Trial Protocol for the REACH Intervention for Caregivers of Veterans and Service Members with TBI: Efficacy and Implementation Planning across the VA Polytrauma System of Care

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Abstract

Background: The responsibility of care for Veterans and Service Members (V/SMs) with traumatic brain injury (TBI) often defaults to informal family caregivers. Caregiving demands considerable knowledge, skill, and support to facilitate the health and well-being of V/SMs and themselves. Persistent and common TBI caregiver issues include strain, depression, and anxiety. While evidence-based, brief interventions have been developed and implemented for family caregivers in Veteran neurodegenerative populations, few interventions have been developed, adapted or tested to support the unique needs of caregivers of V/SMs with TBI.

Objective: This study will adapt and test an evidence-based, personalized, six-session telehealth caregiver intervention, "Resources for Enhancing All Caregivers' Health" (REACH), to meet the unique needs of caregivers of V/SMs with TBI. If successful, a community-based participatory research team will develop an implementation plan to roll out REACH TBI across the national VA Polytrauma System of Care (PSC).

Methods: This mixed-methods, crossover waitlist control clinical trial will use a Type 1 Hybrid Effectiveness-Implementation approach to adapt and then test the effects of REACH TBI on key TBI caregiver outcomes.

Results: This study was funded by the Department of Defense in September 2023. It was approved by the institutional review board at the University of Virginia in November 2023. Participant enrollment and data collection will begin in 2024.

Conclusions: If effective, REACH TBI will be the first evidence-based intervention for caregivers of V/SMs with TBI that can be scaled to implement across the VA PSC and fill a notable gap in clinical services. Clinical Trial: The REACH Intervention for Caregivers of Veterans and Service Members With TBI (REACH TBI)
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Running Head: REACH TBI PROTOCOL

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Keywords: Traumatic Brain Injury; Telehealth; Caregiver; Methodology

Introduction

Between 2000 and 2021, a total of 444,328 U.S. military Service Members were diagnosed

with TBI,[1] leading to TBI's designation as the "signature injury" of Operation Enduring Freedom, Iraqi Freedom, and New Dawn (OEF/OIF/OND).[2,3] Between 7-23% of OEF/OIF/OND-era V/SMs have experienced a TBI.[2–5] V/SMs receiving services in the VA have over 93,000 documented TBIs.[6] TBI can result in a constellation of long-term physical, cognitive, and neurobehavioral impairments.[7–10] Recovery time is variable, and many symptoms remain years or decades after injury, especially with more severe injuries.[11] As a result of these long-term consequences and care needs, rehabilitation medicine now unequivocally considers TBI a chronic health condition requiring long-term management and support.[12]

Informal family TBI caregivers experience a myriad of unmet emotional, instrumental, and professional support needs regarding symptom management,[13] and research has shown these high rates of unmet needs are closely associated with mental health problems in caregivers.[14] Caregivers often receive little formalized training or support in caregiving and symptom management, and physical symptoms in individuals with TBI are associated with greater family household needs, and emotional symptoms with greater family informational needs.[15] Among caregivers of V/SMs with TBI, over 40% of their needs go unmet; greater environmental barriers keeping the V/SM from participating in activities and the presence of V/SM mental health issues translate into more unmet emotional, community, and professional support needs.[16] Despite some parallels to civilian populations with TBI, V/SMs can have unique features of TBI (e.g., polytraumatic, blast-related) and high rates of particular comorbid conditions (e.g., posttraumatic stress and pain) that impact V/SMs' health and needs[17–19] and may require additional and unique caregiving skills. Few military family members expect to provide the sort of long-term care that may be required by these complex injuries,[20] and lack of training or formal supports can compound caregivers' strain and emotional distress.[21] Over time, military TBI caregivers experience declines in physical and mental health,[22] reporting worse health than the general population.[23] Higher levels of TBI symptoms experienced by V/SMs are associated with greater caregiver strain and distress,[24] which are in turn associated with

caregiver grief and depression.[24,25]

At present there is no standardized, evidence-based, and widely implemented intervention for caregivers of V/SMs with TBI. Thus, there is significant need for an evidence-based, portable caregiver telehealth intervention that is: (a) adapted to TBI-specific needs, (b) relevant to caregivers of younger V/SMs with a range of neurobehavioral symptoms and strong potential for a positive recovery trajectory, and (c) readily accessible in rural and resource-limited communities. Resources for Enhancing All Caregivers' Health (REACH) VA is a successful evidence-based, four- or six-session telehealth behavioral intervention for caregivers and a VA national program for dementia, spinal cord injuries and disorders, amyotrophic lateral sclerosis, multiple sclerosis, and posttraumatic stress disorder caregivers. REACH has never been tailored specifically for or tested in caregivers of V/SMs with TBI. This study protocol describes the adaptation, evaluation, and implementation of a telehealth intervention, REACH TBI, for caregivers of V/SMs with TBI during the chronic phase of recovery.

Methods

Study Design

This study is a prospective mixed-methods, Type 1 Hybrid Effectiveness-Implementation study, with a crossover waitlist control clinical trial. This is a multi-aim, multi-phase, VA-wide clinical trial that will include: (a) engagement with caregivers of V/SMs with TBI and PSC clinicians to inform REACH adaptation for TBI; (b) a national waitlist control clinical trial; (c) development of an ambitious PSC implementation plan; and (d) a foundational community-based participatory research (CBPR) approach with stakeholders throughout every phase. The study is expected to recruit over 18 months.

Setting

There are four research cores in this multi-center study. The University of Virginia (Charlottesville, VA, USA) is the Administrative Core responsible for overseeing and directing the

clinical trial in collaboration with Multiple Principal Investigators (MPIs) leading the other three study cores. The James A. Haley Veterans' Hospital (Tampa, FL, USA) is the Data Core where recruitment and data collection will be conducted. Virginia Commonwealth University (Richmond, VA, USA) is the Intervention Core where the REACH TBI intervention will be delivered via telehealth. The University of Utah (Salt Lake City, UT, USA) is the Implementation Core where evidence-based strategies will be developed to implement REACH TBI throughout the VA Polytrauma System of Care (PCS). Additionally, the University of Tennessee Health Science Center Caregiver Center (Memphis, TN, USA) will inform intervention protocol development and train REACH TBI interventionists. The UVA Institutional Review Board (IRB) will be overseeing research activities carried out at all civilian research universities. The University of South Florida is the reliance-agreement IRB of the James A. Haley Veterans' Hospital and will be responsible for the oversight of the work occurring at this VA Medical Center.

Intervention Development

Central to our team is the VA National Caregiver Center to leverage the foundational REACH[26] intervention—including its associated tools (e.g., Caregiver Notebook, Risk Assessment), trainings, and delivery resources (Coach Manual[27] with scripts and checklists)—to accelerate a deployable REACH TBI protocol for clinical trial testing within 6 months of grant commencement. During the first 6 months of the grant timeline, adapting REACH for TBI will include extensive qualitative assessment involving CBPR engagement with subject matter experts (SME) research team members throughout the PSC, including caregivers of V/SMs with TBI, clinicians, clinical researchers, and administrators.

Participants, Recruitment, and Sample Size

The eligibility criteria for V/SMs with TBI and caregivers are: (a) age of 18 years and older, (b) English-speaking, (c) primary caregiver for a V/SM who sustained a VA-documented TBI at least 6 months prior, (d) provide some level of daily supervision or assistance with either a physical,

cognitive, or behavioral issue they think is likely related to TBI, (e) believe that at least half of their caregiving responsibilities are likely related to TBI rather than another health condition(s), (f) endorse a score of at least high burden (a score of 8 or higher) on the Zarit Burden Inventory-4.[28] The exclusion criteria are: (a) no access to telephone, (b) auditory impairment that would make telephone use difficult.

A power analysis was completed to determine the number of participants necessary to achieve 80% power on the primary outcome assuming 10% attrition. Baseline scores will be used as a covariate in the model as this increases statistical power, given that baseline and follow-up scores are usually highly correlated, resulting in a reduction in the error term of the model. Assumptions used in computations included equal sample sizes in each contrast group, equal variances and attrition, probability of Type I error of .05, and two-sided testing of the null hypotheses. Accordingly, 55 participants will be randomized to each group (total n=110). With this sample size, we will have 80% power to detect a Cohen's d of .50 assuming a correlation of pre- and post-intervention scores of .50.

Using the VA's corporate Data Warehouse, Veterans will be identified with a TBI diagnosis. Recruitment of their caregivers will be conducted remotely by research coordinators. After consent is obtained and baseline data collected, participants will be randomly assigned to the immediate intervention group or waitlist control group. Each caregiver will be offered $25 for each completed data collection and the exit interview for a total of $100 (immediate intervention group) or $125 (waitlist control group).

Randomization

A block randomization schedule (with six participants per block) will be created with a web-based computerized random number generator. The UVA research coordinator will maintain allocation concealment and eliminate possible selection or recruitment biases by keeping the randomization schedule concealed from the on-site research coordinator engaged in recruiting. The

randomization schedule will be generated by the UVA research coordinator who will not have any contact with participants, and sequentially numbered sealed envelopes will be prepared prior to recruitment of any participants. After the recruiting research coordinator determines eligibility for a prospective dyad and obtains informed consent, the UVA research coordinator will be notified and then open the next sealed envelope in the assignment sequence; the group assignment for that participant to one of the two groups will be revealed at that point. In this fashion, only the postdoctoral fellow interventionist assigned to provide REACH TBI will know the group assignment of a specific TBI caregiver. Because the intervention will be delivered by trained personnel who will have minimal contact with the waitlist control group (other than during the randomization call when the caregiver is informed of their study arm), we anticipate minimal overlap or "contamination" between these intervention and waitlist control group participants. Although participants and interventionists cannot be blinded during the study, all research staff involved in data collection and biostatistics staff involved in formal statistical analyses will be blinded to reduce bias and preconceptions in collecting and analyzing data.

Intervention Implementation

The REACH TBI intervention will be carried out by a postdoctoral fellow interventionist who will be trained with didactic and hands on content, knowledge assessment, skills practice, and role playing for certification. Interventionist training includes strategies for overcoming problems associated with telephone interactions such as decreased cues and technological difficulties. The interventionist will use a mock caregiver to complete a role play of two key areas of the intervention: Target Concern Plan and Cognitive Reframing. The Certification Role Play Observation Checklist for Individual Sessions used by the Caregiver Center will be used for the role play. The checklist includes behaviorally anchored ratings of specific procedural techniques (e.g., correct use of forms) and clinical skills (e.g., active listening). Performances will be observed for content and process. Feedback will be individually provided for each of the items listed on the Checklist. Structure of the

feedback will include positive behavior demonstrated; what behaviors should have occurred or occurred and were not in keeping with the protocol; and rationale for the behavior that was expected. To assess intervention benefit accurately, early sessions for each interventionist will be monitored by study investigators, with caregiver permission. The investigators will provide feedback to the interventionist immediate after each session, focusing on fidelity, interventionist delivery, and evidence of caregiver receipt and enactment.

Intervention

REACH TBI will be delivered by telephone in six individual hour-long sessions over 3 months, about every 2 weeks by a trained and certified interventionist. The REACH TBI sessions incorporate evidence-based components that have been shown to be crucial to successful caregiving interventions including problem solving, cognitive reframing, and stress management.[26] The interventionist and caregiver negotiate the concerns to be addressed using those identified by the risk assessment.[27,29] Using problem solving techniques, the interventionist and caregiver attempt to find effective and workable solutions to a specific Target Concern that is causing strain and stress for the caregiver, using the Caregiver Notebook. The Target Concern could be something related to the caregiver, such as asking family members for help, or to the care recipient, such as bathing or driving. In this way, the intervention accommodates whatever concern the caregiver is experiencing – from activities of daily living/instrumental activities of daily living (ADLs/IADLs) challenges to caregiver stress, guilt or grief.

Each session is structured to build on the previous session using the protocol. Although tasks are structured and pre-determined (e.g., problem solving), the focus of the task is a risk area (e.g., safety), concern (e.g., lack of support), or patient problem (e.g., angry outbursts) that the caregiver has identified as troubling. One of the main foci of REACH is problem solving. The interventionist teaches the ABC (Antecedent, Behavior, Consequences) method of problem solving, and the caregiver and interventionist identify action-oriented behavioral strategies to address caregiving

problems or V/SM behaviors using topics from the Caregiver Workbook in a Targeted Concern Plan. An outline of the intervention can be seen in Table 1.

Data Collections

Quantitative Data Collection. Demographic and baseline data will be collected either by telephone or Qualtrics after enrollment and before randomization. Baseline data collection includes validated measures of key TBI caregiver outcomes such as strain, depression, anxiety, self-efficacy, and health care frustration. Follow-up data will be collected at 3 and 6 months from all participants and at 9 months from waitlist control participants using the same validated measures as during the baseline data collection. The study timeline is illustrated in Figure 1.

Qualitative Data Collection. A qualitative telephone exit interview will be conducted of all participants at the 3-month follow up, after their last session, to evaluate their experiences using REACH TBI with a focus on caregiver satisfaction, usefulness, benefits, challenges, and implementation.

Outcome Measures

TBI-CareQOL Caregiver Strain – Short Form 6a assesses caregiver strain.[30] Six items are scored from 1 (never) to 5 (always), with higher scores indicating greater strain. **PROMIS Emotional Distress – Depression – Short Form 4a** assesses caregiver depression.[31] Eight items are scored from 1 (never) to 5 (always), with higher scores indicating greater depression. **PROMIS Emotional Distress – Anxiety – Short Form 4a** assesses caregiver anxiety.[31] Eight items are scored from 1 (never) to 5 (always), with higher scores indicating greater anxiety. **PROMIS General Self-Efficacy** assesses caregiver self-efficacy.[32] Ten items are scored from 1 (I am not at all confident) to 5 (I am very confident), with higher scores indicating greater self-efficacy. **TBI-CareQOL Health Care Frustration – Self – Short Form 6a** assesses frustrations a TBI caregiver has had with health care services.[33] Six items are scored from 1 (not at all) to 5 (very much), with higher scores indicating greater frustration with services received.

Data Analysis

Preliminary analyses. Descriptive statistics will be computed for the total sample and stratified by treatment group for baseline participant characteristics. Means and standard deviation (or medians and interquartile ranges) or counts and proportions will be calculated for continuous and categorical variables, respectively. In addition, an analysis of missing data will be conducted to examine factors that may be associated with the likelihood of missing data. Any factor found to be associated with the likelihood of missing data will be included in the final model.

Once assigned to a study arm, participants will be considered in the study, and we will follow an *intention-to-treat (ITT)* approach (see below for details). Primary outcomes are measured for all participants at baseline, at 3 months, and after 6 months (or 9 months for the waitlist control group). We estimate the necessary sample size based on comparing groups at three months post-randomization using baseline scores as a covariate. Note that due to expected carryover effects for those assigned to REACH TBI in the first 3 months, a traditional carryover design statistical analysis is not used.

Primary Quantitative Analyses. The *ITT* principle will be applied for all analyses. Once a participant is assigned to a treatment group, they will be included in the group in all analyses even if they end treatment or are lost to follow-up. Parallel analyses will be completed for each outcome. A linear mixed effects model will be used to test the effectiveness of the REACH TBI intervention compared to a waitlist control initially for the primary outcome of caregiver strain. Contrasts will be coded to allow for tests of the mean difference between groups at 6 months post-intervention and 3 months post intervention with 3-months measurements as the primary outcome. Each participant's baseline score on the outcome will be included in the model in addition to a random intercept and fixed effects of treatment, time, and the treatment by time interaction. To account for multiple testing, Hochberg's step-up procedure will be used to control the false discovery rate to .05. All analyses will be completed using the lme4 package[34] in the R statistical software.[35]

Secondary Quantitative Analyses. Parallel analyses to those described in the primary analysis section will be completed for all secondary outcomes (e.g., depression, anxiety, self-efficacy, and military health care frustration). In addition, group means will be compared at 6 months post-randomization. Given that both groups will have been exposed to the intervention at this point, no difference between groups is expected. Lastly, pairwise change within each group (e.g., baseline vs. 3 months and baseline vs. 6 months within the control group) will be tested. We expect that the treatment group will show improvement from baseline to 3 and 6 months post-randomization but not between 3 and 6 months. For the control group, it is anticipated there will be no improvement or worsening between baseline and 3 months post-randomization but will show improvement for comparisons of baseline and 3 months with 6 months post randomization.

Exploratory Quantitative Analyses. A moderation analysis will be completed to examine how disability level and V/SM health conditions impact the effect of the intervention. Each variable and their interaction with treatment will be added separately to the linear mixed effects models described in the primary analyses section. If statistically significant interactions are found, results will be reported with the mean treatment effect, and ± 1 standard deviation on the moderator to improve results interpretability.

Qualitative Analyses. Qualitative transcript data will be analyzed using descriptive content methods to identify domains/taxonomies about REACH TBI experiences. To adequately capture access determinants among participants, a qualitative codebook will be developed using deductive codes generated by construct relevance and inductively from interview data, as well as input from SME stakeholders (e.g., TBI caregivers, PSC clinicians). Interview transcripts will be coded by the qualitative team using the codebook augmented by our SMEs to assess intervention satisfaction and implementation issues. Additional codes will emerge inductively from the interview data. The coding team will read one interview transcript separately and discuss the addition of new codes with examples. This process will continue with subsequent transcripts until no new codes are generated

(code saturation). Inter-coder reliability will be established when the coding team reaches at least 80% coding agreement. Inter-coder reliability will be routinely monitored to ensure consistency and limit potential drift in coding. Any discrepancies will be discussed and resolved among study staff during weekly meetings to ensure coding and analysis are completed on schedule or earlier. ATLAS.ti v.22, a qualitative analysis software program, will be used to manage and code interview text using a constant comparative approach. Coded text will be displayed in Excel spreadsheets to conduct a matrix analysis, a rapid assessment approach, which will be used to develop themes for the overall sample. Comparative matrices enable identification of the most relevant, shared, and perhaps representative components, thereby enhancing the potential representation of the findings and allowing discernment of the most salient and representative experiences with REACH TBI identified by participants.

Results

This study was funded by the Department of Defense in September, 2023. It was approved by the IRB at the University of Virginia in November, 2023. Participant recruitment and data collection are expected to begin in 2024. Once REACH TBI effectiveness is demonstrated, the intervention will need to be spread throughout the VA PSC. Rigorous and systematic implementation planning will start in 2026 to broaden the impact of this clinical trial by rolling out REACH TBI among TBI clinicians across the PSC and sustain intervention delivery.

Discussion

Presently, there is no formalized or structured intervention for caregivers of V/SMs with TBI at a national level, and the existing services provided to caregivers for this population tend to be spread unevenly throughout the VA PSC. These gaps in services will be bridged through adapting the flagship program of the VA Caregiver Support Program's National Caregiver Center—the evidence-based REACH intervention—to be responsive and relevant to needs of caregivers of V/SMs with TBI. This intervention has potential to serve the caregivers currently supporting the needs of nearly

half a million V/SMs with TBI, remediating the adverse strain and mental health effects of caregiving, as well as improve self-efficacy and health care frustration. Supporting caregivers directly impacts V/SMs with TBI: higher caregiver health-related quality of life is associated with better functioning in V/SMs with TBI,[36] and better caregiver outcomes directly impact the quality of informal care they can provide.[37] The REACH TBI intervention represents a substantial improvement over the current complete lack of a TBI-tailored, standardized but flexible, and evidence-based telehealth intervention available for caregivers of V/SMs with TBI. Further, the telehealth delivery format of the intervention makes it highly suitable for caregivers in rural or other resource limited environments. This intervention has the potential to increase resilience within caregiving families, sustain gains made in functional recovery through the PSC, and ameliorate the negative impacts of TBI-related disability for caregivers.

The near-term impact of this clinical trial will include multiple knowledge products advancing our options to prevent and treat complications resulting from TBI for V/SMs and their caregivers. The immediate outcome will include a manualized, highly portable intervention that can be delivered broadly by TBI clinicians. The intervention will include a resource companion, the REACH TBI Caregiver Notebook, which is being developed in consultation with subject matter experts in the areas of TBI, Military and Veteran health, and caregiving, as well as people with lived experience as TBI caregivers. This product will contain a wealth of information that will be relevant to caregivers of V/SMs regarding practical aspects of managing TBI, problem-solving, and reducing negative mood or affect. The long-term impact of this study is a standardized, evidence-based approach to supporting caregiving families for V/SMs with TBI throughout the entire PSC. By engaging key stakeholders throughout the development, testing, and planning to implement REACH TBI, we expect that the resulting intervention will be highly relevant to the target population, usable to a range of providers in multiple settings, and scalable to disseminate broadly.

Beyond its potential impact on the recovery and rehabilitation of V/SMs with a TBI and the

wellbeing of caregiving military families, REACH TBI could be readily adapted and implemented in civilian health care systems. The modular nature of the training materials, modifiability of the resource guide, and virtual option to train a broad range of patient-facing staff throughout health care systems well positions REACH TBI to be used in a dual-capacity among civilian populations.

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Declaration of Interest

The authors report no conflicts of interest.

Data Availability

Data are available upon request by contacting the corresponding author.

References

1. DoD TBI Worldwide Numbers. Military Health System. Accessed May 12, 2021. https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/Research-and-Development/Traumatic-Brain-Injury-Center-of-Excellence/DOD-TBI-Worldwide-Numbers

2. Cifu DX, Taylor BC, Carne WF, et al. Traumatic brain injury, posttraumatic stress disorder, and pain diagnoses in OIF/OEF/OND Veterans. *J Rehabil Res Dev*. 2013;50(9):1169-1176. doi:10.1682/JRRD.2013.01.0006

3. Hendricks AM, Amara J, Baker E, et al. Screening for mild traumatic brain injury in OEF-OIF deployed US military: an empirical assessment of VHA's experience. *Brain Inj*. 2013;27(2):125-134. doi:10.3109/02699052.2012.729284

4. Terrio H, Brenner LA, Ivins BJ, et al. Traumatic brain injury screening: Preliminary findings in a US Army brigade combat team. *The Journal of Head Trauma Rehabilitation*. 2009;24(1):14-23. doi:10.1097/HTR.0b013e31819581d8

5. Taylor BC, Hagel EM, Carlson KF, et al. Prevalence and costs of co-occurring traumatic brain injury with and without psychiatric disturbance and pain among Afghanistan and Iraq war veteran VA users. *Medical Care*. 2012;50(4):342-346.

6. Cornis-Pop M, Hinds S 2nd, Picon L, Tapia R. Rehabilitation in the Department of Veterans Affairs Polytrauma System of Care: Historical perspectives. *Phys Med Rehabil Clin N Am*. 2019;30(1):1-12. doi:10.1016/j.pmr.2018.09.002

7. Thurman DJ, Alverson C, Dunn KA, Guerrero J, Sniezek JE. Traumatic brain injury in the United States: A public health perspective. *J. Head Trauma Rehabil.* 1999;14(6):602-615.

8. Corrigan JD, Cuthbert JP, Whiteneck GG, et al. Representativeness of the Traumatic Brain Injury Model Systems National Database. *J. Head Trauma Rehabil*. 2012;27(6):391-403. doi:10.1097/HTR.0b013e3182238cdd

9. Coronado VK, Xu L, Basavaraju SV, et al. Surveillance for traumatic brain injury-related deaths: United States, 1997-2007. Published 2011. Accessed August 28, 2022. https://stacks.cdc.gov/view/cdc/6014

10. Laborde A. NIH Consensus Development Panel on Rehabilitation of Persons with Traumatic Brain Injury. *J. Head Trauma Rehabil.* 2000;15(1):761-763.

11. Huang SJ, Ho HL, Yang CC. Longitudinal outcomes of patients with traumatic brain injury: A preliminary study. *Brain Inj*. 2010;24(13-14):1606-1615. doi:10.3109/02699052.2010.523056

12. Corrigan JD, Hammond FM. Traumatic brain injury as a chronic health condition. *Arch Phys Med Rehabil*. 2013;94(6):1199-1201. doi:10.1016/j.apmr.2013.01.023

13. Arango-Lasprilla JC, Quijano MC, Aponte M, et al. Family needs in caregivers of individuals with traumatic brain injury from Colombia, South America. *Brain Inj*. 2010;24(7-8):1017-1026. doi:10.3109/02699052.2010.490516

14. Doyle ST, Perrin PB, Díaz Sosa DM, Espinosa Jove IG, Lee GK, Arango-Lasprilla JC. Connecting family needs and TBI caregiver mental health in Mexico City, Mexico. *Brain Inj*.

2013;27(12):1441-1449. doi:10.3109/02699052.2013.826505

15. Sung C, Perrin PB, Mickens M, et al. Influence of TBI impairments and related caregiver stress on family needs in Guadalajara, Mexico. *The Australian Journal of Rehabilitation Counselling*. 2013;19(2):100-118. doi:10.1017/jrc.2013.14

16. Finn JA, Klocksieben FA, Smith AN, et al. Family needs after traumatic brain injury: A VA TBI Model Systems study. *J. Head Trauma Rehabil.* 2022;37:327-337. doi:10.1097/HTR.0000000000000799

17. Armistead-Jehle P, Soble JR, Cooper DB, Belanger HG. Unique aspects of traumatic brain injury in military and veteran populations. *Phys Med Rehabil Clin N Am*. 2017;28(2):323-337. doi:10.1016/j.pmr.2016.12.008

18. Friedemann-Sánchez G, Sayer NA, Pickett T. Provider perspectives on rehabilitation of patients with polytrauma. *Arch Phys Med Rehabil*. 2008;89(1):171-178. doi:10.1016/j.apmr.2007.10.017

19. Olenick M, Flowers M, Diaz VJ. US veterans and their unique issues: Enhancing health care professional awareness. *Adv Med Educ Pract*. 2015;6:635-639. doi:10.2147/AMEP.S89479

20. Collins RC, Kennedy MC. Serving families who have served: providing family therapy and support in interdisciplinary polytrauma rehabilitation. *J Clin Psychol*. 2008;64(8):993-1003. doi:10.1002/jclp.20515

21. Stevens LF, Pickett TC, Wilder Schaaf KP, et al. The relationship between training and mental health among caregivers of individuals with polytrauma. *Behav Neurol*. 2015;2015:185941. doi:10.1155/2015/185941

22. Saban KL, Griffin JM, Urban A, Janusek MA, Pape TLB, Collins E. Perceived health, caregiver burden, and quality of life in women partners providing care to Veterans with traumatic brain injury. *J Rehabil Res Dev*. 2016;53(6):681-692. doi:10.1682/jrrd.2015.07.0143

23. Brickell TA, French LM, Lippa SM, Lange RT. Burden among caregivers of service members and veterans following traumatic brain injury. *Brain Inj*. 2018;32(12):1541-1548. doi:10.1080/02699052.2018.1503328

24. Griffin JM, Lee MK, Bangerter LR, et al. Burden and mental health among caregivers of veterans with traumatic brain injury/polytrauma. *Am J Orthopsychiatry*. 2017;87(2):139-148. doi:10.1037/ort0000207

25. Moriarty H, Winter L, Short TH, True G. Exploration of factors related to depressive symptomatology in family members of military veterans with traumatic brain injury. *J Fam Nurs*. 2018;24(2):184-216. doi:10.1177/1074840718773470

26. Belle SH, Burgio L, Burns R, et al. Enhancing the quality of life of dementia caregivers from different ethnic or racial groups. *Ann Intern Med*. 2006;145(10):727-738. doi:10.7326/0003-4819-145-10-200611210-00005

27. Nichols LO, Martindale-Adams J, Burns R, Graney MJ, Zuber J. Translation of a dementia caregiver support program in a health care system—REACH VA. *Archives of Internal Medicine*. 2011;171(4):353-359. doi:10.1001/archinternmed.2010.548

28. Bédard M, Molloy DW, Squire L, Dubois S, Lever JA, O'Donnell M. The Zarit Burden Interview: A New Short Version and Screening Version. *The Gerontologist*. 2001;41(5):652-657. doi:10.1093/geront/41.5.652

29. Nichols LO, Martindale-Adams J, Burns R, Zuber J, Graney MJ. REACH VA: Moving from translation to system implementation. *The Gerontologist*. 2016;56(1):135-144. doi:10.1093/geront/gnu112

30. Carlozzi NE, Kallen MA, Hanks R, et al. The TBI-Care-QOL Measurement System: Development and preliminary validation of health-related quality of life measures for caregivers of civilians and Service Members/Veterans with traumatic brain injury. *Arch Phys Med Rehabil*. 2019;100(4, Supplement):S1-S12. doi:10.1016/j.apmr.2018.08.175

31. Pilkonis PA, Choi SW, Reise SP, Stover AM, Riley WT, Cella D. Item banks for measuring emotional distress from the Patient-Reported Outcomes Measurement Information System (PROMIS®): Depression, anxiety, and anger. *Assessment*. 2011;18(3):263-283. doi:10.1177/1073191111411667

32. Salsman JM, Schalet BD, Merluzzi TV, et al. Calibration and initial validation of a general self-efficacy item bank and short form for the NIH PROMIS®. *Qual Life Res*. 2019;28(9):2513-2523. doi:10.1007/s11136-019-02198-6

33. Carlozzi NE, Lange RT, French LM, et al. TBI-CareQOL military health care frustration in caregivers of service members/veterans with traumatic brain injury. *Rehabil Psychol*. 2020;65(4):360-376. doi:10.1037/rep0000305

34. Bates D, Mächler M, Bolker B, Walker S. Fitting Linear Mixed-Effects Models Using lme4. *Journal of Statistical Software*. 2015;67(1):1-48. doi:10.18637/jss.v067.i01

35. R Development Core Team. *R: A Language and Environment for Statistical Computing.* the R Foundation for Statistical Computing; 2018. http://www.R-project.org/

36. Brickell TA, Cotner BA, French LM, et al. Severity of military traumatic brain injury influences caregiver health-related quality of life. *Rehabil Psychol*. Published online January 23, 2020:10.1037/rep0000306. doi:10.1037/rep0000306

37. Gulin SL, Peralta SV, Stolfi ME, et al. The influence of personal strengths on quality of care in dementia caregivers from latin america. *J Rehabil*. 2018;84(1):13-22.

Figure 1. Waitlist Control Clinical Trial Timeline

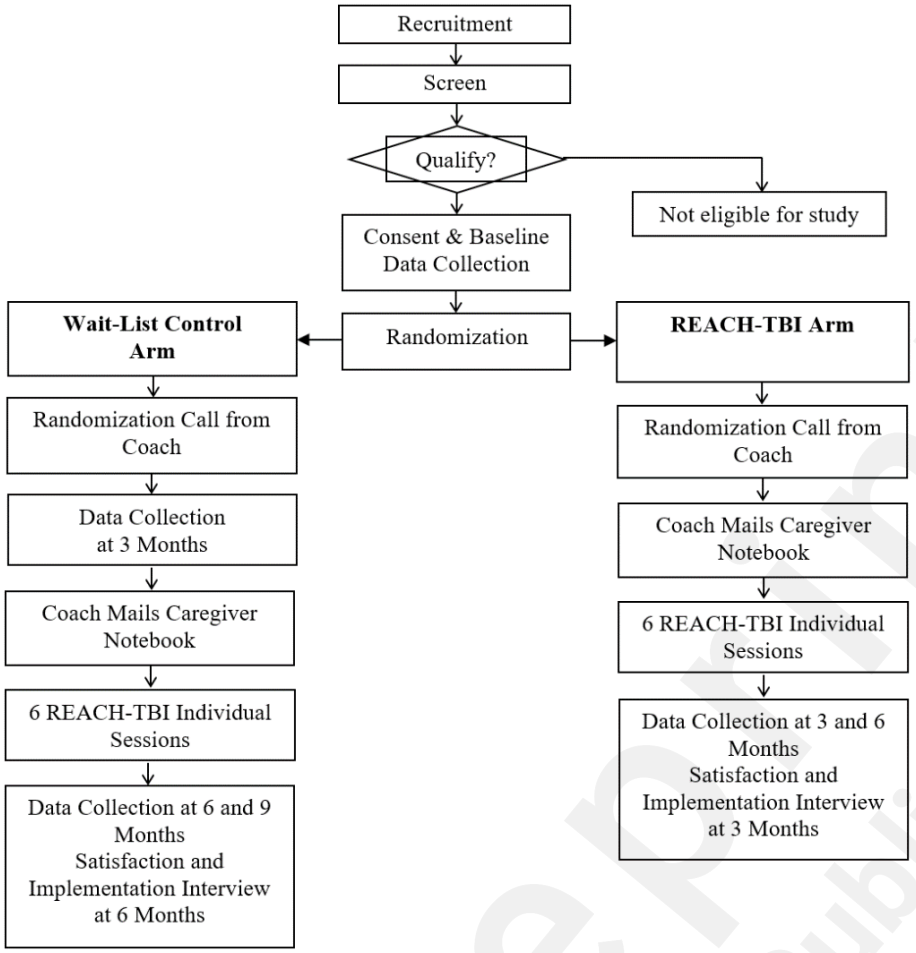

Table 2. Outline of the REACH TBI Intervention

REACH TBI Session/Topic	**Overview of Content and Structure**
Assessment & Session 1 **Stress Management**	Caregiver Assessment Introduce Intervention and Review Caregiver Notebook Discuss stress Introduce stress management technique, Signal Breath
Session 2 **Problem Solving**	Introduce Session Review/modify last session commitment - Signal Breath Provide general information about Veteran or Service Member's health condition Present safety material Introduce health care issues and Health Guide Problem Solve – Target Concern #1
Session 3 **Cognitive Reframing**	Review Health Guide and safety Review/modify Problem Solving Plan #1 Make Commitment for Problem Solving Plan #1 Introduce Cognitive Reframing
Session 4 **Problem Solving or Cognitive Reframing or Stress Management**	Review Health Guide and safety Determine caregiver goal attainment for Cognitive Reframing and Review/Modify, if needed Review/modify Problem Solving Plan #1 Determine caregiver goal attainment for Problem Solving Plans and Review/Modify, if needed If appropriate, identify Target Concern #2 Introduce Problem Solving Plan #2 **Or** Work on Cognitive Reframing Thought Record
Session 5 **Problem Solving, Cognitive Reframing, Stress Management**	Review Health Guide and safety Determine caregiver goal attainment for any Problem Solving Plans and Review/Modify Review/modify Cognitive Reframing Offer stress management technique
Session 6 & Closure **Problem Solving, Stress Management, and Cognitive Reframing review**	Review Caregiver Notebook Review safety recommendations Review health and use of Health Guide Review Caregiver Well Being Review stress management techniques and strategies that worked Review Cognitive Reframing techniques Review Problem Solving Plans covered and strategies that worked

Supplementary Files

Multimedia Appendixes

DoD Peer Review Summary Statement.
URL: http://asset.jmir.pub/assets/bd400cf05b355fe8b46ce7f5c970e296.pdf