

**AWARD NUMBER:** W81XWH-21-1-0743

**TITLE:** Teaching Self-Management Skills to Improve Self-Efficacy and Quality of Life for Caregiver Dyads in TBI and Dementia Populations

**PRINCIPAL INVESTIGATOR:** Denise Krch, PhD

**CONTRACTING ORGANIZATION:** Kessler Foundation

**REPORT DATE:** SEPTEMBER 2022

**TYPE OF REPORT:** Annual

**PREPARED FOR:** U.S. Army Medical Research and Development Command  
Fort Detrick, Maryland 21702-5012

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# REPORT DOCUMENTATION PAGE

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<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> The proposed study evaluates the efficacy of WeCAN (Wellness, Coping, & Adaptation for Neurocognitive Conditions), a group-based treatment designed to teach both the patient and the caregiver (“dyads”) long-lasting skills to better manage the medical condition. WeCAN teaches stress management, coping, and problem-solving skills and by design, is broadly applicable to a variety of populations and roles, as wellness is the driving focus. The study involves three Sites, with a different clinical population targeted at each site. Kessler Foundation, the Coordinating Center, will enroll 60 individuals with moderate to severe TBI. Franciscan Health (Indiana) and University of Michigan are Partnering Sites, and will enroll 60 individuals with chronic remote mild TBI and 60 with mixed dementia, respectively. The research protocols at each Site will be unique to the population, but harmonized through unified project goals: 1) to evaluate the efficacy of WeCAN to improve self-efficacy and quality of life, and 2) to identify behavioral, neuroimaging, and blood biomarkers that predict treatment efficacy. It is expected that findings generated from this study will lead to improved holistic approaches for brain injury and dementia systems of care.					
<b>15. SUBJECT TERMS</b> Dementia, concussion, self-management traumatic brain injury, coping, quality of life, self-efficacy					
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## 1. INTRODUCTION:

Approximately 5.3 million people (2% of the U.S. population) live with a long-term disability as a result of Traumatic Brain Injury (TBI) and between 5-8% of those older than 60 suffer from Alzheimer's disease or other forms of dementia. These populations endure many of the same cognitive, behavioral, and emotional symptoms. Without the proper skills to manage stress and to regulate emotion associated with these sequelae, overall quality of life (QOL) is negatively impacted for both patients and their caregivers. Standard, community-based interventions primarily provide support and psychoeducation services. This approach may help people in the moment, but it does not provide lasting skills to manage stress beyond the treatment contact. The proposed study evaluates the efficacy of WeCAN (Wellness, Coping, & Adaptation for Neurocognitive Conditions), a group-based treatment designed to teach both the patient and the caregiver ("dyads") long-lasting skills to better manage the medical condition. WeCAN teaches stress management, coping, and problem-solving skills and by design. The study involves three Sites, with a different clinical population targeted at each site. Kessler Foundation, the Coordinating Center, will enroll 60 individuals with moderate to severe TBI. Franciscan Health (Indiana) and University of Michigan are Partnering Sites, and will enroll 60 individuals with chronic remote mild TBI and 60 with mixed dementia, respectively. The 180 patient caregiver dyads will be randomized to either the WeCAN treatment group or an Active Peer Support Control. Both groups will undergo one 2-hour session/week for 12 weeks. Participants will be evaluated on outcome measures at baseline, post-treatment and at 6-months post-treatment. The research protocols at each Site are harmonized through unified project goals:

Aim 1. Evaluate the efficacy of WeCAN to improve self-efficacy and QOL relative to an Active Peer Support Control post-treatment (week 13) and 6-month follow-up in individuals with chronic mild TBI, moderate to severe TBI, and dementia, and their caregivers.

Aim 2. To determine whether patient neurobehavioral functioning moderates the relationship between treatment outcomes and burden in caregivers.

Aim 3. To determine the neural, behavioral and blood biomarkers which best predict improved self-efficacy and QOL for individuals with chronic mild TBI, moderate to severe TBI, and dementia.

It is expected that findings generated from this study will lead to improved holistic approaches for brain injury and dementia systems of care.

## 2. KEYWORDS:

Dementia, concussion, self-management traumatic brain injury, coping, quality of life, self-efficacy

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?**

	Months	% Completed
<b>Major Goal 1: Coordinate Study Staff for Clinical Trial</b>		
Subtask 1: Prepare Regulatory Documents and Research Protocol	1-6	95%
Subtask 2: Training of Study Staff	5-6	85%
Subtask 3: Facilitate and Coordinate with Sites for training, supervision and fidelity checks as needed for attrition	6-7	75%
<b>Major Goal 2: Study Preparation</b>		
Subtask 1: Prepare Research Protocol and Study Materials	5-7	95%
<b>Major Goal 3: Randomized Controlled Trial (n=180)</b>		
Subtask 1: Conduct Study	8-45	0%

Subtask 2: Maintaining Treatment and Data Integrity	9-45	0%
<b>Major Goal 4: Project outcomes and deliverables</b>		
Subtask 1: Data analysis and Dissemination	45-48	0%

**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.*

Major Activities by Goal	Specific Objectives Achieved
<b>Major Goal 1: Coordinate Study Staff for Clinical Trial</b>	
Subtask 1: Prepare Regulatory Documents and Research Protocol	
Coordinate with Sites for contracts and nondisclosure agreements (NDAs).	<ul style="list-style-type: none"> <li>Study launch meeting for all investigators and staff occurred on 9/29/21, during which study start-up tasks were discussed. Each site reported on the progress for signing of contracts for subaward.</li> <li>Per KF administration, in lieu of NDA, only a licensing agreement is needed to conduct the work specified. A licensing agreement was therefore signed by Drs. Ibarra and Backhaus as well as KF CEO Rodger DeRose on October 7, 2021.</li> <li>UM signed contract on 9/24/21.</li> <li>RHI signed contract on 11/12/21.</li> <li>UCSD signed contract on 9/17/21.</li> <li>Consultant agreement for Dr. Ibarra signed on 11/22/21.</li> <li>Consultant agreement for Dr. Polsinelli signed on 11/23/21.</li> <li>Talks with FH site continuing, with current subaward documents under review by legal staff at FH since 9/22/2021.</li> <li>On 12/15/21, FH subaward was approved.</li> </ul>
	<b>SUBTASK COMPLETE</b>
Finalize consent form & human subjects protocol	<ul style="list-style-type: none"> <li>8/2/21 – Submitted initial application to KF IRB. Since KF is the IRB of record, this submission contained KF consents and consents approved by both collaborating sites. (2 consents per site - one for person with neurologic condition and one for their support person).</li> <li>9/1/21 – KF IRB met and conditionally approved the protocol pending minor consent changes.</li> <li>9/11/21 – Revised consents sent to KF IRB.</li> <li>9/27/21 - KF IRB approval given to final protocol and consents. Approval dated 9/1/21.</li> <li>Submitted KF IRB Continuation application on 7/18/2022.</li> </ul>

	<ul style="list-style-type: none"> <li>Received approval for continuation from KF IRB on 8/4/2022.</li> <li>Sent KF IRB continuation approval to UM on 8/8/2022.</li> <li>Submitted IRB amendment application 8/16/2022 for revised protocol and consent forms and updated recruitment flyers.</li> <li>Resubmitted IRB amendment application for revised protocol, consent forms, and updated recruitment flyers on 8/23/2022 as per IRB request for clarification.</li> </ul>
<p>Coordinate with Sites for IRB protocol submission or waivers to defer to KF IRB</p>	<ul style="list-style-type: none"> <li>KF and FH IRB proposals both fully approved (see Human Subjects section).</li> <li>As of 11/6/21, UM's IRB remains in progress due to internal review by local neuroimaging leadership to ensure consistency with other studies regarding description of PET procedures (see Human Subjects section).</li> <li>As of 2/8/22, all four of UM's IRB subcommittees had approved the IRB protocol to be released to UM's IRB for full review where they will determine ceding approval to KF.</li> <li>All sites have ceded regulatory control to KF IRB. (The last site to cede was UM, which occurred on 3/18/22.)</li> </ul> <p><b>SUBTASK COMPLETE</b></p>
<p>Coordinate with Sites for Military 2nd level IRB review (OHRO)</p>	<ul style="list-style-type: none"> <li>Protocol submitted to OHRO on 5/12/22.</li> <li>OHRO submission was placed in queue for assignment with a reviewer on 5/19/22.</li> <li>Emma Gentry was assigned as our point of contact at OHRO on 5/24/22.</li> <li>On 6/3/22, based on OHRO review, Ms. Gentry requested additional documentation and information, and minor modifications to consent forms.</li> <li>On 6/6/22, PI asked for clarification of OHRO's requests. Response received 6/24/22.</li> <li>PI submitted some of the requested information on 6/24/22; the balance of the information was submitted on 6/30/22; this latter submittal contained minor PI-initiated changes to consent form and flyers which Ms. Gentry approved.</li> <li>On 7/11/22, Ms. Gentry asked the PI to submit all modifications made to consents and flyers throughout the OHRO review process to the KF's IRB for approval. Upon modification approval, we are to forward the modification application and approval to Ms. Gentry.</li> </ul>
<p><b>Subtask 2: Training of Study Staff</b></p>	
<p>Coordinate with Sites for training Research Assistants (RAs)</p>	<ul style="list-style-type: none"> <li>Study launch meeting (9/29/21) reviewed objectives and procedures for RA training.</li> <li>KF RA (Laura Marino) initiated training on human subjects and study procedures.</li> <li>FH RA (Hannah Jeske) was hired on 02/07/22 and has initiated training on human subjects and study procedures.</li> <li>Two RAs at UM (Gianna Tunzi and Carine El Jamal) have been identified within current staff, and so they</li> </ul>

	<p>are already trained on general human subjects protocols.</p> <ul style="list-style-type: none"> <li>• Assessment training conducted mid-March.</li> <li>• KF hired an additional half-time RA (Sebastian Grajales) in late April 2022, who began training on overall research procedures.</li> <li>• Assessment training across sites was conducted by Co-I Dr. Weber via Microsoft Teams on 3/23/2022, with follow-up training on 4/19/2022. This was attended by all RAs and coordinator-level staff.</li> <li>• Continued education and training was conducted via email and calls as needed. RAs practiced assessment procedures under the guidance of a Site PI or Co-I in order to complete an independent assessment by end of July.</li> <li>• Eyetracking training from Dr. Mark Ettenhofer conducted remotely for FH in July.</li> <li>• KF RAs completed MRI Safety training 7/27/22.</li> <li>• Test-out for RAs at UM occurred on 8/3/22 and 8/5/22.</li> </ul>
<b>Major Goal 2: Study Preparation</b>	
<b>Subtask 1: Prepare Research Protocol and Study Materials</b>	
<p>Purchase equipment, assessment measures, and study supplies. Configure for study methods and set up at study sites.</p>	<ul style="list-style-type: none"> <li>• Study launch meeting (9/29/21) reviewed necessary equipment, assessment measures, and study supplies that would need to be procured or purchased.</li> <li>• Email sent to study sites with specific URLs and amounts to purchase for study set-up.</li> <li>• KF submitted the PO for a -80 degree freezer for blood storage. We also completed construction to modify existing space to accommodate blood draws.</li> <li>• Purchasing and gathering of assessment materials for KF is 100% complete.</li> <li>• KF received the -80 degree freezer for blood storage, as well as the centrifuge, phlebotomy chair and other blood-related equipment.</li> <li>• UM completed all necessary purchases for the study.</li> <li>• FH completed all necessary neuropsych purchases, coordinated purchase of blood supplies through on-site hospital laboratory services, and identified a laptop for purchase (to deliver the eye tracking paradigm).</li> </ul>
<p>Finalize imaging protocol and program MRI/PET sequences.</p>	<ul style="list-style-type: none"> <li>• Neuroimaging protocol for KF has been established as directed by DTI expert Dr. Jeff Ware. Scanning protocols have been programmed into the scanner by KF Imaging Center's physicist.</li> <li>• Neuroimaging protocol at UM follows existing PET and fMRI protocols as per the MADRC.</li> <li>• Eye tracking paradigm for FH has been finalized.</li> </ul> <p><b>SUBTASK COMPLETE</b></p>
<p>Finalize blood biomarker protocol (draw, processing, storage, shipping, analysis).</p>	<ul style="list-style-type: none"> <li>• PI Dr. Krch continued contact with Quanterix (blood analysis lab) to confirm study-wide blood SOP and ascertained disaster plan in event of freezer failures.</li> <li>• The FH plan for blood draw procedures has been established between the Site PI, FH clinical staff, and laboratory director.</li> </ul>

	<ul style="list-style-type: none"> <li>• KF internally identified a phlebotomy-trained staff member who will conduct blood draws for this study in accordance with the SOP.</li> <li>• UM has confirmed that they will use existing blood draw infrastructure from the MADRC for this study.</li> </ul> <p><b>SUBTASK COMPLETE</b></p>
Prepare study assessment, outcome measures, organize participant folders.	<ul style="list-style-type: none"> <li>• Test materials have arrived at all Sites and have begun to be organized into participant folders.</li> </ul>
Adapt WeCAN treatment and control condition for all study populations	<ul style="list-style-type: none"> <li>• All three WeCAN study manuals have been adapted for their neurological condition. The moderate to severe manual has been edited by KF's Communications department for professional layout. The mild TBI and ADRD manual are currently being mapped onto this same layout.</li> <li>• The protocol for the peer support manual (i.e., control condition) has been established, written, and completed. The study team is in the process of copy-editing this manual for professional layout.</li> </ul>
Establish appropriate physical space for location of WeCAN groups at each site	<ul style="list-style-type: none"> <li>• All study sites have established appropriate spaces for conducting WeCAN and control group sessions.</li> </ul> <p><b>SUBTASK COMPLETE</b></p>
Create scoring database through REDCap. Coordinate data entry for study sites.	<ul style="list-style-type: none"> <li>• PI Krch, Co-Is Weber, Chiaravalloti, Ibarra, &amp; Parrott met with FITBIR staff on 10/7/21 to discuss data entry that would be optimal for FITBIR reporting requirements.</li> <li>• Study statistician Parrott explored viability of FITBIR data entry tool vs. REDCap.</li> <li>• Based on conversations with study statistician (Parrott) and meetings with FITBIR Ops analyst Alex Burnett, we have determined that the FITBIR ProForms tool will be preferable over REDCap for our study.</li> <li>• PI Krch and study statistician Parrott submitted FITBIR data submission requests and were granted a study account and access to the website.</li> <li>• KF study coordinator Smith and RA Marino submitted FITBIR data submission requests.</li> <li>• It was determined that the timeline for adapting the assessment questionnaires to FITBIR may delay study launch. In light of this, we decided to initiate the study using KF REDCap for data collection and storage, as this expedites the progress due to full control of programming and local IT support. The ultimate goal will be to concurrently establish data collection procedures in FITBIR, and to shift to FITBIR for questionnaire administration once REDCap set-up is complete and fully tested.</li> <li>• KF RA Grajales has been inputting all questionnaires into REDCap, with PI Krch and Co-I Weber reviewing for adherence to paper forms as completed.</li> <li>• Identification of all raw and standardized variables to be included in study database has been completed.</li> <li>• REDCap surveys completed; all sites reviewed their surveys for accuracy; edits based on feedback is</li> </ul>

	underway.
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**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.*

<b>Nothing to report.</b>
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**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.*

<b>Nothing to report.</b>
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**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.*

- Obtain approval on KF IRB modifications, obtain approval from OHRO to begin clinical trial
- Begin setting up FITBIR database.
- After receiving all regulatory approvals, launch first wave of clinical trial at all Sites.

**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).*

**Nothing to report.**

**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.*

**Nothing to report.**

- 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.*

We have experienced delays in obtaining regulatory approvals to begin the clinical trial. The primary delay was associated with obtaining IRB ceding approval from the University of Michigan (UM). Specifically, UM required multiple IRB subcommittees to sign off on the study documentation before sending it to full IRB for ceding review. In particular, the IRB Imaging subcommittee spent extensive time in reviewing and editing the consents for potential risks of PET imaging to participants. Once UM ceding was approved (March 2022), we sought and obtained local IRB approval, submitted documentation to OHRO and are in the final stages of obtaining regulatory approval. However, given these initial delays, we are behind the proposed timeline. To mitigate further delay and compensate for past delays, we are pre-identifying potential participants (we have not yet contacted participants) and pursuing multiple recruitment avenues so that once approval is granted, we may begin immediately.

**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.*

There have been no impacts on expenditures.

**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**

Nothing to report.

**Significant changes in use or care of vertebrate animals**

N/A

**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.*

**Nothing to report.**

- **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.*

**Nothing to report.**

- **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.*

**WeCAN treatment manuals have been developed under this project; one each for concussion, moderate to severe TBI, and Alzheimer's disease related dementias. For the duration of the clinical trial, the manuals will only be utilized in the context of the study, however, at the conclusion of data collection, these manuals will be provided to the professional community for free download from the [kflearn.org](http://kflearn.org) website.**

## **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".*

### **Kessler Foundation**

*Name:* Denise Krch, PhD  
*Project Role:* Principal Investigator  
*Researcher Identifier (e.g. ORCID ID):* 0000-0002-2037-8436  
*Nearest person month worked:* 3.0  
*Contribution to Project:* Dr. Krch contributed to study organization and set-up, personnel training, acted as a liaison between personnel across study sites, conducting Leadership meetings.

*Name:* Erica Weber, PhD  
*Project Role:* Co-Investigator  
*Researcher Identifier (e.g. ORCID ID):* 0000-0002-7569-1630  
*Nearest person month worked:* 2.4  
*Contribution to Project:* Dr. Weber has worked closely with Dr. Krch in contributing to personnel training, study organization and set-up (particularly at KF), and organized study supply procurement information.

*Name:* Angela Smith  
*Project Role:* Study-Wide Coordinator  
*Researcher Identifier (e.g. ORCID ID):* n/a  
*Nearest person month worked:* 2  
*Contribution to Project:* Ms. Smith managed administrative and IRB tasks, as well as organized the regulatory and IRB/OHRO documentation for KF, other sites (UM and FH).

*Name:* Laura Marino  
*Project Role:* Research Assistant  
*Researcher Identifier (e.g. ORCID ID):* n/a  
*Nearest person month worked:* 4  
*Contribution to Project:* Ms. Marino completed human subjects training and training on the study protocol, FITBIR/ REDCap, and the neuropsychological battery.

*Name:* Sebastian Grajales  
*Project Role:* Research Assistant  
*Researcher Identifier (e.g. ORCID ID):* n/a  
*Nearest person month worked:* 1.5  
*Contribution to Project:* Mr. Grajales completed human subjects training and training on the study protocol, FITBIR/ PROFORMS/ REDCap, and the neuropsychological battery.

**University of Michigan**

*Name:* Benjamin Hampstead, PhD  
*Project Role:* Site PI  
*Researcher Identifier (e.g. ORCID ID):* 0000-0003-2717-6375  
*Nearest person month worked:* 2  
*Contribution to Project:* Dr. Hampstead contributed to study organization and set-up at UM, and coordination of subaward contract and IRB submission.

*Name:* Eileen Robinson  
*Project Role:* Research Manager  
*Researcher Identifier (e.g. ORCID ID):* n/a  
*Nearest person month worked:* 1.5  
*Contribution to Project:* Ms. Robinson is working closely with the ADRC to facilitate regulatory and IRB documentation for UM, coordinating with Ms. Smith from KF, and is setting up the study protocol and training staff.

*Name:* Tessa Wilcox  
*Project Role:* Research Supervisor  
*Researcher Identifier (e.g. ORCID ID):* n/a  
*Nearest person month worked:* 3  
*Contribution to Project:* Ms. Wilcox is in charge of day-to-day RA management and training.

*Name:* Cynthia Burton  
*Project Role:* Treating Clinician  
*Researcher Identifier (e.g. ORCID ID):* n/a  
*Nearest person month worked:* 1  
*Contribution to Project:* Dr. Burton contributed to treatment manual adaptation and conducted first-level neuropsychological evaluation test-outs for Ms. El Jamal and Ms. Tunzi.

*Name:* Carine El Jamal  
*Project Role:* Research Assistant  
*Researcher Identifier (e.g. ORCID ID):* n/a  
*Nearest person month worked:* 2.5  
*Contribution to Project:* Ms. El Jamal completed human subjects training and training on the study protocol, FITBIR/ REDCap, and the neuropsychological battery.

*Name:* Gianna Tunzi  
*Project Role:* Research Assistant  
*Researcher Identifier (e.g. ORCID ID):* n/a  
*Nearest person month worked:* 2.5  
*Contribution to Project:* Ms. Tunzi completed human subjects training and training on the study protocol, FITBIR/ REDCap, and the neuropsychological battery.

**Franciscan Hospital**

*Name:* Summer Ibarra, PhD  
*Project Role:* Site PI  
*Researcher Identifier (e.g. ORCID ID):* 0000-0002-1071-0167  
*Nearest person month worked:* 2.25  
*Contribution to Project:* Dr. Ibarra contributed to study organization and set-up at FH, and coordination of subaward contract and IRB submission. She led adaptation of treatment manuals and conducted WeCAN treatment training.

*Name:* Amy Swier-Vosnos  
*Project Role:* Treating Clinician  
*Researcher Identifier (e.g. ORCID ID):* n/a  
*Nearest person month worked:* 1  
*Contribution to Project:* Dr. Swier-Vosnos contributed to treatment manual adaptation

*Name:* Hannah Jeske  
*Project Role:* Research Assistant  
*Researcher Identifier (e.g. ORCID ID):* n/a  
*Nearest person month worked:* 2.5  
*Contribution to Project:* Ms. Jeske completed human subjects training and training on the study protocol, FITBIR/ PROFORMS/ REDCap, and the neuropsychological battery.

**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.*

**Nothing to report.**

**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.*

**University of Michigan (UM)**

Department of Psychiatry  
2101 Commonwealth Boulevard, Suites C and D  
Ann Arbor, MI 48109-2700

Contributions: UM is a Partnering Site and will serve as one of the 3 performance sites where the clinical trial will take place. In this role, UM will serve as our 1) Collaborators, and they will utilize their 2) Facilities to conduct the proposed research.

**Franciscan Health (FH)**

8111 S. Emerson Avenue Indianapolis, IN 46237

Contributions: FH is a Partnering Site and will serve as one of the 3 performance sites where the clinical trial will take place. In this role, FH will serve as our 1) Collaborators, and they will utilize their 2) Facilities to conduct the proposed research.

**Rehabilitation Hospital of Indiana (RHI)**

4141 Shore Drive  
Indianapolis, IN 46254

Contributions: RHI is the organization where the study statistician is based. RHI’s role is Collaboration only.

**University of California, San Diego (UCSD)**

9500 Gilman Drive #0603  
La Jolla, CA 92093-0603

Contributions: UCSD is the organization where the eye tracking expert is based. UCSD’s role is Collaboration only.

## 8. SPECIAL REPORTING REQUIREMENTS

**COLLABORATIVE AWARDS:** *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (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://ebrap.org/eBRAP/public/index.htm> for each unique award.*

**QUAD CHARTS:** *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil/Pages/Resources.aspx>) 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.*