AWARD NUMBER: W81XWH-19-1-0032

TITLE: Identifying Cognitive Barriers to Effective Pressure Ulcer Self-Care

PRINCIPAL INVESTIGATOR: James Bjork

CONTRACTING ORGANIZATION: Virginia Commonwealth University

REPORT DATE: May 2021

TYPE OF REPORT: Annual Progress Report

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

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
MAY 2021	Annual Report	15 Apr 20 – 14 Apr 21

4. TITLE AND SUBTITLE

Identifying Cognitive Barriers to Effective Pressure Ulcer Self-Care

5a. CONTRACT NUMBER
W81XWH-19-1-0032

5b. GRANT NUMBER
W81XWH-19-1-0032

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER
0011283973

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

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8. PERFORMING ORGANIZATION REPORT NUMBER

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

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

10. SPONSOR/MONITOR'S ACRONYM(S)

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

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Pressure ulcers (PU) in persons with spinal cord injury (SCI) incur a substantial health burden, especially in individuals who exhibit poor preventative PU self-care. This study utilizes validated methods to characterize multiple facets of impulsivity in persons with paraplegia who use and do not use substances, in order to assess the predictive role of impulsivity in poor SCI self-care and prognostic value of impulsivity in SCI quality of life (QoL) outcomes. Funding began in April 2019 and approval to begin research activities was secured in August 2019. From August 2019 until the COVID-19 shutdown March 2020, 19 SCI patients were recruited, screened, and enrolled; 2 have completed follow-up. Recruitment was shut down for most of a year due to COVID-19. In response to the pandemic, that research team has worked with the testing software platform to develop a completely remote means of recruitment, collection of informed consent, remote interview, and remote neurobehavioral testing on the participant's own device, and accrual has resumed at the VCU site.

15. SUBJECT TERMS
Spinal Cord Injury, Impulsivity, Pressure Ulcers, Self-care, Computational Modeling

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	10	19b. TELEPHONE NUMBER *(include area code)*

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1. Introduction

Pressure ulcers (PU) in persons with spinal cord injury (SCI) incur a substantial psychosocial and health burden, especially in individuals who exhibit poor preventative PU self-care. This study will utilize mobile technology to characterize multiple facets of impulsivity in SCI patients who use substances, in order to assess their role in poor SCI self-care and prognostic value SCI quality of life (QoL) outcomes. Impulsivity is defined as “acting without thinking” on short time-scales, and as a myopic preference for small but immediate rewards over larger but delayed rewards. It increases risk for addictions, obesity, and poor adherence to treatment regimens. However, the role of impulsivity in spinal cord injury (SCI) health outcomes has been essentially unexplored. This dearth of research is remarkable in light of the role of impulsivity in smoking and binge drinking (which themselves portend poorer self-care of PU and other health outcomes in SCI). Moreover, there is likely elevated incidence of impulsivity as a contributor to accidents and violence that can lead to a traumatic SCI or exacerbation of injury.

2. Keywords

Spinal Cord Injury, Impulsivity, Pressure Ulcers, Self-care, Computational Modeling

3. Accomplishments

a) What were the major goals of the project?

Major Task 1: Prepare sites for data collection (Award months -3 to 1)

[100% Completed: All equipment was procured; software was programmed; recruitment strategies were established; research assistant was hired and trained. Human Research Protections Office (HRPO) approval obtained for commencing research activities at the Virginia Commonwealth University (VCU) site 15 July 2019 (Award month 4) and at the Richmond Hunter Holmes McGuire Veterans Affairs Medical Center (RICVAMC) site on 12 September 2019 (Award month 6)]

Major Task 2: Conduct a baseline assessment of laboratory task impulsivity and SCI quality of life in 120 spinal cord injury (SCI) patients recruited from two SCI ambulatory outpatient clinics (Award months 2 to 12)
[Major Task 2 is approximately 20% complete at the end of the 12-month reporting period. Thirty five participants have enrolled and 25 have completed follow-up interviews, with eight currently pending.]

Major Task 3: Analyze and publish data on individual differences at baseline assessment (Award months 13 to 18)
[Analysis has begin, in the course of preparation of a pre-application for a follow-on Expansion Award stemming from this work.]

Major Task 4: Conduct a follow-up assessment of SCI quality of life in the 120 SCI patients who completed the baseline assessment (Award months 7 to 18)
[Major Task 4 is approximately 17% complete at the end of the 12-month reporting period. Twenty (20) participants have completed follow-up phone interviews.]

Major Task 5: Analyze and publish longitudinal (follow-up) data on the moderating effects of baseline impulsivity on changes in quality of life and on substance use over time, from baseline to six-month follow-up) (Post-award)
[Task has not begun.]

b) What was accomplished under these goals?

Major Task 1: Prepare sites for data collection.

Specific Accomplishments:

1) Study coordinator/research assistant was interviewed, identified, and hired by Virginia Commonwealth University Institute for Drug and Alcohol Studies.
2) Research assistant obtained without-compensation (WoC) appointment at RICVAMC to recruit and collect data under the parallel VA protocol.
3) Behavioral testing materials were obtained and Inquisit stimulus-delivery software platform was programmed to administer individual task scripts.
4) Biological testing materials were procured and researchers were trained in the use of breathalyzers and drug tests.
5) Despite initial assurances from the RICVAMC and VCU IRB directors that a reliance agreement could be struck with the core VCU IRB, central VA human-subject-protection authorities ultimately precluded the RICVAMC IRB from entering a reliance agreement. Therefore, the PI was obliged to reconfigure essentially identical application packages to each of the VCU and RICVAMC IRBs independently.
6) DoD Human Research Protection Office (HRPO) approved both study site protocols after each respective IRB approval and prior to each study initiation.
7) Electronic medical records search strategies for prospective participant identification were established at RICVAMC and VCU Health systems.

8) Standardized Operating Procedures were established for each study site.
9) In response to the COVID-19 pandemic, the VCU site worked with the behavioral testing software company (vendor Millisecond Software LLC) to convert laptop PC-based testing by research assistants to a totally remote solution for remote contactless testing that relies on an app that the participant can install on his or her own mobile phone, tablet or other device using a specialized URL link unique to that participant (that will tag the participant's data) sent by the research team.
10) In response to the COVID-19 pandemic, the team worked with VCU IRB to develop a nascent platform for remote electronic collection of informed consent, to complete the contactless participation experience.
11) The VCU team obtained approval from IRB and VCU IT offices to commence all-remote testing for those participants who would prefer a contactless experience.
12) The PI continues to work with officials at the Department of Veterans Affairs (VA) to get approval for remote testing of Veterans using their own devices, but has yet to secure approval for this at the VA.
13) In the wake of the newfound capacity for completely remote testing, the study team has been forging relationships with rehabilitation centers (e.g. Brooks Rehabilitation in the Miami area) to enable nationwide recruitment.

Major Task 2: Conduct baseline assessments for 120 SCI patients.

Specific Accomplishments:

1) Medical records were used to identify prospective participants, in collaboration with attending physicians at each of the VCU Health and RICVAMC SCI clinics.
2) RA conducted in-person recruitment for patients with scheduled clinic appointments, when possible.
3) Prospective participants were contacted by phone and screened for eligibility criteria.
4) Baseline assessments have been conducted for 19 SCI patients.
5) In consultation with clinicians, advertisements were created and approved by the IRB to expand recruitment to other clinics known to the clinical investigators and social media.
6) Assessments have resumed post-COVID, almost entirely remotely, with 35 participants tested at baseline to date.

Major Task 4: Conduct a follow-up assessment of SCI quality of life in the 120 SCI patients who completed the baseline assessment.

Specific Accomplishments:

1) Twenty participants have completed the follow-up assessment by phone, with eight follow-ups pending.

Two participants have been lost to follow-up, such that we currently have a 93% rate of successful follow-up.

<u>Significant developments</u>:

1) The true population of patients who meet inclusion/exclusion criteria of the original proposal was smaller than expected, in part due to specific histories of substance use endorsed during research phone prescreening that were not previously revealed to clinicians or otherwise evident in medical records.
2) Those SCI patients who do have clinic appointments continue to prefer to have a separate home visit for the baseline research testing, rather than combining with the same clinical care visit.
3) Participants continue to enjoy study participation. They are generally pleased with researchers taking an interest in their condition and seeking to improve health outcomes for future patients. They understand how the interview addresses outcomes that are directly relevant to their well-being, and are interested in the neurocognitive approach.
4) Whenever possible, a clinician continues to initiate contact (i.e. "warm handoff") between the research assistant and prospective participants.
5) The protocol was modified to allow for testing at the VCU Institute for Drug and Alcohol Studies, which provides participants who live far away easier access than VCU Health Center and additionally provides an option of cash payment.

6) The PI tweaked the inclusion/exclusion criteria, to allow for distant past histories of non-clinically-significant (comorbid) substance use, to allow for e-cigarettes to be interpreted as synonymous with tobacco cigarettes for the purposes of inclusion in "smoking" groups, and to allow for a broader range of nicotine use for –ALC and –CAN group participants. These changes expanded eligibility while still retaining and maintaining the core aims of the grant. Since this change did not affect risks to subjects nor alter the aims, pre-approval from HRPO or DoD was not sought.
7) Recruitment continued to occur below projected levels, so the research team consulted with the coordinator for the Virginia Spinal Cord Injury Outreach and Services Database and designed additional recruitment strategies.

4. Impact

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

Despite the lower accrual to date due to COVID-19, we are seeing trends in the data that are supportive of the hypotheses of the original grant application. These preliminary data have been submitted to the DoD in the form of a pre-application for an Expansion Award. Therefore, the impact of the data to date is to warrant additional data collection.

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

Testing Location:

The protocol was first modified to allow for testing at the VCU Institute for Drug and Alcohol Studies, which provides participants who live far away easier access than VCU Health Center and additionally provides an option of cash payment. Since the shutdown for COVID-19 and the need for social distancing, the team has worked with the behavioral testing software vendor to convert PC laptop executable-file based testing of behavioral tasks to scripts for use with an app that the participant can download on his or her own device. This has enabled completely contactless remote participation, which is preferred by prospective participants, even as COVID-19 restrictions have begun to ease.

Inclusion/Exclusion Criteria:

The PI expanded and clarified the inclusion/exclusion criteria in light of the patterns of substance use emerging in phone an in-person interviews of the SCI patients. These changes have allowed for distant

past histories of non-clinically-significant (comorbid) substance use, to allow for e-cigarettes to be interpreted as synonymous with tobacco cigarettes for the purposes of inclusion in “smoking” groups, and to allow for a broader range of nicotine use for –ALC and –CAN group participants. These changes expanded eligibility while still retaining and maintaining the core aims and “spirt” of the grant. Since this change did not affect risks to subjects nor alter the aims, pre-approval from HRPO or DoD was not sought.

Recruitment Strategies:

Prior to COVID-19, recruitment continued to occur below projected levels, so the research team consulted with Ms. Emily Reed, the coordinator for the Virginia Spinal Cord Injury Outreach and Services Database, to identify additional advocacy groups for SCI, and to design additional recruitment strategies to reach them, which were approved by the IRB. As a benefit to the significant undertaking to convert testing to be all-remote if necessary, this does enable the protocol to recruit and scale nationwide. As a result, the team has worked to start recruiting through national online and other national sources:

Table 1. Recruitment contacts

Local Richmond-area	Internet/remote-based
United Spinal Association of Virginia	Spinal Cord Injury USA Facebook group
Sportables	Brooks Rehabilitation (Fla)
Samaritans Walk (gym)	Veterans & Athletes United
Sheltering Arms	Reddit groups:
NOW center in short pump	r/spinalcordinjuries,
VCU Health	r/disability,
Spinal Cord Injury Network	r/disabledgamers,
Kennedy-Krieger Institute	r/rva_events,
Sports Center of Richmond	r/paralympics,
Paralyzed Veterans of America (Mid-Atlantic chapter)	r/Virginia

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

COVID-19:

COVID-19-related public health concerns and regulations have suspended new enrollment in this project indefinitely. While the resolution of the delay is beyond the control of the researchers, there are multiple actions that may be taken to mitigate the effects on the research.

1) Enrolled participants at the time of COVID-19 shutdown completed follow-up interviews by phone as projected.

2) The PI has monitored communications from the Department of Defense CDMRP and HRTO regarding policies toward clinical research affected by the COVID-19 pandemic.

3) The team has monitored CDC and WHO recommendations to implement all policies to minimize risk to researchers or participants, once in-person research is permitted to resume.

4) Research staff are poised to vigorously pursue additional recruitment once restrictions are lifted, with appropriate PPE precautions.

Changes that had a significant impact on expenditures

Since most prospective participants have preferred all-remote testing, there has been decrease in the anticipated utilization of costs to cover personal vehicle usage by the study coordinator.

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

The advent of all remote testing has enabled reduced potential for COVID-19 and other germ transmission to or from research staff.

Significant changes in use or care of human subjects

The advent of all remote testing has enabled reduced potential for COVID-19 and other germ transmission to research participants, thus lowering risk.

Significant changes in use or care of vertebrate animals.

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. Products

Publications, conference papers, and presentations

Nothing to Report

Website(s) or other Internet site(s)

Nothing to Report

Technologies or techniques

The team and the project have successfully adapted the neurobehavioral testing procedures to utilize the Millisecond Inquisit 6 Web application, so that participants can download the free Inquisit 6 app in order to complete the task. Although this award did not contribute or fund the development of this software, to our

knowledge it was the first conversion of an in-person dedicated computer-based testing to all remote in a disability population.

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:	*James M. Bjork*
Project Role:	*Principal Investigator*
Researcher Identifier (e.g. ORCID ID):	*https://orcid.org/0000-0003-0593-3291*
Nearest person month worked:	*2*
Contribution to Project:	*Dr. Bjork has managed project implementation, including hiring the research assistant and facilitating cooperation between research staff and medically-responsible clinicians at each site. Dr. Bjork also managed the programming of specific task scripts in Inquisit stimulus-delivery software and establishing medical record search strategies, and oversaw the transition to all-remote testing as a possibility.*

Name:	*Paul E. Plonski*
Project Role:	*Research Assistant*
Researcher Identifier (e.g. ORCID ID):	*https://orcid.org/0000-0002-6748-6020*
Nearest person month worked:	*6*
Contribution to Project:	*Mr. Plonski helped set up the behavioral testing equipment and establish standard operating procedures, and coordinated with medically-responsible clinicians to identify prospective participants at each site. Mr. Plonski also conducted the telephone screenings and assessments.*

Name:	*Jordan Price*
Project Role:	*Research Assistant*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*6*
Contribution to Project:	*With the departure of Mr. Plonski to graduate school, his coordination and testing duties were taken over by Ms. Price, who has extensive experience working with Dr. Bjork's other projects at VCU. She has continued recruitment and has expanded recruitment sources, in addition to coordinating and conductingremote testing (and in-home and in-lab testing as preferred) and has also conducted follow-up phone interview assessments.*

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?

None

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8. Special Reporting Requirements

9. Appendices

Titled as Appendix A and uploaded into eBRAP in this Annual Report package is the pre-application for a DoD Expansion Award, that describes in greater detail the supportive preliminary findings from data to date.