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TITLE:
Perspectives on Recovery and Interventions to Restore Function Across the First Year of Spinal Cord Injury

PRINCIPAL INVESTIGATOR:
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CONTRACTING ORGANIZATION:
Case Western Reserve University

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

Case Western Reserve University
MetroHealth Rehabilitation Institute of Ohio; 2500 MetroHealth Drive, Room OBC S4-15, Cleveland, OH 44109

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
The present study will focus on needs of Veterans who have experienced spinal cord injury (SCI), as well as needs of those Veterans' caregivers, during the first year of injury as they attempt to reintegrate into the community. This study will compare the experiences of Veterans and their caregivers with those of civilians to identify treatment and policy needs that are shared and different, which may lead to more successful rehabilitation and community reintegration. *Aim #1 – To study how people with newly-acquired SCI define and experience recovery and how that experience shapes priorities and interest in treatment options and clinical trials that may restore function and improve reintegration. Aim #2 – To study experiences of family and other support systems of people with SCI as they navigate resources for treatment options and clinical trials that may restore function and improve reintegration of their loved one.* As of June 30, 2020, 8 civilians with SCI and 8 of their support persons have been enrolled and have completed the first interview and almost half of them have completed their second interview. Due to COVID-19 research restrictions, no Veterans' have been enrolled yet. Currently, 22 of the planned 90 civilian interviews have been conducted and are being coded/analyzed.

15. SUBJECT TERMS
Recovery; community reintegration; spinal cord injury; rehabilitation experience; access to treatments

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
Unclassified	Unclassified	Unclassified	Unclassified	9	

TABLE OF CONTENTS

The text of the report must include all sections addressed in the table of contents to include the following. DO include the bolded section headings, but DO NOT include the italicized descriptions of section contents in your submitted reports.

1) INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

The present study will focus on needs of Veterans who have experienced spinal cord injury (SCI), as well as needs of those Veterans' caregivers, during the first year of injury as they attempt to reintegrate into the community. This study will compare the experiences of Veterans and their caregivers with those of civilians to identify treatment and policy needs that are shared and different, which may lead to more successful rehabilitation and community reintegration. It is critical to have a better understanding of the barriers that Veterans living with SCI experience as they seek to return home, return to work, and reintegrate into society, including factors that are unique to Veterans and their caregivers. Obtaining perspectives across the continuum of injury is crucial, particularly during the first year, as perspectives may vary depending upon psychosocial factors and experiences of recovery over time. **Specific Aims:** ***Aim #1 – To study how people with newly-acquired SCI define and experience recovery and how that experience shapes priorities and interest in treatment options and clinical trials that may restore function and improve reintegration. Aim #2 – To study experiences of family and other support systems of people with SCI as they navigate resources for treatment options and clinical trials that may restore function and improve reintegration of their loved one.*** **Study Design:** We will conduct a series of in-depth, semi-structured interviews in a cohort of individuals with newly-acquired SCI (15 Veterans, 15 civilians) as well as a family member or other person of support designated by the participant with SCI (15 matched with Veterans, 15 matched with civilians). Three interviews will be conducted with each participant over the first year after injury (one during inpatient rehabilitation, one approximately 6 months post-injury, and 1at 12 months post-injury).

2) KEYWORDS: Provide a brief list of keywords (limit to 20 words).

Recovery; community reintegration; spinal cord injury; rehabilitation experience; access to treatments

3) ACCOMPLISHMENTS:

a) What were the major goals of the project? List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project identify these dates and show actual completion dates or the percentage of completion.

Major Task 1 – Coordinate research team and finalize study processes/materials
Milestone: Finalized study material – due month 1 – 100% complete, Metro and VA
Milestone: Obtain local IRB approval – due month 3 – 100% complete, Metro and VA
MetroHealth IRB – approved 6/17/19 and 12/2/19; renewed 5/26/20
Cleveland VA IRB – approved 2/21/20
Milestone: Obtain HRPO approval – due month 3 – 100% complete, Metro and VA
HRPO for MetroHealth – approved 12/27/19
HRPO for Cleveland VA – approved 4/1/20

Major Task 2 – Study recruitment and interviews
Milestone: 1st dyad consented, screened, and enrolled – due month 4 – 100% complete Metro; 0% complete VA
Milestone: 50% of dyads consented, screened, and enrolled – due month 11 – 100% complete Metro; 0% complete VA
Milestone: 1st interview completed – due month 4 – 100% complete Metro; 0% complete VA
Milestone: 50% of interviews completed – due month 16 – 49% complete Metro; 0% complete VA

Major Task 3 – Data Analyses and Dissemination
Milestone: 50% of interviews coded – due month 17 – 49% complete Metro; 0% complete VA
Milestone: Preliminary interim data analyses and dissemination – due month 18 – in progress
Milestone: Report results from final data analyses – due month 36

b) What was accomplished under these goals? For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

1) MAJOR ACTIVITIES

Target Enrollment:

	Year 1	Year 2	Year 3

Target Enrollment (per quarter)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
LSCVAMC (N=30)	0	6	6	6	2	0	6	4	0	0	0	0
MRIO (N=30)	0	6	6	6	2	0	6	4	0	0	0	0
Target Enrollment (cumulative N=60)	**0**	**12**	**24**	**36**	**40**	**40**	**52**	**60**	**60**	**60**	**60**	**60**

Actual Enrollment:

	Year 1				**Year 2**				**Year 3**			
Actual Enrollment (per quarter)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
LSCVAMC (N=30)	0	0	0	0								
MRIO (N=30)	0	0	8	8								
Actual Enrollment (cumulative N=60)	**0**	**0**	**8**	**16**								

MetroHealth site:
Number of subjects reviewed for eligibility: 41 (SCI)
Number of subjects screened/original planned target: 18 (SCI)/100 (SCI)
Number of subjects enrolled/original planned target: 16 (8 SCI, 8 Support)/30
Number of subjects completed/original planned target: 0/30

Cleveland VA site:
Number of subjects reviewed for eligibility: 6 (SCI)
Number of subjects screened/original planned target: 0/100
Number of subjects enrolled/original planned target: 0/30
Number of subjects completed/original planned target: 0/30

2) SPECIFIC OBJECTIVES

Our primary objective has been to begin enrollment and interviews. After the informed consent process, participants undergo 3 study visits.

Visit 1: International SCI Core dataset, SCIM III, Mooring Self-Efficacy Scale, interview #1 [duration 1.5 hours]; this visit is conducted in the participant's room or other quiet space in the rehabilitation center or by telephone while the person with SCI is still in inpatient rehabilitation.
Visit 2: Interview #2 [duration 1 hour]; this visit is conducted in person or by telephone when the person with SCI is between 5-7 months post-injury (target is 6 months post-injury).
Visit 3: SCIM III, Mooring Self-Efficacy Scale, interview #3 [duration 1.5 hours]; this visit is conducted in person or by telephone when the person with SCI is between 11-13 months post-injury (target is 12 months post-injury).

All interviews are audio recorded and then transcribed (by Rev.com). Upon receipt of the transcript, the PI ensures it is completely deidentified and cross checks it with the audio recording for accuracy. The PI and 3 Co-I's individually code each transcript (with NVivo software) and then come together to discuss and agree upon the final codes, which are kept in a master coded file. The master coded file will be used for data analyses.

3) PRELIMINARY RESULTS

Demographics

Participant	Age	Gender	Race	Status	Injury level	SCIM during inpatient	Moorong self-efficacy during inpatient
MH-101	54	M	African American	Civilian	C4 AIS C	22	97
MH-201	54	F	White	Spouse			
MH-102	36	M	White	Civilian	C7 AIS A	53	102
MH-202-1* MH-202-2*	36 35	F F	White White	Girlfriend Sister			
MH-103	65	F	White	Civilian	C4 AIS A	13	52
MH-203	66	M	White	Spouse			
MH-104	73	M	White	Civilian	T7 AIS A	43	73
MH-204	71	F	White	Spouse			
MH-105	28	M	African American	Civilian	C4 AIS B	18	88
MH-205	47	F	African American	Mother			
MH-106	69	F	White	Civilian	C6 AIS D	32	71

MH-206	69	F	White	Friend			
MH-107	29	M	White	Civilian	T6 AIS C	59	94
MH-207	36	F	White	Girlfriend			
MH-108	56	M	White	Civilian	T11 AIS B	54	95
MH-208	24	F	White	Daughter			

*202-1 completed the first interview, but withdrew before the second interview; 102 asked 202-2 to be a replacement

Interviews completed

Participant	Interview 1 (inpatient)	Interview 2 (6 months post)	Interview 3 (12 months post)
MH-101, MH-201	✓	✓	
MH-102, MH-202	✓	✓	
MH-103, MH-203	✓	✓	
MH-104, MH-204	✓	Scheduled	
MH-105, MH-205	✓		
MH-106, MH-206	✓		
MH-107, MH-207	✓		
MH-108, MH-208	✓		

From the coded interviews during inpatient rehabilitation, we have evaluated the definitions of recovery and successful community reintegration from the perspective of the person with SCI as well as their support person. We've categorized them below.

Participant	**Recovery**	**Reintegration**
MH-101	Return to same work; Improve speech; Be mobile	Work; Go to church; Cook
MH-201	Use of hands and arms	Go home
MH-102	Become more independent; Upper body strength; Lower body sensation	Go home; Take care of self
MH-202-1* MH-202-2*	Walking; taking one day at a time N/A	Staying positive; Not giving up N/A
MH-103	Use of arms; Walk; Remove trach	Be involved with family and friends
MH-203	Missing	Travel; Garden
MH-104	Gain mobility; Be less dependent; Leg movement and sensation	Get outside; Tinker around farm; Fish; Grocery shop with wife
MH-204	Stand; Use a walker	Get home; Be more independent so she has free time
MH-105	Regain movement; Walk; Live normal life; Upper body and hands	Play with children; Provide for them financially
MH-205	Be independent; Get off ventilator	Modify house to go home
MH-106	Walk; Use fingers	Return to same work; Socialize with friends
MH-206	Live independently	Return to work; Make new friends
MH-107	Be self-sustainable; Take care of self	Go home; Find new employment
MH-207	Upper body strength	Minimize help; Accessible environment; Be active in community
MH-108	Walk; Bowel; Urinary	Return to same work in new role
MH-208	Motivating to not give up; Strengthen feet	Ride motorcycle again; Walk daughter down aisle at wedding

Other emerging themes during inpatient rehabilitation include:

- People with SCI are only able to focus on interventions offered to them by the rehabilitation team.
- Support persons are overwhelmed figuring out what to do for their loved one upon discharge – either preparing to go home or finding a skilled nursing facility – and do not have time to seek out other interventions to impact recovery.
- People with SCI and their support persons are interested in research interventions, but they do not receive much information from the rehabilitation team.
- Support persons bear the brunt of navigating health insurance and institutional policies surrounding access to health resources and this is a significant barrier.

4) OTHER ACHIEVEMENTS

Nothing to Report.

c) What opportunities for training and professional development has the project provided?
Nothing to Report.

d) How were the results disseminated to communities of interest?
Nothing to Report.

e) What do you plan to do during the next reporting period to accomplish the goals? Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

As described in section 5.b, we are able to proceed with research activities at MetroHealth despite the COVID-19 pandemic and we have a plan in place for the Cleveland VA research activities. We expect to complete enrollment at MetroHealth during the next 6 months. Our goal is to try to complete enrollment at the Cleveland VA by the end of the next grant year.

We are already coding the interviews we have completed thus far and have begun preliminary analyses of interim data. This summer we will seek input from our VA collaborators and our community partner on the emerging themes. We will also submit an abstract for the 2021 American Spinal Injury Association annual meeting and a separate abstract for the 2021 American Sociological Association annual meeting. We will continue coding and analysis throughout the grant year. Submission of distinct abstracts to additional meetings will be considered throughout the year as dictated by the data analyses.

4) IMPACT:
a) What was the impact on the development of the principal discipline(s) of the project?
Nothing to Report.

b) What was the impact on other disciplines?
Nothing to Report.

c) What was the impact on technology transfer?
Nothing to Report.

d) What was the impact on society beyond science and technology?
Nothing to Report.

5) CHANGES/PROBLEMS:
a) Changes in approach and reasons for change
Nothing to Report.

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

The COVID-19 pandemic was unanticipated; as a result, in-person research activities were temporarily suspended by MetroHealth on March 15, 2020 and by the Cleveland VA on March 20, 2020. On April 8, 2020, we received approval from the MetroHealth IRB to obtain verbal consent via the telephone; this enabled us to resume enrollment. We already had approval to conduct interviews by telephone. On April 30, 2020, MetroHealth removed the temporary suspension of in-person research activities. We have retained the ability to obtain consent in written or verbal format and to conduct interviews in-person or by telephone and are therefore confident that the study will proceed at MetroHealth even if another temporary suspension of in-person activities occurs.

We have experienced delays with the Cleveland VA IRB that were uncontrollable by us, but we now have all approvals secured as of 4/1/20. However, the Cleveland VA IRB has not enabled consent to be obtained verbally and has not yet allowed in-person research activities to resume. We did submit a risk assessment and mitigation form (related to COVID-19 and our study) to the Cleveland VA IRB on June 26, 2020. We are told that in-person activities are anticipated to resume in July or August. We hope that the flexibility we built into our enrollment timeline will allow us to be able to make up delays. We have been screening for potentially eligible participants since April; there have been 6 potentially eligible inpatients, of which 2 have now passed the eligible time window. Our goal will be to enroll 4 dyads per quarter once in-person activities are allowed to resume. This would enable us to get back on target by the end of year 2.

c) Changes that had a significant impact on expenditures
Nothing to Report.

d) Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Nothing to Report.

6) PRODUCTS:

a) Publications, conference papers, and presentations
   i) Journal publications.
   Nothing to Report.

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

   iii) Other publications, conference papers, and presentations.
   Nothing to Report.

b) Website(s) or other Internet site(s).
   Nothing to Report.

c) Technologies or techniques.
   Nothing to Report.

d) Inventions, patent applications, and/or licenses.
   Nothing to Report.

e) Other Products.
   Nothing to Report.

7) PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS
   a) What individuals have worked on the project?

Name:	Kim Anderson
Project Role:	PI
Researcher Identifier (e.g. ORCID ID):	orcid.org/0000-0001-9252-161X
Nearest person month worked:	3
Contribution to Project:	Overall study oversight and execution of all activities

Name:	Anne Bryden
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	orcid.org/0000-0003-4381-1156
Nearest person month worked:	3
Contribution to Project:	Assist with study oversight, interviews, and analyses

Name:	Brian Gran
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	orcid.org/0000-0003-0923-4412
Nearest person month worked:	3
Contribution to Project:	Assist with study oversight, interviews, and analyses

Name:	Susan Hinze
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Assist with interviews and analyses

Name:	Kimberly Mackay
Project Role:	Study Coordinator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to Project:	Recruitment, screening, data collection, data entry, scheduling

Name:	Mary Ann Richmond
Project Role:	Collaborator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	PI of Cleveland VA IRB protocol, review emerging themes

Name:	Angela Kuemmel
Project Role:	Collaborator

Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Screening at Cleveland VA, review emerging themes

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

Anderson, previous effort 37% active; current 92% active:
Ended – DOD SCIRP – Perspectives in management of severe neuropathic pain after SCI; 3% effort
Ended – NIH NINDS – Restoration of grasp and reach in cervical SCI; 4% effort
Now Active – DOD SCIRP – Perspectives on recovery and interventions to restore function across the first year of SCI; 25% effort
Now Active – DOD SCIRP – Restoring multidimensional coordinated reaching and dexterous grasping to persons with chronic tetraplegia through functional electrical stimulation; 4% effort
Now Active – CHNF – Development of pain education for improving pain health literacy and quality of life after SCI; 8% effort
New – DOE NIDILRR – Northeast Ohio Regional SCI System; 20% effort
New – CHNF – Institute for Functional Restoration; 5% effort

Bryden, previous effort 91% active; current 99% active:
Ended – VA RR&D – Evaluation of a fully implanted neuroprosthesis for incomplete spinal cord injury, including developing the screening methods and outcome measures to perform valid clinical studies in this population; 25% effort
Now Active – DOD SCIRP – Perspectives on recovery and interventions to restore function across the first year of SCI; 25% effort
Now Active – DOD SCIRP – Restoring multidimensional coordinated reaching and dexterous grasping to persons with chronic tetraplegia through functional electrical stimulation; 8% effort

c) What other organizations were involved as partners?

Organization Name: United Spinal Association Northeast Ohio Chapter
Location of Organization: Cleveland, Ohio
Partner's contribution to the project (identify one or more): Collaboration (e.g., partner's staff work with project staff on the project)

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

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. Reminder: Pages shall be consecutively numbered throughout the report. DO NOT RENUMBER PAGES IN THE APPENDICES.