AD

AWARD NUMBER:
W81XWH-14-1-0584

TITLE: Successful Strategies for Activity and Wellness after Spinal Cord Injury

PRINCIPAL INVESTIGATOR: Beatrice Kiratli PhD

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Palo Alto, CA 94304

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14. ABSTRACT

The purpose of this study is to identify best practices for overcoming and adapting one’s life to spinal cord injury (SCI). This study takes a more positive point of view and identifies strategies that enable persons living with SCI to successfully navigate the barriers and limitations. Our goal is to better understand the motivations, practices, and strategies used by people with SCI to combat inactivity and achieve healthier lifestyles. Through this reporting period, recruitment for year one is 92% complete (37/40) with 25% of transcript analysis accomplished. Staff training in qualitative research and use of mind mapping software has been completed with rapid progress being made on data analysis. Patient-centered summaries and cross-interview codes are being developed and discussed in preparation to designing the codebook to be implemented toward identification of Key Themes which is the primary activity for the next quarter. Recruitment for Phase 2 (mixed qualitative and quantitative study to apply findings of Phase 1) is 90% complete and a testing schedule is in progress.
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</table>
1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

   The purpose of this study is to identify best practices for overcoming and adapting one’s life to spinal cord injury (SCI). After SCI, many people reduce their levels of physical activity which contributes to weight gain and greater risk of diabetes and cardiovascular disease and overall decreased quality of life; this effect is compounded with aging. Prior studies have identified the barriers people with SCI face to participating in activity such as transportation problems, limited availability of accessible facilities, and low motivation and body image. Nonetheless, there are many people with SCI who find ways around these hurdles and adopt active lifestyles despite their disability. Rather than focusing on the barriers and limitations of persons living with SCI, we plan to take a more positive point of view and look for the “success stories,” that is, people who have identified strategies that enable them to successfully navigate the barriers. The overarching goal of this study is to better understand the motivations, practices, and strategies used by people with SCI to combat inactivity and achieve healthier lifestyles. This information can be then be incorporated into clinical and therapeutic support programs to motivate those who are less active.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

   Paralysis
   Physical Activity
   Qualitative Research
   Lifestyle
   Social Participation
   Health Behavior
3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

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

<table>
<thead>
<tr>
<th>Major Goals/Specific Aims:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Obtain community/stakeholder input and define activity paradigm.</td>
</tr>
<tr>
<td>Completion projected – Month 3; Expected Month 15.</td>
</tr>
<tr>
<td>2) Obtain information on attitudes toward wellness and strategies for being active by use of qualitative methods. Completion projected - Month 12; Expected Month 15.</td>
</tr>
<tr>
<td>3) Evaluate similarities and differences in behavioral and psychosocial constructs between persons with SCI who are active in the community and those who are not active; Explore physical, physiologic, and health correlates that may (i) correspond with self-perception of activity and (ii) differ between individuals with SCI who are active and those who are not.</td>
</tr>
<tr>
<td>Completion (i) projected – Month 15; Expected Month 18</td>
</tr>
<tr>
<td>Completion (ii) projected – Month 24</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Milestones – Year 1</th>
<th>Projected Completion</th>
<th>% Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Formation of SCI Community Research Advisory Board and Meeting Schedule</td>
<td>12 month</td>
<td>60%</td>
</tr>
<tr>
<td>2) Consensus definition of activity, based on meaningful input from stakeholders</td>
<td>12 month</td>
<td>50%</td>
</tr>
<tr>
<td>3) Comprehensive list of local resources encompassing all ability levels</td>
<td>12 month</td>
<td>75%</td>
</tr>
<tr>
<td>4) Publication of results</td>
<td>12 month</td>
<td>25%</td>
</tr>
</tbody>
</table>
What was accomplished under these goals?

Accomplishments are presented in alignment with the Statement of Work (SOW) approved at study initiation. Qualitative research is heavily dependent on the processes of acquisition and review of information as precursor to interpretation. We have achieved and surpassed goals related to processes; descriptive and summative outcomes are under development, but no specific findings are yet reportable.

Specific Aim 1: Obtain community/stakeholder input and define activity paradigm

**Major Activities**

Task 1. Establish SCI Community Research Advisory Board. Members will be recruited to include individuals with SCI (veterans and non-veterans, male and female, with tetraplegia and paraplegia) as well as non-disabled individuals who regularly work with persons with SCI in non-medical settings. Advisory Board members will not serve as research participants.

**Specific Objective**
- Identify a panel of engaged community members to provide input to research team on study outcomes.

**Key Outcomes**
- Board members have been identified to include a range of male and female, recently injured and those with chronic injuries, a range of levels of SCI, Veteran and non-Veterans

Task 2. With input from the SCI Community Research Advisory Board, establish a working definition of “activity” to guide interview strategies.

**Specific Objectives**
- Establish research priorities from the perspective of community members and stakeholders
- Establish an operational definition of “activity” taking into consideration both the potential relevance to health outcomes and the range of abilities and limitations of persons with SCI at different levels

**Key Outcomes**
- In early project planning including discussions with stakeholders, it was determined that this objective could not be met a priori and would require study data to decide. In fact, this is the core of the project – to explore through inquiry (ie, qualitative methods) the perspectives and attitudes of the community. Therefore, the convening of this Board is delayed until Year 2.

Task 3. Review proposed selection of community resources and solicit input from the SCI Community Research Advisory Board regarding additional programs/resources.

**Specific Objectives**
- Establish a comprehensive compilation of community resources.

**Key Outcomes**
- Our initial list included commonly identified resources, confirmed by community members. This has continued to expand as interviews are completed and new resources identified by individual stakeholders.

Goals not Met
- The formal convening of an SCI Community Advisory Board was not achieved per original SOW. The reasons for this include significant delay in hiring and completing administrative initiation activities and a subsequent focus on developing training for research team members on qualitative methods (detailed below). However, in discussions with individual stakeholders/community members and further consideration of study methodology, we decided to maintain a broad definition at the outset and proceed with the interviews. In fact, the interview guide was expanded to include additional categories to ensure that each participant would have the opportunity to provide a comprehensive narrative from his/her perspective.
Specific Aim 2: Obtain information on attitudes toward wellness and strategies for being active by use of qualitative methods.

Major Activities

Task 1. Project Planning. Define scope of work, timelines, project plan and expectations for first phase, and obtain interview equipment for research teams. Formalize team meeting structure and schedules.

Specific Objective
a. Define scope of work, timelines, project plan and expectations for first phase, and obtain interview equipment for research teams.
b. Formalize team meeting structure and schedules.

Key Outcomes
- Detailed project planning was accomplished among key investigators.
- Equipment was identified and acquired. This included video equipment as opposed to a single camera per original proposal as it was determined that interviews in the home should include expanded documentation of in-place resources and spatial orientation. In addition, laptops were requested for study staff to facilitate collecting field notes during interviews. Note that this did not incur extra project costs as laptops were supplied by VA.
- Information technology needs were identified to include the need for significantly expanded storage space on the secure VA server as well as VPN (remote access) for all study team members.
- Regular team huddles were scheduled with structured agendas to review project goals and establish action plans.

Task 2. Conduct training of staff in qualitative methods to include workshops, practice sessions of interview techniques, and protocols for information management.

Specific Objectives
a. Create tailored content and exercises
b. Conduct training workshop with field exercises for conducting focus groups and semi-structured interviews
c. Establish schedule for integration into SCI Center activities and exposure to routine care and lifestyle issues

Key Outcomes
- Extensive training materials were developed by Dr. Dalal to introduce all study staff to qualitative methods from a theoretical framework. This includes a series of PowerPoint slides on applying ethnographic methodology within the clinical setting and detailed instructions on interviewing.
- Numerous training sessions occurred and field exercises were implemented to accomplish training ethnographic methods. Training focused on: conducting interviews with probing inquiry, listening skills, identification of interviewer biases prior to and during interviews, taking field notes, viewing videotapes and observing behavioral cues.
- All study staff were integrated into SCI Center activities including orientation by study PI as well as inclusion in SCI Center staff meetings and daily functioning.

Task 3. Develop interview guides and recruiting criteria and review with staff procedures related to obtaining informed consent. (overlaps with Tasks 1 & 2)

Specific Objectives
a. Create the following documents: recruiting criteria for research participants, interview guides for veterans and caregivers, interview guide for focus groups
b. Pilot test interview guides in real time; revise and update protocols, if needed. Repeat training, if needed.
c. Refine IRB protocol and submit modification(s) for review, if needed.
d. Obtain final IRB and HRPO approvals.

**Key Outcomes**
- All study materials were developed through an iterative method incorporating input from study team and stakeholders, interactive discussions, pilot testing and revision.
- A screening protocol was developed for recruitment to incorporate detailed eligibility (in- and exclusion criteria). A formal screening form was implemented and revised. Recruitment materials were developed to include flyers, letters, and postings (newsletter and online). A methodology was developed for tracking calls and potential interest and scheduling, including the consent tracking log.
- All needed local and DoD approvals were obtained.

**Task 4. Begin data collection for focus group sessions and semi-structured interviews**

**Specific Objectives**
- **a.** Recruit and schedule focus groups and interviews.
- **b.** Conduct 5 focus groups or 10 dyads.
- **c.** Conduct interviews, observations; with field notes, questions, issues lists.

**Key Outcomes**
- Recruited and screened a total of 37 individuals in Year 1.
- Completed interviews per protocol.

**Task 5. Interim data analysis.**

**Specific Objectives**
- **a.** Create data summaries, video and textual data extracts for weekly co-viewing sessions.
- **b.** Data management and organization (upload large audio-visual files, convert formats for transcripts, log interviews).

**Key Outcomes**
- Interim analysis completed; data collection and analysis protocols refined, revised and streamlined.
- Data stream procedures refined for uploading, conversion, and management of large AV files.
  Support from VA Information Technology Service has been essential to navigate security issues.

**Task 6. Complete data collection, target total is 40 individuals.** (concurrent with Tasks 4 & 5)

**Specific Objectives**
- Complete enrollment, interviews, review of transcripts, and data entry into spreadsheet.

**Key Outcomes**
- Interviews have been completed on 37 individuals who are representative of a breadth of demographics.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Injury Level</th>
<th>Age</th>
<th>SCI Duration</th>
<th>Veteran Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>Tetraplegia 54%</td>
<td>&lt; 50</td>
<td>≤ 6 years</td>
<td>Veteran 54%</td>
</tr>
<tr>
<td>Female</td>
<td>Paraplegia 46%</td>
<td>≥ 50</td>
<td>&gt; 6 years</td>
<td>Non-Vet 46%</td>
</tr>
</tbody>
</table>

- Multi-level, iterative review of transcripts and derived information by study team dyads and in group discussion has been instrumental in developing concurrence on codes for data entry.

**Task 7. Complete data analysis, analyze, interpret findings, and disseminate findings.**

**Specific Objectives**
- **a.** Analyze corpus of transcripts, field notes, summaries, audio and video data.
- **b.** Conduct series of 2 hour co-viewing sessions.
- **c.** Collate and draft findings.
- **d.** Prepare manuscript(s) and submit to peer-review; revise and re-submit as needed for publication.
**Key Outcomes**

- 92% interviews completed and data analysis in process with preliminary identification of Key Themes; this includes establishing processes for obtaining accurate transcription, systematic error-checking and verification of information, and structured coding.
- MindMap software was acquired for graphic processing as an aid to begin to identify key themes from transcript data. 25% MindMaps completed. Content for the MindMaps was developed based on precodes (topics and domains in the interview guide) as well as emerging codes gleaned from reviews and discussions of each interview. A draft of the patient-centered Codebook is in process, which seeks to balance data that is both quantifiable (e.g. the number of assistive devices people use in their homes) and reveal qualitative insights (e.g., how and what those devices are used for).
- Interim analysis has identified preliminary key themes including i) availability of equipment in the home and ii) importance of support systems.

**Goals Not Met**

1. Participant enrollment and data collection was not completed in Year 1 as originally projected.
2. Focus groups with support personnel (e.g., gyms, adaptive education, coaches) was purposely delayed until individual interview data could better inform targeted discussion topics and relevant themes.
3. Manuscript submission was not completed in Year 1 as originally projected.

**Specific Aim 3: Evaluate similarities and differences in behavioral and psychosocial constructs between persons with SCI who are active in the community and those who are not active**

**Major Activities**

**Task 1. Project Planning for Study 2 (Quantitative data collection)**

**Specific Objectives**

a. Develop structured questionnaires and select outcome measures, based on findings from focus groups and semi-structured interviews.

b. Train staff on measurement protocols and data collection procedures.

**Key Outcomes**

- Specific questionnaires are in development based on preliminary analysis; expected to be completed in Quarter 1 of Year 2. Outcome measures are designed to reflect codes and themes from interview data in order to facilitate comparison of qualitative and quantitative findings.
- Study staff have been trained in assessment techniques.

**Task 2. Study Initiation**

**Specific Objectives**

a. Recruit participants into two groups by self-identification of activity status

b. Begin data collection of quantitative measures (field-based assessments), concurrent with interviews and field observations, target is 30 individuals

**Key Outcomes**

- Recruitment has begun; approximately 50% complete. Initial identification of participants from Study 1 to complete Study 2 activities.
- Criteria for comparison group (not active) are being established based on codes from interview data.

**Progress**

Although many tasks are delayed due to late start of project, Study 2 initiation is progressing per plan.

**Other Achievements:** Based on preliminary consideration of information obtained during participant interviews, a new grant proposal was developed and submitted to CDMRP-SCIRP to better understand barriers and successes with food preparation.
What opportunities for training and professional development has the project provided?

The study was not designed to provide training and professional development opportunities. 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?

1) Ongoing recruiting and screening for eligibility toward completing interviews for Phase 1.
2) Continue to develop team familiarity and competency in reviewing video/audio transcriptions for both accuracy and interpretation of dialog including continued use of Mindmaps and spreadsheets.
3) Complete coding of transcripts for thematic data.
3) Conduct preliminary data analysis from subsample of coded transcripts.
4) Use coded transcript findings to help refine focus group questions.
5) Schedule and conduct focus groups.
6) Begin Phase 2 to quantification enrollment and testing.

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?

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 – as we are in data analysis phase of project.

We anticipate that our findings will have a significant impact on improving knowledge on attitudes regarding participation and community integration. We further expect that our findings can be incorporated into the clinical support provided by psychosocial clinicians and therapists in the outpatient and acute inpatient setting as well as recreation therapy programming in the community. It is our expectation that improved community participation will be associated with better health and enhanced quality of life.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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**

Nothing to Report.

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

There was an initial delay in hiring of all program staff due to administrative issues. This effectively delayed the project start by approximately one quarter. Our plan to resolve is simply to increase staff hours in the second year of the project, using available funds. This will allow us to accelerate analyses of Phase 1 data (in progress) and catch up to our original timeline for completion of milestones and tasks.

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

As noted above, there was an initial delay in hiring staff which resulted in lower expenditures than projected. Our action plan includes increased funding in the second year, using available funds carried over, to complete the study on schedule. Increasing staff hours in Year 2 will allow us to accomplish study goals by project end.

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

**Significant changes in use or care of human subjects**

None
Significant changes in use or care of vertebrate animals.

Not Applicable. No use of vertebrate animals.

Significant changes in use of biohazards and/or select agents

Not Applicable. No use of biohazards.

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
  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

Based on preliminary consideration of interviews and informal preliminary analysis, we have identified an additional area for study using expanded qualitative research methodology. This concept was developed into a research proposal submitted in the FY16 CDMRP-SCIRP round, entitled, “Keeping Veterans Healthy after Spinal Cord Injury: A Qualitative Study of Nutrition Practices” (SC150235).
What individuals have worked on the project?

<table>
<thead>
<tr>
<th>Name:</th>
<th>Project Role:</th>
<th>Nearest person month worked:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beatrice Jenny Kiratli</td>
<td>Project Director/Principal Investigator</td>
<td>2</td>
</tr>
<tr>
<td>Brinda Dalal</td>
<td>Co-Investigator</td>
<td>8</td>
</tr>
<tr>
<td>Jeffrey Jaramillo</td>
<td>Research Manager</td>
<td>12</td>
</tr>
<tr>
<td>Ramya Gopalan</td>
<td>Study Coordinator</td>
<td>4</td>
</tr>
<tr>
<td>Jessica Greene</td>
<td>Research Assistant</td>
<td>4</td>
</tr>
</tbody>
</table>

**Contribution to Project:**

- **Beatrice Jenny Kiratli**
  - Oversight of all study-related activities; position development and hiring activities; IRB submissions, communications with local R&D committee; interactions with DoD; study coordination with clinical co-investigators.

- **Brinda Dalal**
  - Development of qualitative methodology; development of project plan grid; exploration of audio-visual equipment to accommodate VA requirements; facilitating development of working definition of “activity” to drive semi-structured interviews; oversight on study materials (interview guides, tracking sheeting, etc); training of personnel in ethnographic methodology and data analysis approaches.

- **Jeffrey Jaramillo**
  - Administrative support

- **Ramya Gopalan**
  - Development of participant recruiting, screening and enrollment materials. Maintenance of study regulatory materials for research compliance. Participation in interviews and data analysis and interpretation.

- **Jessica Greene**
  - Assist with recruiting materials, building community resource database and data management. Participation in interviews and data analysis. As a person with a SCI, she provides valuable consumer input related to study activities.
Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Beatrice Jenny Kiratli (PI) – Research has changed as follows: Two completed projects and two projects begun since the initiation of the current CDMRP-SCIRP project funding. Dr. Kiratli is Co-investigator on all of these and there is no overlap. Conducting research on multiple projects is within her job purview and there is no anticipated effect on the current CDMRP-SCIRP project.

### Completed Support:

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Time Commitment</th>
<th>Supporting Agency</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predictive Outcome Model over Time for Employment (PrOMOTE)</td>
<td>1.2 Calendar Months</td>
<td>VA Rehab R&amp;D</td>
<td>Co-Investigator</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Time Commitment</th>
<th>Supporting Agency</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessing Skeletal Risk during Rehabilitation in Patients after Chronic Disuse</td>
<td>0.6 Calendar Months</td>
<td>VA Rehab R&amp;D</td>
<td>Co-Investigator</td>
</tr>
</tbody>
</table>

### Current Support:

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Time Commitment</th>
<th>Supporting Agency</th>
<th>Agency Contact</th>
<th>Performance Period</th>
<th>Level of Funding</th>
<th>Project Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluating Neural Adaptation after Tendon Transfer and Task-Based Training in SCI</td>
<td>0.6 Calendar Months</td>
<td>VA Rehab R&amp;D</td>
<td>Audrey Kusiak</td>
<td>7/1/15 – 6/30/17</td>
<td>$197,203</td>
<td>The purpose of the study is to obtain pilot data consisting of functional magnetic resonance imaging (fMRI) and functional performance measures to evaluate neural predictors and correlates of successful muscle re-education after tendon transfer.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Time Commitment</th>
<th>Supporting Agency</th>
<th>Agency Contact</th>
<th>Performance Period</th>
<th>Level of Funding</th>
<th>Project Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exoskeletal-Assisted Walking in Persons with SCI: Impact on Quality of Life</td>
<td>1.2 Calendar months</td>
<td>VA Cooperative Studies Program Protocol #2003</td>
<td>Grant Huang, PhD Acting Director of CSP</td>
<td>10/01/2015 to 9/30/2016 (only year 1 is approved so far)</td>
<td>$4,000,000 (Year 1)</td>
<td>This 10-site randomized trial will evaluate whether Veterans with chronic SCI who use an exoskeletal-assisted walking (EAW) device in the home and community environments experience clinically meaningful improvement in patient-reported outcomes related to mental health, bladder, bowel, and pain compared with those who do not use an EAW device.</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>PI</th>
<th>Role</th>
<th>Overlap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johanson</td>
<td>Co-Investigator</td>
<td>None</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PI</th>
<th>Role</th>
<th>Overlap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spungen (Bronx VA) / Local Site PI: Ota</td>
<td>Local Site Co-Principal Investigator</td>
<td>None</td>
</tr>
</tbody>
</table>
What other organizations were involved as partners?

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to https://ers.amedd.army.mil for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

9. APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.