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

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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. <i><u>Aim #1</u> - 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. <u>Aim #2</u> - 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.</i> 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					
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1) INTRODUCTION:

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 1 at 12 months post-injury).

2) KEYWORDS:

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

3) ACCOMPLISHMENTS:

a) What were the major goals of the project?

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, 4/16/21

Cleveland VA IRB – approved 2/21/20, does not require renewal

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 and VA

Milestone: 50% of dyads consented, screened, and enrolled – due month 11 – 100% complete Metro; 60% complete VA

Milestone: 1st interview completed – due month 4 – 100% complete Metro; 100% complete VA

Milestone: 50% of interviews completed – due month 16 – 100% complete Metro; 20% complete VA

Major Task 3 – Data Analyses and Dissemination

Milestone: 50% of interviews coded – due month 17 – 100% complete Metro; 2% 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?

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=8)	0	0	0	0	0	1	2	5				
MRIO (N=34)	0	0	8	9	8	1	2	6				
Actual Enrollment (cumulative N=60)	0	0	8	17	25	26	30	41				

MetroHealth site:

Number of subjects reviewed for eligibility: 94 (SCI)
 Number of subjects screened/original planned target: 64 (SCI)/100 (SCI)
 Number of subjects enrolled/original planned target: 34 (16 SCI, 16 Support)/30
 Number of subjects completed/original planned target: 17/30

Cleveland VA site:

Number of subjects reviewed for eligibility: 23 (SCI)
 Number of subjects screened/original planned target: 11 (SCI)/100 (SCI)
 Number of subjects enrolled/original planned target: 8 (5 SCI, 3SP)/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		Moorong	
						initial	final	initial	final
MH-101	54	M	African American	Civilian	C4 AIS C	22	16	97	104
MH-201	54	F	White	Spouse					
MH-102	36	M	White	Civilian	C7 AIS A	53	54	102	87
MH-202-1*	36	F	White	Girlfriend					
MH-202-2*	35	F	White	Sister					
MH-103	65	F	White	Civilian	C4 AIS A	13	18	52	54
MH-203	66	M	White	Spouse					
MH-104	73	M	White	Civilian	T7 AIS A	43	39	73	63
MH-204	71	F	White	Spouse					
MH-105	28	M	African American	Civilian	C4 AIS B	18	18	88	63
MH-205	47	F	African American	Mother					

MH-106	69	F	White	Civilian	C6 AIS D	32	85	71	92
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	83	95	94
MH-208	24	F	White	Daughter					
MH-109	25	F	African American	Civilian	C4 AIS C	24	38	57	80
MH-209	47	F	African American	Mother					
MH-110	21	F	African American	Civilian	C5 AIS D	24		81	
MH-210	60	F	African American	Grandmother					
MH-111	22	M	African American	Civilian	C8 AIS D	55		95	
MH-211	38	F	African American	Mother					
MH-112	42	M	African American	Civilian	T12 AIS D	55		88	
MH-212	63	F	African American	Mother					
MH-113	38	M	African American	Civilian	T10 AIS A	57		59	
MH-213	28	F	African American	Girlfriend					
MH-114‡	48	M	African American	Civilian	T10 AIS A				
MH-115	52	M	Alaska Native	Civilian	L1 AIS C	72		99	
MH-215	33	F	Alaska Native	Daughter					
MH-116	27	M	White	Civilian	L1 AIS B	64		87	
MH-216	29	F	White	Girlfriend					
MH-117	18	M	White	Civilian	T9 AIS C	59		101	
MH-217	57	F	White	Mother					
VA-101°	22	M	White	Veteran	C6 AIS D	46		91	
VA-102	69	M	White	Veteran	C5 AIS C	33		102	
VA-202	74	F	African American	Wife					
VA-103	39	M	White	Veteran	T6 AIS A	pending		pending	
VA-203		F	White	Wife					
VA-104	71	M	African American	Veteran	C4 AIS D	20		63	
VA-204		F	African American	Wife					
VA-105	72	M	White	Veteran	C1 AIS D	78		91	
VA-205		F	White	Daughter					

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

†MH-207 withdrew self prior to 2nd interview stating the relationship with MH-107 ended; MH-107 was lost to follow-up

‡MH-114 completed 1st interview but support person never enrolled; PI therefore withdrew MH-114

°VA-101 was never able to get support person to enroll, tried through 2nd interview; PI therefore withdrew VA-101 after 2nd interview

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	✓	✓	✓
MH-105, MH-205	✓	✓	✓
MH-106, MH-206	✓	✓	✓
MH-107, MH-207	✓	Lost; Withdrew	Lost; Withdrew
MH-108, MH-208	✓	✓	✓
MH-109, MH-209	✓	✓	✓; 209 pending
MH-110, MH-210	✓	✓	Pending
MH-111, MH-211	✓	✓	✓
MH-112, MH-212	✓	✓	
MH-113, MH-213	✓	✓	
MH-114, NO MH-214	✓, then withdrawn	Withdrawn	Withdrawn
MH-115, MH-215	✓		
MH-116, MH-216	✓		
MH-117, MH-217	✓		

VA-101, NO VA-201	✓	✓	Withdrawn
VA-102, VA-202	✓		
VA-103, VA-203	✓		
VA-104, VA-204	✓		
VA-105, VA-205	✓		

Civilian data analysis

From the interviews coded thus far, 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 have identified the thematic categories below.

RECOVERY

Autonomic = bowel, urinary, bowel control back

Be Active/Participation = be active, get out of house/go places, drive, enjoy life, get outside

Complacency = can't get him interested in much

Education/Knowledge = further education

Emotional = build up self-confidence, emotional part, getting stronger mentally, not give up on myself, it grows within herself, coping with injury

Employment = return to work, return to career, pursue career, generate income

Full recovery = live normal life, recover and be a success story, getting better, 100% functionality, everything working like before, make a full recovery, getting back to before hurt, be functional like before

Home/Adaptation/Activities = go home, get out of nursing home, get power wheelchair, get hospital bed

Identity = get back to herself, be the same person he was, blossoms back to himself

Independence = become more independent, be less dependent, able to do for myself, be self-sustainable, take care of self, be independent, take care of baby, be functional, live independently, get in/out of home by himself, build up independence, do some things for herself, more independent, getting independent, getting better to totally being able to do stuff on her own, keep working for me and my baby, use cell phone, more control over environment, do more by herself

Mobility = be mobile, gain mobility, gain, being able to move, regain movement, manage transferring independently (in/out of bed), more mobile, sliding transfer

Motor functions = upper body strength, use arms, walk, leg movement, upper body and hands, use fingers, use of hands and arms, stand, use walker, strengthen feet, use a walker when go home,

exercise leg muscles, use of my hands, able to move his legs, work on strength, walk without walker, physical part, getting stronger physically, improving balance, walk without walker, increase endurance, walk again, strengthen left hand, walking, arm, left arm, hands, walk, raise arms, movement in hands

Pain reduction = less pain, alleviate pain in arms

Pragmatism = realistic and reachable goals, keeping focus on realistic goals, it's gonna be just like it is now

Positivity = take one day at a time, motivating to not give up, be positive, accept any progress, get through this, staying focused, trying my best, continuing to be his support, uplift him as he deals with injury, not putting expectations on progress, keep motivating him, continue to make progress, day-by-day, day-by-day, living each day as it comes

Progress = Really good, came a long way, he's comin' through

Respiratory = improve speech, remove trach, get off ventilator, get trach hole completely closed

Sensation = lower body sensation, leg sensation, feeling in legs, sensation down to legs, sensation in fingers

Spasticity/Tone reduction = reduce tightness in left hand, reduce tightness in left ankle, stop arms from automatically raising up

Spiritual = be a praying young lady

Time = Slow, slow, slow process, Slow

COMMUNITY REINTEGRATION

Be active/Participation = cook, get outside, tinker around farm, fish, be outside, garden, garden, get outside, be active in community, ride motorcycle again, drive car, able to drive myself places, get out of house/go places, drive, get back to her regular doing, get outside, get back out, cook, go to gym, helping out around the house, get out, work some outdoors, overcoming the pandemic so he can go out in the community, write a book about depression and coping, write a book

Education/Knowledge = going back to school, therapist to help know what to do, education

Emotional = learn to accept his situation, maintain this state mentally, finding some level of acceptance, adjusting to new lifestyle based on level of recovery, healing right, adapt to her surroundings, he does whatever his mind and body is gonna let us do, if we all know we gave it our best, look forward to going out

Employment = work, provide for children financially, return to work, find new employment, return to work in new role, good career, return to work, return to work, work, generating more income for my kids, I am back to work, able to find a job, start a business, work, working, go back out in the work field, work, get back to work

Full reintegration = being able to function the way I did before

Home/Adaptation = go home, go home, go home, get home, modify house to go home, get in/out of house by self, come home, get out of house by himself, w/c big and bulky, hard to get close to things, bathroom is inaccessible, go home, set up technology in house so she has more independence, modify house so he can get in more rooms and do more by himself

Identity = back to being herself, good lifestyle/own property, bring him more back to life

Independence = take care of self, be more independent so she has free time, take care of himself, be in accessible environment, get more independent, handle my business, do some things for herself, his independence, doing things on his own without assistance, do things for himself, manage myself by myself, use cell phones, tablets, computers

Mobility = having mobility, mobile

Motor functions = use hands, walk, walk, able to climb up and down, use hands, walk without cane or walker, improve hand function, use cane instead of walker, arm (brachial plexus injury), get her hands to function

Positivity = stay positive, feel supported, support son's definition of success

Respiratory = get trach hole completely closed

Sensation = feel fingers

Social activities/roles = go to church, see mother, be involved with family and friends, grocery shop with wife, play with children, socialize with friends, play with children, walk with daughter, walk down aisle with fiancé, being home with baby, being with family and children, make new friends, walk daughter down aisle at wedding, be on the go, be with her daughter, help others, visit friends and family, hold daughter, take care of her, helping and inspiring other women, getting right with my family, see friends, socialize with friends, see family, talk to people

Travel = travel, day trips, travel, travel, travel

The current evaluation of how these definitions change across the first year post-injury are in the tables below.

Recovery themes over time (Civilians, Persons With SCI):

Participant	Inpatient rehabilitation	6 months post-injury	12 months post-injury
MH-101; C4 AIS C	Employment; Respiratory; Mobility	Motor functions	Time; Pragmatism; Mobility; Home/Adaptation/Activities
MH-102; C7 AIS A	Independence; Motor functions; Sensation	Independence; Sensation	Time; Positivity; Motor functions
MH-103; C4 AIS A	Motor Functions; Respiratory	Motor functions	Time; Independence; Motor functions; Pain
MH-104; T7 AIS A	Mobility; Independence; Motor functions; Sensation	Sensation; Autonomic	Positivity; Be active/Participation
MH-105; C4 AIS B	Mobility; Motor functions; Full recovery; Independence	Independence; Mobility; Employment	
MH-106; C6 AIS D	Motor functions	Motor functions; Be active/Participation; Sensation	
MH-107; T6 AIS C	Independence	LOST	LOST
MH-108; T11 AIS B	Motor functions; Autonomic	Full recovery; Motor functions;	
MH-109; C4 AIS B	Full recovery; Mobility	Motor functions; Emotional; Independence	
MH-110; C5 AIS D	Full recovery; Mobility; Be active/Participation	Emotional; Independence	
MH-111; C8 AIS D	Full recovery; Education	Spasticity/Tone; Motor functions	
MH-112; T12 AIS D	Full recovery; Motor functions	Positivity; Motor functions	
MH-113; T10 AIS A	Positivity		
MH-115; L1 AIS C			
MH-116; L1 AIS B			
MH-117; T9 AIS C			

Recovery themes over time (Civilians, Support Persons):

Participant	Inpatient rehabilitation	6 months post-injury	12 months post-injury
MH-201; C4 AIS C	Motor functions	Independence	Home/Adaptation/Activities
MH-202; C7 AIS A	Motor functions; Positivity	Independence; Emotional; Identity	Emotional; Home/Adaptation/Activities
MH-203; C4 AIS A	Missing	Be active/Participation; Independence; Respiratory	Independence; Motor functions; Pain; Be active/Participation; Spasticity/Tone
MH-204; T7 AIS A	Motor functions	Motor functions	Complacency; Pragmatism
MH-205; C4 AIS B	Respiratory; Independence; Employment	Time; Pragmatism; Motor functions	
MH-206; C6 AIS D	Independence	Motor functions; Emotional	

MH-207; T6 AIS C	Motor functions	WITHDREW	WITHDREW
MH-208; T11 AIS B	Positivity; Motor functions	Progress; Positivity	
MH-209; C4 AIS B	Identity; Be active/Participation; Positivity	Progress; Independence	
MH-210; C5 AIS D	Independence; Employment; Motor functions;	Emotional; Spiritual; Motor functions; Full recovery	
MH-211; C8 AIS D	Positivity	Identity; Positivity	
MH-212; T12 AIS D	Full recovery	Progress; Motor functions	
MH-213; T10 AIS A	Positivity		
MH-215; L1 AIS C			
MH-216; L1 AIS B			
MH-217; T9 AIS C			

Community reintegration themes over time (Civilians, Persons With SCI):

Participant	Inpatient rehabilitation	6 months post-injury	12 months post-injury
MH-101; C4 AIS C	Employment; Social activities/roles; Be active/Participation	Employment; Be active/Participation; Motor functions	Independence; Home/Adaptation; Employment
MH-102; C7 AIS A	Home/Adaptations; Independence	Home/Adaptation	Be active/Participation; Social activities/roles
MH-103; C4 AIS A	Social activities/roles	Motor functions	Full reintegration; Travel; Be active/Participation; Independence
MH-104; T7 AIS A	Be active/Participation; Social activities/roles	Motor functions	Be active/Participation; Social activities/roles
MH-105; C4 AIS B	Social activities/roles; Employment	Independence; Mobility; Employment	
MH-106; C6 AIS D	Employment; Social activities/roles	Employment; Be active/Participation; Social activities/roles	
MH-107; T6 AIS C	Home/Adaptations; Employment; Social activities/roles	Lost	Lost
MH-108; T11 AIS B	Employment	Employment; Motor functions	
MH-109; C4 AIS B	Social activities/roles	Be active/Participation; Employment; Social activities/roles; Independence	
MH-110; C5 AIS D	Education/Knowledge; Social activities/roles	Social activities/roles; Be active/Participation; Travel	
MH-111; C8 AIS D	Employment; Identity	Emotional; Employment; Education/Knowledge	
MH-112; T12 AIS D	Employment; Social activities/roles	Emotional; Social activities/roles	
MH-113; T10 AIS A	Mobility; Emotional		
MH-115; L1 AIS C			
MH-116; L1 AIS B			
MH-117; T9 AIS C			

Community reintegration themes over time (Civilians, Support Persons):

Participant	Inpatient rehabilitation	6 months post-injury	12 months post-injury
MH-201; C4 AIS C	Home/Adaptations	Home/Adaptation; Motor functions; Sensation	Emotional
MH-202; C7 AIS A	Positivity	Home/Adaptation; Identity	Be active/Participation
MH-203; C4 AIS A	Travel; Be active/Participation	Be active/Participation; Independence; Respiratory	Home/Adaptation; Emotional; Travel; Motor functions
MH-204; T7 AIS A	Home/Adaptations; Travel; Be active/Participation; Independence	Home/Adaptation; Education/Knowledge	Home/Adaptation
MH-205; C4 AIS B	Home/Adaptations	Independence	
MH-206; C6 AIS D	Employment; Social activities/roles	Employment; Motor functions; Be active/Participation; Social activities/roles	

MH-207; T6 AIS C	Independence; Be active/Participation; Positivity	Withdrew	Withdrew
MH-208; T11 AIS B	Be active/Participation; Social activities/roles	Social activities/roles; Motor functions	
MH-209; C4 AIS B	Identity; Social activities/roles	Be active/Participation; Emotional;	
MH-210; C5 AIS D	Missing	Missing	
MH-211; C8 AIS D	Positivity	Independence; Employment	
MH-212; T12 AIS D	Emotional	Independence; Employment; Motor functions	
MH-213; T10 AIS A	Emotional		
MH-215; L1 AIS C			
MH-216; L1 AIS B			
MH-117; T9 AIS C			

We have also begun analyzing people's experiences seeking options for furthering their recovery and reintegration. We have identified the thematic sources and options, below, that have been expressed during inpatient rehabilitation. Further data analysis is continuing.

Sources:

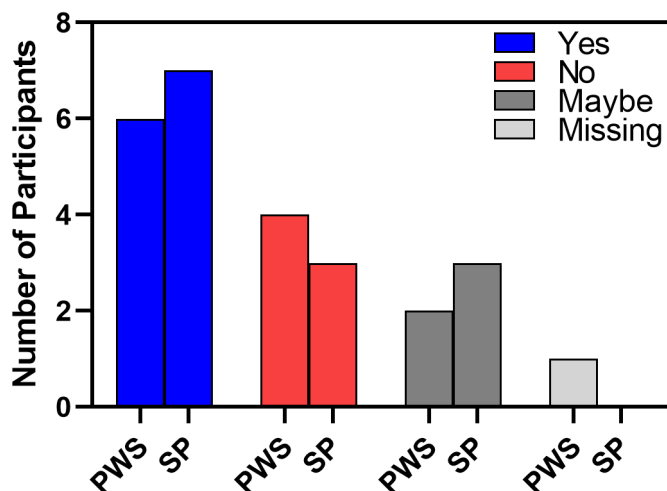
- Inpatient staff (mentioned by 12 participants)
- None (mentioned by 10 participants)
- Family and friends (mentioned by 4 participants)
- Online (mentioned by 4 participants)
- Outside healthcare providers (mentioned by 2 participants)
- Research staff (mentioned by 1 participant)
- Newspapers/TV (mentioned by 1 participant)

Options:

- None (mentioned by 9 participants)
- Outpatient therapy (mentioned by 8 participants)
- Skilled Nursing Facilities (mentioned by 7 participants)
- Ways to maintain mental stability (mentioned by 4 participants)
- Environmental control technology (mentioned by 2 participants)
- Surgical interventions (future) (mentioned by 2 participants)
- Adaptive equipment (mentioned by 2 participants)
- Community gym (mentioned by 1 participant)
- Complimentary medicine (mentioned by 1 participant)
- Experimental interventions (mentioned by 1 participant)

There is moderate interest in clinical trials during the inpatient rehabilitation time frame.

Interest in CT



Sample quotes related to interest in clinical trials:

Yes

SP-MH-208 *“Um, I mean, honestly it depends on how long the clinical trial has been going on, what sort of success rate that they have had with what they've done. And I mean the negative side effects, is it going to put him back or is it going to move him forward? I think. So... Yes. I mean, if it is going to be better for him in the long run and there's good, like substantiated facts behind what the study is about or the trial is about, then we'll make that decision on if he wants to go through with it.”*

No

PWS-MH-112 *“Uh, to me I wouldn't want to do it because I, I would rather let somebody else do it before me. Clinical trial means that it is an experiment and they don't know what it is and if it's going to work or not... Yeah, I feel uncomfortable because I want to know what would, uh, what would happen. What the symptoms of, of, uh, what would happen after I try. It makes me uncomfortable.”*

Maybe

PWS-MH-110 *“Uh, I'd say it would be if everything wasn't... Or if over time I see things weren't working or, you know, I try the therapy or... Excuse me, the therapy, the surgery and didn't notice any improvement there or not much. Just to see what that could offer... Yeah, just still focused on everything, you know, coming back naturally, just, uh, wait and see before I decide.”*

Lastly, we had the opportunity to evaluate the impact of the COVID-19 pandemic as we had 4 dyads that were enrolled pre-pandemic, 4 dyads enrolled during the 2-month lockdown, and 5 dyads enrolled during the 7 months' post-lockdown during which there were two surges in cases. The initial analysis reveals the following observations:

- Pre-pandemic 2020 – Significant family support while inpatient; access to peer mentors
- During lockdown 2020 – No visitors or peer mentors; isolation in rooms; loneliness; masks introduced
- Post-lockdown 2020 – Limitations on number and type of visitors (1-2 adults, no children) and visitation hours; some fear of visiting hospital (catching COVID-19); no peer mentors; limited social interactions with other patients; limited support persons' interactions with physicians

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.

Over the next year, we expect to complete conducting the remaining interviews of participants enrolled at MetroHealth and to complete enrollment at the Cleveland VA. We will then request a no cost extension for an additional year during which we will finish all Veteran interviews.

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. We were allowed to resume research activities at the VA on 9/17/20, however, in-person access to the SCI inpatient floor is still restricted. Our collaborators (Drs. Richmond and Kuemmel) are able to consent participants and connect team with the rest of the research team by telephone. However, the Cleveland VA IRB has not enabled consent to be obtained verbally. However, we have submitted an amendment to request the ability to verbally consent just support persons. The VA has a larger catchment area and it is common for patients to be from out-of-state. Family members are not always able to be in Cleveland while their loved one is undergoing rehabilitation. It has proven cumbersome and burdensome to try having an out-of-state family member physically sign a consent form.

There has also been a prolonged period of low census at the VA SCI unit. In discussion with our VA team members and their VA colleagues, it appears that many SCI units at VA centers across the country are having low census of new spinal injuries. This appears to be due to COVID, but the precise reason(s) for the decrease in new injuries is not clear. Our plan is to work closely with our VA team members to try to enroll every new SCI possible that does get admitted. Near the end of the current reporting period we were able to work on enrolling 3 dyads.

Our plan is to finish enrolling the remaining Veteran dyads during the upcoming reporting period, year 3. We will then request a 1-year no cost extension to complete the remaining follow-up interviews and analyses.

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.

Conference presentations

Anderson KD, Bryden AM, Gran B, Hinze S. (2021). Experiences During Inpatient Rehabilitation, Perspectives on Recovery, and Impact of COVID-19. *Abstract for American Spinal Injury Association Annual Meeting, July 2021.*

Bryden AM, Gran B, Hinze S, Anderson KD. (2021). Experiences in Skilled Nursing Facilities after SCI. *Abstract for American Spinal Injury Association Annual Meeting, July 2021.*

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?

Bryden, new:

CHNF - Psychosocial Impacts of Navigating Care Transitions on Caregivers of People with SCI, 13%
Ohio Department of Higher Education - Controlling Functional Reaching with Eye and Head Movements of People with High Cervical Spinal Cord Injuries, 1%
NSF - Collaborative Research: Assistive Robotics and Functional Electrical Stimulation - A Synergistic Combination to Reanimate Paralyzed Limbs (PI), 1%

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:

9) APPENDICES: