Interventions for Parent Caregivers of Injured Military/Veteran Personnel

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INTERVENTIONS FOR PARENT CAREGIVERS OF INJURED MILITARY/VETERAN PERSONNEL

CLINICAL TRIALS ID: 14029002

Original Proposal – May 20, 2014

Parent Statement of Work (SOW)

Task 1: Develop Manual of Operations (MOP) **Months 1-6** **Sept 14-Feb 15**

Activities
- Finalize individual intervention format
- Finalize informational webinar sessions
- Finalize intervention materials
- Finalize screening materials
- Finalize data collection protocol/battery
- Develop recruitment materials

Products
- Intervention format, topics and scripts
- Informational webinar format, topics and scripts
- Participant Workbooks and Welcome Packs
- Screening forms and scripts
- Data collection forms, scripts and documentation
- Brochures, web site, social media blurbs
- Participant Workbooks and Welcome Packs

Task 2: IRB approval **Months 1-6** **Sept 14-Feb 15**

Activities
- Develop informed consent documents

Products
- Approved consent

Task 3: Hire and train personnel **Months 1-6** **Sept 14-Feb 15**

Activities
- Write job descriptions, interview, hire, train

Products
- Trained and certified staff

Task 4: Recruitment and Randomization **Months 7-27** **Mar 15-Nov 16**

Activities
- Work with recruitment sources
- Telephone and screen potential participants
- Randomize and assign to Study Arms 1,2

Products
- Approximately 336 participants screened
- 160 participants recruited
- 80 participants randomized to each arm

Task 5: Intervention (Individual Sessions) **Months 7-29** **Mar 15-Jan 17**

Activities
- Schedule and provide sessions

Products
- Sessions provided

Task 6: Attention Control (Webinar Sessions) **Months 7-29** **Mar 15-Jan 17**

Activities
- Schedule and provide sessions for participants

Products
- Sessions provided

Task 7: Data Collection/Data Entry/Cleaning **Months 7-35** **Mar 15-Jul 17**

Activities
- Collect full data at baseline, 3 and 6 months
- Enter and clean data

Products
- Completed data entry

Task 8: Data Analysis **Months 28-36** **Dec 16-Aug 17**

Activities

Products

- Analyze data
- Completed data analysis

Task 9: Preparation and Dissemination of Results Months 28-36 Dec 16-Aug 17

Activities
- Prepare papers and presentations
- Develop protocol for dissemination

Products
- Papers and Presentations
- Manuals and materials and plan for dissemination

Background

Almost half (49.3%) of active military members are 25 years of age or younger and more than half of veterans receiving services at Veterans Affairs (VA) facilities are under age 30. Compared to previous wars, younger service members associated with the current conflicts, Operation Enduring Freedom (OEF)/Operation Iraqi Freedom (OIF)/Operation New Dawn (OND), tend to be in newer marriages or are still dating (43.3% are unmarried). Due to this younger population, parents are typically the caregivers of injured OEF/OIF/OND veterans (1), especially those returning with polytraumatic injuries (1-3) or traumatic brain injury (TBI), which can require long term rehabilitation under the care of a family member (4). This randomized clinical trial will test a well-established caregiver intervention, compared to attention control, to provide education, training in coping skills, and support to parent caregivers of post deployment military personnel (active duty, Guard, Reserve, veteran).

OEF/OIF/OND service members have experienced a high amount of combat trauma (5). Due to technology advances, more service members are returning with injuries they would not have survived in previous conflicts (6-10). Nearly half who served in Iraq or Afghanistan have been in close proximity to a blast (11) and according to the Department of Defense (12), more than 51,000 service members have returned injured.

Injuries resulting from blasts are often polytraumatic (injuries to multiple body systems) (1,13). Sayer et al. defined the "polytrauma triad" as consisting of TBI, post traumatic stress disorder (PTSD), and pain (13). However, polytraumatic injuries (14) typically result in multiple comorbid conditions, hearing or eye sight loss, chronic pain, PTSD, spinal cord injury/disorders (SCI/D), or amputations, in addition to TBI (1,10,15).

These coexisting injuries often lead to problems in physical, cognitive, and psychosocial functioning (8,16). Combat injured service members are more likely to develop PTSD than those not injured in the same combat event (1). According to the "Costs of War" project, based at Brown University (17), 253,330 individuals have been diagnosed with TBI and 103,792 with PTSD. Mental health issues have a prevalence of 37% in the VA, and 10 to 20% of service members develop long term issues from TBI (2,11,13,18,19). For veterans seen by the VA during 2009 to 2011, 9.6% were diagnosed with TBI, 29.3% with PTSD, and 40.2% with pain. Of those with TBI, nearly half had both PTSD and pain diagnoses (16).

Christensen et al. found that 89% of caregivers of seriously ill or wounded service members are women with 76% under age 55 (20). Most of these are parents (62%) with mothers the most common caregivers for unmarried service members (20). About a fifth of caregivers provide more than 40 hours of care a week and about 30% provide more than 30 hours of care per week (2,20). For veterans classified with high intensity needs from polytrauma, 50% of their caregivers provide care for at least 80 hours per week. Service members with high intensity needs require help with activities of daily living (ADL), such as bathing or feeding, and instrumental activities of daily living (IADL), such as shopping or managing finances. Even for low and moderate intensity care recipients, caregivers provide care from 5 to 80 hours per week. Moderate intensity care requires help with IADLs (not ADLs) and low intensity care requires assistance with complex tasks, i.e., help with the benefit or health care system and emotional support (3).

Caregivers often schedule appointments, assist with medication, drive the service member, provide personal care, pay bills, assist in household chores, and supervise childcare. Seriously injured service members are often apprehensive in large groups or around people they do not know, so they spend most of their time with their caregiver (6,20).

Many caregivers become legal guardians because of care recipients' cognitive limitations in handling budgeting (6). Family members may also need to temporarily relocate away from support systems, jobs, schools, and homes to be closer to a facility where a service member is being treated. Those with polytraumatic injuries typically require long-term and life-long care. Once a service member is discharged from the VA, care typically shifts from the institution to a family member (21) and many families struggle with long-term care, leading to high levels of divorce, stress, and burden (2).

Parents must often decide who will return to work and who will continue caregiving duties. Time away from a job can extend up to 4 years depending on an injury's severity. Two-thirds of veterans' caregivers work outside the home (10), and many have to either reduce their work hours (62%) or quit altogether (10,20,22,23). In addition to quitting work or cutting back hours, caregivers may also lose pension accruals or promotions or may experience financial stress by changing jobs and from costs of care (3). For example, high intensity care is the primary reason for debt or asset depletion (3,24). Financial stress may hinder recovery of the injured person because the strain impacts the family unit (3).

About 31% of caregivers are also caring for someone else such as children and/or other adults, which places further burdens on finances and the caregiver's health (2,20). Most of these caregivers are not paid for their work and about 60% have no help in providing care. When caregivers ask for help, about 32% reported getting little if any help from others (2). Consequently, family members caring for an injured service member report high levels of caregiver burden and stress (25). When the service member is suffering from polytrauma, caregiver burden increases substantially (24). Caregivers put off addressing their own health needs, often leading to depression and becoming burned out (10,26).

Providing education and mental health resources to families can help reduce caregiver burden, which in turn positively affects the health of the care recipient (27,28). Carlson et al. found that caregivers with higher levels of depression, anxiety, or any physical health problems increased the chance of subsequent injuries to the patient (29). Service members returning with TBI made less progress in treatment if the family unit was distressed (18). Conversely, PTSD symptoms often decrease as family and social support increases (19). Improving caregiver social support also improves outcomes for both (1,15). Consequently, there has been a call to provide services for caregivers of injured service members, including additional support (13,15,30), education and counseling to decrease stress and increase coping skills (14,18,24,29), skills training and information about rehabilitation (13,18), and education about the military system (15,20).

Despite this identified need and potential benefits of helping caregivers, more research is needed to evaluate intervention effectiveness for this caregiving population (31). Future research needs to examine coping strategies for caregivers taking care of service members with polytraumatic injuries because most caregiving research to date has focused on dementia (15). There are gaps in our knowledge of caregiving for these service members/veterans, including information on TBI caregiving (18) and what factors cause higher levels of anxiety and depression in TBI/PTSD/polytrauma caregivers (32). Research is needed to determine strategies caregivers need to better care for themselves and their patients with polytrauma and TBI (14), communication methods between the caregiver and care recipient, and best practices to help families adjust (4,15). Few TBI interventions exist for spouses and parents (31,33). Although there is a growing body of knowledge on spouses providing care for post deployment reintegration, research should also look at parents' perceptions of changes within the family due to caring for a young adult with TBI (34).

Finally, many families do not live near services that offer TBI treatment (1,35) and there are not enough psychiatrists to meet needs in rural or low income areas (9). Providing services by phone or online may offer ways to reach families in isolated areas, which in turn may improve family outcomes (1,15). Providing more resources may provide more coping skills and resiliency leading to reduced anxiety and stress (9,15).

To meet this need, this randomized clinical trial will test a well-established caregiving intervention, developed for dementia caregivers and also used with spinal cord injury/disorders caregivers, compared to attention control, for parent caregivers of military personnel (active duty, Guard, Reserve, veteran) who are post deployment. The two study arms are: structured and targeted individual sessions offered by telephone, and webinar education sessions, which will provide an attention control and are analogous to the usual standard of care. Each arm will have 80 participants, for a total of 160 participants.

The caregiver individual sessions intervention is theoretically based and includes multiple components that have been proven successful in helping caregivers: education; support; and practical skills building, including problem solving, cognitive restructuring, communication, and stress management (21,36,37). A strength of the intervention is its ability to provide important knowledge and skills that caregivers need, expressly targeted to the specific concerns of each caregiving dyad.

The individual sessions intervention is based on two well-established programs, Resources for Enhancing Alzheimer's Caregivers Health (REACH II) and Resources for Enhancing All Caregivers' Health in the VA (REACH VA). REACH II was a multisite National Institute on Aging/National Institute of Nursing Research randomized controlled trial (RCT) to provide behavioral interventions for dementia caregivers (2000-2003) (36). REACH VA, based on REACH II, was the first national translation of a behavioral intervention for dementia caregivers, (2007-2009) (38), and with the passage of Public Law 111-163 Caregivers and Veterans Omnibus Health Services Act of 2010 became a VA clinical program for dementia and spinal cord injury/disorders caregivers, soon to expand to multiple sclerosis/amyotrophic lateral sclerosis (MS/ALS) and chronic mental illness caregivers.

During the past twenty years, the REACH intervention has proven to be extremely robust. It is one of the most well studied behavioral interventions for caregivers and has been nationally recognized as a dementia intervention. It was a Senate Special Committee on Aging exemplary geriatrics project to be used to inform aging policy. REACH VA was selected for the 2009 Rosalynn Carter Leadership in Caregiving Award, which recognizes leadership in implementing innovative partnerships between community agencies and caregiving researchers that bridge the gap between science and practice to move caregiver support programs to widespread use in the community more quickly and efficiently. The National Plan to Address Alzheimer's Disease mandates that lessons learned through VA caregiver support strategies, specifying REACH VA, should be shared with other federal agencies; currently it is being implemented into the Indian Health Service. The Rosalyn Carter Institute on Caregiving provides funding and training to sites across the country each year to implement the REACH VA intervention and the Administration on Aging has used REACH II and REACH VA as models for sites in its Alzheimer's Disease Supportive Services Program (ADSSP) program as part of community implementation of evidence based behavioral interventions.

The REACH intervention is designed to provide caregivers with tools and skills to diagnose and manage ongoing and evolving problems that arise during caregiving. The intervention provides education, support, and skills building face-to-face and/or by telephone. It is structured through a protocol that specifies activities to occur at each session and is targeted to meet caregiving dyad needs, which has been shown to be effective in managing caregiving distress (39). The targeting is through a Risk Priority Inventory that identifies specific caregiver/care recipient concerns in the main caregiving risk areas: education, safety, emotional well-being, health and self-care, social support, and disease specific patient

behaviors or problems. The Interventionist teaches problem solving and provides action-oriented behavioral strategies to address caregiving problems or patient behaviors identified by the risk assessment. The Interventionist also provides training on cognitive restructuring to modify thoughts and feelings about situations that cannot be changed. Stress management training includes signal breath, stretching, guided imagery, and pleasant events. An important component of the intervention is a Caregiver Notebook, which provides educational information and practical strategies for behavioral and stress/coping topics that can be personalized for the caregiver.

The structured but targeted nature of the intervention has made it successful with all types of stressed and burdened caregivers such as spouses, children, and other family members, and with caregivers who are coping with varying challenges and levels of disease. For REACH II, intervention caregivers showed significant improvement in burden, depression, health and self-care, social support, and management of patient behaviors, caregiving frustrations, which can lead to potential abuse, and gained 1 extra hour per day not spent in caregiving tasks compared to control caregivers (36,40). For the REACH VA two year clinical translation, from baseline to 6 months, caregivers reported significantly decreased burden, depression, impact of depression on daily life, caregiving frustrations, and number of troubling dementia-related behaviors. A 2-hour decrease in hours per day on duty approached statistical significance (38). Other versions of the REACH intervention have produced similar outcomes (41-45).

Because REACH VA was implemented in the VA healthcare system as a clinical program it was modified from the original six month, twelve home and telephone sessions to provide staff and caregiver flexibility while retaining critical skills to empower caregivers. There are now six core individual sessions during three months; this number is consistent with other REACH models (41,45). The Memphis Caregiver Center is funded nationally by VA's Caregiver Support Program to help VA facilities in implementing the intervention and has provided training, certification and coaching to 110 VA sites and 337 staff members to date.

As shown in Table 1, preliminary results document that the REACH VA four session intervention provided benefit to caregivers. Just as for REACH II and the REACH VA clinical translation, caregivers experienced significant decreases in burden, depression, and caregiving frustrations during the intervention. Although the research studies used longer scales with different cut points, effect sizes are comparable with those from the REACH VA clinical translation, which computed clinical effects and found an effect size for burden of .33, for depression of .26, and for frustration of .30. These effect sizes are consistent with effect sizes reported for psychosocial interventions with clinical significance (46).

Table 1. REACH VA Six-Session Program Outcomes (N = 125)

Variable	Baseline $M \pm SD$	Follow-up $M \pm SD$	p-value	Cohen's d
Burden (0-16)	7.7 ± 4.0	6.4 ± 3.5	<.001	.33
Depression (0-6)	2.0 ± 1.9	1.5 ± 1.7	.006	.26
CG Frustration (0-4)	1.3 ± 0.9	1.0 ± 0.8	<.001	.33

This study is based on two conceptual frameworks. The rationale for intervening with parents is grounded in the life course theory model (47), as articulated for military families (48). Service member injuries and/or cognitive or psychological symptoms resulting from injury lead parents to assume the role of caregiver at an unexpected time in life (48). When parents become caregivers of adult children their emotional well-being suffers and employment (and health care insurance) can be affected.

The intervention's ability to reduce caregiving stress may be understood through a stress/health process model, which is the second conceptual framework. Caregivers experience stress if they perceive that demands placed on them are greater than their resources and their capacity to manage demands (49). The

Lazarus and Launier stress model (50) expands this framework to focus on actions caregivers can take to cope with stress: action-oriented management of environmental demands and intrapersonal efforts to manage cognitive and emotional responses to situational demands. Effective action-oriented coping depends partly on information and skills to diminish, tolerate, or master situational demands. Both these mechanisms have been found to be important for mediating stressors for military families (51-53). However, although it has been shown that specific resources that help military families cope include services available on base to active duty families (48,52), these resources are not generally available to parent caregivers.

A major component of the intervention is managing patient behaviors and activities of daily living/instrumental activities of daily living (ADLs/IADLs), a major situational demand for caregivers of individuals with polytrauma and/or PTSD. Perceptions of demands and coping are individualized (36) and both the internal responses of the stressed individual, and techniques to tolerate demands that cannot be changed, are critically important (54). Internal responses of the stressed individual are also targeted. Although caregivers are taught more efficient strategies to manage patient behaviors, they are also taught cognitive restructuring skills to reduce distress over behaviors and circumstances not amenable to change and strategies to manage stress. Dementia caregivers provided with behavioral interventions alone, without attention to intrapersonal coping strategies, have poorer affective outcomes (55), which may lead to a decrease in the quality of care provided and/or institutionalization of the care recipient.

The attention control condition will provide online education webinars. Webinars do not require face-to-face interaction or a presence on a military base or VA facility. These types of resources, such as internet sites and internet chat rooms may provide an ongoing linkage to reduce depression and assist with coping (56).

Drs. Nichols, Martindale-Adams, Burns, and Graney have the expertise to implement behavioral interventions for stressed caregivers, specifically parents of OEF/OIF/OND service members. For more than twenty years, they have been involved with the REACH intervention as Principals and Co-Investigators of the original REACH I, REACH II, and REACH VA intervention studies. Drs. Martindale-Adams and Nichols are Co-Directors of the Memphis Caregiving Center, which provides training, certification and coaching to VA staff nationally in the REACH VA intervention and the Spouse Telephone Support intervention for post 9/11 spouses. In addition to their work with the REACH intervention in the community and the VA, they have extensive experience in working with military families.

Their current DoD Medical Operations Management Research Program funded RCTs examine telephone support to spouses and significant others of post 9/11 service members. One for post deployed spouses (Spouse READI, W81XWH-09-1-0242) is ending and one for deployed spouses is ongoing (Spouse Deployed, W81XWH-11-2-0087). Both examine telephone support groups of 6 to 10 participants and a group leader to provide education, skills building and support to spouses and significant others of service members/veterans. Each study also includes education webinars that provide the same content without group leader led active skills building and support as attention control. Their previous DoD CDMRP (Congressionally Directed Medical Research Programs) sponsored pilot (W81XWH-08-2-0195) was designed to demonstrate the feasibility and effectiveness of a telephone support group intervention for spouses of returning Iraq and Afghanistan service members. For 86 wives of active duty, Guard and Reserve service members who were post deployment, from baseline to follow-up, spouses reported significantly improved depression, anxiety and social support. Two of the three statistically significant findings, depression and anxiety, also met criteria for clinical significance with clinical effectiveness scores (Cohen's d) ranging from .17 to .44. During the study, spouses reported a decreased level of concern about effects of reintegration on their social life, their home life, their family, their husband, and themselves. Spouses who were dealing with injuries that caused care difficulties were more burdened, but

had a stronger clinical response to the intervention than spouses who were not coping with care difficulties (57,58).

With the passage of the Caregiver Law, Public Law 111-163, this telephone support group research intervention was adopted by the VA as a national clinical program, the Spouse Telephone Support program. The Memphis Caregiver Center trains, certifies, and coaches VA clinicians to deliver the intervention to spouses of post 9/11 veterans. More than 100 sites have been trained to date.

This team brings decades of experience working with caregivers, an understanding of struggles faced by military families post deployment, and familiarity with designing and implementing caregiving interventions to help ensure the success of the proposed project. Thus, the proposed study unites sound theoretical perspectives, distance-neutral methodologies that will alleviate many access barriers, proven strategies for improving the coping abilities of stressed caregiving populations, and a team of investigators with the unique skills to make the study successful.

Hypotheses

Hypothesis 1: Education Webinar arm participants will improve during the course of the study on outcomes, including depression, anxiety, and burden.

Hypothesis 2: Individual Session arm, compared to the Education Webinar study arm, will be significantly more effective in improving outcomes, including depression, anxiety, and burden.

The effect of potentially confounding variables will be controlled for in analysis, i.e., determining whether impact is equivalent for participants who differ on a range of variables such as number of sessions completed, amount and type of care provided, and type of service member injury/disability.

Technical Objectives

Objectives. This randomized clinical trial will test a behavioral caregiving intervention that has been used successfully for dementia and SCI/D caregivers to provide services to stressed and burdened parent caregivers of OEF/OIF/OND service members. This intervention is six intensive individual sessions that will teach problem solving, cognitive restructuring and stress reduction targeted to an individual assessment of the care dyad's needs. It will be compared to another method of delivering content, education webinar sessions, which are analogous to the usual standard of care and will function as an attention control arm. The objective of the study is to determine which of these delivery mechanisms is more effective at helping parent caregivers of injured OEF/OIF/OND returning troops to improve their depression, anxiety, and burden, and to determine the feasibility of using individual sessions with this population of caregivers.

The long-term objective is to develop materials for parent caregiver interventions that can be disseminated across the Department of Defense (DoD) and the Department of Veterans Affairs (VA) Veterans Health Administration (VHA). Each of the interventions (the individual sessions and the education webinars) have different strengths, and may be more acceptable for different organizations and staff, according to varying logistic constraints and organization, patient, caregiver, and staff needs. Research goals include:

1) Determine effective strategies for providing education, skills building and support for parent caregivers of OEF/OIF/OND returning service members; and

2) Determine feasibility of conducting interventions with parent caregivers.

The technical aims of the study are: 1) determine characteristics of those who are recruited in the study arms; 2) determine satisfaction; 3) determine commitment and adherence to therapeutic recommendations; and 4) develop manuals for clinical translation.

Project Milestones

Project Activities	Year 1		Year 2	Year 3
Develop Manual of Operations	******			
IRB approval	******			
Hire and Train Personnel	******			
Recruitment		******	**********	***
Interventions		******	**********	*********
Collect Data		******	**********	**********
Enter/Clean Data		******	**********	**********
Analyze Results				**********
Prepare/Disseminate Results				**********

Military Significance

Almost half (49.3%) of active military members are 25 years of age or younger, with the highest percentage of younger members in the Marines (68.5%), and 43.3% are unmarried, according to Military One Source (59). These young, single service members are often dependent on parents for any care they need post deployment (1), especially those returning with polytraumatic injuries (1-3) or traumatic brain injury, which can require long term rehabilitation under the care of a family member (4). To date, 103,792 service members have been diagnosed with PTSD and 253,330 with TBI. Injuries resulting from blasts are often polytraumatic (injuries to multiple body systems) (1,13). However, care needs may be at different levels, ranging from full time, 24/7 care needed for polytrauma/TBI injuries to supervision of risky behavior to assistance with reintegration challenges due to PTSD. Economically, the toll is high with treatment cost estimates for 2020 estimated to be $8 billion annually. Personally, PTSD caregivers' care burden is twice that of other caregiving populations and is similar to that of dementia and chronic schizophrenia caregivers (60) with care provision upwards of 80 hours per week and care more likely to last longer than 10 years.

Carlson et al. found that caregivers with higher levels of depression, anxiety, or any physical health problems increased the chance of subsequent injuries to the patient (29). Service members returning with TBI made less progress in treatment if the family unit was distressed (18). Conversely, PTSD symptoms often decrease as family and social support increases (19). Providing education and mental health resources to families can help reduce caregiver burden, which in turn positively affects the health of the care recipient (27,28). Improving caregiver social support also improves outcomes for both (1,15).

This proactive approach to military family service delivery would remove or mitigate several barriers to care: lack of local services, access, privacy concerns, distance, and travel. By offering low-cost preventive interventions reflective of the public health model, these interventions would offer an alternative to centralized services that may not be used by military families, particularly those in rural areas and/or in the Guard/Reserve. In addition, parents may not be eligible for services from traditional military and veteran sources. The proposed interventions are focused on prevention and will be delivered to participants at high-risk for diminished general well-being related to depression, anxiety, and role strain/overload, to boost their self-efficacy and coping behaviors. With limitations of distance and transportation removed, this study is designed to increase access to services and to take the intervention to the people who need it most – parent caregivers who are experiencing difficulties providing post deployment care.

In addition, this study tests a model of delivery that could function well in multiple clinical and support settings of DoD and VA and is currently being implemented nationally for different populations by VA and community clinicians and social service providers. The individual sessions may provide an opportunity for participants to build skills and focus on topics of immediate interest one-on-one with an

Interventionist. For DoD and VA clinicians or individuals who would be providing the interventions, the ability to work with caregivers in person or remotely would meet different clinical goals and maximize staff flexibility. The intervention has the capability of activating formal and informal networks of support that can improve individual and family outcomes, and more importantly, build the capacity of the individuals and the military to meet future challenges (61).

VA and DoD resources are limited. The study will offer this under-served demographic of parents post deployment support. The intervention uses empirically proven components (problem solving, cognitive restructuring, stress management). The individual sessions have been shown to be an efficient intervention with stressed caregiving populations that improves outcomes and could be a low cost way to offer practical help to military families. Because the military and VA system may not be always available to work with parent caregivers, the REACH design, training, and materials empower caregivers with knowledge and skills to manage ongoing caregiving challenges.

Public Purpose

Parents of adult and younger children who have acquired traumatic head injury will benefit from the findings of this research. Family concerns are similar, whether the injury is acquired in combat or the community, focusing on financial and social stressors (61), disruption to the family system (31), lack of emotional support (33), and need for information, particularly addressing behavioral, affective and quality of life changes of the head-injured person (33).

Community caregivers report high levels of caregiver distress (32), and high levels of unhealthy functioning (26). Depression, anxiety, and somatic symptoms are common among caregivers (26,62). Distress levels among spouses, parents, and other caregivers are comparable (26); however, parents are more distressed by fear of the future and physical burdens than spouses (33), and that fathers report greater injury-related stress and distress than mothers over time (63). Some of the stress of caregiving is related to the patient's characteristics. Higher caregiver distress is associated with caring for survivors who have worse functional status, receive more supervision, are less satisfied with life, and use alcohol excessively (26). Conversely, poorer caregiver functioning is associated with poorer patient functioning. For example, decreased patient participation in society is associated with a passive coping style by the primary caregiver (64).

Family coping and functioning are frequently strained for parents after a head injury. Mothers report family difficulties in getting along with each other, facing new financial hurdles, going separate ways as the family copes, and the family splitting apart (34). For parents of young children who have been injured there are differences between parents, with fathers more likely to use denial to cope while mothers are more likely to use acceptance and emotion-focused strategies (63).

There has been little comprehensive research (31) to determine what makes head injury caregivers depressed (32) and what caregivers need (33). Information concerning emotional and behavioral changes subsequent to head injury for family members should help families adapt better. Caregivers' needs can be more fully met by a combination of addressing common themes and the identification of individual family needs (33). Other families have expressed a desire for increased peer support (61).

Thus, this research will provide benefit to military, veteran and civilian parents struggling with the needs of their injured children.

Methods

Overview. This randomized clinical trial will study a well-established intervention to provide education, training in coping skills (problem solving, cognitive restructuring, stress management), and support to parent caregivers of military personnel to an attention control arm. Both interventions have been used successfully in our work with military and veteran family members and caregivers. Study arms include:

1) individual telephone sessions with caregivers; and 2) education webinar sessions, analogous to usual care. There will be 80 parents recruited and randomized in each study arm, for a total of 160. A Caregiver Workbook will include comprehensive materials for all sessions and topics. All sessions will be taped and treatment fidelity will be monitored and ensured through assessment of intervention delivery, receipt, and enactment.

Outcomes will include depression, anxiety, and burden. Trained Research Associates will collect data by telephone at baseline, 3, and 6 months. Participant satisfaction will be measured with a project evaluation focused on benefit, utility and support.

Study Population and Inclusion and Exclusion Criteria. The sample will be 160 stressed and burdened caregiver parents of post 9/11 service members. Participants will vary by race/ethnicity, age, region, rural/urban location, socioeconomic status, and service member rank and service branch, which will increase generalizability. To be eligible for the proposed study, the participant must: 1) identify as a parent who serves as the primary/main caregiver for an OEF/OIF/OND service member or veteran with a diagnosis of TBI or PTSD or physical injury and at least 1 ADL limitation or 2 or more IADL limitations; 2) provide 3 hours or more of care per day for at least 6 months; and 3) endorse at least 2 caregiving stress behaviors (overwhelmed, often needing to cry, angry/frustrated, cut off from family/friends, moderate/high levels of stress, and declining health). Caregiver exclusion criteria include: 1) current diagnosis of schizophrenia or other major mental illness; or 2) auditory impairment that would make telephone use difficult. We have used these criteria successfully in our dementia caregiver studies to identify a stressed population. For caregivers of post 9/11 veterans with high intensity care needs from polytrauma, 76% report spending more than 20 hours per week with 49% spending greater than 80 hours per week (15). In our work with post deployment spouses, spouses providing care for a service member who had injuries or diagnoses leading to care difficulty were more at risk for adverse outcomes and showed a stronger benefit from supportive interventions (57).

Settings. Caregivers will participate from home, anywhere in the country. The Interventionist will be at the VA Medical Center (VAMC) Memphis or at home for night or weekend sessions.

Interventions and Materials

Caregiver Workbook. The Caregiver Workbook will be sent to each participant after randomization. The Workbook will structure materials used by participants in the active intervention and additional material for the webinars, serve as a "central location" to place all materials, and provide a resource after study end. Modeled after those used in the REACH VA programs, the Workbook has patient disease and behavioral management topics, caregiver stress and coping topics, and additional resource material that expands on each topic. The Workbook has activities throughout, including worksheets related to each topic and questions to deepen participants' interactions with the material and personalize issues. The Workbook also addresses red flag issues. During the individual and webinar sessions, the Interventionist will make participants aware of relevant red flags – areas that may exacerbate problems, add a level of difficulty or distress, and/or indicate a need for referrals – and highlight referral information and additional commercial or public resources (in the Workbook) that will expand on the particular didactic topic. Examples of Red Flags include Guide and Safety Plan for unsafe or dangerous behaviors; Abuse and Addictions – Finding help and assistance.

Supplemental materials we currently include in our spouse telephone groups Participant Workbooks include: Worksheets for activities, Relaxation Techniques, Signal Breath, Rate your tension level, Change Worksheet, Active Listening, and Crisis Hotline Numbers. Additional commercially available materials include: Suicide Prevention materials (Suicide Prevention Men and Women Veterans – Knowing the Warning Signs of Suicide – Brochure, magnet and warning signs card), Poison Help

stickers, Stress and PTSD materials (Stress, Job Stress, Let's Talk About Post Traumatic Stress Disorder, TBI and PTSD).

Individual Sessions Arm. The individual sessions intervention focuses on education, skills building, and support. It will be delivered in six sessions by telephone over three months. We will use the format that is used nationally in the VA in the REACH VA intervention for dementia and SCI/D caregivers.

The strength of the individual sessions intervention is that it is structured, standardized and targeted to help caregiver focus on what needs to be done in the short and long term, without being overwhelmed by the many challenges of care. The sessions are structured through a protocol that specifies activities to occur at each session. There are materials for staff in an Interventionist Manual including protocols, and scripts and talking points for each topic. The intervention is standardized to ensure that the five caregiving risk areas of safety, social support, problem behaviors, caregiver emotional well-being, and caregiver health are covered and core skills are taught.

Most importantly, however, the intervention is targeted and individualized to the concerns of the specific caregiver and care recipient through a risk assessment. The Risk Priority Inventory (RPI) assesses the main caregiving risk areas for the specific caregiving dyad. The RPI is used to tailor the intervention for care recipient behaviors or safety issues and/or caregiver centered issues/concerns related to health, physical and emotional well being, and/or social support.

The individual sessions incorporate evidence-based components that are crucial to successful caregiving interventions (36,21,37) including problem solving, cognitive restructuring/mood management, and stress reduction. The Interventionist and caregiver negotiate the concerns to be addressed using those identified by the risk assessment. Using problem solving techniques, Interventionist and caregiver attempt to find effective and workable solutions to a specific target behavior/issue that is causing stress and burden for the caregiver. The target behavior/issue 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 ADL challenges for seriously compromised service members to risky behaviors of service members with mild TBI or PTSD, or to caregiver stress, guilt or grief.

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 patient behaviors using topics from the Caregiver Workbook in a targeted behavior/issue plan. Problem solving steps include:

1. Determine problem
    - Patient behavior
    - Caregiver reaction or concern
2. Define/operationalize the problem
    - Frequency
    - Duration
    - Intensity
    - Characteristics
    - Antecedents and consequences of behavior (ABC Process)
3. Assess previous attempts to address
4. Set goals and realistic outcome
5. Treat or eliminate antecedents and triggers
    - Unmet physical needs (e.g., pain)
    - Unmet psychological needs (e.g., loneliness)
    - Environmental causes (e.g., stimulation, noise)

- Psychiatric causes (e.g., depression)

6. Develop plan
   - Brainstorm best practice and evidence-based strategies, using the Caregiver Notebook
   - Help caregiver select strategies based on problem type and dyad's needs, abilities, and resources
   - Write strategies down
   - Teach caregiver to use strategies, practice and role model
7. Review and troubleshoot plan

The plan is implemented by the caregiver and revisited at the next session to discuss success, failure, barriers, and/or need for modification. At each session following the introduction of the target behavior/issue plan the Interventionist reviews the suggestion and strategy implementation by the caregiver (i.e., what have you tried) and the status of the behavior/issue (i.e., goal attainment, better, worse, the same).

The Interventionist also provides training on cognitive restructuring using caregiver identified concerns and stress management techniques such as signal breath, stretching, guided imagery, and pleasant events. Training in skills for managing caregiver mood and behavior focuses on two overarching approaches: reducing negative affect/mood and increasing positive affect/mood. The Interventionist helps the caregiver reduce negative affect/mood (frustration/anger and sadness/depression) by learning to appraise the situation more realistically and learning to identify and challenge negative thinking. The Interventionist also works with the caregiver to increase positive mood through an awareness of the connection between mood and activities, learning to relax in the stressful situation and manage stress, along with strategies for increasing simple everyday pleasant activities.

Each session is structured to build on the previous session using a 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.

Session 1

- Review caregiver Risk Priority
- Ask caregiver to tell story
- Introduce intervention
- Review Caregiver Notebook
- Discuss effects of stress
- Introduce stress management technique, Signal Breath
- Obtain closure to session

Session 2

- Introduce session
- Review/modify Signal Breath stress management technique
- Provide general education about patient's condition, as needed
- Present safety material (including alerts if appropriate)
- Introduce health care issues (including alert if appropriate)
- Introduce Heath Guide designed to help manage health care and develop healthy habits
- Introduce target behavior/issue plan #1
- Obtain closure to session

Session 3

- Introduce session
- Review/modify target behavior/issue plan #1

- Introduce cognitive restructuring/mood management
- Obtain closure to session

Session 4 and Session 5

- Introduce session
- Review/modify mood management or stress management technique
- Determine caregiver goal attainment for target behavior/issue #1 (better, the same, worse, and barriers)
- If needed, review/modify target behavior plan #1
- If appropriate, problem solve - identify target behavior/issue #2
- Introduce target behavior/issue plan #2
- If needed, modify target behavior/issue plan #2 (Session 5)
- Offer stress management technique, Power of Music, Stretching or Pleasant Events
- Obtain closure to session

Closure Session

- Introduce session
- Review use of Health Guide and safety recommendations
- Review target behavior/issue plans covered and strategies that worked
- Review cognitive restructuring/mood management techniques
- Review stress management techniques and strategies that worked
- Validate caregiver use of strategies
- Encourage use of available formal and informal support services
- Obtain closure

Education Webinar Sessions Arm. One common type of control condition involves equal attention without the therapeutic components being tested in the intervention condition. Attention control tests the hypothesis that improvements in the outcome occur because of participant expectancies and the attention received during the course of the treatment, rather than from the treatment itself (65,66). For the education webinar sessions, topics addressing each of the caregiving risk factors topics but without the skills building or cognitive restructuring components present in the individual intervention sessions will be available online in webinars. The education webinar sessions will focus on general information safety, social support, problem behaviors, caregiver emotional well-being, and caregiver health. Education webinar session participants will also receive the Workbook.

Each individual assigned to the education webinar arm will be called and informed how to access the session through the VA Memphis website, using a participant code. This code will be specific to the individual participant, but will not contain any identifiable information. Once a participant logs in to view the session an email will be sent back to the Interventionist to let her/him know who did, or did not, view each topic. The Interventionist will send a reminder email every two weeks to notify education webinar participants that a new session is ready to be viewed. In our current study of OEF/OIF/OND spouses, all spouses have had internet access and have expressed a preference to be contacted through the internet. Paper copies of slides can be sent to individuals who request them.

Each session will last approximately thirty minutes through PowerPoint slide presentation format. The education webinar sessions are pre-recorded by an Interventionist to reduce information variability to improve consistency. For maximum flexibility for participants, once the session has been uploaded to the Spouse/Family Support website the session can be viewed at any time during the two weeks the webinar is available. We will examine number of sessions viewed by each participant as dosage in analysis.

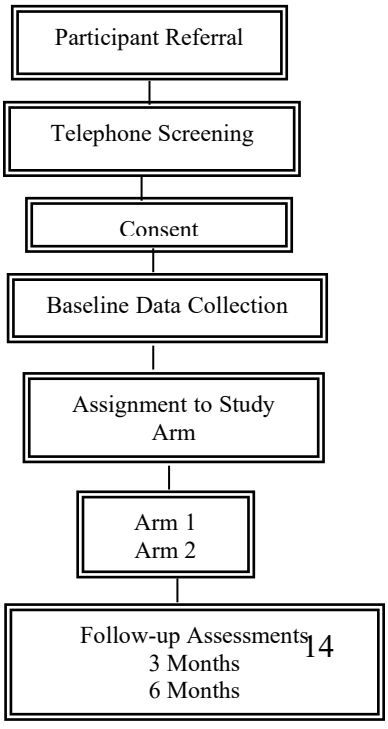
Interventionists Training and Certification. The Interventionists will be masters level healthcare or mental health experienced clinician/educators. As we currently do in the REACH VA national clinical program, each will be trained with didactic and hands on content, knowledge assessment, skills practice, and role playing for certification. The Interventionist will use a mock caregiver to complete a role play of two key areas of the intervention: identify and introduce target behavior/issue plan, and mood management/cognitive restructuring. Based on observation of the role play at least two senior investigators will complete the Certification Role Play Observation Checklist for Individual Sessions. The checklist includes behaviorally anchored ratings of specific procedural techniques (e.g., correct use of forms) and clinical skills (e.g., active listening). Performances are observed for content and process until two investigators give marks of 90 to100% on the treatment fidelity form. Feedback is individually provided for each of the items listed on the Checklist. Structure of the feedback includes: statement(s) about any positive behavior demonstrated; statement(s) about what behaviors should have occurred or occurred and were not in keeping with the protocol; then rationale for the behavior that was expected. Feedback will also include "Required Activities" that must be completed before certification can be granted. Any item scored as a zero on the checklist will automatically result in a required activity.

Training for Interventionists will include strategies for overcoming problems associated with telephone interactions such as decreased cues and technological difficulties. These strategies include behaviors such as use of prompts/open ended questions to solicit information; use of rephrasing, reflection, summarization; use of participant's own language/descriptors; active listening (e.g., summarize comments correctly); assessment of participant's understanding of the intervention by "checking in" and by asking questions; appropriate level of assertiveness (e.g., guides the intervention according to protocol, redirects participant appropriately as needed); and use of empathetic responses while remaining on protocol.

Treatment Fidelity Assessment. To assess intervention benefit accurately, it is necessary to determine whether the intervention is being delivered as intended, whether participants are hearing and understanding, and whether participants are acting on the intervention. This has been lacking in previous trauma research (67). For the active intervention arm we will assess delivery, receipt, and enactment using direct and indirect measures and a quantitative assessment (68) as we have in our past and current research (69). The investigators will listen to the sessions, all of which are taped. We will score all sessions in the early stages until satisfactory performance standards (90% range consistent scores) are met, and continue to check sessions throughout the study to assess maintenance or drift in integrity. Reliability checks will be conducted on 25% of the scored tapes by an independent second rater.

For Delivery Assessment, for each session, there are components that are intended (positive) and plausible confounding parts that should not occur (negative). Positive score minus negative score yields the overall session evaluation score. Receipt Assessment is accomplished by determining whether the participant understands the materials. For delivery and receipt, raters listen for specified cues. Enactment is assessed at the following session, using the same scoring procedure. Enactment allows a determination of which suggestions were tried, which were most helpful for specific problems, and which do not work for certain problems and certain participants. Follow-through on target behavior/issue plans will determine enactment.

Study Flow Chart



Participant Identification and Recruitment

There will be multiple avenues of recruitment, as we have utilized in our previous DoD and VA studies for deployed and post deployment spouses and dementia and spinal cord injury/disorders caregivers, all of which have exceeded recruitment goals. Several military and military family websites routinely post our information so that potential participants can contact us directly. As we routinely do, we will contact VHA staff who work with post 9/11 veterans and caregivers, including Caregiver Support Coordinators and OEF/OIF/OND Program Managers. Each VA facility has these positions and we have access to national mail groups and national education sessions that target each group. The VA's Polytrauma System of Care will be a major source of referrals; this system of care includes Polytrauma/TBI care and staff at each facility, including transitional residential inpatient care and local clinics (see http://www.polytrauma.va.gov/index.asp).

We will also have a website hosted on the VAMC Memphis internet site similar to our current study information (http://www.memphis.va.gov/spousesupport/), a blurb on the VAMC Memphis Facebook page (https://www.facebook.com/MemphisVAMC), and a Twitter page (https://twitter.com/MemphisVAMC).

Telephone Screening and Participant Consent. As shown in the flow chart, within one week of receiving an inquiry from a potential participant or a referral, a Research Associate will telephone to screen the participant. This is the process we currently use successfully.

- Participants must give permission to be screened after hearing a study description that includes the components of informed consent, including information about the research study and the screening process itself. Research study components include a statement of the research (purpose, procedures), reasonably expected benefits to subjects or others, and costs. Screening process components include duration of screening, alternatives, extent of confidentiality, and authorization for release of protected health information for research purposes.
- After screening, consent forms, signed by the person who will be obtaining consent, are mailed to the participant with a post-paid return envelope. Written informed consent from the participant is an integral part of the study. Informed consent will follow the procedures of the IRB and Research and Development (R&D) Committee of the VAMC Memphis. All participants **must** give written informed consent before becoming study participants and assent must be obtained from the service member and reported by the participant.
- During the informed consent call the potential participant will be asked to read the informed consent and be given the opportunity to ask questions. A Research Associate will review all key aspects of the study with the potential participant. Staff will question to ascertain whether the potential participant has understood the information. Potential participants who are illiterate or have impaired vision will have the consent read to them and will be given an opportunity for questions and discussion. A signed informed consent is required prior to data collection. Participants will be encouraged to ask for clarification about the forms and discuss concerns about the study at this time.
- The consent form is carbon color coded. After the participant initials and signs the form, one copy of each page is kept by the participant, and one is filed in the study office. To protect participant confidentiality and per IRB waiver, no witness is required.
- After consent is obtained and baseline data collection, the Data Analyst (DA) will randomly assign each participant to one of the study arms. Participants are independently assigned to study arms and there will be no stratification based on covariates at the time of assignment to study arm. The DA will maintain a confidential, locked register of names, study identification numbers, and treatment arm assignments.

- As soon as baseline data collection and randomization are completed for a participant, a staff member will call and provide information on assignment and the intervention.

Retention. Because all interaction is by telephone, travel will not affect retention. We offer $25 for each completed data collection call to offset time required (baseline, three and six months, project evaluation) for a total of $100. In our work with spouses of post 9/11 service members, lost to follow-up rates are 17 to 20%. For our caregiver intervention studies, lost to follow-up rates are lower, around 10% (70).

Alerts/Adverse Event Protocols. Alerts may be recognized during data collection, outside scheduled contacts, and during intervention sessions. Alerts/adverse event standardized procedures will be those we currently use for post deployment spouses and caregivers. Alerts include suicidal ideation, increased alcohol/drug use, and clinical depression levels plus dangerous patient behaviors. Our current procedure ensures that any alert be discussed immediately with Dr. Martindale-Adams and appropriate action taken, based on standardized procedures. For example, in our current study, for clinical depression levels, we follow up with the participant who is also advised to contact her physician or other resource. All alert events are recorded on the Project Alert Form that includes event date, whether event is treatment related, and date event was addressed. The form is given to Dr. Martindale-Adams within 24 hours of learning of the event and the event documented by the appropriate staff member in progress notes, and reported to IRB, if appropriate. Alerts, adverse events, and referrals will not cause a participant to be dropped from the study, but will be considered in analysis. Any contact outside group or data collection will be documented (time, reason, actions taken, initiator) on the Delivery Assessment tracking form.

Data Collection and Variables

Research Associates Training and Certification. Training for Research Associates (RA), who will be masters prepared, will include interviewing over the telephone, asking sensitive questions, use of study instruments, five practice interviews, and a final certifying audiotaped interview with a volunteer participant. The investigators and each RA rate responses on three mock interviews to determine inter-rater reliability. RAs will be evaluated on their conduct during data collection interviews. The Researcher Evaluation Form is scored by the investigators using recorded calls. Scores are determined by 1) those things executed (e.g., asks questions as written, probes consistently and only when necessary) and 2) negative items (e.g., volunteers personal information that may bias answers, uses directional probes), with 100 being a perfect score and 90 being acceptable. After training, periodic checks of RA performance are conducted.

Data Collection. Data collection will occur at baseline, 3, and 6 months post randomization by telephone. All calls are recorded. Data collection takes approximately 45 minutes, based on our current telephone data collection with caregivers and OEF/OIF/OND spouses, using the same and similar instruments. We send response cards to the participant to make answering more efficient. The same masked RA performs all data collection for a participant.

Measures (shown below) were specifically chosen 1) to capture the mechanisms of action related to the theoretical model for individual stress process, and 2) to map onto measures being used by DoD and VHA clinicians and researchers to provide maximum utility and generalizability for the study results. Independent measures have been selected to characterize the study sample and to assess factors that have potential to impact the outcome measures. Many of the instruments and concepts are used in the Rand study of military caregivers (23), or were developed for use in research with OIF/OEF/OND family members, using expert panel input and focus group interviews (71). We are using several of these outcomes and instruments in our two current military spouse studies and our REACH VA clinical program.

Category	Name of Measure/Form	Battery (B) Screening (S)

		Risk Priority Inventory (RPI)
Depression	Patient Health Questionnaire (PHQ-9)	B
Anxiety	Generalized Anxiety Disorder (GAD-7)	B
Burden	Zarit Burden Interview (ZBI) short version	B
Caregiver self-efficacy	Revised Scale for Caregiving Self-Efficacy	B
Safety concerns	General questions	RPI
Caregiving frustrations	Frustrations questions	RPI
Time spent in caregiving	Caregiver Vigilance Scale	RPI
Social support	Satisfaction and someone to take over	RPI
Health behaviors	General questions	RPI
Patient disability status and rating	General questions	RPI
Demographics	Participant and service member demographics	B
Social support	Received support, negative interactions, satisfaction, and social networks	B
Health	SF 36	B
Patient functioning and disability	World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0)	B
ADLs	Katz ADL Scale	S, B
IADLs	Lawton and Brody IADL Scale	S, B
Financial strain	Economic Strain Scale	B
Career impact	General questions	B
Caregiver strain	Caregiver Strain Index	B
Life Stress events	Social Readjustment Rating Scale	B
Relationship quality	General questions	B
Impact on children	Impact of Caregiving on Family Life	B

Outcomes.

Outcomes are change in scores for depression, anxiety, and burden. Depression, burden and anxiety are important caregiver outcomes (23,36) and depression and anxiety have been identified in the Land Combat study, Caliber Associates work (72), as present or increasing post deployment for spouses. The Patient Health Questionnaire (PHQ-9) will be used to assess depression (73). The PHQ-9 has 9 items based on the DSM-IV depression diagnostic criteria that are scored from 0 (not at all) to 3 (nearly every day). Scores are summed to characterize depression as minimal (0 to 4), mild (5 to 9), moderate (10 to 14), moderately severe (15 to 19), or high/severe (20 to 27). On the PHQ-9, major depressive disorder is suggested if 5 or more items or the first two items, (interest and feeling depressed, also known as the PHQ-2) are scored positive (at least "more than half the days"). PHQ-9 Cronbach's alpha is .86 (73). The GAD-7 will be used to assess anxiety. The GAD-7 contains a 7-item checklist of anxiety symptoms focusing primarily on generalized anxiety disorder. The measure has good performance in also detecting other anxiety disorders (panic disorder, social anxiety disorder, and PTSD) (74). Scoring for each item ranges from 0 (not at all) to 2 (more than half the days) for an overall score of 0 to 14; higher scores indicate more anxiety. GAD-7 sensitivity is .89 and specificity is .82 (75). Caregiver burden will be assessed using the 12-item Zarit Burden Interview (ZBI) short version (76,77). Items are scored 0 (never) to 4 (nearly always), with higher scores indicating more burden. ZBI Cronbach's alpha is .85 for a sample (N = 1095) of Canadian dementia caregivers (78).

Independent Measures.

Risk Priority Inventory. The Risk Priority Inventory (RPI), adapted from REACH (79), is collected by the RA as part of data collection and a copy given to the Interventionist who will review it with the caregiver to use as the basis for discussion of concerns and intervention targeting. Measures assessing the outcomes are also provided to the Interventionist. The RPI assesses caregiving risk areas of education, safety, health and healthy behaviors, social support, and caregiving frustrations. Safety questions will examine service member access to dangerous objects, driving, and risky behaviors and are scored from 0 (never) to 2 (often). Higher scores indicate greater safety risk. Caregiver's self-care and preventive health behaviors (e.g., getting enough rest, keeping medical appointments, smoking) will be assessed using four REACH II questions (36). All self-care items are scored 0 or 1 (no or yes), and summed 0 to 4. Higher scores indicate increase health risk. Three social support items assess satisfaction with help and emotional support and whether the caregiver had someone to take over care if needed. Satisfactions items are scored 1 (not at all) to 3 (very). Higher scores indicate increased social support risk. Two items assess caregiver frustrations (e.g., feel like yelling at or hitting patient). Items are scored from never (0) to often (2). Higher scores indicate more frustrations (41). Service member disability status and rating from the VA or DoD will also be collected (23). Caregiving time spent on duty and in care activities in hours and minutes per day will be assessed with two questions from the Caregiver Vigilance Scale questions. Cronbach's alpha for the 4-item scale is .66 (80). In addition to the RPI items, depression, anxiety, and burden measures are provided to the Interventionist to use in targeting concerns for the dyad.

Demographics for caregiver and care recipient will include name; date of birth; age; gender; race/ethnicity; marital status; years married; relationship to service member; employment status; number of people in household, ages and relationships; income (categories by income/month); and military service; time and era of service; branch of service, age, rank, time in military, and previous deployments.

Caregiving self-efficacy will be measured by the Revised Scale for Caregiving Self-Efficacy (81,82). The 15-item scale has three subscales (five items per subscale), self-efficacy for obtaining respite (SE-OR), self-efficacy for responding to disturbing behaviors (SE-RDB), and self-efficacy for controlling upsetting thoughts (SE-CUT). Participants rate their level of confidence to perform each item on a scale from 0 (cannot do at all) to 100 (certain can do). Subscale scores are reported separately. In a Chinese sample, Cronbach's α for SE-OR, SE-RDB, and SE-CUT were 0.91, 0.96, and 0.96, respectively (83).

Social support is an important buffer against stress for caregivers and a family resilience factor (53). More than half of post 9/11 military caregivers have no caregiving network (23). We will examine social support using questions from instruments utilized in several previous REACH studies (84-87). Nineteen social support items measure received support and negative interactions (85), satisfaction (85,86), and social networks (87). The first three domains use a scale of 0 (never, not at all) to 3 (very often, very). Social network items use a scale of 0 (none) to 5 (9 or more). For total social support items' sum, 0 through 69, higher scores indicate more support. A study of 1103 U.S. older people yielded Cronbach's alphas of .84 for received support (88), .71 for support satisfaction (89), and .83 for negative interactions (90). Social networks had a Cronbach's alpha of .83 in a European validation study of 7432 older people (91).

Health will be assessed from 1 (poor) to 5 (excellent) with one question from the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) (92). Relationship quality will be assessed with a four item measure (93) used in the Rand caregiving study (23) that assesses closeness, communication, similarity, and general relationship. Items are rated on a five point scale from 1 (not at all) to 5 (extremely) and averaged.

Financial strain will be measured with two Economic Strain Scale (94) items. Participants rate how much difficulty the household had paying bills in the past six months on a scale from 1 (no difficulty) to 4 (a great deal) and whether the household has enough money to afford housing, food and clothes you feel you

should have, on a scale from 0 (definitely enough) to 3 (definitely not enough). Further economic impact on the caregiver's career will be examined by seven questions taken from the National Alliance for Caregiving, also used in the Rand military caregiver study (23). These items (e.g., take unpaid time off, take early retirement) will be scored either 0 (no) or 1 (yes). Caregiver strain (e.g., physical, work, family) will be measured using the 12 item Modified Caregiver Strain Index (95,96). Responses are coded 0 (no), 1 (yes, sometimes), or 2 (yes, on a regular basis) and summed. Reliability is .90 and test-retest reliability coefficient is .88 (96).

At screening, care recipient function will be assessed using the 6-item Katz ADL Scale (97) and 8-item Lawton and Brody IADL Scale (98). Each item is scored 0 (no help needed) or 1 (help needed). ADL and IADL items are summed separately, with higher scores indicating greater impairment. Cronbach's alpha is .75 across three studies for ADL (99) and IADL averaged .84 in multiple study review (100).

The World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) (101) provides a measure of impairment because of military or health-related problems, can be used across diseases, including mental, neurological and addictive disorders, is culturally neutral, and produces standardized disability levels and profiles. It is based on the International Classification of Functioning, Disability and Health and is one of the scales recommended for use in assessing PTSD disability (102). There is a proxy version, which will be used in this study to ask participants about the service member's functioning. The scale provides a profile of functioning across 6 activity domains, understanding and communicating, mobility, self-care, interpersonal, work and household, and participation in society, and a general disability score. In research on participation after TBI, proxy report has been shown to be an acceptable substitute for missing participant report on productivity and community activity outcomes (103). In the WHODAS 2.0 12 +24 version, positive responses to the 12 core items (which explain 81% of variance of the more detailed 36-item version) trigger further questions. Items are scored as level of difficulty within the past 30 days from 1 (none) to 5 (extreme or cannot do). Scoring takes into account multiple levels of difficulty for each item, coding each item response separately, and uses an algorithm to determine the summary score by differentially weighting the items and the levels of severity. Summary score ranges from 0 (no disability) to 100 (full disability).

The Social Readjustment Rating Scale (SRRS) is a list of 43 stressful life events, both positive and negative, that can contribute to illness (104). Twelve of these events that we have used before and are most likely for this age cohort will be measured, such as change in employment or financial state. Occurrence of the event in the last six months is scored as no (0) or 1 (yes). Each event has points assigned to it based on how stressful it is. Points for all events present are added for a total score that ranges from 0 to 437.

For those parents who have younger children or are taking care of grandchildren, a six-item measure from the Rand military caregivers study (23) will examine how caring for the patient has changed the family. A scale of 1 (strongly disagree) to 5 (strongly agree) will be used with higher scores indicating more impact.

Project Evaluation. Participant satisfaction, collected at final follow-up as part of project evaluation, will assess participant perception of satisfaction, usefulness, benefit, and relevance.

Data Analysis

Primary outcomes are measured for all participants at baseline, at three months, and after six months. We estimate the necessary sample size based on analysis of a pretest-posttest control group design. The final analysis of the data will, in addition to this approach, use a mixed-effects model. These models allow us to assess whether other factors, such as a participant's age or the patient's level of disability, are related to the measured outcomes.

Randomization will likely lead to slightly different group sizes in the study arms because participants are independently assigned to the arms, but we are not concerned about this as group sizes will also be different due to expected drop outs in each group. Once assigned to a study arm, participants will be considered in the study and we will primarily follow an intention-to-treat (ITT) approach, both for ANOVA and the mixed-effects modeling approach described below. Individuals will be included in their assigned group even if they do not participate in some or all of the intervention components (i.e., does not comply with the "treatment").

The benefit of ITT is twofold. First, we do not bias the result by defining "sufficient compliance" with the treatment/intervention after data are collected. Second, we assure that our study result is relevant in the sense that any effect of the intervention is actually achievable with the level of encouragement to stay in the intervention as provided in this study. Especially, potential future benefits from the intervention will *not* be conditional on future participants who comply fully with the advised meetings and exercises, even in case many individuals have difficulties in study compliance.

Having said that, we will record the level of participation for each individual in each intervention arm (number of sessions that the individual participated in), and we will investigate the importance of this compliance. We expect that compliance will be an important indicator of how engaged an individual was, and how much of the offered support or education an individual could benefit from. This is an exploratory part of our data analysis.

A second data analysis strategy will be to analyze data for only those participants who complete the study, which is an efficacy analysis. This introduces a self-selection bias, and statistical power is diminished by loss to follow-up during the course of the study. However, our estimates of treatment effects are unbiased by random attrition. The chief advantage of this primary data analysis strategy is that it has increased ability to document positive findings for participants able to maintain compliance with the intervention. However, when analyzing efficacy it is especially important to document any differences between participants who completed the study and those who were either withdrawn or lost to follow-up. Baseline demographic and clinical characteristics will be compared between completers and non-completers using chi-square tests for contingency tables, or independent-samples t-tests, as appropriate.

Sample Size and Statistical Power

Study participants will be randomly assigned to one of two arms: 1), the Individual Sessions arm, and 2) the Education Webinar arm. Hypothesis testing will compare Education Webinar arm pre-post outcomes, and Individual Sessions arm data to that of the Education Webinar arm. In accordance with the study hypotheses, our power analysis calculations are based on pretest-posttest gain score difference between contrast groups analyzed using repeated measures analysis of variance testing for a significant group by time interaction effect. Power analysis calculations use reliability data in estimating variance of gain scores (38,73,75). We base our power calculations on ANOVA because the "research on power analysis for mixed models is sparse" (105).

Power analysis assumptions used in computations included equal sample sizes in each contrast group of the study, equal variances and attrition in each contrast group, probability of Type I error of 0.05, non-directional testing of null hypotheses, and test-retest reliability as established by prior research (Table 2). Sample estimates of population parameters are assumed to be normally distributed with a mean error of zero. Accordingly, eighty or more subjects will be randomized to each arm of the study allowing attrition equal to 20% before the end of the study, which is the maximum we anticipate. This yields complete data for at least 60 caregivers in each arm of the study. More than 60 caregivers in a contrast group will increase statistical power above 0.80. The baseline data tabulated are values observed from our REACH and READI studies.

Table 2. Power analysis data.

Outcome Variable (Reference)	Baseline (M ± SD)	Reliability (r)	Power	Detectable Difference
Caregiver Measures				
Depression (PHQ-9) (73)	7.80 ± 5.94	0.84	0.80	1.78
Anxiety (GAD-7) (75)	7.61 ± 5.14	0.83	0.80	1.54
Burden (Zarit) (38)	17.56 ± 9.74	0.88	0.80	2.92

The values tabulated in the Detectable Difference column of the table document the minimum true between contrast group difference in gain scores in population data sampled needed for statistical power to attain 0.80 or better to reject a false null hypothesis of no group by time interaction effect in repeated measures data. In general terms, we will have statistical power of 0.80 or better to reject a false null hypothesis when the between contrast group difference in gain scores attains approximately 0.30 or more of the population standard deviation estimated from REACH and READI study baseline data. For statistically significant comparisons, effect size of $d \geq 0.2$ will be considered clinically significant, consistent with psychosocial interventions' small to medium effect sizes (46). Interaction effect sizes will be estimated as mean between-group gain score change relative to estimated population standard deviation (106).

Mixed-Effects Modeling Approach. Randomization into the two arms, respectively, guarantees that individuals are not systematically assigned to one arm. Regardless, when analyzing the data it should be beneficial to account for the actually present covariates for the individuals. In addition, the mixed-effects modeling approach allows us to incorporate individuals in the study who are lacking the final outcome measurements after six months. Furthermore, we can utilize all the information from the data and can utilize the post-intervention measurements for the individuals.

We will fit separate mixed-effects models for each of the primary outcomes. For each of the $i = 1, \dots, 160$ individuals there are n_i measurements available (for a specific outcome). The primary outcomes are measured at baseline (B), and after three, and six months (t = B, 3, 6). It is not essential that the measurements are taken for all individuals at the same time, but we do not elaborate on this here because the data collection is planned to follow the above timeline. If all measurements are available for an individual, $n_i = 3$ (for each primary outcome). Each individual will have measurements for at least baseline, so $n_i \geq 1$ for all i. In mixed-effects models "individuals borrow strength" from each other and it is therefore not required that all individuals have two or more measurements in order to fit straight lines to each individual.

We build the mixed-effects models by a forward selection procedure for the covariates of particular interest to us. Because over-parameterization is a concern in this analysis, we will give priority to covariates that are individually contributing to the model fit (evaluated by significance of parameters in the model as well as AIC and SC) and are (if possible) independent of each other. To improve model fitting we will center or standardize some or all covariates. Interaction terms will be included as needed.

We investigate intervention effectiveness by comparing the slope of the linear fits for individuals that were assigned to individual sessions with the slope of individuals that were assigned to the webinars. A mixed-effects model contains *fixed effects* and *random effects*. The mixed-effects model allows us to study whether other variables are an important factor for the development of the primary outcomes Besides the indicator of individual i intervention assignment and demographic information such as race, age, or rural/urban location, covariates of interest to us are the participant's family composition, participant gender, and the general social support the caregiver receives. We also collect the participant's perception of the patient's disability at baseline (WHODAS 2.0 level of disability from 0 to 100) and will investigate the role that covariate might play in each model. These questions will be addressed by investigating the statistical significance of the corresponding parameters in the fitted mixed-effects model. SPSS will be used for analysis.

In addition, we will investigate possible drop out patterns in the data. This is, however, an exploratory part of our analysis and we will assume that measurements are *missing at random* in the primary analysis.