

**AWARD NUMBER:** W81XWH-18-1-0254

**TITLE:** Telepsychology Intervention for Individuals with Spinal Cord Injury and Depression

**PRINCIPAL INVESTIGATOR:** Dr. Kazuko Shem

**CONTRACTING ORGANIZATION:** SANTA CLARA VALLEY MEDICAL CENTER  
San Jose, CA 95128-2604

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**TYPE OF REPORT:** Annual

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# REPORT DOCUMENTATION PAGE

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<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  Santa Clara Valley Medical Center 751 South Bascom Ave. San Jose, CA 95128				<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>				<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> Spinal cord injury (SCI) is often accompanied by the development of mood disorders, particularly depression and anxiety, that affect quality of life (QoL). The objective of this single-center, controlled, randomized, intention-to-treat study is to assess the efficacy of CBT telepsychology intervention via iPad FaceTime on depressive symptomology, anxiety, and QoL compared to usual care. One-hundred sixty adults with acute SCI and mild to moderate depression will be enrolled in the study at the time of discharge from acute inpatient rehabilitation. Subjects will be randomized into the intervention and control groups using a block design in a 1:1 ratio. The CBT intervention will consist of 10 sessions over 12 weeks. All outcome measures will be obtained 2, 14, and 26 weeks post-discharge. Assessments will include the Patient Health Questionnaire-9, Generalized Anxiety Disorder-7, and Satisfaction with Life Scale, as well as demographic, resource utilization, and substance abuse surveys.  No findings are available to date. After study initiation, recruitment and enrollment is ongoing, with 48 potential participants identified and approached, 20 screened, and 10 enrolled. Cognitive Behavioral Therapy began and is ongoing for the active treatment arms.					
<b>15. SUBJECT TERMS</b> Spinal Cord, Spinal Cord Injury, Depression, Anxiety, Quality of Life, Telemedicine, Telepsychology, Psychology, Rehabilitation, Mood, Cognitive Behavioral Therapy					
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## 1. INTRODUCTION:

This study will be a single-center, controlled, and randomized intention-to-treat study. Adults with acute spinal cord injury (SCI) and mild to moderate depression (target sample size of 160) will be enrolled in the study at the time of discharge from Santa Clara Valley Medical Center's (SCVMC) acute inpatient rehabilitation program. Subjects will be randomized into the intervention and usual care control groups using a block design in a 1:1 ratio. Participants in the intervention group will be given an iPad with a 4-month data plan at enrollment. The CBT intervention via iPad FaceTime (two-way video) will consist of 10 sessions (1 hour each) over 12 weeks. All outcome measures will be obtained in a blinded fashion for both groups at baseline (2 weeks post-discharge), 12 weeks post-baseline (short-term assessment), and 24 weeks post-baseline (intermediate assessment). Assessments will include the Patient Health Questionnaire-9, Generalized Anxiety Disorder-7, and Satisfaction with Life Scale, as well as demographic, resource utilization, and substance abuse surveys. Repeated measures of depressive symptomology, symptoms of anxiety, and quality of life will be analyzed using linear mixed models (LMM) or generalized estimating equations (GEE), as appropriate based on initial testing of statistical assumptions.

## 2. KEYWORDS:

Spinal Cord, Spinal Cord Injury, Depression, Anxiety, Quality of Life, Telemedicine, Telepsychology, Psychology, Rehabilitation, Mood, Cognitive Behavioral Therapy

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

**What were the major goals of the project?**

*List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.*

Major Task 1: Study Initiation

Milestone: Local IRB Approval at SCVMC

Y1Q1; 100% complete, Dec. 21, 2018.

Milestone: HRPO approval for all protocols

Y1Q2; 100% complete, Jan. 4, 2019.

Milestone: File structure and database created on secure server

Y1Q1; 100% complete, Dec. 7th, 2018

Milestone: Staff Trained

Y1Q2; 100% complete, Feb. 20, 2019

Milestone Achieved: Randomization chart and database structure created

Y1Q2; 100% Complete, Jan. 15, 2018

Order supplies

Quarterly; 100% complete, Sep. 16, 2019

Major Task 2: Data Collection

Milestone Achieved: Enroll 80 participants

Y2Q4; 12.5% complete

Milestone Achieved: Complete Enrollment (160 participants)

Y4Q1; 6.25% complete

Milestone Achieved: Complete data collection on 80 participants

Y3Q2; 0% complete

Milestone Achieved: Complete data collection (160 participants)

Y4Q3; 0% complete

Major Task 3: Data Management

Milestone: Complete data entry (baseline, short-term, and intermediate assessments) on 80 participants (40 usual care and 40 intervention)

Y3Q2; 0% complete

Milestone Achieved: Complete data entry (160 participants)

Y4Q3; 0% complete

Clinical Trial Monitor Biannual;

Biannual; 0% complete

Major Task 4: Data Analysis and Dissemination

Milestone Achieved: Preliminary data analysis

Y2Q2; 0% complete

Milestone Achieved: Midway data analysis

Y3Q1; 0% complete

Milestone Achieved: Final cohort analysis

Y4Q4; 0% complete

Milestone Achieved: Submit findings to scientific conference

Y2Q3- Y4Q4; 0% complete

Milestone Achieved: Submit scientific manuscript for publication

Y3Q1- Y4Q4; 0% complete

**What was accomplished under these goals?**

*For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.*

During the first year of the study, HRPO and local IRB approvals were obtained, and network folder structures were created, including a folder on a secure network drive for storage of patient data, managed by the local IT Department. Staff training was completed for all study assessments and data storage and management. Regular staff meetings were organized and held to coordinate staff training, supply ordering, regulatory compliance, subject recruitment, and data collection. Recruitment and enrollment were initiated, with 48 potential participants identified and approached, 20 screened, and 10 enrolled. Cognitive Behavioral Therapy began and is ongoing for the active treatment arms.

**What opportunities for training and professional development has the project provided?**

*If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. “Training” activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. “Professional development” activities result in increased knowledge or skill in one’s area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.*

All assessors have completed a training on the study assessments, which was conducted by the study psychologist or online MoCA certification module.

**How were the results disseminated to communities of interest?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.*

Nothing to Report.

**What do you plan to do during the next reporting period to accomplish the goals?**

*If this is the final report, state “Nothing to Report.”*

*Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.*

During the next reporting period, we plan to continue recruitment and enrollment, begin preliminary data analysis, and submit biannual reports to the Clinical Trial Monitor.

**4. IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

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

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

A Cognitive Behavioral Therapy protocol was developed specifically for this project that is tailored for persons with Spinal Cord Injury. This may help to more effectively treat depression in this population.

**What was the impact on other disciplines?**

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

**What was the impact on technology transfer?**

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- transfer of results to entities in government or industry;
- instances where the research has led to the initiation of a start-up company; or
- adoption of new practices.

Nothing to Report.

**What was the impact on society beyond science and technology?**

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- improving public knowledge, attitudes, skills, and abilities;
- changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or
- improving social, economic, civic, or environmental conditions.

Newly developed techniques and approaches for this project may help provide psychological services to persons with spinal cord injury after they are discharged back to the community. Additionally, this study may provide a better understanding of psychological and quality of life changes in this population.

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

**Changes in approach and reasons for change**

*Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.*

Nothing to Report.

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

*Describe problems or delays encountered during the reporting period and actions or plans to resolve them.*

Recruitment was initially slower than expected. Implementation of new approach techniques, including physician involvement via warm hand-offs to research assistants, has helped to increase recruitment rates.

New systems were set up within county procurement and technology management departments to prevent future delays in purchasing of iPads for the study.

The standard language for the contract between Santa Clara Valley Medical Center and University of California, San Francisco is currently under negotiations between both institutions. The details of the contract that pertains to the scope of work being performed and the compensation being provided is not in dispute. Once the standard language is agreed upon, this contract should be executed. The contract between Santa Clara Valley Medical Center and Dr. Hoffman was delayed to resolve questions regarding the type of data being reviewed by Dr. Hoffman. County Legal and Compliance Departments have forwarded the final contract revision to Dr. Hoffman and we are awaiting an executed copy.

**Changes that had a significant impact on expenditures**

*Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.*

Nothing to Report.

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

*Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.*

## Significant changes in use or care of human subjects

Suicidal Ideation plan and updated Protocol, ICF, and HIPAA submitted to local IRB for review: August 07, 2019

Approved by local IRB: August 07, 2019

Not a substantive change.

## 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:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**

*Report only the major publication(s) resulting from the work under this award.*

**Journal publications.** *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume; year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report.

**Books or other non-periodical, one-time publications.** *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report.

**Other publications, conference papers and presentations.** *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (\*) if presentation produced a manuscript.*

Shem, K., Held, M., Ota, D. (2019, November). Telemedicine: Bringing Specialized Care to Persons with Spinal Cord Injury. Presentation at American Congress of Rehabilitation Medicine 96th Annual Conference, Chicago, IL. (Accepted, awaiting presentation and conference abstract publication)

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Clinical Trials.gov Page:

<https://clinicaltrials.gov/ct2/show/NCT03711760>

Project page on the ClinicalTrials.gov site.

Research Center Active Projects Page:

<https://www.scvmc.org/health-care-services/Rehabilitation/Rehabilitation-Research-Center/Pages/Research-Projects.aspx>

Page containing summaries of all major projects being run by the Rehabilitation Research Center at Santa Clara Valley Medical Center. Will include links to published articles when available.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report.

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report.

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- data or databases;
- physical collections;
- audio or video products;
- software;
- models;
- educational aids or curricula;
- instruments or equipment;
- research material (e.g., Germplasm; cell lines, DNA probes, animal models);
- clinical interventions;
- new business creation; and
- other.

Nothing to Report.

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

*Name:* Dr. Kazuko Shem  
*Project Role:* Principal Investigator  
*Researcher Identifier:* 0000-0002-9267-025X  
*Nearest person month worked:* 2  
*Contribution to Project:* Dr. Shem has monitored research progress, provided clinical and research supervision, and led research meetings.  
*Funding Support:* N/A

*Name:* Dr. Mark Held  
*Project Role:* Sub-Investigator  
*Researcher Identifier:* N/A  
*Nearest person month worked:* 1  
*Contribution to Project:* Dr. Held has provided clinical supervision and performed Cognitive Behavioral Therapy for the active treatment arms.  
*Funding Support:* N/A

*Name:* Ben Dirlikov  
*Project Role:* Sub-Investigator  
*Researcher Identifier:* 0000-0002-9987-5178  
*Nearest person month worked:* 2  
*Contribution to Project:* Mr. Dirlikov has monitored research progress and provided research supervision.  
*Funding Support:* N/A

*Name:* Cria-May Khong  
*Project Role:* Research Assistant  
*Researcher Identifier:* N/A  
*Nearest person month worked:* 5  
*Contribution to Project:* Ms. Khong has performed work in the areas of subject recruitment, subject follow-up, subject safety monitoring, coordination between the psychologist and the participants, and data entry.  
*Funding Support:* N/A

*Name:* Michael Prutton  
*Project Role:* Research Associate  
*Researcher Identifier:* N/A  
*Nearest person month worked:* 2  
*Contribution to Project:* Mr. Prutton has performed work in the areas of compliance, blinded data collection, and data entry.  
*Funding Support:* N/A

<i>Name:</i>	Kathleen Dossetti
<i>Project Role:</i>	Administrative Support
<i>Researcher Identifier:</i>	N/A
<i>Nearest person month worked:</i>	1
<i>Contribution to Project:</i>	Ms. Dossetti has provided administrative support to the study team and managed inventory.
<i>Funding Support:</i>	N/A

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

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.*

<b>Dr. Kazuko Shem (Closure of Previously Active Grant)</b>	
<i>Title:</i>	Weight Management in Spinal Cord Injury – Intervention and Monitoring via Tele-Nutrition (PI - Shem)
<i>Time Commitment:</i>	0.3 calendar months
<i>Support Agency:</i>	Christopher and Dana Reeve Foundation
<i>Funding Agency Contact:</i>	Donna Valente
<i>Telephone:</i>	
<i>Email:</i>	
<i>Performance Period:</i>	07/01/2018- 06/30/2019
<i>Level of Funding:</i>	
<i>Project Goals:</i>	The aim of this project was to show that nutrition counseling and monitoring via tele-nutrition by a Registered Dietitian Nutritionist (RDN) can improve quality of life and maintain weight in persons with SCI
<i>Specific Aims:</i>	<ol style="list-style-type: none"> <li>1) Prospectively evaluate changes in QoL pre- and post-tele-nutrition counseling as measured by the Life Satisfaction Index-A.</li> <li>2) Prospectively evaluate changes in body mass index (BMI) and waist circumference pre- and post- tele-nutrition counseling.</li> </ol>

**What other organizations were involved as partners?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.*

*Provide the following information for each partnership:*

*Organization Name:*

*Location of Organization: (if foreign location list country)*

Partner's contribution to the project (identify one or more)

- Financial support;
- In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);
- Facilities (e.g., project staff use the partner's facilities for project activities);
- Collaboration (e.g., partner's staff work with project staff on the project);
- Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and
- Other.

Dr. Jeanne Hoffman  
1959 NE Pacific St., Seattle, WA 98195  
Other - Clinical Trial Monitor  
Contract pending approval

University of California, San Francisco  
533 Parnassus Ave, San Francisco, CA 94143  
Other – Biostatistician services (Dr. Adam Ferguson)  
Contract pending approval

**8. SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:**

Not Applicable

**QUAD CHARTS:**

Quad Chart Attached.

**9. APPENDICES:**

Not Applicable