AWARD NUMBER: W81XWH-21-1-0589

TITLE: The Impact of Injustice Appraisals on Pyschosocial Outcomes Following Spinal Cord Injury: A Longitudinal Study

PRINCIPAL INVESTIGATOR: Kimberley Monden, PhD

CONTRACTING ORGANIZATION: University of Minnesota, Minneapolis, MN

REPORT DATE: July 2022

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

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The Impact of Injustice Appraisals on Pyschosocial Outcomes Following Spinal Cord Injury: A Longitudinal Study

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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Minneapolis, MN 55455

Minneapolis VA
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Minneapolis, MN 55417-2309

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Thomas Jefferson University
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8. PERFORMING ORGANIZATION REPORT

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The activities accomplished in Year 1 include obtaining IRB and HRPO approvals for UMN and Jefferson sites and submitting the initial submission to CIRB for the two VA sites. We also established team-meeting teleconferences, developed the online survey and database entry platform, and pilot tested the study measures with members of the SCI community. Based on feedback received about the study measures, changes were made and subsequently submitted for IRB approval. We also trained UMN and Jefferson study staff in qualitative and quantitative data collection, including use of the online data entry platform. Study start-up has been delayed by the reliance process between UMN and Jefferson (site approval granted on 2/8/2022), HRPO approval of Jefferson site granted on 6/2/2022, and the finalization of study measures and screening procedures. Study start-up has also been delayed due to CIRB review for the two VA sites.

15. SUBJECT TERMS
None listed.

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
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1. INTRODUCTION:

Individuals with spinal cord injury (SCI) face a set of unique challenges, including poor psychosocial adaptation to disability, changes in social roles and relationships, decreased independence, and physical pain and discomfort. Injustice appraisals are a potentially modifiable risk factor for poor psychosocial adjustment to various chronic health conditions, including SCI. *Injustice appraisal* is defined as the severity of injury or disability-related loss and perceived unfairness. Appraisals of injustice are relevant when individuals feel a sense of undeserved suffering and loss or are struggling to understand why they were injured (i.e., Why me), as may be the case after SCI. Appraisals are associated with psychological distress and coping following SCI and may be more amenable to change than coping strategies. The objectives of this study are to (1) determine the course and impact of SCI-related injustice appraisals among civilians and Veterans who have recently acquired an SCI, and (2) use qualitative research to gain a rich, in-depth understanding of appraisals as individuals adjust to a newly acquired SCI.

2. KEYWORDS:

spinal cord injury; injustice appraisals, qualitative

3. ACCOMPLISHMENTS:

What were the major goals of the project?

SOW Task	Timeline (Months)	Progress
Major Task 1: Study Startup		
Subtask 1: Establish team meeting teleconferences	1	Complete (100%) – monthly recurring meetings are taking place.
Subtask 2: Hire (as needed) study coordinator and research assistants	1-3	Complete (100%) – all study sites have identified study staff.
Subtask 3: Coordinate with sites for IRB protocol submission	1-3	In progress (65%) – Reliance agreement between Jefferson and UMN executed on 1/11/2022. Jefferson p-Site initial approval granted by UMN IRB on 2/8/2022. VA sites submitted to CIRB on 5/10/2022.
Subtask 4: Coordinate Military 2nd level IRB review (ORP/HRPO)	4-6	Complete (65%) – HRPO approved UMN initial documents on 1/31/2022. Jefferson initial documents submitted 3/28/2022 and approval granted on 6/2/2022.
Milestone(s) Achieved: Teleconference schedule established between sites; study staff hired; sIRB approval for UMN and Jefferson; HRPO approval for UMN and Jefferson; VA initial submission submitted to CIRB.	*6*	*In progress as noted above.*
Major Task 2: Collect and analyze quantitative data.		
Subtask 1: Identify and invite study participants currently hospitalized for inpatient rehabilitation	6-18	Not started (0%)
Subtask 2: Collect baseline data during	6-18	Not started (0%)

inpatient rehabilitation.		
Subtask 3: Collect follow-up 6-month (T1) and 12-month (T2) data.	18-30	Not started (0%)
Subtask 3: Perform ongoing data entry into web-based database	18-30	Not started (0%)
Subtask 4: Perform ongoing data quality checks and data cleaning	18-30	Not started (0%)
Subtask 5: Conduct data analysis	30-33	Not started (0%)
Subtask 6: Manuscript preparation	33-36	Not started (0%)
Milestone(s) Achieved: 1st participant enrolled	*6*	*Not started, as noted above.*
Milestone(s) Achieved: 1st 6-month follow-up (T1) data collection interview complete	*12*	*Not started, as noted above.*
Milestone(s) Achieved: 1st 12-month follow-up (T2) data collection interview complete	*18*	*Not started, as noted above.*
Milestone(s) Achieved: Baseline (inpatient rehabilitation) data collection complete	*18*	*Not started, as noted above.*
Milestone(s) Achieved: 6-month follow-up (T1) data collection complete	*24*	*Not started, as noted above.*
Milestone(s) Achieved: 12-month follow-up (T2) data collection complete	*30*	*Not started, as noted above.*
Milestone(s) Achieved: Longitudinal quantitative data collection complete, all data entered and cleaned in preparation for analysis	*31*	*Not started, as noted above.*
Milestone(s) Achieved: Data analysis complete	*33*	*Not started, as noted above.*
Milestone(s) Achieved: Aim 1 and Aim 2 manuscripts complete	*36*	*Not started, as noted above.*
Major Task 3: Collect and analyze qualitative data.		
Subtask 1: Conduct baseline (inpatient rehabilitation) qualitative interviews	6-18	Not started (0%)
Subtask 2: Concurrently analyze baseline qualitative data	6-18	Not started (0%)
Subtask 3: Conduct 12-month follow-up qualitative interviews	18-30	Not started (0%)
Subtask 4: Concurrently analyze 12-month qualitative interviews	18-30	Not started (0%)
Subtask 5: Manuscript preparation	31-36	Not started (0%)
Milestone(s) Achieved: 1st baseline (inpatient rehabilitation) qualitative interview complete	*6*	*Not started, as noted above.*
Milestone(s) Achieved: 1st 12-month qualitative interview complete	*18*	*Not started, as noted above.*
Milestone(s) Achieved: Baseline (inpatient rehabilitation) qualitative interviews complete	*18*	*Not started, as noted above.*
Milestone(s) Achieved: Baseline (inpatient rehabilitation) qualitative data analysis complete	*20*	*Not started, as noted above.*
Milestone(s) Achieved: 12-month qualitative interviews complete	*30*	*Not started, as noted above.*
Milestone(s) Achieved: 12-month qualitative data analysis complete	*31*	*Not started, as noted above.*
Milestone(s) Achieved: Aim 3 manuscript complete	*36*	*Not started, as noted above.*

What was accomplished under these goals?

Major activities:

- Established monthly team meetings
- Hired study staff
- Established sIRB
- Reliance agreement between UMN and Jefferson fully executed
- Pilot tested study measures and finalized
- Protocol submitted/approved internally at Jefferson and UMN
- Protocol submitted/approved by HRPO for Jefferson and UMN
- Database built, online data collection platform tested and live
- Jefferson site training conducted
- CIRB initial submission submitted on 5/10/2022 and under review

Specific objectives: Specific objectives have been accomplished as described above.
Significant results: Not applicable at this time.
Other achievements: Not applicable at this time.

Enrollment goals have not been met due to the delay in startup. The reliance process took longer than anticipated. The initial UMN submission was on 6/14/2021 and was not approved until 9/24/2021. Jefferson site approval was granted on 2/8/2022 but required modifications to the HIPAA authorization form and, per HRPO review, required revisions to the ICF. Final approval for the Jefferson site was granted on 6/2/2022. Further, given that UMN will not serve as the IRB of record for VA sites, the two collaborating VAs were required to submit to CIRB. Until December 2021, the VA collaborators had not yet identified study personnel to start the regulatory process, thus the CIRB submission process started shortly thereafter. The initial application was submitted to CIRB on 5/10/2022 and is currently under review. Now that UMN and Jefferson are approved for enrollment, we expect to catch up and meet our targets moving forward. We expect the VA sites will follow suit once they receive CIRB and HRPO approval.

TOTAL PROTOCOLS: 2

			Enter information regarding number of subjects					
HRPO Protocol Number	**Protocol PI Name**	**Organization (Site)**	**# Target**	**# Enrolled**	**# Completed**	**# Screened**	**# Recruited**	**Other**
Quantitative Data Collection								
E02274	Monden	UMN/Jefferson	150	0	0	0	0	0
E02274	McDonald	MVAHCS/ Richmond VAMC	30	0	0	0	0	0
Qualitative Data Collection								
E02274	Monden	UMN/Jefferson	13	0	0	0	0	0
E02274	McDonald	MVAHCS/ Richmond VAMC	12	0	0	0	0	0

PROTOCOL (_1 of 2_ total):

Protocol [HRPO Assigned Number]: E02274

Title: The Impact of Injustice Appraisals on Psychosocial Outcomes Following Spinal Cord Injury: A Longitudinal Study

Target required for clinical significance: Quantitative: 150; Qualitative: 13

Target approved for clinical significance: Quantitative: 150; Qualitative: 13

SUBMITTED TO AND APPROVED BY:

- UMN IRB – approved sIRB request for UMN to serve as IRB of record on 06/04/2021.
- UMN IRB – initial application submitted on 6/14/2021. Deferred on 7/9/2021.
- UMN IRB – initial application submitted on 8/20/2021. Approved on 9/24/2021.
- HRPO – initial application submitted on 09/30/2021, comments returned to PI on 11/18/2021
- HRPO – PI addressed comments and resubmitted 1/14/2022; approved on 1/31/2022
- HRPO for Jefferson – initial application submitted on 3/25/2022; comments returned on 3/28/2022
- HRPO for Jefferson – Addressed comments and resubmitted on 5/6/2022; approved on 6/2/2022

STATUS:

(i) Number of subjects recruited/original planned target: Quantitative: 0/150, Qualitative: 0/13
Number of subjects screened/original planned target: Quantitative: 0/150, Qualitative: 0/13
Number of patients enrolled/original planned target: Quantitative: 0/150, Qualitative: 0/13
Number of patients completed/original planned target: Quantitative: 0/150, Qualitative: 0/13

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:

- UMN IRB – mod 1 (personnel) submitted on 9/28/2021; approved on 9/29/2021
- UMN IRB – mod 2 (misc. protocol) submitted 2/16/2022; approved 3/23/2022
- UMN IRB for Jefferson – mod 1 (HIPAA form) submitted 2/25/2022; approved 3/14/2022
- UMN IRB – mod 3 (misc. protocol) submitted 3/24/2022; approved 3/31/2022
- UMN IRB – mod 4 (personnel and misc. protocol) submitted 4/26/2022; approved 4/29/2022
- UMN IRB – mod 5 (personnel) submitted 5/4/2022; approved 5/5/2022
- UMN IRB for Jefferson – mod 2 (update ICF) submitted 4/7/2022; approved 4/14/2022
- UMN IRB for Jefferson – mod 3 (update ICF per HRPO) submitted 5/3/2022; approved 5/23/2022
- UMN IRB – mod 6 (change screening process) submitted 5/23/2022; approved 6/15/2022
- UMN IRB for Jefferson – mod 4 (add personnel to study materials) submitted 6/8/2022; approved 6/22/2022
- UMN IRB – CR submitted 6/14/2022; approved 7/6/2022
- UMN IRB – mod 7 (retention materials) submitted 6/16/2022; approved 6/17/2022
- UMN IRB for Jefferson – mod 5 (site-specific retention materials) submitted 6/22/2022; approved 7/15/2022

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:

Nothing to report.

PROTOCOL (_2 of 2_ total):

Protocol [HRPO Assigned Number]: E02274

Title: The Impact of Injustice Appraisals on Psychosocial Outcomes Following Spinal Cord Injury: A Longitudinal Study

Target required for clinical significance: Quantitative: 30; Qualitative: 12

Target approved for clinical significance: Quantitative: 30; Qualitative: 12

SUBMITTED TO AND APPROVED BY:

- CIRB initial application submitted 5/10/2022

STATUS:

(i) Number of subjects recruited/original planned target: Quantitative: 0/30, Qualitative: 0/12
Number of subjects screened/original planned target: Quantitative: 0/30, Qualitative: 0/12
Number of patients enrolled/original planned target: Quantitative: 0/30, Qualitative: 0/12
Number of patients completed/original planned target: Quantitative: 0/30, Qualitative: 0/12

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:

- Nothing to report.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:

Nothing to report.

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

Nothing to report

How were the results disseminated to communities of interest?

Nothing to report.

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

Y2 Q1 we anticipate receiving CIRB approval and will submit to HRPO for approval of our VA sites. In the same quarter, we intend to enroll our first participants.

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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

Delays in IRB startup has put us behind on our enrollment goals. WE expect to have all IRB approvals in the next quarter and anticipate all sites will be enrolling by Y2Q2

Changes that had a significant impact on expenditures

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report**.**

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS:

- **Publications, conference papers, and presentations**

  Nothing to report

- **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:	Kimberley Monden, PhD
Project Role:	Principal Investigator
Research Identifier:	ORCID ID: 0000-0002-5207-0452
Nearest person-month worked:	1.41 CM
Contribution to Project:	Dr. Monden has directed all current study activities.

Name:	Robert Wudlick
Project Role:	Co-Investigator/Advocate
Research Identifier:	ORCID ID: 0000-0001-6021-1238
Nearest person-month worked:	0.25 CM
Contribution to Project:	Mr. Wudlick has worked on recruitment strategies with local and national SCI organizations.

Name:	Angela Philippus, MS
Project Role:	Study Coordinator
Research Identifier:	ORCID ID: 0000-0001-7427-8660
Nearest person-month worked:	1.96 CM
Contribution to Project:	Ms. Philippus has overseen all IRB activities and matters related to HRPO approval. Ms. Philippus also built the database and provided training to Jefferson's study staff.

Name:	Quinn Kellerman, PhD
Project Role:	Site PI, Minneapolis VAMC
Research Identifier:	ORCID ID: 0000-0001-5998-3783
Nearest person-month worked:	1.2 CM donated effort (100% VA appointment)
Contribution to Project:	Dr. Kellerman is assisting with the VA CIRB submission and hired her research coordinator.

Name:	Scott McDonald, PhD
Project Role:	Site PI, Richmond, Virginia VAMC
Research Identifier:	ORCID ID: 0000-0003-1490-0096
Nearest person-month worked:	0.96 CM
Contribution to Project:	Dr. McDonald is overseeing the VA CIRB submission and hired his research coordinator.

Name:	Maryjane Mulcahey, PhD
Project Role:	Site PI, Thomas Jefferson University
Research Identifier:	ORCID ID: 0000-0002-0837-714X
Nearest person-month worked:	0.60 CM
Contribution to Project:	Dr. Mulcahey is overseeing Jefferson's research activities and hired a research coordinator.

Name:	Dana Johnson
Project Role:	Research Coordinator (Thomas Jefferson University)
Research Identifier:	N/A
Nearest person-month worked:	1.20 CM

Contribution to Project:	Ms. Johnson is working with Ms. Philippus on the sIRB and startup activities at Jefferson.

Name:	Eric Hansen
Project Role:	Research Coordinator (Minneapolis VAMC)
Research Identifier:	N/A
Nearest person-month worked:	3.00 CM
Contribution to Project:	Mr. Hansen is working with Ms. Philippus, Dr. Kellerman, and Dr. McDonald on the VA CIRB submission

Name:	Liron McCauley
Project Role:	Research Coordinator (Richmond, Virginia VAMC)
Research Identifier:	N/A
Nearest person-month worked:	3.00 CM
Contribution to Project:	Ms. McCauley is working with Ms. Philippus, Dr. Kellerman, and Dr. McDonald on the VA CIRB 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?

New Grants:

1. Role: Co-Principal Investigator
   Grant Title: Communication of the Spinal Cord Injury Physical Activity Guidelines
   Grant Number: 856011
   External Granting Agency: Craig H. Neilsen Foundation
   Project Dates: April 30, 2022 - April 29, 2025

2. Role: Co-Principal Investigator
   Grant Title: Minnesota Regional Spinal Cord Injury Model System
   Grant Number: 90SIMS0008
   External Granting Agency: US Dept. of Health & Human Services ACL, National Institute on Disability, Independent Living, and Rehabilitation Research
   Project Dates: September 1, 2021 - August 31, 2026

3. Role: Co-Investigator
   Name of PI: Lauren Strober, PhD
   Grant Title: Reinventing Yourself with Multiple Sclerosis (MS): An Intervention Aimed at Increasing Self-Efficacy, Coping, Psychological Well-Being and Overall Quality of Life in MS
   Grant Number: 90IFRE0053
   External Granting Agency: U.S. Department of Health & Human Services ACL, National Institute on Disability, Independent Living, and Rehabilitation Research
   Project Dates: September 1, 2021 - August 31, 2024

Grants Ended:

1. Role: Principal Investigator
   Grant Title: Adaptation and Dissemination of the Spinal Cord Injury Physical Activity Guidelines
   Grant Number: N/A
   External Granting Agency: Paralyzed Veterans of America

Project Dates: June 1, 2021 - May 31, 2022

What other organizations were involved as partners?

Organization Name:	Minneapolis VA
Location of Organization:	Minneapolis, MN
Partner's contribution to the project:	Collaborator

Organization Name:	McGuire Research Institute
Location of Organization:	Richmond, VA
Partner's contribution to the project:	Collaborator

Organization Name:	Thomas Jefferson University
Location of Organization:	Philadelphia, PA
Partner's contribution to the project:	Collaborator

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

Not applicable.

QUAD CHARTS:

See below.

9. APPENDICES:

Nothing to report.

The Impact of Injustice Appraisals on Psychosocial Outcomes Following Spinal Cord Injury: A Longitudinal Study

Log Number: SC200102; Y1 Annual Report

Award Number: W81XWH-21-1-0589

PI: Kimberley Monden, PhD **Org:** University of Minnesota **Award Amount: $669,457**

Study/Product Aim(s)

Aim 1.1 (Quantitative): To determine the course of injustice appraisals during the first year of recovery from of recovery from acquired SCI.

Aim 1.2 (Quantitative): To determine if injustice appraisals during the acute stage of SCI (inpatient rehabilitation) predict psychosocial outcomes at the sub-acute (6 months post-discharge) and chronic (12 months post-discharge) stages of injury.

Aim 2 (Qualitative): To develop an in-depth, contextual understanding of injustice appraisals and factors contributing to injustice appraisals in the acute (inpatient rehabilitation) and sub-acute (12 months post-injury) phases of SCI among civilians and Veterans.

Approach

This longitudinal, cohort study will collect quantitative data from civilians and Veterans with acquired SCI during the first year post-injury at the following time points: inpatient rehabilitation/acute phase (baseline), 6 months post-discharge/sub-acute phase (T1), and 12-months post-discharge/chronic phase (T2). Qualitative data will be collected at baseline and T2.

Timeline and Cost

Activities FY	21-22	22-23	23-24
IRB, identify subjects, longitudinal quantitative data collection.			
Baseline qualitative data collection & analysis.			
12 month qualitative data collection & analysis.			
Analyze quantitative data and prepare manuscript/presentations.			
Estimated Budget ($K)	**$242,483**	**$208,506**	**$218,467**

Injustice appraisals are a potentially modifiable risk factor for poor psychosocial adjustment to spinal cord injury.

Goals/Milestones

FY21-22 Goal – IRB approvals and begin data collection.

- ❑ Obtain IRB approval at all study sites.
- ✓ Begin quantitative data collection.
- ❑ Begin baseline qualitative data collection.

FY22-23 Goals – Continue longitudinal quantitative data collection.

- ❑ Complete baseline qualitative data collection.
- ❑ Analyze baseline qualitative data.
- ❑ Begin 12-month qualitative data collection

FY23-24 Goal – Complete all data collection, conduct analyses, and prepare manuscripts.

- ❑ Complete longitudinal quantitative data collection.
- ❑ Complete 12-month qualitative data collection.
- ❑ Conduct Aim 1 statistical analyses and prepare manuscript.
- ❑ Complete Aim 2 qualitative data analysis and prepare manuscript.

Comments/Challenges/Issues/Concerns

- To be determined

Budget Expenditure to Date

- $80,880.45