AD_____

AWARD NUMBER: W81XWH-17-1-0476

TITLE: Development of a Biopsychosocial Prospective Surveillance Model of Shoulder Pain in Individuals with Spinal Cord Injury

PRINCIPAL INVESTIGATOR: Margaret A. Finley, PT, PhD

RECIPIENT: Drexel University
Philadelphia PA 19104-2816

REPORT DATE: August 2019

TYPE OF REPORT: Annual

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

REPORT DOCUMENTATION PAGE		*Form Approved OMB No. 0704-0188*
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1. REPORT DATE *(DD-MM-YYYY)* August 2019	**2. REPORT TYPE** Annual Technical	**3. DATES COVERED *(From - To)*** 1 Aug 2018 - 31 Jul 2019
4. TITLE AND SUBTITLE Development of a Biopsychosocial Prospective Surveillance Model of Shoulder Pain in Individuals with Spinal Cord Injury		**5a. CONTRACT NUMBER** 5b. GRANT NUMBER W81XWH-17-1-0476 **5c. PROGRAM ELEMENT NUMBER**
6. AUTHOR(S) Margaret Finley, PT, PhD; Thomas Trojian, MD; Ed Gracely, PhD; Henry York, MD; Paula Geigle, PT, MS, PhD; Leigh Casey, BS; UMRehab research clinicians		**5d. PROJECT NUMBER** **5e. TASK NUMBER** **5f. WORK UNIT NUMBER**
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Drexel University 3141 Chestnut St Philadelphia PA 19104-2816		**8. PERFORMING ORGANIZATION REPORT NUMBER**
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) USA Med Research Acq Activity 820 Chandler St Fort Detrick MD 21702-5014		**10. SPONSOR/MONITOR'S ACRONYM(S)** **11. SPONSOR/MONITOR'S NUMBER(S)**

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

13. SUPPLEMENTARY NOTES

14. ABSTRACT
The overall purpose of this study is to investigate progression of impairments the first year following injury beginning with inpatient rehabilitation in the acute phase. In the second year of the 3-year award we met nearly all aspects of our proposed SOW. Both sites maintained all regulatory requirements, IRB approvals from local institutions, maintained all modifications and continuing renewal. Collection of baseline data at sites continued (total SCI = 33 and control = 27) with 75% of 6-month follow-up assessments completed on appropriate timeframes. One-year assessments for both group with SCI and controls were initiated. The addition of GSRH to the Drexel site for recruitment of SCI enhanced enrollment with 16/17 completed by year end. Monthly PI meetings and quarterly full team meetings facilitated ongoing communication to include strategies for recruitment and problem solving as needed. All reports (quarterly technical and annual financial) were comprehensive and were submitted on time. We disseminated preliminary information in January 2019 presentation at Combined Sections Meeting of the American Physical Therapy Association. Three abstracts have been submitted for the CSM of APAT 2020 conference.

15. SUBJECT TERMS
Spinal cord injury, Shoulder, pain, musculoskeletal

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
				27	
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			**19b. TELEPHONE NUMBER** ***(include area code)***

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1. INTRODUCTION:

This study is investigating the progression of musculoskeletal (shoulder muscle flexibility, muscle strength, movement coordination, and rotator cuff health) and psychosocial (fear of movement, pain catastrophizing) impairments for the first year following SCI, starting with inpatient rehabilitation, at 6 months, and at 1 year following SCI. Age- and gender-matched controls will be compared at baseline and at 1 year. Our research is being performed at two main facilities: Drexel University (in collaboration with Magee Rehabilitation Hospital and Good Shepherd Rehabilitation Hospital) and the University of Maryland Rehabilitation & Orthopaedic Institute. This report reflects progress through end of Year 2 (7/31/19).

2. KEYWORDS:

Spinal cord injury; pain, shoulder, musculoskeletal, psychosocial

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Statement of Work (SOW) Major Tasks and Milestones are listed below, with target completion dates and status towards completion

Required for all AIMS:	**Target Completion (YearQuarter)**	**Status**
Major Task 1: Complete start-up protocols, regulatory reviews, data management and training	Completed Y1Q1	
• *Milestone(s) Achieved: Sites prepared to conduct research project*	Y1Q1	Completed Y1Q1
• *Milestone Achieved: Site specific & DoD/HRPO Approval*	Y1Q2	Completed Y1Q1
• *Milestone Achieved: Database Management established*	Y1Q2	Completed Y1Q1
Major Task 2: Recruitment, enrollment, data collection	Ongoing	
• *Milestone(s) Achieved: Baseline data collected*	Y2Q2	Ongoing (87% total; 97% of group with SCI)
• *Milestone(s) Achieved: 6-month assessments completed*	Y2Q4	Ongoing
• *Milestone(s) Achieved: One-year assessments completed*	Y3Q3	Ongoing
Major Task 3: Data Analysis, reporting and dissemination	Ongoing	
• *Milestones Achieved: Data analysis completed*	Y3Q2	Analysis of initial data for three additional abstracts and initiation of manuscripts

• *Milestones Achieved: Required reporting completed*	Ongoing	Ongoing-all reports were comprehensive and submitted on time

What was accomplished under these goals?
Below are the subtasks scheduled during this reporting period (Year 2) and status towards completion

Required for all AIMS:

Subtask 2: Obtain Regulatory Approval	**Target Timeframe (Year/Quarter)**	**Status**
IRB Modifications (as indicated) and Continuing Reviews	As needed/ CR annually	Completed Modifications (data forms, inclusion wording, OSPRO, personnel changes) at both sites submitted and approved. Continuing review acquired both sites through IRB and HRPO (approval through UM 4/9/19, Drexel 4/17/19)

Major Task 2: Recruitment, enrollment, data collection		
Subtask 1: Initial assessments (baseline)	**Target Timeframe (Year/Quarter)**	**Status**
Recruitment, screening and enrollment (consenting) of participants with acute SCI (n=34, 17 per site) and age-matched controls (n=34, 17 per site)	Y1Q3 through Y2Q2	Recruitment, screening and enrollment are ongoing. Drexel has enrolled a total of 18 with SCI (one withdrew, one placed on hold prior to data collection due to medical complications prior to data collection), 12 matched controls enrolled. UM Rehab has enrolled 20 with SCI (3 withdrew for personal and medical reasons prior to data collection), 13 controls (see Actual Problems and Actions to Resolve below)
Baseline musculoskeletal (MPS, WUSPI, PM, MSK, strength, and psychosocial (TSK, PCS, FOP, CPCI, SQoL) measures (n=68, 34 per site)	Y1Q3 through Y2Q2	Baseline data has been collected on 33 with SCI (97%) and 26 control participants (76%). Scheduling for August 2019 (Y3Q1) includes participants. (see Actual Problems and Actions to Resolve below). Drexel: 16 with SCI (94%) and 11 control completed (65% - with 4 scheduled for 8/2018, Y3Q1) UM Rehab: 17 with SCI (100%) and 13 control participants (76%) completed. Remaining controls have been identified and will be scheduled in Y3Q1

Baseline musculoskeletal (SMC) assessment (n=34, all Drexel)	Y1Q3 through Y2Q2	Baseline motion analysis on 10 of 16 with participants with SCI. Unable to collect on 6 due to inability to wearing TLSO brace and safety concerns. All controls completed the motion analysis.
Subtask 2: 6-month assessments	**Target Timeframe (Year/Quarter)**	**Status**
6-month musculoskeletal (MPS, WUSPI, PM, MSK, strength, and psychosocial (TSK, PCS, FOP, CPCI, SQoL) measures (n=34, 17 per site)	Y2Q1-Y2Q4	Fifteen of twenty (75%) 6-month data collection for participants who completed baseline evaluations. Total of four have been determined to be "lost to follow-up" at 6-months. see Actual Problems and Actions to Resolve below). Drexel has completed 6 of 7 of the 6-month follow-up sessions as per timeframe for return, one lost to follow-up. UM Rehab completed 9 of 13 of the 6-month follow-up sessions as per timeframe for return with one scheduled August, 2019 and 3 lost to follow-up.
Subtask 2: 6-month musculoskeletal (SMC) assessment (n=17, all Drexel)	Y2Q1-Y2Q4	All 5 participants with SCI who completed the baseline analysis also completed the 6-month motion analysis

Subtask 3: One year assessment	Target Timeframe (Year/Quarter)	Status
One-year musculoskeletal (MPS, WUSPI, PM, MSK, strength, and psychosocial (TSK, PCS, FOP, CPCI, SQoL) measures (n=68, 34 per site)	Y2Q3 – Y3Q2	In the SCI group a total 3 of 5 one-year assessments were completed. For controls 5 0f 6 were completed. Drexel: One SCI and two controls were completed for 100% of those on timeframe for one-year UM: 2 of 5 (40%) of SCI completed one-year assessments on schedule with the remaining 3 scheduled for August, 2019. Controls - 3 of 4 (75%) completed one-year assessments on schedule. The final one is scheduled for August, 2019.
One year musculoskeletal (SMC) assessment (n=34, all Drexel)	Y2Q3 – Y3Q2	The 1 participant with SCI who completed the baseline analysis and the 6-month motion analysis completed the one-year analysis. All controls (2) completed the motion analysis.
Major Task 3: Data Analysis, reporting and dissemination		
Subtask 1: Data analysis	**Target Timeframe (Year/Quarter)**	**Status**
Verify accuracy of data	Y1Q2-Y3Q2	Ongoing review of data entry for a consistency and accuracy
Analysis of primary measures	Y2Q2- Y3Q2	Analysis with abstracts generated on baseline comparisons of SCI and controls as well as preliminary analysis of 6-month changes

Subtask 2: Prepare and Submit Ongoing Regulatory Reports	Target Timeframe (Year/Quarter)	Status
Provide quarterly reports to DoD	Quarterly	All quarterly reports comprehensive and submitted on time, as required
Provide annual reports to DoD and respond to queries	Annually	Annual financial report submitted 1/22/19 Current report is Year 2 annual report
Provide annual reports to site IRB and DSMB (not required)	Annually	Annual report to Drexel and UM IRB approvals received 4/3/19 (Drexel) and 3/26/19 (UM)
Subtask 3: Dissemination	**Target Timeframe (Year/Quarter)**	**Status**
Prepare abstracts, presentations and manuscripts	Y2Q2-Y3Q2	Three abstract for presentation at the 2020 Combined Section Meeting of the APTA were submitted 7/10/19

Participant enrollment

- As July 31, 2019 Drexel enrolled 18 with SCI with one withdrawal, one due to medical issue that prohibited data collection (will attempt to resume if stable) and 12 controls; UM Rehab enrolled 20 participants with SCI (3 withdrew) and 13 controls.
- Total enrolled to date is 63 across both groups and sites—with numerous matched controls identified to be enrolled in early August-September, 2019 (Y3Q1)
- Total anticipated enrollment at this time was 68.
- **Explanation of efforts and strategies to promote enrollment and retention described in Actual Problems and Actions to Resolve**

What opportunities for training and professional development has the project provided?
We have held annual full team training and review of procedures. Site specific training (GSRH) has been held on three occasions.

How were the results disseminated to communities of interest?
Preliminary data from baseline (SCI n=27, control n= 23, and 6-month analysis of SCI n=15) was submitted in three abstracts for presentation at the 2020 Combined Sections Meeting of American Physical Therapy Association.

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

During the next reporting cycle (Year 3, 8/1/2019-7/31/20) we will continue recruitment, enrollment, and data collection to complete all 34 SCI baseline assessments, identify, and enroll all 34 matched controls. We will employ additional efforts (early phone calls, written communication) with enrolled participants to facilitate retention for the 6-month and one-year data collection, particularly in those with SCI and also control group. Given our attrition with the SCI group of four to-date we plan to enroll an additional 4-6 individuals with SCI.

To insure fidelity of data collection, on-site investigator training will occur on in the Fall of 2019 with continued communication regarding procedures. Monthly meeting with the site PIs and investigators as well as quarterly full team meeting are scheduled and will continue appearing on the group calendar to foster open communication and early identification of any issues as well as strategies to enhance enrollment and retention.

To facilitate accuracy, all data entry is reviewed at least one per monthly by investigators not involved in initial entry to address any data concerns that arise or identified data entry errors. All data is spot checked for accurate entry. Once 34 participants with SCI and 34 matched control baseline data are collected analysis of this baseline data (AIM 1) will be performed with intent of initial finding dissemination in a manuscript.

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

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

Preliminary data indicate individuals with new SCI reported increased upper extremity musculoskeletal pain, and demonstrated reduced ROM and strength along with maladaptive psychosocial pain factors. These factors continued 6-months post inpatient rehabilitation during initial community reintegration. Pain remained unchanged at 6-months along with psychosocial pain factors. An increase in strength was found, although not approaching matched control participants.

Shoulder pain management for individuals with SCI is reactive not proactive. Strength deficits are present immediately after injury and persist at six months. Causes of weakness such as poor nutrition status and ineffective strengthening programs should be identified and addressed early to maintain shoulder stability and prevent pain. Early identification of clinical impairments and directed interventions are warranted to ameliorate pain and its related reduction of activity and participation for individuals with SCI.

What was the impact on other disciplines?

Preliminary findings that individuals with new SCI demonstrate physical impairments reported increased upper extremity musculoskeletal pain, and demonstrated reduced ROM and strength along with maladaptive psychosocial pain factors. Furthermore, findings indicate that the psychosocial patterns associated with musculoskeletal pain may be different in individuals with SCI as compared to other population with chronic pain. The pain and maladaptive psychosocial factors remain at 6-montsh even when physical impairments are reducing. Management of shoulder pain in the SCI population is reactive rather than proactive.

Interventions focusing on impairments occur after the onset of pain as opposed to providing regular screens to identify and treat pain-related factors prior to the development of pain and dysfunction. Early identification of pain-related factors, physical and psychosocial, may ameliorate associated reduction of activity and participation for individuals with SCI.

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: Nothing to Report.

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

At the 6-month assessment timeframe we have lost 4 participants with SCI to follow-up. This was our overall anticipated attrition. In an assessment of our participants with SCI who enrolled, over 50% of our sample have violence (gunshot wound) as the cause of injury. The US the national average of SCI due to gunshot/violence is only 13.5%. Of the 4 who have been lost to follow-up, 3 were in this category of cause of injury. Below are the factors we determined to be potential obstacle to retention and plans to foster improved follow-up

1) Inaccurate or incomplete contact information.
- We will continue to obtain multiple phone, email and addresses for all enrolled. We will verbally confirm the information as baseline. For existing participants, we will begin contact at least 30 days prior to follow-up due date. We will send written information via email and USPS as well as phone contacts. We will utilize the referring sources (UM, Magee, GSRH) to determine if return visits are scheduled and try to coordinate in an effort to minimize participant burden.

2) Underestimation of attrition rate at protocol development
- We are aware that our initial estimate of attrition was based on previous studies, however, we did not foresee the potential for the large percentage of participants with violence in their daily lives. In an effort to account for potentially higher than anticipated attrition, we will enroll an additional 6 individuals with SCI. We will also employ additional efforts for retention as described above.

Changes producing a significant impact on expenditures
Nothing to Report.

Significant changes in use or care of human subjects
No significant changes in use or care of human subjects occurred. Below is the log of all IRB/HRPO tasks/approvals for this reporting cycle (8/1/19-7/31/19)

Organization	Task	Reason	approval date	expiration date
Drexel	Modification	personnel changes due to completion/initiation of fellowship of fellowship	8/3/19	4/17/19
Drexel	Modification	Addition of Good Shepherd Rehabilitation Hospital for recruitment and data collection and inclusion of new personnel at GSRH	11/27/18	4/17/19
Drexel	Continuing Renewal 19-20	Continuing renewal for 2019-2020 year	4/18/19	4/17/20
UMRehab	Continuing Renewal 19-20	Continuing renewal for 2019-2020 year	3/26/19	3/25/20
UMRehab	Modification	Personnel changes-addition of new research clinician	6/14/16	3/25/20
Drexel	Personnel changes	Addition of a GRA, removal of research fellows and investigators no longer at Drexel	7/8/19	4/17/20

Significant changes in use or care of vertebrate animals.
Not applicable

Significant changes in use of biohazards and/or select agents
Not applicable

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

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  - **Journal publications.**
    Nothing to Report

  - **Books or other non-periodical, one-time publications.**
    Nothing to Report

  Other publications, conference papers, and presentations.

  - **Website(s) or other Internet site(s)**
    Nothing to Report

  - **Technologies or techniques**
    Not applicable

- **Inventions, patent applications, and/or licenses**
  Not applicable

- **Other Products**
  Not applicable

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Drexel:

Name: Margaret Finley, PT, PhD
Project Role: PI
Researcher Identifier (e.g. ORCID ID): N//A
Nearest person month worked: 0.6 calendar months
Contribution to Project: Dr. Finley directed all aspects of the project to date. She completed quarterly reporting, annual technical report and annual financial reporting as required. She is responsible for the financial management of the project. She submitted IRB continuing review materials and acquired approval. Dr. Finley oversees the monitoring of the shared databases, ongoing recruitment with Magee Rehab Hospital and Good Shepherd Rehab Hospital including in-services and bi-weekly communication with clinical research personnel, supply acquisition, organization and leading of monthly and quarterly meetings. She participates in all data collection sessions for the Drexel site (to include GSRH). Following departure of Dr. Ebaugh (end Q3) she has picked up his tasks and effort. She has maintained monthly meetings with UMRehab team as well as led quarterly full-team meetings.

Name: Dave Ebaugh PT, PhD
Project Role: Co-I
Researcher Identifier (e.g. ORCID ID): N//A
Nearest person month worked: 0.15 calendar months until January 31, 2019
Contribution to Project: Dr. Ebaugh reviewed screening eligibility criteria and assisted with data collection through Y2Q2. Dr. Ebaugh left Drexel University and has been removed from the study, including IRB. Dr. Finley has taken over his tasks and effort.

Name: Thomas Trojian, MD
Project Role: Co-I
Researcher Identifier (e.g. ORCID ID): N//A
Nearest person month worked: 0.15 calendar months
Contribution to Project: Dr. Trojian participated in the ongoing training on ultrasound (GSRH and UMRehab review training), performing baseline, 6-month and one-year US on participants, analysis of all masked US files (Drexel, GSRH, UMRehab), participated in local team meetings as scheduled and all quarterly meetings.

Name: Elizabeth Euiler, MS
Project Role: Research Assistant (graduate Student)

Researcher Identifier (e.g. ORCID ID): N//A
Nearest person month worked: 0.3 calendar months (paid through Drexel University Fellowship)
Contribution to Project: Ms. Euiler participated in all participant data collection at Drexel (and GSRH) as well as data entry and data checking for the shared database. She participated in local team meetings as scheduled and all quarterly meetings.

UM Rehab:
Name: Paula Geigle, PT, MS, PhD
Project Role: Co-I
Nearest person month worked: 0.45 calendar months
Contribution to Project: Dr. Geigle provided oversight of all UM Rehab project aspects since initiation to date. Dr. Geigle continued oversight of all aspects of the UM Rehab site including: developing recruitment strategies and planning flow of assessment activity, consulted with Dr. York for medical oversight and ultrasound procedures, supported sponsor reporting, supported preliminary data analysis and publications, co-led monthly conference call meetings and quarterly full team meetings.

Name: Henry York, MD
Project Role: Site PI
Nearest person month worked: 0.3 calendar months
Contribution to Project: Dr. York performed ultrasound assessments for all participants, consulted with Drs. Geigle and Finley on ultrasound procedures based upon observations, entered ultrasound data to one-drive database, and provided oversight for financial and contractual reviews.

Name: Sara Kate Frye, MS OTR/L ATP
Project Role: Research Clinician
Nearest person month worked: 0.15 calendar months
Contribution to Project: Ms. Frye performed clinical evaluations and self-report measures with SCI participants, consulted on recruitment and retention strategies for SCI subjects, and supported preliminary data analysis and presentations.

Name: Marni Kallins, PT DPT OCS
Project Role: Research Clinician
Nearest person month worked: 0.15 calendar months
Contribution to Project: Dr. Kallins performed clinical evaluations and administered some self-report measures for control participants, and led recruitment and retention strategies for control subjects.

Name: Leigh Casey, BA
Project Role: Research Coordinator
Nearest person month worked: 0.15 calendar months
Contribution to Project: Ms. Casey coordinated recruitment and retention initiatives, facilitated recruitment of control participants, supported consent process and administered some self-report measures for control participants; entered self-report and clinical data in shared database; coordinated participant payments and prepared payment records for audit; supported monthly and quarterly conference call meetings.

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?

Organization Name: University of Maryland Rehabilitation and Orthopedic Institute
Location of Organization: 2200 Kernan Dr, Baltimore, MD 21207
Partner's contribution to the project:

- UMROI is our collaborating site. Investigators are recruiting, screening, consenting and collecting data on both individuals with SCI and age-matched controls.
- Facilities – we are collecting data in the facility
- Collaboration- Henry York, MD, Paula Geigle, PT, MS, PhD, Leigh Casey, BA, Sara Kate Frye MS OTR/L ATP and Marni Kallins DPT are investigators/research clinicians with roles for recruiting, screening and consenting participants.

Organization Name: Magee Rehabilitation Hospital
Location of Organization: 513 Race St, Philadelphia, PA 19102
Partner's contribution to the project:

- Facilities – we are collecting baseline data on individuals with SCI in the facility
- Collaboration- Mary Schmidt, DPT and Director of Research is on the research team with a role for recruiting, screening and consenting participants.

Organization Name: Good Shepherd Rehabilitation Hospital
Location of Organization: 850 S 5th St, Allentown, PA 18103
Partner's contribution to the project:

- Facilities – we are collecting baseline data on individuals with SCI in the facility
- Collaboration- Three individuals are members of the investigative team: Mary Brownsberger, PsycD, ABPP obtains the psychosocial surveys; Rosa Cooper, RN, DNP is responsible for obtaining consent of participants and William Gleason, MD performs the musculoskeletal ultrasounds

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: Not applicable

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

- Quad Chart included

Development of a Biopsychosocial Prospective Surveillance Model of Shoulder Pain in Individuals with Spinal Cord Injury
Log No. SC160041
Award W81XWH-17-1-0476

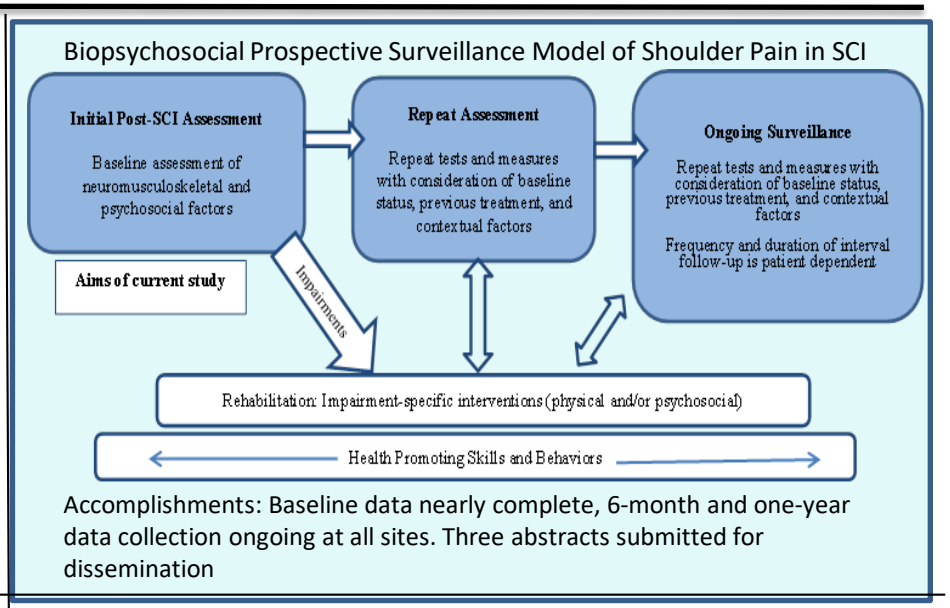
PI: Finley, Margaret **Org: Drexel University** **Award Amount:** $664,270

Study Aim

Aim 1*:* Determine musculoskeletal and psychosocial factors associated with shoulder pain in individuals with acute SCI. **Aim 2**: Establish the changes in musculoskeletal and psychosocial factors in individuals with SCI between the acute phase of rehabilitation, 6 months and one year post–SCI. **Aim 3**: Determine the relationship between shoulder pain, musculoskeletal factors, psychosocial factors, and QoL, during the first year following SCI.

Approach

A multi-site repeated-measures investigation of individuals with SCI across the first year of injury will be compared with an age-gender matched control group. Primary measures of physical impairment (shoulder and general musculoskeletal pain, muscle extensibility, shoulder muscle strength ratios, rotator cuff integrity via musculoskeletal ultrasound) and psychosocial measures (Tampa Kinesiophobia Scale, Pain Catastrophizing Scale, Fear of Pain Questionnaire, QoL) will be obtained from all participants. Three dimensional kinematic data that will be used to derive intersegmental coordination measures during a functional reaching task will be obtained from the Drexel cohort.



Accomplishments: Baseline data nearly complete, 6-month and one-year data collection ongoing at all sites. Three abstracts submitted for dissemination

Timeline and Cost

Activities	CY 17	18	19	20
Regulatory approval & collaboration structure				
Participant data collection				
Data Analysis and interpretation				
Dissemination				
Estimated Budget ($664K)	**$226,237**	**$224,332**	**$213,701**	

Updated: (Philadelphia, PA July 31, 2019)

Goals/Milestones

CY17 Goal – Regulatory approvals
✓ Complete site and HRPO regulatory approval
✓ Collaboration structure developed
✓ Initiated participant enrollment and baseline data collection

CY18 Goals – Data Collection
✓ Data collection initiated and ongoing
☐Participant enrollment and data collection all baseline and 6-month completed

CY19 Goal – Final data collection, analysis & interpretation
☐ Complete one-year data collection sessions
☐ Complete data analysis and interpretation

CY20 Goal – Dissemination
☐ Abstracts, presentations, publications

Comments/Challenges/Issues/Concerns:

Budget Expenditure to Date
Projected Expenditure: $450,569 (end Y2); $664,270 total
Actual Expenditure: $376,814

9. APPENDICES:

- Copy of abstracts submitted to the Combined Section Meeting of the American Physical Therapy Association for dissemination at Annual meeting, February 12-15, 2020 – Denver, Colorado Acceptance decisions expected in September 2019.

Your Abstract Submission Has Been Received

Print this page

You have submitted the following abstract to 2020 Combined Sections Meeting (CSM) . Receipt of this notice does not guarantee that your submission was complete or free of errors.

Musculoskeletal Pain and Clinical Factors in Individuals with New SCI: Longitudinal Study Preliminary Data

Margaret Anne Finley, PT, PhD
Drexel University *Philadelphia, PA*
Elizabeth Euiler
Philadelphia, PA
Thomas Trojian
Philadelphia, PA
Sara Kate Frye
Philadelphia, PA
Marni Lynn Kallins, PT, DPT
Marriottsville, MD
Paula Richley Geigle, PT, MS, PhD
University Maryland Rehabilitation *Asheville, NC*

Abstract Text:

Purpose/Hypothesis: Individuals with a spinal cord injury (SCI) display a high prevalence of shoulder pain which is associated with loss of function and independence, participation restrictions in self-care, work, and leisure activities, and decreased quality of life (QoL).[1,2] Common clinical and biomechanical mechanisms of shoulder pain in individuals with chronic SCI are known.[3-5] However, evidence regarding impairments during the initial, acute phase of SCI is limited.[6-8] Our longitudinal study examines the relationship and temporal characteristics of musculoskeletal shoulder pain, biopsychosocial factors, and QoL during the first year after SCI. Preliminary comparisons of musculoskeletal pain and clinical factors at baseline and 6-months in individuals with SCI and matched controls are presented. We hypothesized no difference would been found in impairments at the onset of inpatient rehabilitation (baseline) between groups, however, this difference would increase at 6-months and at 1-year.

Number of Subjects: Individuals participating in inpatient SCI rehabilitation (n=27) and age, gender matched controls without SCI (n=23).

Materials and Methods: Demographics, Musculoskeletal Pain Survey upper extremity (MPS_UE) and shoulder (MPS_shdr) subscales.[8] Clinical measures of shoulder range of motion (ROM), peak isometric strength and pectoralis minor muscle extensibility (PMm).

Results: No group difference in age, ethnic identification, racial group, occupational status, marital status, education level, or annual income existed. MPS_UE (p=0.02), MPS_shdr (p=0.05) was greater in SCI compared to controls. In those with SCI, baseline ROM and muscle strength was reduced (p≤0.05) in all cardinal plane motions and shoulder muscle groups compared to controls. Dominant limb PMm was not different between groups. At 6-months following inpatient rehabilitation, musculoskeletal pain remained elevated, but muscle strength increased in individuals with

SCI (n=15). However, all muscle strength, except adduction, remained significantly lower for individuals with SCI compared to the control group.

Conclusions: Our preliminary data indicate that during the acute inpatient rehabilitation phase individuals with SCI reported increased upper extremity musculoskeletal pain, and demonstrated reduced ROM and strength. Pain remained unchanged at 6-months with an increase in strength, although not approaching matched control participants.

Clinical Relevance: Shoulder pain management for individuals with SCI is reactive not proactive. Strength deficits are present immediately after injury and persist at six months. Causes of weakness such as poor nutrition status and ineffective strengthening programs should be identified and addressed early to maintain shoulder stability and prevent pain. Early identification of clinical impairments and directed interventions are warranted to ameliorate pain and its related reduction of activity and participation for individuals with SCI. This longitudinal study investigates these shoulder pain determinants in the year following SCI.

Abstract Submission Type:
Research Report

Section:
Neurology

Presentation Type:
Platform

Title:
Musculoskeletal Pain and Clinical Factors in Individuals with New SCI: Longitudinal Study Preliminary Data

Submitter's E-mail:
maf378@drexel.edu

References:

Lysack C, Komanecky M, Kabel A, Cross K, Neufeld S. Environmental factors and their role in community integration after spinal cord injury. Canadian Journal of Occupational therapy Revue Canadienne d'ergotherapie. 2007;74 Spec No.:243-254.
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Funding Source:
Department of Defense SCIRP Award No. W81XWH-17-1-0476

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You have submitted the following abstract to 2020 Combined Sections Meeting (CSM) . Receipt of this notice does not guarantee that your submission was complete or free of errors.

Optimal Screening for Prediction of Referral and Outcome (OSPRO)-Individuals with Musculoskeletal Pain Following SCI

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Abstract Text:

Purpose/Hypothesis: Individuals with spinal cord injury (SCI) display a high prevalence of musculoskeletal pain associated with loss of function, independence, participation restrictions in self-care, work, and leisure activities, and decreased quality of life (QoL).[1-3] Furthermore, pain associated psychological distress is associated with increased reports of pain[4], pain-related behavior, use of medication and other health care services, and longer hospital stays.[5] Psychosocial determinants of musculoskeletal pain have not been identified in individuals with acute SCI nor the interdependence of determinants predisposing individuals to chronic pain and secondary disability. The Optimal Screening for Prediction of Referral and Outcome (OSPRO) predicts selected quartile thresholds and full-length questionnaire scores for negative coping, negative mood, and positive affect/coping domains in individuals with a variety of musculoskeletal disorders.[6,7] The purpose of this longitudinal study is to determine the relationship and temporal characteristics of biopsychosocial factors, musculoskeletal pain, and QoL during the first year following SCI.

Number of Subjects: Individuals (n = 21, age =34±12 yrs) with musculoskeletal pain participating in inpatient SCI rehabilitation (baseline); subset reassessed at 6-month post rehabilitation (n=8)

Materials and Methods: Surveys completed at baseline and 6-months following inpatient discharge were the Musculoskeletal Pain Survey (MPS_Total) [8], Tampa Kinesiophobia Scale-11 (TSK), Pain Catastrophizing Scale (PCS), and OSPRO-17. The OSPRO tool provides estimates for the TSK, PCS, Chronic Pain Acceptance Questionnaire (CPAQ), Fear-Avoidance Beliefs Questionnaire physical activity subscale (FABQ-PA) and work

subscale (FABQ-W), Pain Anxiety Symptoms Scale (PASS-20), Patient Health Questionnaire-9 (PHQ-9), Pain Self-Efficacy Questionnaire (PSEQ), Self-Efficacy for Rehabilitation (SER), State-Trait Anxiety Inventory (STAI), and the State-Trait Anger Expression Inventory (STAXI).

Results: At baseline, strong, correlations existed for OSPRO predicted score of PCS ($r = 0.610$, $p = 0.003$) and TSK ($r = 0.761$, $p < 0.001$) and the PCS and TSK full tool scores. Baseline OSPRO predicted significant risk (X^2, $p < 0.05$) for vulnerability (positive yellow flag) in baseline FABQ-PA, TSK, STAI, PHQ-9, and PASS-20. At 6-months ($n = 8$ completed), MPS_Total increased ($p=0.040$) while indication of vulnerability (positive yellow flag) decreased in TSK ($p= 0.028$), STAI ($p=0.028$), and PHQ-9 ($p=0.035$).

Conclusions: Preliminary data from the OSPRO tool indicate vulnerability in several psychosocial pain-related domains for individuals with musculoskeletal pain following SCI. Musculoskeletal pain increased over the initial 6-months of community reintegration in a subset providing follow up, vulnerability was reduced in several key areas including kinesiophobia, anxiety, and depression.

Clinical Relevance: Preliminary findings indicate that the psychosocial patterns associated with musculoskeletal pain may be different in individuals with SCI. Furthermore, outcomes from this cohort of patients with SCI indicate that the OSPRO has broader application to various populations experiencing musculoskeletal pain.

Abstract Submission Type:
Research Report

Section:
Orthopaedics

Presentation Type:
Platform

Title:
Optimal Screening for Prediction of Referral and Outcome (OSPRO)-Individuals with Musculoskeletal Pain Following SCI

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References:

McCasland LD, Budiman-Mak E, Weaver FM, Adams E, Miskevics S. Shoulder pain in the traumatically injured spinal cord patient: evaluation of risk factors and function. J Clin Rheum : Pract Reports Rheum & Musculo Dis. 2006;12(4):179-186.
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Student Category:
Not a Student

Sub-Section:
Pain Management

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Funding Source:
Department of Defense SCIRP Award No. W81XWH-17-1-0476

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You have submitted the following abstract to 2020 Combined Sections Meeting (CSM) . Receipt of this notice does not guarantee that your submission was complete or free of errors.

Musculoskeletal Pain and Psychosocial Characteristics of Individuals with New SCI: Preliminary Data from Longitudinal Study

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Abstract Text:

Purpose/Hypothesis: Individuals with a spinal cord injury (SCI) display a high prevalence of shoulder pain which is associated with loss of function and independence, participation restrictions in self-care, work, and leisure activities, and decreased quality of life (QoL).[1-3] Higher pain catastrophizing has been demonstrated in individuals with SCI creating a relationship of reduced function and increased pain.[4] Psychosocial determinants of shoulder pain have not been identified for individuals with acute SCI nor has the interdependence of determinants facilitating chronic pain and secondary disability. Our longitudinal study investigates the relationship and temporal characteristics of musculoskeletal pain, biopsychosocial factors, and QoL during the first year following SCI. Preliminary findings of musculoskeletal pain and psychosocial factors at baseline (n=27) and 6-months (n=15) are presented.

Number of Subjects: Individuals participating in inpatient SCI rehabilitation (n=27) and age and gender matched controls without SCI (n=23).

Materials and Methods: Demographics, Musculoskeletal Pain Survey upper extremity (MPS_UE) and shoulder (MPS_shdr) subscales,[5] along with psychosocial measures [Tampa Kinesiophobia Scale-11 (TSK), Pain Catastrophizing Scale (PCS), Fear of Pain Questionnaire (FPQ), and Subjective Quality of Life Questionnaire (SQoL)].

Results: No baseline difference in age, ethnic identification, racial group, occupational status, marital status, education level, or annual income existed between the groups. Baseline MPS_UE ($p=0.02$), MPS_shdr ($p=0.05$), PCS ($p<0.001$), TSK ($p<0.001$), and FOP ($p=0.01$) scores were higher and SQoL was lower ($p<0.001$) in individuals with SCI compared to matched controls. At 6-months following discharge from inpatient rehabilitation,

musculoskeletal pain remained elevated and maladaptive psychosocial characteristics were unchanged for people with SCI (n=15).

Conclusions: Preliminary data indicate individuals with new SCI demonstrate upper extremity musculoskeletal pain along with maladaptive psychosocial pain factors. These factors continued 6-months post inpatient rehabilitation during initial community reintegration.

Clinical Relevance: Shoulder pain management for people with SCI is currently reactive rather than proactive. Early identification of pain-related factors may ameliorate potential pain linked activity and participation decline. Our longitudinal study will identify shoulder pain determinants in the year after SCI.

Abstract Submission Type:
Research Report

Section:
Neurology

Presentation Type:
Platform

Title:
Musculoskeletal Pain and Psychosocial Characteristics of Individuals with New SCI: Preliminary Data from Longitudinal Study

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References:

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Not a Student

Sub-Section:

SCI SIG

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Funding Source:
Department of Defense SCIRP Award No. W81XWH-17-1-0476

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