AWARD NUMBER: W81XWH-20-1-0786

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

PRINCIPAL INVESTIGATOR: David S. Tulsky, Ph.D.

CONTRACTING ORGANIZATION: University of Delaware, Newark, DE

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

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6. AUTHOR(S)
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5e. TASK NUMBER

5f. WORK UNIT NUMBER

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13. SUPPLEMENTARY NOTES

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

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
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TABLE OF CONTENTS

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 Human Research Protection Office (HRPO). 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 HRPO approvals	100%
0.4 Consultation with consumer advocates	17%
0.5 Oversight by Data & Safety Monitoring Board (DSMB)	5%
0.6 Obtain IRB and HRPO continuing approvals	33%
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	5%
1.7 Revise and/or create self-management videos	0
1.8 Update iManage-SCI platform	5%

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	60%
2.3 Draft clinical trial protocol	40%
2.4 Conduct 2 Stakeholder Advisory Board meetings (to review videos)	0
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	0
3.2 Prepare manual of procedures for pilot clinical trial	0
3.3 Train EOVA and KF RAs for data collection	0
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?

Following substantial COVID- and regulatory-related delays during Project Year 1, we were able to successfully obtain all necessary approvals in Project Year 2. Since we did not receive full regulatory approval until midway through Year 2, **no grant funds were expended prior to 5/1/2022.** Nonetheless, we have been able to make progress in preparing "back-end"/non-human-subjects materials. Project investigators and study coordinators have been meeting by Zoom at least biweekly to ensure ongoing progress across all aspects of the project. In Q4 of Year 2, we held an in-person investigators' meeting for all project investigators and consumer advocates.

As soon as the subaward from UD to the East Orange VA (EOVA) is fully executed, we will immediately commence the demonstration sessions.

Major Task 0.1 Obtain VA privileges (i.e., "WOC status") for UD Investigators, if necessary
We were advised by our collaborators at EOVA that VA privileges ("WOC status") for UD study personnel are not necessary for this project, so we are no longer pursuing this task.

Major Task 0.2 Obtain initial IRB approvals
As described in last year's report, the EOVA received an exemption from the Single IRB requirement, and submitted their own application, while UD and Kessler are covered under a Single IRB through the Kessler Foundation.

During the previous project year, we received initial approval from the Kessler IRB (July 2021). To complete the requirements for the Kessler IRB's full approval, we registered the study with clinicaltrials.gov (#NCT05095506) in October 2021. A reliance agreement between the UD IRB and the Kessler IRB was executed on October 22, 2021, and we received full approval from the Kessler IRB in December 2021.

EOVA, which (as described above) has authorization to obtain its own regulatory approvals, has been granted an exemption by its IRB. The EOVA R & D Committee subsequently reviewed the protocol and granted approval on April 14, 2022. All initial IRB approvals have now been received.

Major Task 0.3 Obtain initial HRPO approvals
HRPO approval or exemption was obtained for all sites during the Year 2 reporting period. Specifically, the HRPO package for UD (#E01660.1a) and Kessler (#E01660.1b) was submitted in December 2021, and HRPO approval for these 2 sites was received in January 2022. The EOVA HRPO package (#E01660.1c) was submitted in April 2022 (immediately upon receipt of VA R&D approval). On June 17, 2022, HRPO concurred with the EOVA IRB's determination of exemption, and communicated that it requires no further HRPO review

or oversight of the EOVA site activities as currently described in the SOW. That is, HRPO will continue to oversee the UD and Kessler site activities and has closed the log file on the EOVA site activities. Thus, all necessary HRPO approvals are now in place to begin study activities.

Major Task 0.4 Consultation with consumer advocates

During the current reporting period, the project team learned that one of the consumer advocates (Nick LiBassi) originally listed to participate in this project was no longer able to do so due to the increased time commitment of a new job. Thus, we recruited Hashim Garrett, a person with more than 30 years of lived experience with SCI, to join Ian Betz, a Veteran living with SCI, to help guide this research. During this reporting period, we have engaged both Mr. Garrett and Mr. Betz. Mr. Garrett attended the in-person kickoff meeting held at Kessler on June 13, 2022. Mr. Garrett and Mr. Betz have agreed to participate in two follow-up meetings that are scheduled for September and October 2022.

Major Task 1.1 Prepare REDCap database for data collection

During the current reporting period, the REDCap databases (one at UD and one at the EOVA) were prepared, finalized, and went through extensive quality assurance checks. Both databases are fully ready for data collection.

Major Task 1.2 Prepare research assistant (RA) training materials

All Aim 1 data collection training documents, including recruitment procedures, instructions on the study flow, site communication, and participant compensation, were completed during the reporting period. Aim 1 is fully ready to launch.

Major Task 1.3 Train UD RAs for data collection

To ensure that we obtain quality data in a timely fashion, UD Co-Investigator Pam Kisala will be moderating the Aim 1 demonstration sessions, instead of Ms. Kisala training an RA to conduct these sessions under her supervision. Ms. Kisala has more than 15 years of experience moderating qualitative interviews and other interactive sessions with participants with spinal cord injury. Ms. Kisala has prepared and reviewed all interview materials; thus, Major Task 1.3 is now considered complete.

Major Task 1.6 Determine iManage-SCI modifications

During the current reporting period, we generated a preliminary list of needed modifications to the iManage-SCI system, based on our prior work (pilot study with n = 17 individuals with SCI recruited through Kessler) and based on feedback from project investigators, staff, and the consumer advocates. We met at least biweekly with our IT vendor, BrightOutcome, to discuss changes and timelines. Additional needed modifications will be determined, documented and implemented following the completion of the Aim 1 demonstration sessions.

Major Task 1.8 Update iManage-SCI platform

During Year 2, our IT vendor has started making the changes in the preliminary list described in Major Task 1.6, above, including significant upgrades to the participant reports. This major task will be completed during Year 3.

Major Task 2.2 Create active control condition materials

During Year 2, we developed 2 of the 6 control condition videos (Healthy Behaviors and Nutrition), including full scripting and voiceovers. We presented these during our in-person study team meeting with all investigators and consumer advocates, and received valuable feedback. Our collaborating site, Kessler Foundation, has an additional source of control condition video content (that had been utilized previously in a different study). The advantage of this new video material is that it is focused on issues specific to individuals with SCI. Therefore, our investigative team is currently reviewing and evaluating this content to fit it into the necessary format. We expect that the control condition videos will be completed by Year 3, Quarter 2.

Major Task 2.3 Draft clinical trial protocol

During the reporting period, the project team submitted an overview of the clinical trial protocol to Clinicaltrials.gov. This submission was approved and assigned the study number NCT05095506 We have made additional progress on the full clinical trial protocol, including definitions of adverse events and how they will be approached by the study team, explanations of study procedures, and data management and handling

practices. During our June 2022 in-person meeting, we identified aspects of the protocol that warrant further consideration, such as a priori hypotheses for success and more detailed explanation of study endpoints. Furthermore, we have had multiple meetings with the investigators at Kessler and the EOVA to identify and streamline recruitment, screening, and adverse event/emergent situation procedures for the Aim 3 pilot clinical trial. An initial draft of this protocol is about 65% complete. Additional Kessler, EOVA, and UD team revisions will be needed to finalize this protocol.

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?

Once IRB and HRPO approvals/exemptions were obtained, funds were released at UD and the subaward documents were provided to Kessler and EOVA sites. These subawards will be fully executed in the next reporting period. Substantial progress has been made on “back-end” tasks during the current reporting period; as a result, we are in position to make significant progress during the coming year. We are poised to conduct the Aim 1 Demonstration sessions with 10 Veterans with SCI and plan to complete this task by November 2022. Based upon this qualitative data, we will update the list of needed changes to the iManage-SCI system and begin working with our IT vendor and animator to complete the changes. All changes to the system should be completed by February 2023. We will conduct and complete extensive quality assurance testing of the revised iManage-SCI web-based system by March 2023. During the next reporting period, we also will finalize the control condition slides and videos, finalize the clinical trial protocol, and submit IRB and HRPO amendments with the revised protocol and all Aim 3 materials. We will meet with the consultants with lived experience at least quarterly. We will draft training manuals and train and certify data collection personnel at the two Aim 3 recruitment sites (Kessler and EOVA). We will schedule and convene the initial meeting with the full DSMB and formalize oversight procedures. Finally, we plan to launch the pilot clinical trial in early April 2023.

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

There have been no changes in objective or scope of this project. While we have had to overcome obstacles to regulatory approvals in Year 1, we have not made any changes to our approach or SOW.

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

As mentioned previously, significant regulatory and administrative delays have resulted in the project starting later than planned. To mitigate these delays, we spent more than half of Year 2 working on project "back-end" activities to prepare for the launch of Major Task 1.4 demonstration sessions while we awaited regulatory approvals. Most importantly, we did not bill effort to the project for these start-up activities and **did not spend any grant funds until we received regulatory approval for the study.** We will do our best to accelerate our efforts going forward, and are planning to complete the full proposed scope of the study. However, we will likely need additional time and we will plan on submitting a no-cost extension if needed.

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 (e.g. ORCID ID): 0000-0002-4335-4509
Nearest person month worked: 1
Contribution to Project: No change

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

Name: Pamela Kisala, MA
Project Role: Co-I
Researcher Identifier: 0000-0003-3234-795X
Nearest person month worked: 1
Contribution to Project: No change

Name: Aaron Boulton, PhD
Project Role: Co-I
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-I, 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: 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

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:

1. Title: iManage-Sexual Wellness: Development of a symptom-monitoring/self-management program to enhance sexual wellness after SCI and TBI
   Funding Agency: National Institute on Disability, Independent Living, and Rehabilitation Research
   Project dates: 2/4/2022 – 08/31/2025
   Effort: 1.2 academic, 0.66 summer
   Description: The goal of this five-year project is to create and evaluate a web-based symptom-monitoring/self-management system to improve sexual wellness in individuals with SCI or TBI.
   Overlap: none

Previous funding:

- Online Symptom-Monitoring/Self-Management for Pandemic-Related Emotional Distress (ACCEL), ended 06/30/2022

Jerry Slotkin, PhD

New funding:

1. Title: iManage-Sexual Wellness: Development of a symptom-monitoring/self-management program to enhance sexual wellness after SCI and TBI
   Funding Agency: National Institute on Disability, Independent Living, and Rehabilitation Research
   Project dates: 2/4/2022 – 08/31/2025
   Effort: 0.48 calendar
   Description: The goal of this five-year project is to create and evaluate a web-based symptom-monitoring/self-management system to improve sexual wellness in individuals with SCI or TBI.
   Overlap: none
2. Title: ARMADA: Advancing Reliable Measurement in Alzheimer's Disease and cognitive Aging
   Funding Agency: Northwestern University/National Institutes of Health
   Project dates: 5/1/2022 – 12/31/2022
   Effort: 0.70 calendar
   Description: Cognitive decline and dementia due to Alzheimer's Disease, both associated with advancing age over 65, are increasing in the US due to the reduction of other illnesses that, in the past, limited life expectancy. This project will provide a brief, comprehensive assessment tool (in English and Spanish versions), applicable to diverse populations, to screen for a decline in cognitive health and associated neurological functions. The burden of age-related cognitive decline and dementia on older adults and the health care system make their early identification a critical public health goal in order to pave the way for prevention trials.
   Overlap: none

Previous funding:

- Online Symptom-Monitoring/Self-Management for Pandemic-Related Emotional Distress (ACCEL), ended 06/30/2022

Pamela Kisala, MA

New funding:

1. Title: iManage-Sexual Wellness: Development of a symptom-monitoring/self-management program to enhance sexual wellness after SCI and TBI
   Funding Agency: National Institute on Disability, Independent Living, and Rehabilitation Research
   Project dates: 2/4/2022 – 08/31/2025
   Effort: 1.6 calendar
   Description: The goal of this five-year project is to create and evaluate a web-based symptom-monitoring/self-management system to improve sexual wellness in individuals with SCI or TBI.
   Overlap: none

Previous funding:

- Online Symptom-Monitoring/Self-Management for Pandemic-Related Emotional Distress (ACCEL), ended 06/30/2022

Aaron Boulton, PhD

New funding:

1. Title: iManage-Sexual Wellness: Development of a symptom-monitoring/self-management program to enhance sexual wellness after SCI and TBI
   Funding Agency: National Institute on Disability, Independent Living, and Rehabilitation Research
   Project dates: 2/4/2022 – 08/31/2025
   Effort: 0.12 calendar
   Description: The goal of this five-year project is to create and evaluate a web-based symptom-monitoring/self-management system to improve sexual wellness in individuals with SCI or TBI.
   Overlap: none

Previous funding:

Nothing to report

Trevor Dyson-Hudson, MD
New funding:
Nothing to Report

Previous funding:
Nothing to report

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

Previous funding:
Nothing to Report

Denise Fyffe, PhD
New funding:
Nothing to Report

Previous funding:
Nothing to report

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

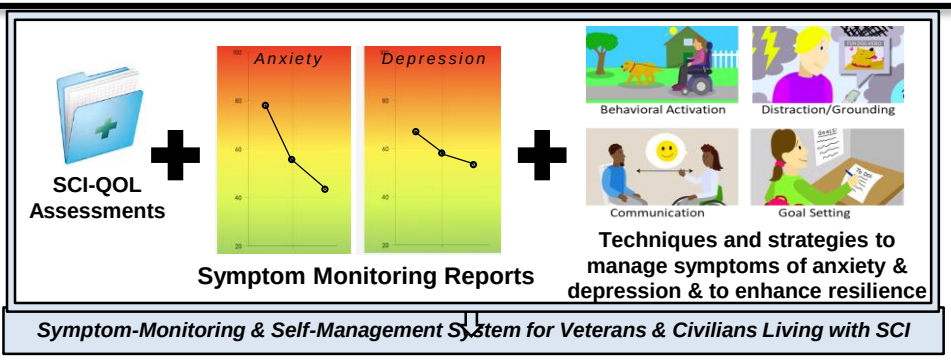
PI: David Tulsky, Ph.D. **Organization:** University of Delaware **Award Amount:** $1,748,467

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 IRB and HRPO approvals/exemptions have been obtained. The UD and EO VA teams are fully ready for the Aim 1 Demonstration Sessions, including the REDCap databases and training materials. Significant progress has been made on the Aim 2 activities of creating the active control condition materials and drafting the pilot clinical trial protocol for Aim 3. The project team launched quarterly meetings with Consumer Advocates and held an in-person team meeting for all project investigators, staff, and Consumer Advocates in June 2022. We met with the IT vendor and animator to review preliminary changes to iManage-SCI system and videos.

Timeline and Cost

Activities	Year 1	Year 2	Year 3
Obtain regulatory and administrative approvals			
Consult with consumer advocates, conduct Data Safety Monitoring Board meetings			
Prepare REDCap database, training materials, and train RAs (for Feasibility Testing data collection)			
Conduct 1-on-1 Demonstration Sessions and analyze Feasibility Testing data			
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 Pilot Clinical Trial data collection)			
Conduct Pilot Clinical Trial and analyze data			
Disseminate study results			
Estimated Budget ($K)	*$564*	*$576*	*$608*

Note: UD = University of Delaware; EOVA = East Orange VA; KF = Kessler Foundation
Updated: 30-Sept-2022

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: ***$1,178,362***
Actual Expenditure: ***$27,578***

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.