processing; involving sensory, affective, and cognitive components, increases the difficulty of proper pain management. Behaviors such as motivation, cognition and attention, depression, learning and memory, and perceived fear can be altered in chronic pain states. For example, catastrophizing, fear avoidance behavior, and kinesiophobia are common in chronic pain patients and contribute to physical limitations chronic pain patients place on themselves. Unfortunately, opioid therapy continues to be the predominant pharmacologic treatment for most chronic pain diagnoses and involve many risks and controversial benefits. There is evidence of prescription opioids association with increased risk of adverse clinical outcomes, including opioid-related accidents and overdoes, which is particularly elevated in veterans with PTSD. While healthcare providers struggle to identify specific pathophysiological mechanisms responsible for persistent pain, rehabilitation may aid in re-training the mind and body of any functional limits that may not truly exist. Given the need to reduce narcotic-based analgesics, the complexity of chronic pain processing effecting psychological health, and the debilitating nature of pain due to immobilization; an interdisciplinary, holistic approach to chronic pain management seems advantageous and imperative. Utilizing the biopsychosocial aspects of chronic pain to manage and asses each component to the chronic pain epidemic may be the most precise evaluation and strategy available for chronic pain patients and providers. Functional Restoration Programs (FRPs) are an intensive interdisciplinary approach involving physical strengthening, psychological conditioning, and education of chronic pain in a group setting. It addresses the biopsychosocial aspects of chronic pain and has potential to minimize narcotic based pain management, decrease disability, and improve overall quality of life. This study will evaluate the impact of FRP on activity levels, sleep health, psychological health, body composition, pain scores, and analgesic use in active duty military and veterans with chronic pain.

2. KEYWORDS

Functional restoration, chronic pain, biopsychosocial, rehabilitation, quality of life

3. ACCOMPLISHMENTS

What were the major goals of the project? (Goals to be accomplished and status.)

Specific Aim 1: Specific Aim 1- Establish, for active duty and veterans, the feasibility of the use of Actiwatch Actigraphy to determine changes in sleep and activity levels pre and post participation in the SAMMC IPMC-Functional Restoration Program (FRP) (months 4-24).

- STATUS: yet to start; due to COVID-19, we have been unable to begin recruiting for this study. We are projecting an October 2020 start date.

Specific Aim 2: Specific Aim 2- Compare changes in sleep and activity levels along with changes in physiological measures, body composition, and psychological measures in active duty and veterans pre, during, and post SAMMC FRP (months 4-24).

- STATUS: yet to start; due to COVID-19, we have been unable to begin recruiting for this study. We are projecting an October 2020 start date.

Specific Aim 3: Specific Aim 3- Compare activity level, sleep patterns, and changes in medical profile/utilization of medical services between ages, sexes, and types of chronic pain enrolled in FRP (months 4-24).

STATUS: yet to start; due to COVID-19, we have been unable to begin recruiting for this study. We are projecting an October 2020 start date.

What was accomplished under these goals? (Detailed progress and results.)

Specific Aim 1: Specific Aim 1- Establish, for active duty and veterans, the feasibility of the use of Actiwatch Actigraphy to determine changes in sleep and activity levels pre and post participation in the SAMMC IPMC-Functional Restoration Program (FRP) (months 4-24).

Although recruitment has been stalled on this project due to COVID-19, we have been able to complete the purchase and initial testing of the study equipment and are in the final stages of IRB review. We anticipate an October start date.

Key Findings or Accomplishments:

No data analysis has been performed.

Specific Aim 2: Compare changes in sleep and activity levels along with changes in physiological measures, body composition, and psychological measures in active duty and veterans pre, during, and post SAMMC FRP (months 4-24).

See Specific Aim 1 for overall study progress.

Key Findings or Accomplishments:

No data analysis has been performed.

Specific Aim 3: Compare activity level, sleep patterns, and changes in medical profile/utilization of medical services between ages, sexes, and types of chronic pain enrolled in FRP (months 4-24).

See Specific Aim 1 for overall study progress.

Key Findings or Accomplishments:

No data analysis has been performed.

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

Not applicable

How were the results disseminated to communities of interest?

Nothing to report.

Plans for the next reporting period to accomplish the goals

We hope to begin recruitment and data collection as soon as possible, however, as this project is a two-year project and has been delayed significantly due to COVID-19, we will likely need to request an extension to reach statistical significance. We hope to have data collection complete in 2022.

4. IMPACT

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

Nothing to report.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS

Changes in approach and reasons for change

Nothing to report.

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

This study has been significantly delayed due to COVID-19. Because of this, our projected timeline has been shifted one year and an extension will need to be requested in order to reach statistical significance/power.

Changes that had a significant impact on expenditures

Due to the delays associated with COVID-19 a cost extension will likely need to be requested to achieve statistical significance. TO date expenditure has not been impacted.

Significant changes in use or care of human subjects

None.

Significant changes in use or care of vertebrate animals

TOTAL PROTOCOL(S): Not applicable.

PROTOCOL (X of Y total):
IACUC Protocol Number:
ACURO Protocol Number:
Protocol PI:
Protocol Site:
Protocol Title:
Number of Animals Approved for Use:
IACUC INITIAL APPROVAL DATE:
ACURO INITIAL APPROVAL DATE:
RENEWAL APPROVAL DATES:

-

AMENDMENTS:

-

ADVERSE EVENTS OR UNANTICIPATED PROBLEMS:

-

Significant changes in use of biohazards and/or select agents

Not applicable.

6. PRODUCTS

Journal publications

Nothing to Report.

Books or other non-periodical, one-time publications

Nothing to Report.

Other publications, conference papers, and presentations

Nothing to Report.

Website(s) or other Internet site(s)

Nothing to Report.

Technologies or techniques

Nothing to Report.

Inventions, patent applications, and/or licenses

Nothing to Report.

Other Products

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Dr. Reginald O'Hara
Project Role:	PI
Researcher Identifier:	
Nearest person month worked:	3
Contribution to Project:	Oversight
Name:	Dr. Margaux Salas
Project Role:	Co-PI
Researcher Identifier:	
Nearest person month worked:	3
Contribution to Project:	Oversight, protocol development, and IRB submission
Name:	Jessica Krusel
Project Role:	Research Coordinator
Researcher Identifier:	
Nearest person month worked:	3
Contribution to Project:	Protocol development, regulatory oversight, IRB submission

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

A change in PI was submitted, due to COL Goff's retirement. The PI is now Reginald O'Hara, PhD. All other research team members remain the same.

What other organizations were involved as partners?

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHART

Convert this report to a PDF file and append updated quarterly Quad Chart in PDF as an appendix.

9. APPENDICES

Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.