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TITLE: Initial Evaluation of an eHealth Self-Management System to Reduce Depression and Increase Resilience After SCI

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14. ABSTRACT

The sudden, devastating nature of Spinal Cord Injury (SCI) and the potential for lifelong physical limitations and medical complications pose significant mental health challenges for affected individuals. High prevalence rates for depressive disorders and anxiety disorders have been found in both Veterans and civilians with SCI. Resilience is associated with decreased risk for psychological distress following SCI. Unfortunately, it can be challenging to identify and address symptoms of emotional distress and promote resilience in individuals who are learning to function with a new disability. Developing easily accessible interventions to reduce mental health symptoms and increase psychological resilience after SCI is therefore critical to improving quality of life. The goal of this project is to further build, refine, and conduct a pilot clinical trial to fully prepare an existing eHealth intervention for large-scale clinical trial evaluation. This tool, called iManage-SCI, is a symptom monitoring and self-management tool specifically designed to provide a low-cost and empirically founded method of reducing mental health symptoms and increasing resilience among individuals with SCI.

15. SUBJECT TERMS
Spinal Cord Injuries, Psychosocial Functioning, Outcomes Measurement, Symptom Monitoring, PRO Measures, Self-Management, Symptom Monitoring, eHealth, Depression, Anxiety, Psychological Resilience

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1. INTRODUCTION:

The sudden, traumatic, and life-altering nature of spinal cord injury (SCI) presents a significant challenge to emotional health and well-being. Furthermore, individuals with SCI must perform regular self-care activities to avoid a variety of serious medical complications, and mental health symptoms can reduce motivation for completing skin, bowel, and bladder management activities and in turn contribute to the increased likelihood of severe complications. These complications significantly detract from quality of life (QOL) and in many cases result in rehospitalization. Developing interventions to reduce mental health symptoms following SCI is therefore critical to improve the lives of individuals, as well as alleviate resource strain on military and civilian health care systems. This research project will provide an initial evaluation of an innovative symptom-monitoring and self-management program, called iManage-SCI, to treat symptoms of depression and anxiety and enhance resilience in Veterans and civilians with SCI. At the conclusion of this proposed project, we will be fully prepared to conduct a full-scale efficacy trial of the iManage-SCI system.

2. KEYWORDS:

Spinal Cord Injuries, Psychosocial Functioning, Outcomes Measurement, Symptom Monitoring, PRO Measures, Self-Management, Symptom Monitoring, eHealth, Depression, Anxiety, Psychological Resilience, Health Promotion

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The major goals of the project are: (1) Optimize iManage-SCI for Veterans and prepare system for feasibility and efficacy testing (8 major tasks); (2) Prepare pilot clinical trial research protocol, including development of an active control condition (4 major tasks); (3) Test the feasibility and preliminary efficacy of iManage-SCI in a sample of Veterans and civilians with SCI (7 major tasks).

A precursor to a majority of these activities is obtaining human subjects' regulatory approval at the Kessler Foundation, University of Delaware (UD, which is relying on the Kessler Foundation), the East Orange VA, and the Office of Human Research Oversight (OHRO). The sites also require administrative approvals prior to study initiation, including data use agreements (DUAs). Please note that Major Task 0.1 [0.1 Obtain VA privileges (i.e., "WOC status") for UD investigators] was deemed unnecessary for this project by our collaborators at the East Orange VA.

Major Tasks	**Estimated % Complete**
Tasks Relevant to All Aims	
0.1 Obtain VA privileges (i.e., "WOC status") for UD investigators	n/a
0.2 Obtain initial IRB approvals	100%
0.3 Obtain initial OHRO approvals	100%
0.4 Consultation with consumer advocates	50%
0.5 Oversight by Data & Safety Monitoring Board (DSMB)	10%
0.6 Obtain IRB and OHRO continuing approvals	35%
Tasks Relevant to Specific Aim (Major Goal) 1: Optimize iManage-SCI for Veterans and Prepare System for Feasibility and Efficacy Testing	
1.1 Prepare REDCap database for data collection	100%
1.2 Prepare research assistant (RA) training materials	100%
1.3 Train UD RAs for data collection	100%
1.4 Conduct 1-on-1 demonstration sessions	0
1.5 Analyze demonstration session data	0
1.6 Determine iManage-SCI modifications	75%
1.7 Revise and/or create self-management videos	100%
1.8 Update iManage-SCI platform	95%

Tasks Relevant to Specific Aim (Major Goal) 2: Prepare Pilot Clinical Trial Research Protocol, Including Development of an Active Control Condition	
2.1 Convene initial DSMB organizational meeting	50%
2.2 Create active control condition materials	100%
2.3 Draft clinical trial protocol	100%
2.4 Conduct 2 Stakeholder Advisory Board meetings (to review videos)	100%
Tasks Relevant to Specific Aim (Major Goal) 3: Test the Feasibility and Preliminary Efficacy of iManage-SCI in a Sample of Veterans and Civilians with SCI	
3.1 Prepare REDCap database for data collection	80%
3.2 Prepare manual of procedures for pilot clinical trial	100%
3.3 Train EOVA and KF RAs for data collection	50%
3.4 Conduct pilot clinical trial	0
3.5 Clean and prepare data for analysis	0
3.6 Analyze pilot clinical trial data	0
3.7 Disseminate study results	0

What was accomplished under these goals?

As described below, we have made significant accomplishments in several aspects of the study. We now have all IRB and OHRO approvals in place, including approval of the University of Michigan as an additional, recruitment-only site. We have developed and finalized our clinical trial protocol and control condition content and are ready to launch Aim 3 data collection. We have modified the iManage-SCI program, conducted a thorough quality check of the technology and have been making significant modifications to ensure a technologically seamless pilot clinical trial. Project investigators and study coordinators have been meeting by Zoom at least biweekly to ensure ongoing progress across all aspects of the project. Meetings with consumer advocates have been held at least quarterly to ensure that the perspectives of individuals with lived experience are included throughout our study activities. We have organized the Data and Safety Monitoring Board. Detailed accomplishments for this year are provided under the corresponding Major Task, below.

Major Task 0.2 Obtain initial IRB approvals

In Q2 of the current reporting period, the investigative team was advised that during a VA IRB audit, it was determined that this study should not be considered exempt at the EOVA, which necessitated a resubmission of the full IRB package to the EOVA IRB in January 2023. In Q3 of the current reporting period, the EOVA IRB reviewed and approved (on 5/25/23) this project as a non-exempt research project.

Additionally, to bolster subject recruitment, the PI arranged to add the University of Michigan as an additional recruitment (only) site to the project, to help ensure data collection targets are reached. A cede agreement was issued by the University of Michigan IRB on March 1, 2023. A Kessler IRB amendment package was submitted to its IRB in June 2023, and the Kessler IRB approved the addition of UM as a recruitment site on 6/20/23. The formal reliance agreement between UM and Kessler was executed on 6/21/2023.

Also, in Q3, we submitted an amendment package to the EOVA IRB. This amendment clarified the measures and procedures to be used in the Aim 3 pilot clinical trial, and included an updated consent form, recruitment script, opt-out letter, recruitment flyers, demographic and health history form, unblinding questionnaire, usability survey, cognitive debriefing interview guide, and medical record abstraction form. This amendment was approved by the EOVA IRB on 5/18/23.

Major Task 0.3 Obtain initial OHRO approvals

During the current reporting period, we prepared an OHRO submission package for the EOVA's new initial OHRO application, which was submitted to OHRO on June 5, 2023. OHRO conditionally approved this protocol on 6/27/23 and issued a full approval on 8/9/2023. We also prepared OHRO application materials for the University of Michigan (UM) site, which were submitted on 7/31/2023 and approved by OHRO on 8/8/2023.

Major Task 0.4 Consultation with consumer advocates

During the current reporting period, the investigative team has continued to engage with both of the project's consumer advocates. Specifically, the study team hosted a Zoom meeting on 9/15/22, which provided an opportunity for the consumer advocates to view all parts of the iManage-SCI system and to provide feedback on new drafts of score reports for inclusion in the system. We then held meetings with Mr. Ian Betz on 3/20/2023 and Mr. Hashim Garrett on 3/24/23 to demonstrate and obtain their input on the ways we had modified the iManage-SCI system and score reports in response to their prior feedback. We also obtained their feedback on the working list of educational control condition video topics, as well as on our first completed control condition video. On 4/7/23, we met with both Mr. Betz and Mr. Garrett to present on the structure of and plans for participant involvement in the Aim 3 pilot clinical trial and to obtain input on how to improve the participants' experience in the study. Finally, during Q4 of the current reporting period, we scheduled practice Aim 3 screening/consent/study set-up sessions with the consumer advocates (scheduled for 9/21/2023) to ensure that all aspects of the screening/consent/study set-up are appropriate and clear for Veterans and civilians with SCI.

Major Task 0.5 Oversight by Data & Safety Monitoring Board (DSMB)

During the current reporting period, we secured a commitment from an additional, VA-affiliated member of the DSMB. Omowunmi Osinubi, MD, MSc, MBA, FRCA, ABIHM, is a Clinical Professor of Environmental & Occupational Health at the Rutgers University School of Public Health, and Director for Clinical Services at the War-Related Illness and Injury Center at the VA-New Jersey Health Care System and has agreed to serve on the DSMB for this project. Preparations for the initial organizing meeting are described in detail under **Major Task 2.1**, below.

Major Task 0.6 Obtain IRB and OHRO continuing approvals

IRB and OHRO continuing approvals were obtained for the UD and Kessler sites during the current reporting period. Specifically, the Kessler IRB continuing review was submitted on 6/5/23 and approved on 6/20/23. The UD IRB continuing review was submitted on 6/21/23 and approved on 7/3/23. Since the VA and UM sites were newly approved (by both IRB and OHRO) during the current reporting period, continuing approvals were not yet needed.

Major Task 1.3 Train UD RAs for data collection

During the current reporting period, we have hired a new lead data collector at UD, who has 15 years of experience conducting qualitative and quantitative interviews with individuals with SCI. As of 8/16/23, she has now been fully trained on the Aim 1 demonstration sessions and has provided a list of available session times to the EOVA to begin scheduling in late September 2023.

Major Task 1.4 Conduct 1-on-1 demonstration sessions

By the first quarter of the current reporting period, we had prepared all the materials and methodology for the Aim 1 demonstration sessions and were ready to begin data collection. Unfortunately, the launch of data collection was postponed due to delays in executing the subcontract between UD and EOVA. It was executed on 11/22/22. Subsequently, the VA administration requested a full re-review of the study protocol by the VANJHSC IRB. The study was not fully approved by the VA IRB until 5/25/23. We were not able to begin the Aim 1 demonstrations immediately since modifications to the iManage-SCI system were underway by BrightOutcome, our technology vendor. Given the length of time that had elapsed between the initial Aim 1 trainings and the actual commencement of Aim 1, we held a refresher training with VA and UD personnel on 8/16/2023. waiting for final system modifications (so participants can react to the most current version of system). We expect the first demonstration session to be conducted early in the next reporting period.

Major Task 1.6 Determine iManage-SCI modifications

During the current reporting period, we synthesized participant feedback from the 17 individuals from Kessler Foundation who completed our prior pilot usability study, as well as additional feedback from consumer advocates and co-investigators, and have been working with technology vendor BrightOutcome to implement and modify the iManage-SCI system prior to the Aim 3 pilot clinical trial. We met at least biweekly with BrightOutcome to discuss changes and timelines. During this reporting period, we have also continued to conduct quality assurance (QA) testing on the iManage-SCI system to note any issues/areas in need of modification prior to initiating the pilot clinical trial. We identified a method of streamlining the participant account

creation system (specifically, by generating a list of all possible study PINs, having our study biostatistician conduct the block randomization, and providing a list of the PINs and randomized study condition ahead of time to BrightOutcome to pre-load into the system). Additionally, to minimize risks to confidentiality, we implemented a method to limit access to participant email addresses only to their local recruitment site (e.g., EOVA or Kessler). We conducted an internal review for Section 508 (accessibility) compliance and identified ways in which BrightOutcome needed to make updates to assure compliance (for example, creating a way to upload a closed captioning file along with each self-management video file).

The study team also determined that an educational summary "Information Sheet" was needed for each weekly session of the control condition, to mirror the time and attention needed by intervention condition participants to review their full score report each week. Six information sheets, each containing textual information and supporting graphics to summarize that week's control condition video content as well as relevant resources, were developed and finalized. Once nearly all modifications to the system were completed, we developed introductory videos for the intervention and control conditions, and corresponding closed captioning files have been created. Additional changes needed to the iManage-SCI system were identified in Q4 of the reporting period. These included developing a way to remove participants from the system who have been withdrawn, moving the entire iManage-SCI system from the QA environment to the production environment, completing video deployment testing in production site, and making minor bug fixes. The last minor fixes (e.g., getting print report function to work on iPhones) are scheduled to be resolved in early September 2023.

Major Task 1.7 Revise and/or create self-management videos

Throughout the current reporting period, we have worked with animator George Berlin to revise existing self-management videos and to create new video content with additional intervention strategies. All the intervention videos have now been finalized, closed captioning files have been created for all videos, and all videos have been uploaded to the iManage-SCI system. Additionally, two introductory videos (one for the control condition and one for the intervention condition) have been developed, finalized, and uploaded into the iManage-SCI system.

Major Task 1.8 Update iManage-SCI platform

Throughout the reporting period, we have been meeting weekly with technology vendor BrightOutcome to discuss needed changes to the system and to review and provide feedback on the updates they have made to date. Substantive updates have now been made to the iManage-SCI system, including the addition of a sixth session to the experimental condition and building in parallel control condition capability. The parallel control condition has been implemented into the system by BrightOutcome, and our team has added content to each of the six weekly control condition sessions. BrightOutcome has added an option to allow resources to be displayed to participants in the experimental condition only, participants in the control condition only, or to participants in both conditions. BrightOutcome conducted a formal Section 508 (accessibility compliance) review, we reviewed their report in detail and identified needed system augmentations, and BrightOutcome made the necessary modifications to the system. BrightOutcome implemented the method identified in **Major Task 1.6** to improve system confidentiality by limiting access to participant email addresses to their recruitment site personnel only. They also implemented a method of adding closed captioning to the intervention and control condition videos and ensured that the closed captioning can be turned on or off by the end user. The six control condition information sheets described under **Major Task 1.6** have been added into the corresponding weeks of the control condition within the iManage-SCI system. We have devised and implemented extensive QA testing procedures for the video deployment logic. BrightOutcome also implemented a method of sending "severe depression alert" emails only to personnel at the participant's recruitment site, rather than to personnel across all sites.

Significant modifications have also been made to the administrative interface to allow assignment of role-based permissions to study team members to: 1) protect the masking of participants' assigned condition, 2) allow administrators to modify the rules for weekly window open/close dates, and 3) enable administrator modification of the content and frequency of automated reminder emails, which will be sent out to participants during the pilot clinical trial. The UD team has been conducting QA testing for all these changes and providing feedback to BrightOutcome in an iterative cycle.

To prepare the system specifically for the Aim 3 pilot clinical trial, randomized study PINs have been pre-loaded into the system by BrightOutcome. BrightOutcome has programmed a section of the system to administer pretest measures, and all three pretest measures (PHQ-8, GAD-7, and CD-RISC-10) have been added into the system. An additional set of static items assessing health-related self-efficacy has been added to each weekly session (for both experimental and control condition participants). We have also developed a method of having the iManage-SCI system send an email to each participant immediately upon completion of their final session. This email will contain each participant's unique link to the posttest measures (PHQ-8, GAD-7, CD-RISC-10, unblinding questionnaire, and usability survey) in REDCap. The UD team created the posttest database and loaded all PINs to obtain the unique link for each participant. Updates have also been made to the administrative side (for example, changing the view of participants' progress to reflect the session open/close dates and to reflect the correct number of sessions) and graphical (e.g., changing x-axis to reflect weekly sessions; changing the view on short report graphs) and textual changes (e.g., changing blocks of text to bullet points) have been made to the reports. The previous national suicide & crisis hotline number has been replaced with 988 throughout the system and videos.

Throughout the conduct of 1.8, we conducted extensive QA testing to ensure that the software was working effectively. The team found several areas that needed attention by the technology team, and we held weekly meetings with BrightOutcome to address these issues and ensure that the iManage program is ready for the Aim 3 pilot clinical trial. Completion of final system changes and UD signoff are expected in early September 2023.

Major Task 2.1 Convene initial DSMB organizational meeting

Dr. Ryan Pohlig met with the project team on 8/11/23 to plan for an initial DSMB organizing meeting. Dr. Pohlig and Co-Investigator Boulton have prepared materials that will be presented at the DSMB organizing meeting with the full board, which is scheduled for Sept 11, 2023.

Major Task 2.2 Create active control condition materials

We have fully developed an eHealth active control condition that includes SCI-specific content provided by our Kessler colleagues. These include closed-captioned video presentations of six discrete PowerPoint slide sets, with accompanying scripted audio narration for the following modules: 1) Getting the Most Out of Your Healthcare Appointment; 2) Preventive Healthcare: Risk and Screening; 3) Communicating Effectively with Providers, 4) Nutrition and Weight Management for People with Spinal Cord Injury; 5) Emergency Preparedness; and 6) Traveling with a Spinal Cord Injury. We believe that this control condition is innovative and provides relevant educational material that will be useful to individuals with SCI, yet does not address issues of depression and anxiety (the target of this intervention). The materials were developed in collaboration with individuals with lived experience of SCI and were reviewed by co-investigators.

We also developed information sheets for each session, which contain textual information and supporting graphics, reiterating the video's key points. The information sheet is intended to be parallel to the score report seen by participants in the iManage-SCI intervention condition.

All the control condition videos and corresponding information sheets have been uploaded to the iManage-SCI system.

Major Task 2.3 Draft clinical trial protocol

During the current reporting period, we have fully developed the clinical trial protocol. We identified a relevant DoD protocol template and received confirmation from our OHRO officer that this template is appropriate for the current study. Information in the original grant application and supporting documents, as well as the already-approved IRB protocols, were used to develop the initial draft. We subsequently held multiple study team meetings to discuss outstanding issues, including how to precisely define and measure the primary and secondary outcomes and endpoints of the study, how to define adverse events, and how to ensure consistent timing of pretest and posttest measures. The project investigators met at least biweekly throughout the reporting period. The final protocol has been reviewed and approved by project investigators. The study's clinicaltrials.gov entry (NCT05095506) was updated accordingly.

Major Task 2.4 Conduct 2 Stakeholder Advisory Board meetings (to review control condition videos)
We held multiple meetings to obtain stakeholder input on the new control condition videos. Stakeholders included SCI researchers and individuals with lived experience of SCI. These meetings were held on 2/2/23, 2/16/23, 3/2/23, 3/3/23, 3/16/23, 3/20/23, 3/24/23, and 4/13/23. Input from stakeholders was used to revise control condition video components and provide further input on the iManage system and the clinical trial protocol.

Major Task 3.1 Prepare REDCap database for data collection
The contents and structure of each REDCap database needed for the Aim 3 pilot clinical trial have been determined, and three REDCap databases (i.e., one for recruitment and screening; one for demographics, health history, and cognitive debriefing interview data; and one for posttest surveys) have been fully populated in UD's REDCap. We have drafted accompanying instructions for data collectors. Thorough QA has been conducted on all Aim 3 databases, and most edits have been completed. All edits will be finalized by early September 2023.

Major Task 3.2 Prepare Manual of Procedures for pilot clinical trial
During the current reporting period, we have prepared three versions of the data collection manual of procedures (MOP) for the Aim 3 pilot clinical trial. The Kessler- and EOVA-specific MOPs have been distributed to site data collectors. PowerPoint slides highlighting the key aspects of the MOP were presented to sites during the Aim 3 implementation meetings (described in **Major Task 3.3**, below). The MOP for the UM/UD site has been prepared and is currently under review by the study team.

Major Task 3.3 Train EOVA and KF RA(s) for data collection
All Aim 3 training materials (MOP, training slides, certification procedures) have been prepared. An Aim 3 procedures meeting was held with all sites on 7/21/2023 to discuss recruitment plans and timelines, study flow, data collection and entry, and plans for emergent situations.

The Kessler site Aim 3 implementation/kickoff meeting was held on 8/18/23. Kessler is currently in the process of interviewing and hiring a new research coordinator who will collect all Aim 3 data for this study, because its previous coordinator recently left. To optimize the resulting "downtime," two practice Aim 3 study setup sessions have been scheduled by the Kessler investigators, one with each consumer advocate, for 9/21/2023.

The EOVA data collection personnel are scheduled be trained on 9/20/2023, and recruitment and data collection will formally begin by 10/1/2023.

Major Task 3.4 Conduct pilot clinical trial
Although data collection has not yet started for the Aim 3 pilot clinical trial, all preparation has been completed. As soon as the final updates are made to the system and all data collector trainings and certifications have been completed, we will launch Aim 3 data collection. As per estimates from BrightOutcome, these changes will be completed by mid-September 2023.

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?

We will use the upcoming no-cost extension year to complete Aim 1 data collection and the full Aim 3 pilot clinical trial. All regulatory approvals are fully in place and all back-end/non-human-subjects activities are nearly complete. As soon as the last minor tasks (e.g., iManage-SCI system updates, UM/UD manual of procedures, EOVA data collector training) have been completed, both Aim 1 and Aim 3 will be officially

launched. Quarterly DSMB meetings will begin with the initial full board organizing meeting on 9/11/2023. We are actively planning alternative backup strategies for recruitment should our sites not reach preliminary targets on schedule. We will submit an IRB amendment to advertise this study to Veterans in the community. We also plan to meet with regional or national spinal injury associations to help implement alternative recruitment strategies.

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

Given delays with regulatory approvals (specifically at the EOVA) and with approval from the project officer, we are now concurrently completing Aim 1 and Aim 3 data collection. Additionally, due to the delayed start of Aim 3 recruitment and to ensure we are able to meet our Aim 3 sampling targets during the forthcoming (and already approved) no-cost extension year, we have added the University of Michigan as a recruitment-only site, with participants to be enrolled, consented, and guided through the study by UD personnel.

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

As described in prior reports and above, there have been substantial delays in establishing regulatory approvals for the EOVA.

To address the delay in Aim 1, the PI discussed options with the project officer, and decided to move Aim 1 activities to be concurrent with Aim 3 activities.

To address the delay in getting EOVA started as a data collection site for Aim 3, we have secured an additional data collection site, the University of Michigan. As described above, UM will serve as a recruitment/referral site, and referred participants will be enrolled by a University of Delaware data collector. Additionally, while the Kessler Foundation was originally scheduled to recruit only civilians into the project, we have worked with our Kessler investigators to identify a database of veterans who have received care at Kessler and have indicated they would like to be contacted for research; thus, the Kessler Foundation will now be able to recruit both veterans and civilians into the study. After we launch the study, we will also be exploring additional options for recruitment of veterans to ensure that sampling targets are met.

During Q4 of the current reporting period, several program bugs were identified through our extensive QA of the iManage-SCI software. This resulted in an additional 3-month delay while BrightOutcome modified the program. We view this as positive as it will help ensure that the system is optimized for the pilot clinical trial.

Finally, to continue to mitigate the initial project start-up delays we experienced, we have been working on project “back-end” activities to prepare for Major Task 3.4 (pilot clinical trial) as much as possible. We are now at the precipice of launching Aim 3 data collection and plan to complete the full proposed scope of data collection during the approved NCE year.

Changes that had a significant impact on expenditures

While the delays described above have impacted the timing of expenditures, no changes in overall project scope or planned expenditures have occurred.

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

Nothing to report

Significant changes in use or care of human subjects

Nothing to report

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

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: David Tulsky, PhD
Project Role: Project PI
Researcher Identifier: 0000-0002-4335-4509
Nearest person month worked: 1
Contribution to Project: No change

Name: Jerry Slotkin, PhD
Project Role: Co-Investigator, University of Delaware
Researcher Identifier: 0000-0001-8199-3056
Nearest person month worked: 1
Contribution to Project: No change

Name: Pamela Kisala, MA
Project Role: Co-Investigator, University of Delaware
Researcher Identifier: 0000-0003-3234-795X
Nearest person month worked: 3
Contribution to Project: No change

Name: Chloe DeHart, BS
Project Role: Research Associate, University of Delaware
Research Identifier: n/a
Nearest person month worked: 5
Contribution to Project: Assisted project investigators with the preparation of IRB/OHRO materials, quality assurance of the iManage-SCI system, preparation of data collection training materials, and REDCap setup and quality assurance.

Name: Aaron Boulton, PhD
Project Role: Co-Investigator, University of Delaware
Researcher Identifier: 0000-0001-7349-162X
Nearest person month worked: 1
Contribution to Project: No change

Name: Trevor Dyson-Hudson, MD
Project Role: Site PI, Kessler Foundation
Researcher Identifier: 0000-0002-0252-2764
Nearest person month worked: 1
Contribution to Project: No change

Name: Denise Fyffe, PhD
Project Role: Co-Investigator, Kessler Foundation
Researcher Identifier: 0000-0001-8484-5171
Nearest person month worked: 1
Contribution to Project: Dr. Fyffe facilitated communication with the Kessler IRB and with the project's Consumer Advocates. Dr. Fyffe attended project meetings and provided feedback on aspects of Project Aims 1, 2, and 3.

Name: Xinwei Zhang, PhD
Project Role: Research Coordinator, Kessler Foundation

Researcher Identifier: n/a
Nearest person month worked: 4
Contribution to Project: Dr. Zhang assisted with preparation of Aim 1 and Aim 3 IRB documents, attended project meetings, and coordinated communication between Kessler investigators and the project team.

Name: Erica Pe Benito
Project Role: Research Coordinator, Kessler Foundation
Researcher Identifier: n/a
Nearest person month worked: 4
Contribution to Project: Ms. Pe Benito assisted with preparation of Aim 1 and Aim 3 IRB documents, attended project meetings, and coordinated communication between Kessler investigators and the project team.

Name: Carol Gill, MD
Project Role: Site PI, Veterans Administration New Jersey Healthcare System (VA)
Researcher Identifier: 0000-0002-0939-9965
Nearest person month worked: 1
Contribution to Project: No change

Name: Monica Clement, PhD
Project Role: Co-Investigator, Veterans Administration New Jersey Healthcare System (VA)
Researcher Identifier: 0000-0002-9581-5514
Nearest person month worked: 1
Contribution to Project: As a clinical psychologist, Dr. Clement has provided guidance on the emergent situation protocol for the study as a whole as well as for the EOVA site specifically, has developed a list of potentially eligible participants to recruit from the EOVA, and has provided guidance on considerations for the psychological well-being of Veteran participants.

Name: Tatiyanna Mingo, MPH
Project Role: Research Coordinator, Veterans Administration New Jersey Healthcare System (VA)
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: As the study coordinator for the EOVA site, Ms. Mingo has prepared and submitted IRB documents, prepared site-specific data collection materials and procedures, attended project meetings, and developed recruitment lists for project Aims 1 and 3.

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

All PIs and key personnel are listed below, along with any changes in the active support of each (if applicable).

David Tulsky, PhD
New funding:
Nothing to report

Previous funding:
Nothing to report

Jerry Slotkin, PhD
New funding:
Nothing to report

Previous funding:
- ARMADA: Advancing Reliable Measurement in Alzheimer's Disease and cognitive Aging, ended 12/31/2022

Pamela Kisala, MA
New funding:
Nothing to report

Previous funding:
Nothing to report

Aaron Boulton, PhD
New funding:
Nothing to report

Previous funding:
Nothing to report

Trevor Dyson-Hudson, MD
New funding:

1. Title: Northern New Jersey Traumatic Brain Injury Model System
Funding Agency: DHHS/ACL/NIDILRR
Project Dates: 9/1/22 – 8/31/27
Effort: 0.30 Calendar Months
Description: Through NNJTBIS, scientists conduct research that benefits the TBI community, contribute research data to the national TBIMS database, translate findings into clinical care, and provide resources for individuals with TBI and their caregivers.

2. Title: Intervening Quickly: A Pilot RCT to Improve Cognitive Processing Speed in Acute SCI
Funding Agency: Craig H. Neilsen Foundation
Project Dates: 4/30/23 – 4/29/25
Effort: 0.12 Calendar Months
Description: The major goals of this double-blind, placebo-controlled, pilot randomized clinical trial (RCT) are to examine the efficacy of an online computerized intervention (BrainHQ) to improve cognitive processing speed in 20 individuals with traumatic spinal cord injury (tSCI) in the acute phase of recovery (i.e., within one year of injury).

3. Title: Early Intervention for Cognitive Processing Speed Deficits in Acute SCI: A Pilot Study
Funding Agency: New Jersey Commission on Spinal Cord Injury Research
Project Dates: 12/1/22 – 11/30/24
Effort: 0.12 Calendar Months
Description: The major goal of this double-blind, placebo-controlled, pilot randomized clinical trial (RCT) is to examine the efficacy of an online computerized intervention (BrainHQ) to improve cognitive processing.

4. Title: Caregiving Skills Training Program
Funding Agency: Anonymous Private Donor
Project Dates: 8/1/23 – 9/30/26
Effort: 0.60 Calendar Months
Description: The major goal of this donor-funded project is to Increase quality of care for persons with SCI by providing intensive in-person training in everyday skills that family and hired caregivers need to prevent medical complications and enable greater independence and participation in the community.

5. Title: SCI Rehabilitation Transition Program
Funding Agency: Anonymous Private Donor
Project Dates: 8/1/23 – 9/30/26
Effort: 0.60 Calendar Months
Description: The major goal of this donor-funded project is to recruit, train, and mobilize a team of SCI Advocates with specialized knowledge about SCI resources and needs. The SCI Advocates will act as

liaisons between people with SCI, their families, and care providers to facilitate transition from the acute hospital to inpatient SCI rehabilitation and from inpatient SCI rehabilitation to home and the community.

6. Title: Treatment of Orthostatic Hypotension in Individuals with Spinal Cord Injury
Funding Agency: Craig H. Neilsen Foundation
Project Dates: 7/31/23 – 7/30/26
Effort: 0.60 Calendar Months
Description: The purpose of this study is to identify the effects of non-pharmacological and pharmacological anti-hypotensive treatment interventions on blood pressure responses, symptoms of autonomic dysreflexia and low blood pressure, and levels of fatigue and comfort in people with spinal cord injury who have low blood pressure.

7. Title: Wheelchair Backs Study
Funding Agency: Craig Hospital
Project Dates: 6/1/23 – 9/30/24
Effort: 0.60 Calendar Months
Description: The overall objective of this randomized controlled trial is to investigate if using a solid backrest on manual wheelchair will improve postural alignment, function and wheelchair mobility, as compared with an upholstery backrest in persons with spinal cord injury; and to explore the impact of overall back height, seat gap, and contour when using a solid backrest.

Previous funding:

-Improving Quality of Personal Care Assistance Services for People with SCI through Online Education, ended 9/29/2022

Carol Gibson-Gill, MD
New funding:
Nothing to Report

Previous funding:
Nothing to Report

Denise Fyffe, PhD
New funding:

1. Title: RRTC: Equity Center in Employment Domain
Funding Agency: DHHS/ACL/NIDILRR
Project Dates: 9/1/22 – 8/31/27
Effort: 0.12 Calendar Months
Description: The major goal of this study is to empower multiply marginalized people with disabilities in obtaining employment, developing careers, and generating entrepreneurial-driven wealth.

2. Title: Caregiving Skills Training Program
Funding Agency: Anonymous Private Donor
Project Dates: 8/1/23 – 9/30/26
Effort: 0.60 Calendar Months
Description: The major goal of this donor-funded project is to Increase quality of care for persons with SCI by providing intensive in-person training in everyday skills that family and hired caregivers need to prevent medical complications and enable greater independence and participation in the community.

3. Title: SCI Rehabilitation Transition Program
Funding Agency: Anonymous Private Donor
Project Dates: 8/1/23 – 9/30/26
Effort: 0.60 Calendar Months
Description: The major goal of this donor-funded project is to recruit, train, and mobilize a team of SCI Advocates with specialized knowledge about SCI resources and needs. The SCI Advocates will act as

liaisons between people with SCI, their families, and care providers to facilitate transition from the acute hospital to inpatient SCI rehabilitation and from inpatient SCI rehabilitation to home and the community.

Previous funding:

-Improving Quality of Personal Care Assistance Services for People with SCI through Online Education, ended 9/29/2022

What other organizations were involved as partners?

Organization Name: Kessler Foundation
Location of Organization: West Orange, NJ
Partner's contribution to the project:

- In-kind support
- Facilities
- Collaboration

Organization Name: Veterans Administration New Jersey Healthcare System (VA)
Location of Organization: East Orange, NJ
Partner's contribution to the project:

- In-kind support
- Facilities
- Collaboration

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

N/A

QUAD CHARTS:

Please see Appendix A for the most current Quad Chart

9. APPENDICES:

See Appendix A for Quad Chart

Appendix A: Initial Evaluation of an eHealth Self-Management System to Reduce Depression and Increase Resilience after SCI (iManage-SCI SCIRP Pilot Clinical Trial)

Log Number: SC190016; **Award Number:** W81XWH-20-1-0786

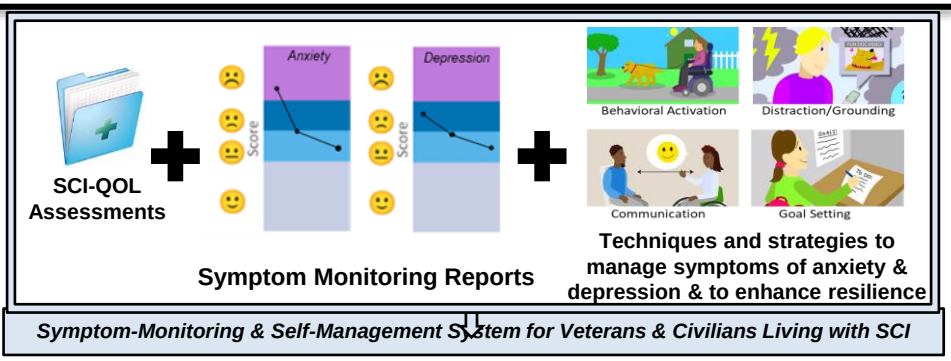
PI: David Tulsky, Ph.D. **Organization:** University of Delaware **Award Amount:** $1,748,467

Specific Aims

1. Optimize iManage-SCI for Veterans and Prepare the System for Randomized Pilot Trial.
2. Prepare Pilot Clinical Trial Research Protocol, Including Refinement of an Active Control Condition.
3. Determine the Feasibility and Preliminary Effects of iManage-SCI in a Sample of Veterans and Civilians with SCI.

Approach

The purpose of this study is to evaluate the effectiveness of the iManage-SCI system with Veterans and civilians. Although iManage-SCI is a fully developed system, we will conduct demonstration sessions specifically with Veterans, and will make adjustments to assure the system's full applicability and relevance to this group. We will elicit feedback from consumer advocates and expert clinical stakeholders to enhance the system, and then will conduct a pilot clinical trial with Veterans and civilians, comparing iManage-SCI to an active control condition. We will compare and evaluate groups on levels of depression, anxiety, and resilience.



Accomplishments: All initial and continuing IRB and OHRO approvals have been obtained. All Aim 1 and Aim 3 back-end/non-human-subjects tasks have been completed or are very near completion (e.g., iManage-SCI system updates, updates to self-management videos, introductory videos, clinical trial protocol, REDCap databases, manual of procedures). Initial trainings for Aim 3 have been conducted and practice runs have been scheduled with the consumer advocates by Kessler investigators. The initial DSMB organizing meeting is scheduled for 9/11/23. We are on track to launch both Aim 1 and Aim 3 early in the next reporting period.

Timeline and Cost

Activities	Year 1	Year 2	Year 3	Year 4
Obtain regulatory and administrative approvals				
Consult with consumer advocates, conduct Data Safety Monitoring Board meetings				
Prepare REDCap database, training materials, and train RAs (for Aim 1 data collection)				
Conduct 1-on-1 demonstration sessions & analyze				
Update iManage-SCI videos and platform				
Create active control condition materials and draft clinical trial protocol				
Conduct stakeholder advisory board meetings				
Prepare REDCap database, manual of procedures, and train RAs (for Aim 3 data collection)				
Conduct pilot clinical trial & analyze data				
Disseminate study results				
Estimated Budget ($K)	**$564**	**$576**	**$608**	

Note: UD = University of Delaware; EOVA = East Orange VA; KF = Kessler Foundation

Updated: 29-Sept-2023

Goals/Milestones

Year 1

- ☑ Obtain IRB and HRPO approvals
- ☑ Prepare for feasibility testing data collection and train RAs
- ☐ Conduct 1-on-1 demonstration sessions (feasibility testing)
- ☐ Analyze feasibility testing data
- ☑ Update iManage-SCI videos and platform
- ☑ Create active control condition materials
- ☑ Draft clinical trial protocol

Year 2

- ☑ Prepare for pilot clinical trial data collection and train RAs
- ☐ Initiate pilot clinical trial

Year 3

- ☐ Complete pilot clinical trial
- ☐ Analyze pilot clinical trial data
- ☐ Disseminate study results

Budget Expenditure to Date
Projected Expenditure: ***$1,748,467***
Actual Expenditure: ***$481,395.99***

Comments/Challenges/Issues/Concerns: Due to the COVID-19 pandemic and to site-specific requirements, initial regulatory approvals were delayed. To manage finances and assure project completion, no grant funds were expended prior to May 2022. All major tasks are on track for completion.