AWARD NUMBER: W81XWH-19-2-0022

TITLE: The Biopsychosocial Aspects of Chronic Pain pre and post Functional Restoration Program within the SAMMC Interdisciplinary Pain Management Clinic

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REPORT DATE: August 2021

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MMM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
August 2021	Annual	15Jul2020-14Jul2021

4. TITLE AND SUBTITLE

The Biopsychosocial Aspects of Chronic Pain pre and post Functional Restoration Program within the SAMMC Interdisciplinary Pain Management Clinic

5a. CONTRACT NUMBER
W81XWH-19-2-0022

5b. GRANT NUMBER
BA160636

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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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Development Command (USAMRDC)
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)
USAMRDC

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT - Approved for Public Release; Distribution Unlimited

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**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	9	**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: 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: Started Y2Q1, Ongoing

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: Started Y2Q1, Ongoing

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: Started Y2Q1, Ongoing

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

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).

Recruitment started Y1Q1 and is ongoing. As of July 14, we had a total of 14 participants enrolled in the study.

Key Findings or Accomplishments:

Due to COVID-19 restrictions, the FRP has significantly reduced the number of participants allowed in each group session, reducing the number of anticipated participants enrolled to date. In addition, availability of statistical assistance from the original planned team has changed. Therefore, 14 patients have been enrolled to date and data analysis has yet to be performed. Discussions of increased group numbers are underway, however, with the new COVID-19 Delta variant having just been announced, the FRP staff may choose to postpone the increase further. An alternative statistician has been identified and plans for analysis are also underway.

Overall, the majority of participants enrolled have been successful in allowing Actigraphy data collection according with the original study design parameters. 12 month follow-up data is not yet available, as the first group of participants has not yet reached the 12 month follow-up timepoint

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:

Data analysis has yet to be performed due to COVID-19 restrictions, as mentioned above.

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:

Data analysis has yet to be performed due to COVID-19 restrictions, as mentioned above.

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

Due to the delays caused by the COVID-19 restrictions, we have requested a no-cost extension for 1 year and plan to continue the study at reduced patient numbers. Initial data analysis is targeted to occur within the month.

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

Due to COVID-19 restrictions, the FRP has significantly reduced the number of participants allowed in each group session, reducing the number of anticipated participants enrolled to date. Therefore, 14 patients have been enrolled to date. The study team is considering removing the 12-month data collection time point in order to feasibly complete the project in a timely manner. This change is considered only because of the current state of COVID-19 and the unforeseen potential disruption the Delta variant may cause on recruitment.

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

This study has been significantly delayed due to COVID-19. However, a no-cost extension has been requested.

Changes that had a significant impact on expenditures

Despite the delays due to COVID-19, impact on expenditures is not significantly reduced aside from a small savings on supplies. This savings will be utilized if/when the group number for each FRP session is increased. A no-cost extension has been requested in order to complete the study.

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. Both the 2020 and 2021 Military Health Science Research Symposia; which are the military platform utilized for findings dissemination, have been cancelled due to COVID-19

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, study execution
Name:	Jessica Krusel
Project Role:	Research Coordinator
Researcher Identifier:	
Nearest person month worked:	3
Contribution to Project:	Protocol development, regulatory oversight, IRB submission, study execution

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

Nothing to Report.

What other organizations were involved as partners?

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHART

9. APPENDICES

The Biopsychosocial Aspects of Chronic Pain within the San Antonio Military Medical Center Interdisciplinary Pain Management Clinic: Functional Restoration Program

PI: Dr. Reginald O'Hara, ACSM-CEP
Org: Integrative Pain Management Center/ SAMMC
Award Number: W81XWH1920022
Award Amount: $704,441

Study/Project Aim(s)

Study 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 BAMC Functional Restoration Program (FRP).

•**Study 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 BAMC FRP.

•**Study 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.

Approach:

Our study has been designed to assess the biopsychosocial affect of the Functional Restoration Program on 1) activity level and sleep 2) body composition and physiological molecules 3) psychological assessments and 4)retention rate, analgesic use, and utilization of medical services in active duty members and veterans with chronic pain enrolled in the BAMC FRP.

Timeline and Cost

ACTIVITIES	FY19	FY20	FY21	FY22
Hire Staff/IRB Approval				
Recruit Patients				
Collect Data and De-identify Data				
Complete Data Analysis				
Present Findings at Military Health System Research Symposium (MHSRS)				
Prepare and Submit Manuscript				
Estimated Total Budget ($704K)	**$391K**	**$313K**		

Updated: August 12, 2021

Goals/Milestones

FY19 Goals

☑ Attain IRB protocol approval as well as hire and train all research personnel

FY20 Goals

☑ Recruitment and data collection will begin – Delayed due to COVID
Completion of data collection and data analysis for presentation and publication – Delayed due to COVID-19

FY21 Goals

☐ Recruitment – goal = 32
☐ Begin data analysis

Comments/Challenges/Issues/Concerns

COVID-19 has pushed back our original timeline. We are currently in the process of requesting a no-cost extension.

Budget Expenditure to Date

Actual Expenditure (July 15, 2019 – July 14, 2021): $536,792.04
Projected Expenditure: $704,441