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

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14. ABSTRACT 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.									
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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:

What were the major goals of the project?

	Months	% Completed
Major Goal 1: Coordinate Study Staff for Clinical Trial		
Subtask 1: Prepare Regulatory Documents and Research Protocol	1-6	100%
Subtask 2: Training of Study Staff	5-6	100%
Subtask 3: Facilitate and Coordinate with Sites for training, supervision and fidelity checks as needed for attrition	6-7	100%
Major Goal 2: Study Preparation		
Subtask 1: Prepare Research Protocol and Study Materials	5-7	100%
Major Goal 3: Randomized Controlled Trial (n=180)		
Subtask 1: Conduct Study	8-45	4%
Subtask 2: Maintaining Treatment and Data Integrity	9-45	1%
Major Goal 4: Project outcomes and deliverables		
Subtask 1: Data analysis and Dissemination	45-48	0%

What was accomplished under these goals?

<i>Major Activities by Goal</i>	<i>Specific Objectives Achieved</i>
Major Goal 1: Coordinate Study Staff for Clinical Trial	
Subtask 1: Prepare Regulatory Documents and Research Protocol	
<p>Coordinate with Sites for contracts and nondisclosure agreements (NDAs).</p>	<ul style="list-style-type: none"> • 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. • 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. • UM signed contract on 9/24/21. • RHI signed contract on 11/12/21. • UCSD signed contract on 9/17/21. • Consultant agreement for Dr. Ibarra signed on 11/22/21. • Consultant agreement for Dr. Polsinelli signed on 11/23/21. • Talks with FH site continuing, with current subaward documents under review by legal staff at FH since 9/22/2021. • On 12/15/21, FH subaward was approved. <p>SUBTASK COMPLETE</p>
<p>Finalize consent form & human subjects protocol</p>	<ul style="list-style-type: none"> • 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). • 9/1/21 – KF IRB met and conditionally approved the protocol pending minor consent changes. • 9/11/21 – Revised consents sent to KF IRB. • 9/27/21 – KF IRB approval given to final protocol and consents. Approval dated 9/1/21. • Submitted KF IRB Continuation application on 7/18/2022 • Received approval for continuation from KF IRB on 8/4/2022 • Sent KF IRB continuation approval to UM on 8/8/2022 • Submitted IRB amendment application 8/16/2022 for revised protocol and consent forms and updated recruitment flyers • Resubmitted IRB amendment application for revised protocol, consent forms, and updated recruitment flyers on 8/23/2022 as per IRB request for clarification • Received approval for revised protocol, consent forms, and updated recruitment flyers on 9/3/2022

	<ul style="list-style-type: none"> • Resubmitted an amended application for revised protocol language (to pre-screen via EPIC) on 9/7/2022 • Received request to submit a HIPAA IRB waiver of Authorization form for revised language in protocol on 9/27/2022 • Submitted HIPAA IRB Waiver request 9/29/2022 • IRB requested clarification in HIPAA Waiver Authorization; submitted clarification with edits on 10/19/2022 • Protocol amendment was approved for HIPAA Waiver Request on 11/4/2022 • <p>SUBTASK COMPLETE</p>
<p>Coordinate with Sites for IRB protocol submission or waivers to defer to KF IRB</p>	<ul style="list-style-type: none"> • KF and FH IRB proposals both fully approved (see Human Subjects section). • 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). • 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. • All sites have ceded regulatory control to KF IRB. (The last site to cede was UM, which occurred on 3/18/22.) <p>SUBTASK COMPLETE</p>
<p>Coordinate with Sites for Military 2nd level IRB review (ORP/OHRO)</p>	<ul style="list-style-type: none"> • Protocol submitted to HRPO on 5/12/22. • OHRO submission was placed in queue for assignment with a reviewer on 5/19/22. • Emma Gentry was assigned as our point of contact at OHRO on 5/24/22. • On 6/3/22, based on OHRO review, Ms. Gentry requested additional documentation and information, and minor modifications to consent forms. • On 6/6/22, PI asked for clarification of OHRO's requests. Response received 6/24/22. • 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. • 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. • Sent all KF IRB approved documents to OHRO on 11/15/2022. • Meeting with OHRO's Human Subjects Protection Scientist, Approval Authority and SRO on 11/30/2022 to discuss UM use of LAR in context of DoD's 10 USC 980 policy.

	<ul style="list-style-type: none"> • OHRO requested changes to UM's consent to include language on feedback report: modification submitted. • Resubmitted to Kessler IRB for UM Consent Changes on 12/07/2022. • OHRO Approval for KF and FH to begin clinical trial, received 12/8/2022. • Kessler IRB approved UM Consent changes 12/21/2022. • OHRO Approval for modified UM Consents 12/22/2022; UM approved to begin clinical trial. <p>SUBTASK COMPLETE</p>
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Subtask 2: Training of Study Staff

<p>Coordinate with Sites for training Research Assistants (RAs)</p>	<ul style="list-style-type: none"> • Study launch meeting (9/29/21) reviewed objectives and procedures for RA training. • KF RA (Laura Marino) initiated training on human subjects and study procedures. • FH RA (Hannah Jeske) was hired on 02/07/22 and has initiated training on human subjects and study procedures. • Two RAs at UM (Gianna Tunzi and Carine El Jamal) have been identified within current staff, and so they are already trained on general human subjects protocols. • Assessment training is scheduled for mid-March. • KF hired an additional half-time RA (Sebastian Grajales) in late April 2022, who has begun training on overall research procedures. • 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. • 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- in order to complete an independent assessment by end of July. • Eye tracking training from Dr. Mark Ettenhofer conducted remotely for in July. • KF RAs completed MRI Safety training 7/27/22. • Test-out for RAs at UM occurred on 8/3/22 and 8/5/22. • Test-out for RA at FH was completed on 10/17/22. • Test-out for RAs at KF was completed on 10/21/22. • Hannah Jeske, RA at FH, informed us on 10/26/2022 that she would be leaving her position. • Centrifuge training for KF phlebotomist conducted on 11/9/22. • A new FH RA Lexus Spicer was hired, and started date on 12/5/2022. • Study-wide scoring training conducted on 1/19/23. • New FH RA Lexus Spicer received training from Site PI Summer Ibarra and via pre-recorded training videos and tested out on 1/24/2023. • UM RAs completed all MRI and PET scheduling and
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	<p>coordination training on 1/31/23.</p> <ul style="list-style-type: none"> UM identified two RAs (Shoshoanah Machlay and Kelsi Broich) who will be cross-trained on our study's protocol and serve as backup in the event that either of UM's WeCAN RAs are unavailable. <p>SUBTASK COMPLETE</p>
Coordinate with Sites for training Treating Clinicians in WeCAN treatment as well as Active Peer Support control arms	<ul style="list-style-type: none"> Summer Ibarra conducted WeCAN training with Treating Clinicians between March and July 2022 Summer Ibarra conducted Active Peer Support training with Treating Clinicians in August 2022. <p>SUBTASK COMPLETE</p>
Train study personnel in double-blind procedures	<ul style="list-style-type: none"> Double-blind training initiated November 2022. Double-blinding procedures reviewed in February, 2023. <p>SUBTASK COMPLETE</p>
Subtask 3: Facilitate and Coordinate with Sites for training, supervision and fidelity checks as needed for attrition.	
Coordinate with Sites to train Treating Clinicians & RAs to maintain 100% concordance	<ul style="list-style-type: none"> Fidelity check procedures established during November WeCAN Leadership Team meeting with Drs. Ibarra, Hampstead and Krch. Scoring Fidelity protocol established includes 1) scoring training workshops, 2) double scoring of protocols, 3) review of first 3 scored batteries by Dr. Weber, 3) double data entry in REDCap. Treatment Fidelity protocol established includes 1) recording treatments sessions, 2) review of recordings by WeCAN Treatment Creator Summer Ibarra, 3) debriefing among Treating Clinicians in team meetings. <p>SUBTASK COMPLETE</p>
Major Goal 2: Study Preparation	
Subtask 1: Prepare Research Protocol and Study Materials	
Purchase equipment, assessment measures, and study supplies. Configure for study methods and set up at study sites.	<ul style="list-style-type: none"> Study launch meeting (9/29/21) reviewed necessary equipment, assessment measures, and study supplies that would need to be procured or purchased. Email sent to study sites with specific URLs and amounts to purchase for study set-up. KF submitted the PO for a -80 degree freezer for blood storage. We also completed construction to modify existing space to accommodate blood draws. Purchasing and gathering of assessment materials for KF is 100% complete. KF received the -80 degree freezer for blood storage, as well as the centrifuge, phlebotomy chair and other blood-related equipment. UM completed all necessary purchases for the study. 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). <p>SUBTASK COMPLETE.</p>
Finalize imaging protocol and program MRI/PET sequences.	<ul style="list-style-type: none"> Neuroimaging protocol for KF has been established as directed by DTI expert Dr. Jeff Ware. Scanning

	<p>protocols have been programmed into the scanner by KF Imaging Center's physicist.</p> <ul style="list-style-type: none"> • Neuroimaging protocol at UM follows existing PET and fMRI protocols as per the MADRC. • Eye tracking paradigm for FH has been finalized. <p>SUBTASK COMPLETE.</p>
Finalize blood biomarker protocol (draw, processing, storage, shipping, analysis).	<ul style="list-style-type: none"> • 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. • The FH plan for blood draw procedures has been established between the Site PI, FH clinical staff, and laboratory director. • KF internally identified a phlebotomy-trained staff member who will conduct blood draws for this study in accordance with the SOP. • UM has confirmed that they will use existing blood draw infrastructure from the MADRC for this study. <p>SUBTASK COMPLETE</p>
Prepare study assessment, outcome measures, organize participant folders.	<ul style="list-style-type: none"> • Test materials have arrived at all Sites and have been organized in participant folders. <p>SUBTASK COMPLETE</p>
Adapt WeCAN treatment and control condition for all study populations	<ul style="list-style-type: none"> • 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. • 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. • All treatment and control manuals completed • In process of printing and binding completed manuals <p>SUBTASK COMPLETE</p>
Establish appropriate physical space for location of WeCAN groups at each site	<ul style="list-style-type: none"> • All study sites have established appropriate spaces for conducting WeCAN and control group sessions. <p>SUBTASK COMPLETE</p>
Create scoring database through REDCap. Coordinate data entry for study sites.	<ul style="list-style-type: none"> • PI Krch, Co-Is Weber, Chiaravalloti, Ibarra, & Parrott met with FITBIR staff on 10/7/21 to discuss data entry that would be optimal for FITBIR reporting requirements. • Study statistician Parrott explored viability of FITBIR data entry tool vs. REDCap. • 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. • PI Krch and study statistician Parrott submitted FITBIR data submission requests and were granted a study account and access to the website. • KF study coordinator Smith and RA Marino submitted FITBIR data submission requests. • It was determined that the timeline for adapting the

	<p>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.</p> <ul style="list-style-type: none"> • 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. • Identification of all raw and standardized variables to be included in study database has been completed. • REDCap surveys completed; all sites reviewed their surveys for accuracy; any necessary edits completed. Surveys ready for clinical trial. • Initiated creation of REDCap database for storing of participants' screening and assessment data. • KF RA and Data Manager actively working with FITBIR Ops to set up database for eventual data sharing. • REDCap Neuropsych database and REDCap surveys are completed, ready for use in clinical trial, and vetted for later cross-walk into FITBIR. <p>SUBTASK COMPLETE</p>
Major Goal 3: Randomized Controlled Trial (n=180)	
Subtask 1: Conduct Study	
FH: Conduct recruitment activities	<ul style="list-style-type: none"> • RA began to pre-screen potential participants through their EPIC system; 503 pre-screened as meeting preliminary inclusion/exclusion criteria • Established relationship with psychiatrist Dr. Mehta, who will assist in recruitment of concussion clinic patients. Protocol will involve provision of flyer to participants, who will then be follow-up contacted by Ms. Spicer. • Of those prescreened 43 pre-qualified individuals contacted for recruitment • Of those contacted, 22 responded • Of those that responded 3 dyads were phone screened • 2 dyads are scheduled for a phone screen • Of those that were phone screened, 3 dyad met preliminary inclusion/exclusion criteria
FH: Conduct in-person screening to evaluate inclusion/ exclusion criteria. Enroll eligible participants.	<ul style="list-style-type: none"> • 3 dyads are scheduled for in-person screen
FH: Randomize Chronic Mild TBI dyads into <i>WeCAN</i> (treatment) or Active Peer Support (control) by wave.	
FH: Conduct baseline assessments in Chronic Mild TBI dyads	
FH: Conduct <i>WeCAN</i> (treatment) and Active Peer Support (control)	

sessions in Chronic Mild TBI dyads.	
FH: Conduct post-treatment assessments in Chronic Mild TBI dyads.	
FH: Conduct long-term follow-up assessments in Chronic Mild TBI dyads.	
KF: Conduct recruitment activities	<ul style="list-style-type: none"> • Established relationships with Dr. Irene Ward, KIR inpatient research liaison, and Dr. Monique Tremaine, neuropsychologist at JFK Rehab, who will assist us with recruiting at their facilities. • 713 individuals prescreened from SIMS, KF's HIPAA-compliant participant database • Of those pre-screened, 627 pre-qualified individuals contacted for recruitment • Of those contacted, 240 responded. • Of those that responded, 24 dyads were phone screened • Of those that were phone screened, 20 dyads met preliminary inclusion/exclusion criteria
KF: Conduct in-person screening to evaluate inclusion/ exclusion criteria. Enroll eligible participants.	<ul style="list-style-type: none"> • 6 dyads declined after phone screen • 3 dyads are going to be scheduled for an in-person screen, 2 dyads are currently scheduled and 1 dyad will be scheduled for the next wave • 10 dyads were screened in-person • Of those screened in-person, 8 dyads qualified, and were consented and enrolled
KF: Randomize Mod-Sev TBI dyads into <i>WeCAN</i> (treatment) or Active Peer Support (control) by wave	<ul style="list-style-type: none"> • A 5-dyad group was randomized by Dr. Parrott.
KF: Conduct baseline assessments in Mod-Sev TBI dyads	<ul style="list-style-type: none"> • Baseline NP assessments were conducted for 8 dyads. • Optional neuroimaging was conducted for 4 clinical participants; 1 additional scan is scheduled. • Blood and questionnaires for randomized dyads in process of being scheduled.
KF: Conduct <i>WeCAN</i> (treatment) and Active Peer Support (control) sessions in Mod-Sev TBI dyads.	
KF: Conduct post-treatment assessments in Mod-Sev TBI dyads.	
KF: Conduct long-term follow-up assessments in Mod-Sev TBI dyads.	
UM: Conduct recruitment activities	<ul style="list-style-type: none"> • We leveraged Dr. Hampstead's roles within the NIA P30-funded Michigan Alzheimer's Disease Research Center (MADRC) to establish protocols for several key study procedures including: Recruiting participants from the MADRC registries, which include two key, non-overlapping sources 1) MiNDSET: a registry of >1,000 older adults who expressed interest in research. 2) UMMAP – The University of Michigan Memory in Aging Project

	<p>currently follows >550 older adults with longitudinal assessment and characterization.</p> <ul style="list-style-type: none"> • WeCAN has been approved for recruitment purposes by the MADRC Executive Committee and all required procedures/reporting processes for tracking co-enrollment have been established. Through MiNDSET and UMMAP, we have received 187 referrals for medical pre-screening that precedes the initial contact/phone screening. We are also informing eligible participants from our other studies and have confirmed several participants' interest. These potential participants will be contacted in the next quarter. • 141 individuals prescreened from Epic, UM's HIPAA-compliant participant database • Of those pre-screened, 108 pre-qualified individuals contacted for recruitment. • Of those contacted, 71 responded. • Of those that responded, 13 dyads were phone screened • Of those that were phone screened, 12 met preliminary inclusion/exclusion criteria
UM: Conduct in-person screening to evaluate inclusion/exclusion criteria. Enroll eligible participants.	<ul style="list-style-type: none"> • 2 dyads are scheduled to be screened in-person • 2 dyads are scheduled to be screened in person at the next wave • 1 dyad declined participation after phone screen • 6 dyads qualified after in person screen and were enrolled <ul style="list-style-type: none"> ○ 1 dyad is scheduled to participate in next wave
UM: Randomize ADRD dyads into WeCAN (treatment) or Active Peer Support (control) by wave.	<ul style="list-style-type: none"> • A 5-dyad group was randomized by Dr. Parrott.
UM: Conduct baseline assessments in ADRD dyads	<ul style="list-style-type: none"> • Baseline assessments, including NP, blood, and questionnaires were conducted for 6 dyads. • Optional neuroimaging was conducted for 3 clinical participants
UM: Conduct WeCAN (treatment) and Active Peer Support (control) sessions in ADRD dyads	
UM: Conduct post-treatment assessments in ADRD dyads	
UM: Conduct long-term follow-up assessments in ADRD dyads	
Subtask 2: Maintaining Treatment and Data Integrity	
Review treatment sessions to evaluate treatment fidelity.	
Monitor data collection rates and data quality.	

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?

- Continue recruitment and enrollment, in preparation for the second wave of groups at KF and UM.
- Continue recruitment and begin enrollment at FH, with the intention of launching first wave.
- Initiate group sessions at KF and UM for first wave.
- Continue fidelity checks of treatment sessions for sites that have launched waves.
- Complete baseline assessments for all dyads participating in current wave.
- Score neuropsych testing batteries for all baseline assessments.
- Enter data into REDCap for all completed baseline assessments.
- Conduct fidelity checks on completed scoring.
- Conduct ongoing discussions regarding recruitment methods and approaches with FH and UM teams.
- Initiated collaboration with JFK Rehabilitation colleague Monique Tremaine, who will assist us with recruiting participants for KF from their catchment area. She will have access to potential participants who are 4 months post injury and further out; her team will recruit via word of mouth and flyers only at this time.
 - As JFK is interested in becoming more involved with study efforts (e.g., recruiting through their EPIC system), we will submit an IRB modification to add JFK as a Site and have their IRB cede to KF as IRB of record; we will subsequently submit all documentation to OHRO and gain that approval before initiating any of these activities.
- Train new (temp) phlebotomist at KF on blood protocol.
- Begin discussions with FITBIR ops regarding setting up blood and imaging elements fo our data repository.

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

Nothing to report.

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

- We remain behind schedule launching clinical trial due to initial delays owing to the lengthy ceding process. We received OHRO approval 12/22/22 to begin the clinical trial at all three sites.
 - **KF:** We began recruitment in January 2023, and to date have enrolled 8 dyads with 3 more scheduled for in-person screening. Enrollment progress has taken longer than we had anticipated. In order to broaden our recruitment pool, we submitted a modification to the IRB and received

approval to decrease the time since injury criteria from one year to 4 months. This opens up the door to us recruiting directly from inpatient facilities. We have identified two partners to help us achieve this objective: Kessler Institute for Rehabilitation (KIR) and JFK Rehabilitation. At KIR, we have partnered with inpatient research liaison Dr. Irene Ward, who will assist us recruiting their TBI patients at time of discharge. At JFK, we are working with Dr. Monique Tremaine, who is assisting us with recruiting participants from their catchment area in Edison, NJ. Dr. Tremaine's staff will speak with and hand out flyers to potential participants in inpatient and outpatient clinics. JFK is additionally interested in contributing more substantially to KF's data collection (e.g., conducting phone screens; pre-screening participants through their EPIC system). In order to obtain permission to conduct these activities, we will submit an IRB modification to KF for permission to add JFK as a Site and to have their IRB cede to KF as IRB of record, and will submit all paperwork to OHRO for second level review and approval. With these new post-acute avenues, we anticipate access to a greater potential pool of participants at the next wave of recruitment.

- **UM:** UM has continued recruitment with increasing success. However, they expressed concern regarding challenges recruiting participants who split their residence between US regions based on seasons ("snowbirds"). In other words, participants enrolled early in a wave cycle may no longer be in Michigan for the full duration of study activities if a wave launch is hampered by recruitment delays. To mitigate this issue, the study-wide decision was made to launch individual groups at the point of 5 enrolled dyads, thereby randomizing by groups of 5 dyads rather than waiting to enroll 10 dyads and then randomizing by dyad. This has allowed all sites to progress more rapidly toward treatment launch, and decreases the likelihood of participant drop-out due to changes in availability.
- **FH:** It was determined that the hardware that had previously been purchased for conducting the eye tracking paradigm is unreliable with the operating systems at FH. Dr. Ettenhofer, the study's eye tracking expert, identified another solution (the Tobii Pico Neo 3 Eye) which will function as a standalone hardware and not require a PC to function. The FH team is in support of this avenue. We have made moves toward acquisition of this new equipment, which we expect to arrive in the next few weeks. Given that recruitment at FH started fairly recently, the issues associated with readying the eye tracking device will not cause any actual delays in clinical trial activities at this site.
- New Phlebotomist identified at KF who will fill in on this project on a temporary basis until a long-term alternative can be identified; this will enable us to avoid delays associated with blood draws.

Changes that had a significant impact on expenditures

There have been no impacts on expenditures.

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

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:

- **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**

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 klearn.org website.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Kessler Foundation

Name: Denise Krch, PhD
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0002-2037-8436
Nearest person month worked: 4.5
Contribution to Project: no change

Name: Erica Weber, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0002-7569-1630
Nearest person month worked: 3.75

Contribution to Project: no change

Name: Brionna Robinson
Project Role: Study-Wide Research Coordinator
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 5
Contribution to Project: no change

Name: Laura Marino
Project Role: Research Assistant
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 9
Contribution to Project: no change

Name: Sebastian Grajales
Project Role: Research Assistant
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 7
Contribution to Project: no change

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: 3.75
Contribution to Project: no change

Name: Cynthia Burton
Project Role: Co-Investigator/ Treating Clinician
Researcher Identifier (e.g. ORCID ID): 0000-0002-9703-8106
Nearest person month worked: 3
Contribution to Project: no change

Name: Eileen Robinson
Project Role: Research Manager
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 2
Contribution to Project: no change

Name: Mateo Lopez
Project Role: Research Coordinator
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 1
Contribution to Project: no change

Name: Gianna Tunzi

Project Role: *Research Assistant*
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 6
Contribution to Project: no change

Franciscan Hospital

Name: *Summer Ibarra, PhD*
Project Role: *Site PI*
Researcher Identifier (e.g. ORCID ID): 0000-0002-1071-0167
Nearest person month worked: 4.25
Contribution to Project: no change

Name: *Amy Swier-Vosnos*
Project Role: *Co-Investigator/ Treating Clinician*
Researcher Identifier (e.g. ORCID ID): NA
Nearest person month worked: 1.25
Contribution to Project: no change

Name: *Lexus Spicer*
Project Role: *Research Assistant*
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 1
Contribution to Project: no change

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

Nothing to report.

What other organizations were involved as partners?

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.

Indiana University (IU)
509 E. Third St.
Bloomington, IN 47401
Contributions: IU is the organization where the study statistician is based. IU'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:

QUAD CHARTS:

9. APPENDICES: