**AWARD NUMBER:** W81XWH-20-1-0786

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

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

**CONTRACTING ORGANIZATION:** University of Delaware, Newark, DE

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Fort Detrick, Maryland 21702-5012

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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 based method of reducing mental health symptoms and increasing resilience among individuals with SCI. During Project Year 1, the team encountered multiple COVID-related and regulatory obstacles. We have now obtained conditional IRB approval at Kessler, a formal exemption from the Single IRB requirement of the Common Rule for the East Orange VA, and the East Orange VA IRB approval is currently pending. HRPO documents have been prepared and will be submitted as soon as all IRB approvals are in place. To ensure adequate funds will remain to complete all aspects of the project once approvals are in place, we have not spent any grant funds during year 1. We have worked on "back-end" tasks related to preparation and training for Aim 1 and will be ready to start data collection as soon as we receive HRPO approval.

**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 most 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 Cooperative Research and Development Agreements (CRADA) for three sites and data use agreements (DUAs) for all sites. 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 | 75% |
| 0.3 Obtain initial HRPO approvals | 0 |
| 0.4 Consultation with consumer advocates | 0 |
| 0.5 Oversight by Data & Safety Monitoring Board (DSMB) | 0 |
| 0.6 Obtain IRB and HRPO continuing approvals | 0 |
| *Milestone: Local IRB approval at all sites* | 75% |
| *Milestone: HRPO approval at all sites* | 0 |
| *Milestone: Consultation provided by consumer advocates* | 0 |
| *Milestone: Project overseen by DSMB* | 0 |
| ***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 | 80% |
| 1.2 Prepare research assistant (RA) training materials | 80% |
| 1.3 Train UD RAs for data collection | 25% |
| 1.4 Conduct 1-on-1 demonstration sessions | 0 |

| | |
|---|---|
| 1.5 Analyze demonstration session data | 0 |
| 1.6 Determine iManage-SCI modifications | 0 |
| 1.7 Revise and/or create self-management videos | 0 |
| 1.8 Update iManage-SCI platform | 0 |
| *Milestone Achieved: iManage-SCI optimized for Veterans* | 0 |
| *Milestone Achieved: iManage-SCI platform prepared for pilot clinical trial* | 0 |
| ***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 | 0 |
| 2.2 Create active control condition materials | 35% |
| 2.3 Draft clinical trial protocol | 35% |
| 2.4 Conduct 2 Stakeholder Advisory Board meetings (to review videos) | 0 |
| *Milestone: DSMB structure and processes finalized* | 10% |
| *Milestone: Active control condition materials finalized* | 35% |
| *Milestone: Pilot clinical trial protocol finalized* | 35% |
| ***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 |
| *Milestone: Pilot study first participants enrolled* | 0 |
| *Milestone: Pilot study 50% completed* | 0 |
| *Milestone: Pilot Study Completed* | 0 |
| *Milestone: Aim III of Study Completed* | 0 |

**What was accomplished under these goals?**

During Year 1, obstacles in obtaining regulatory approval have impacted our ability to move forward in certain areas of our project. Initially, there were some pandemic-related delays in obtaining the IRB review at the University of Delaware. Once it reviewed the submitted protocol, the UD IRB required a single IRB and asked if one of the collaborating medical centers could serve in that role. Subsequently, the Kessler IRB agreed to serve as the IRB of record for this study, and the project has been conditionally approved at Kessler. At the same time, the East Orange VA preferred to obtain approval locally from their IRB, and they have applied for and received an exemption from the Single IRB requirement of the Common Rule. Approval of the East Orange VA IRB is currently pending. **Since we have not yet received regulatory approval, no grant funds have been used during this period (that is, since this is the initial year of the project, no grant funds have been spent to date).** Nonetheless, we have been able to make progress in preparing "back-end"/non-human-subjects materials for our Aim 1 demonstration sessions and we have begun to refine our procedures for the Aim 3 pilot clinical trial, including development of the active control condition and the clinical trial protocol.

**Major Task 0.1 Obtain VA privileges (i.e., "WOC status") for UD Investigators, if necessary**

We were advised by our collaborators at East Orange VA (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**

We began preparation of our IRB materials for the study immediately upon notice of our award. Due to the pandemic, UD's IRB has had more limited capacity to review new studies. On 12/9/20, the UD IRB responded

to our protocol submission with a request for a unified protocol, including EOVA and Kessler entering reliance agreements. The UD IRB also mentioned that if one of the medical centers that have experience treating people with SCI would serve as the lead site, this would be preferable.

The EOVA had voiced their preference to submit their own IRB application. Following extensive communication among the UD study team, the UD IRB, the EOVA study team, and the EOVA IRB, the VA Office of Research and Development granted a VA Cooperative Research Provision Exception for the East Orange VA on 3/29/21. UD study staff prepared study documents, including a protocol, demographic questionnaire, HIPAA waiver, medical record abstraction form, and interview questions for the EOVA study staff to review and send to their local IRB.

Furthermore, it was collaboratively decided that the Kessler IRB would serve as the single IRB of record for this project (that is, the UD IRB would rely on the Kessler IRB). UD study staff prepared a protocol, demographic questionnaire, HIPAA waiver, medical record abstraction form, and interview questions for the Kessler study staff to review and submit to their local IRB. We recently received conditional approval from the Kessler IRB for our project. We have also prepared reliance materials for the UD IRB; approval of these materials is currently pending.

**Major Task 0.3 Obtain initial HRPO approvals**

We have preliminarily prepared all the UD HRPO submission materials; however, we have not yet submitted them pending full IRB approval at Kessler and the EOVA.

**Major Task 0.4 Consultation with consumer advocates**

We have not yet engaged with our consumer advocates. We plan to do so following Major Task 1.4 to obtain consumer feedback about the changes we will make to iManage SCI. We are hopeful that it will be possible to have in-person meetings at Kessler to discuss the iManage program and receive consumer advocates' feedback on an ongoing basis once we have regulatory approval and data collection and preparation of the clinical trial begins.

**Major Task 1.1 Prepare REDCap database for data collection**

During Year 1, the UD team worked to prepare the REDCap database for Aim 1 data collection as part of Major Task 1.4, including programming the demographic questionnaire, the cognitive debriefing interview, and the video feedback survey into REDCap. Specifically, for the REDCap database, all the measures have been programmed, but the logic and transitions are still in progress. Once all components have been finalized, we will implement an extensive QA process to assure the database will be ready for data collection.

**Major Task 1.2 Prepare research assistant (RA) training materials**

During Year 1, the UD team worked to prepare the data collection documents and procedures that comprise the RA training materials for Major Task 1.4 demonstration sessions. These documents include recruitment procedures, instructions on the study flow, site communication, and participant compensation. Initial drafts of these training materials are approximately 80% complete. Full IRB approval, additional multisite review and UD team revisions will be needed before these materials will be considered final.

**Major Task 1.3 Train UD RAs for data collection**

The primary UD RA who will be conducting the demonstration sessions has been trained by a data collector on a similar, civilian-focused project, forming the initial basis of the Major Task 1.3 data collector training. Once preceding major tasks have been completed, this training effort will further progress.

**Major Task 2.2 Create active control condition materials**

During Year 1, we have adapted an interactive eHealth active control condition into 6 discrete PowerPoint presentations with accompanying scripting. Each of these will be recorded as a screen capture and will serve as the active control condition videos for each of the 6 weeks of the project. The 6 sessions cover the following topics: Healthy Behaviors, Nutrition, Pain Management, Sleep Hygiene, Bowel Management, and Pressure Ulcers. The remaining steps of this task are final review of slides and scripts by EOVA, Kessler, and UD investigators and completing the screen capture recordings.

**Major Task 2.3 Draft clinical trial protocol**

During Year 1, the UD team has begun to draft the clinical trial protocol that will be submitted to Clinicaltrials.gov. This protocol includes definitions of adverse events and how they will be approached by the study team, explanations of study procedures and data management and handling practices. Furthermore, we have had multiple meetings with the investigators at Kessler and the EOVA to identify and streamline recruitment and screening 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 before this protocol is considered final.

### 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 believe we are close to overcoming the obstacles in receiving regulatory approval. Our primary goal is thus to obtain approval at all sites and submit to HRPO for protocol review. As soon as approvals are in place, we will begin to engage with our consumer advocates to incorporate their input throughout the project.

We will continue to finalize all back-end work so that data collection can start as soon as we receive regulatory approvals. We will finalize the REDCap database (Major Task 1.1) and perform the necessary QA checks so that the study is ready for data collection. We will also finalize the training materials (Major Task 1.2) and conduct data collector training (Major Task 1.3), so that Major Task 1.4, demonstration session data collection, can launch upon regulatory approval. Once this data collection effort to gather input from Veterans with SCI about the iManage-SCI program is complete, we will begin working with the program development vendor (BrightOutcome) and illustrator (George Berlin) to modify the iManage-SCI platform and content as needed. Once modifications based upon Veteran feedback from Major Task 1.4 is complete, we will prepare the platform for the Aim 3 Pilot Clinical Trial and finalize our active control condition videos.

Later in Year 2, we plan to elicit formal feedback and reviews from our consumer advocates. After the Major Task 1.4 is completed, we will (if health protocols permit) have an in-person meeting at Kessler to obtain the consumer advocates' input on the current version of the iManage-SCI system.

Finally, later in Year 2, we will also meet with Claire Kalpakjian, chair of the DSMB, to establish DSMB procedures and a meeting schedule for when the pilot clinical trial is ready to launch (in Year 3).

## 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 been overcoming obstacles to obtain regulatory approval, we have made significant progress on the back-end tasks that will allow us to initiate data collection shortly after the regulatory approvals are obtained. We are working with our collaborating sites to identify challenges and to help increase the pace of project approvals. Our approach has not changed; only our timeline will need to be modified accordingly.

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

As mentioned previously, the COVID-19 pandemic caused delays for the initial regulatory review at the University of Delaware. Then, the UD IRB requested that we seek a unified protocol due to the "Cooperative Research" requirement from the Common Rule and suggested that one of our sites that is a medical facility would be better equipped to serve as the single IRB site. At the same time, the EOVA requested to pursue IRB approval locally and applied for an exemption from the Common Rule.

Fortunately, the bulk of the IRB delays appear to be behind us. EOVA has obtained an exemption from the Single IRB requirement of the Common Rule from the VA. The EOVA IRB application has been prepared and local IRB review/approval is pending. Kessler has agreed to serve as the IRB of record for the study and has recently received conditional approval from its IRB. Reliance documents are being prepared by the UD IRB and we anticipate a resolution of this process during quarter 1 of year 2. We will submit HRPO documents (for which we have already prepared initial drafts) as soon as the IRB approvals are in place.

To mitigate these delays, we have been working on project “back-end” activities to prepare for the launch of Major Task 1.4 demonstration sessions once regulatory approvals are in place. Most important is that we have not yet billed effort to the project for these start-up activities and **will not spend any grant funds until we successfully receive 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.

### Changes that had a significant impact on expenditures

While the delays described above have impacted the timing of expenditures, no changes 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?

***Note: No grant funds were used during this period, as we are awaiting regulatory approval. Selected study personnel have contributed effort to planning for and preparing IRB documents and other materials.***

**Name: David Tulsky, PhD**
Project Role: Project PI
Researcher Identifier (e.g. ORCID ID): 0000-0002-4335-4509
Nearest person month worked: 0
Contribution to Project: No change

**Name: Jerry Slotkin, PhD**
Project Role: Co-I
Researcher Identifier: 0000-0001-8199-3056
Nearest person month worked: 0
Contribution to Project: No change

**Name: Pamela Kisala, MA**
Project Role: Co-I
Researcher Identifier: 0000-0003-3234-795X
Nearest person month worked: 0
Contribution to Project: No change

**Name: Aaron Boulton, PhD**
Project Role: Co-I
Researcher Identifier: 0000-0001-7349-162X
Nearest person month worked: 0
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: 0
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: 0
Contribution to Project: Dr. Fyffe facilitated the Kessler IRB submission and provided input on the Aim 3 clinical trial protocol.

**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: 0
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: Online Symptom-Monitoring/Self-Management for Pandemic-Related Emotional Distress (ACCEL)
   Funding Agency: NIH/NIGMS
   Project dates: 10/1/2020-6/30/2021
   Description: To adapt an existing, web-based “ehealth” symptom -monitoring/self-management system, iManage, to the needs of the general population in the wake of the COVID-19 crisis.
   Overlap: none

2. Title: Relations between motor social and social communication impairments as well as repetitive behavior severity in children with Autism Spectrum Disorder (ASD)
   Funding Agency: NIH
   Project dates: 6/1/2021-3/31/2024
   Effort: 0.24 academic
   Description: We will determine the risk for motor impairment and how that changes with increasing social communication impairment, repetitive behavior severity, comorbidities, and levels of impairment using parent report measures.
   Overlap: none

**Previous funding:**

1. Development of Psychosocial Symptom Monitoring and Self-Management System for individuals with SCI (CNF), ended 2/28/2021
2. Stakeholder Determination of Patient-Reported Outcomes for Adults with Communication Disorders (NIH/NIGMS), ended 11/30/2020

3. Women's Health & Disability: Building a Clinically Relevant Outcome Measure (Univ Mich/NIH), ended 5/31/2021

***Jerry Slotkin, PhD***
**New funding:**

1. Title: Online Symptom-Monitoring/Self-Management for Pandemic-Related Emotional Distress (ACCEL)
   Funding Agency: NIH/NIGMS
   Project dates: 10/1/2020-6/30/2021
   Effort: 0.24 calendar
   Description: To adapt an existing, web-based "ehealth" symptom -monitoring/self-management system, iManage, to the needs of the general population in the wake of the COVID-19 crisis.
   Overlap: none

**Previous funding:**

1. Development of Psychosocial Symptom Monitoring and Self-Management System for individuals with SCI (CNF), ended 2/28/2021

***Pamela Kisala, MA***
**New funding:**

1. Title: Online Symptom-Monitoring/Self-Management for Pandemic-Related Emotional Distress (ACCEL)
   Funding Agency: NIH/NIGMS
   Project dates: 10/1/2020-6/30/2021
   Effort: 0.48 calendar
   Description: To adapt an existing, web-based "ehealth" symptom -monitoring/self-management system, iManage, to the needs of the general population in the wake of the COVID-19 crisis.
   Overlap: none

**Previous funding:**

1. Development of Psychosocial Symptom Monitoring and Self-Management System for individuals with SCI (CNF), ended 2/28/2021

***Aaron Boulton, PhD***
**New funding:**

1. Title: Relations between motor and social communication impairments as well as repetitive behavior severity in children with Autism Spectrum disorder (ASD)
   Funding Agency: NIH
   Project dates: 6/1/2021-3/31/2024
   Effort: 1.80 calendar
   Description: We will determine the risk for motor impairment and how that changes with increasing social communication impairment, repetitive behavior severity, comorbidities, and levels of impairment using parent report measures.
   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, Ph.D.***
**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 - Quad Chart. 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

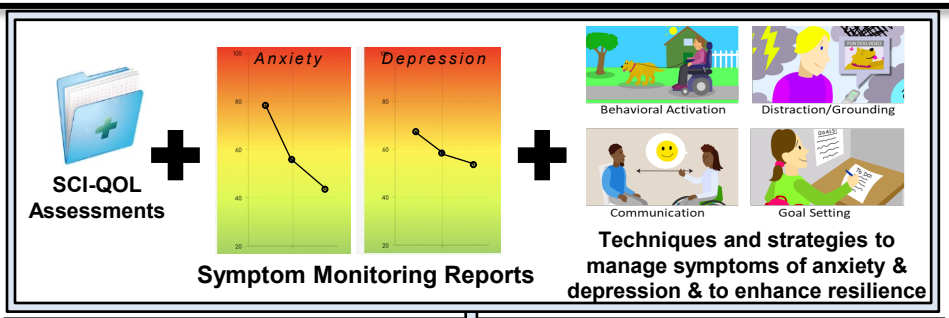
**PI:** David Tulsky, Ph.D. **Organization:** University of Delaware **Award Amount:** $1,748,467

## 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.




***Symptom-Monitoring & Self-Management System for Veterans & Civilians Living with SCI***

**Accomplishments:** UD continued to facilitate extensive communication to resolve regulatory issues among sites. The Kessler Foundation IRB has granted conditional approval for the study. The East Orange VA, which has been granted an exemption to the single IRB requirement from the central VA Office of Research and Development, has drafted its protocol and review by its IRB and R&D teams is pending. The UD study team has continued to work on materials for the Aim 1 demonstration sessions, including the REDCap database and training materials, as well as creating the active control condition materials and drafting the pilot clinical trial protocol for Aim 3.

## 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:** 27-Sept-2021

## 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: ***$565,338***
Actual Expenditure: ***$0***

**Comments/Challenges/Issues/Concerns:** Due to the COVID-19 pandemic and to site-specific requirements, regulatory approvals have been delayed. The timeline has been updated slightly to reflect this. To manage finances and assure project completion, **no grant funds have yet been expended**.