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TITLE: Evidence-Based Mental Health Services for Distressed Post-9/11 Military Family Caregivers

PRINCIPAL INVESTIGATOR: Dr. Linda Garand

CONTRACTING ORGANIZATION: Duquesne University  
Pittsburgh, PA 15282

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<b>14. ABSTRACT</b>  Background: Traumatic brain injury (TBI) is a common injury among armed forces deployed to conflicts in Iraq and Afghanistan. Symptoms of a TBI do not improve over time and are associated with negative mental health outcomes in family caregivers. We sought to determine the efficacy of (9-session) PST for positively impacting TBI family caregivers' burden levels and mental health quality of life (primary outcomes), as well as depression symptom levels (secondary outcome). Using a two-group (PST n = 85 vs. Usual Care or UC n= 64), randomized study design, outcomes were measured at baseline, one-, three-, six-, and 12-months after PST training (or 12 to 14 weeks after baseline for caregivers in the UC group). Data was collected longitudinally on a sample of 149 family caregivers of post-9/11 combat veterans with a self-reported TBI. Data analysis showed a significant main effect for time, and a significant group by time interaction. Relative to caregivers randomized to UC, caregivers randomized to PST endorsed significant improvements in caregiving burden and depression levels. Caregivers in the PST group endorsed lower burden and depression scores one-month after problem-solving training.					
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## **1. Introduction**

Traumatic brain injury (TBI) is a common injury among armed forces deployed to conflicts in Iraq and Afghanistan. Symptoms of a TBI are similar to those experienced by civilians with dementia, and studies show that the symptoms of a TBI do not improve over time and are associated with negative mental health outcomes in family caregivers. The literature also suggests that caregiver mood and the perception of burden are influenced by the nature and severity of cognitive impairment in the care recipient and the caregiver's general coping abilities. The coping abilities of military caregivers may be strengthened through problem-solving therapy (PST) since it is based on the idea that real-life problem solving plays an important role in the relationship between stressful life events and negative mental health outcomes.

Our team of investigators designed a study to evaluate the efficacy of a 9-session problem-solving training (PST)-based intervention to improve burden levels and QOL outcomes (FY15 QUAL Focus Area) among distressed primary family caregivers (co-residing spouse/partner or parent) of post-9/11 Service Member or Veteran (combat veteran) with a TBI (FY15 QUAL Overarching Challenge). Specifically, the study was designed to determine the efficacy of problem-solving therapy (PST) for positively impacting post-9/11 military family caregivers' burden levels and quality of life (primary outcomes), as well as depression symptom levels (secondary outcome). Using a two-group (PST vs. Usual Care or UC), longitudinal, randomized study design, primary and secondary study outcomes were measured at baseline, one-month, three-months, six-months, and 12-months post-randomization.

## **2. Keywords**

Quality of life, Evidence-based treatment, Military Caregiving, Traumatic Brain Injury

### 3. Accomplishments

#### 3.A. Study Start-up Activities

During study months one through seven, the study Operation Manual was written (***Statement of Work or SOW Major Task 2a: Establish a logistical plan for study implementation***) and a comprehensive, password-protected, web-based system was developed to meet the needs of this study while ensuring accurate, secure, Health Insurance Portability & Accountability Act (HIPAA) compliant procedures. (***SOW Major Task 5: Establish a comprehensive web-based system comprised of integrated assessment, tracking, and data management components***) We also adapted all study materials for military caregivers of a combat veteran with a TBI (***SOW Major Task 3: Adapt PST for Family Caregivers of Combat Veterans with a TBI***) while hiring and training study personnel.

The PST intervention was delivered to study participants by five mental health professionals (e.g., graduate-level clinical psychology students) that were certified in PST. Dr. Morse (Key Study Personnel) is a Licensed Clinical Psychologist with certification as a PST Specialist, Trainer, and Supervisor. The Interventionists were given a detailed PST treatment manual, attended a workshop on the principles of PST, role-played the PST intervention, and received verbal feedback on video-taped PST sessions (with study participants) weekly (for 16 weeks) to become certified as a PST Interventionist. (***SOW Major Task 2b: Hire and Train Project Personnel***). All PST sessions with study participants were taped, and a random sample of PST training sessions were reviewed weekly (by the PST Specialist) for treatment fidelity verification or remediation. Once certified in PST, the study Interventionists received twice-monthly supervision with Dr. Morse for treatment fidelity checks. (***SOW Major Task 4: Certify Interventionists and on-going supervision in Problem Solving Therapy***)

Both University-level Institutional Review Board (Duquesne University) IRB Protocol #2017/01/2) and USAMRMC Human Research Protections Office (HRPO Log # AZ150022) approvals were obtained before participant enrollment began on July 14, 2017. This study was

also registered on the Protocol Registration and Results System at ClinicalTrials.gov (NCT03211884). Review Board approvals are currently maintained for data-analyses purposes. (***SOW Major Task 1: Annual IRB and USAMRMC HRPO report for continuing review and approval***).

### **3.B. Study Implementation**

Study implementation began in July 2017 and ended July 2020, when the last study participant completed the one-year follow-up surveys. (***SOW Major Task 7: Study Implementation***) The IRB-approved study flyer was posted on websites of various military caregiving organizations (e.g., Elizabeth Dole Foundation Hidden Heroes Program, Semper Fi Fund, American Red Cross Military and Veteran Caregiver Network, Project New Hope, and Wounded Veteran Family Care). Over a 20-month recruitment period, 357 military caregivers of a post-9/11 combat veteran with a TBI (from across the United States) responded to the IRB-approved study flyer. As illustrated in Appendix Figure 1 (Participant Flow Diagram), twenty-three percent of the respondents (n = 84) were excluded from participating in the study. Of those caregivers, one was under age 18, 14 did not live with the care recipient, and 69 respondents (19.3%) endorsed “low burden” or “no burden” on any one of the four caregiving burden screening questions. Of the 273 eligible caregivers, 169 consented to participate in the study and 149 completed the baseline surveys (54% of eligible caregivers). This data (slightly more than a 50% enrollment rate) is important for planning future recruitment estimates for intervention studies with military caregivers. (***SOW Major Task 6: Screen and enroll study participants***)

Refer to Figure 1 in the Appendix for a consort diagram showing participant flow. Eighty-five caregivers (57%) were randomized to the PST group and 64 (43%) were randomized to the UC group. Of the 85 caregivers assigned to the PST group, 15 (17%) withdrew from study participation during the PST intervention. Two caregivers (3%) in the UC group withdrew from study participation after being assigned to the UC group. In all cases, these caregivers cited

time constraints as the reason for withdrawing from the study. With a 20% attrition rate after collecting baseline data, a decision was made to enroll caregivers from July, 2017 to March, 2019). Given this relatively high attrition rate, In August 2018, IRB and HRPO approval was obtained to increase the sample size from 100 to 200 caregivers and to shift from a 1:1 ( PST to UC) allocation ratio to a 2:1 allocation ratio, with twice as many caregivers being randomly assigned to the PST group than the UC group. Also, in September, 2019, a one-year no-cost extension was obtained to complete the follow-up data assessments through July 2020.

A final sample of 85 caregivers were randomly assigned to receive 9, face-to-face problem-solving training sessions (each about 60 minutes long) approximately every week for six weeks (Phase 1 of PST training), followed by twice-monthly telephone calls to support the caregiver's problem-solving efforts (Phase 2 of PST training). Phase 1 of the PST training sessions were delivered (and recorded) face-to-face over the Internet and Phase 2 of PST was delivered (and recorded) over the telephone. While the full 9-session PST training was designed to take 12-weeks (3 months) to complete, military caregivers in this study typically took 14 weeks (3.5 months) to complete PST training sessions, and not all of the caregivers completed the PST intervention. Three-quarters (n = 64, 75.3%) of the caregivers in the PST group received the full 9-session intervention and the remaining quarter had scheduling conflicts that precluded their study participation. Six caregivers missed one PST session (participated in 8 PST sessions, 7%), three caregivers missed two sessions (participated in 7 PST sessions, 3.5%), three caregivers missed four sessions (participated in 5 PST sessions, 3.5%), two caregivers missed five sessions (participated in 4 PST sessions, 2.4%), and two caregivers missed seven sessions (participated in 2 PST sessions, 2.4%). A session was "missed" when the caregiver requested or could not be contacted by study personnel.

Sixty-four caregivers were assigned to the UC group and provided follow-up data 13-weeks after baseline data, and three,- six- and 12-months later. While caregivers assigned to the UC group did not receive PST training, many of them endorsed participation in caregiver

support programs offered through the Elizabeth Dole Foundation (47%), Department of Defense (DoD, 15%), and the US Department of Veterans Affairs (VA, 42%).

### **3.C. Data Analysis**

The PST and UC-groups were compared on baseline characteristics with chi-square tests and independent-sample t-tests. General linear model, repeated-measures (GLM-RM) analysis was used to analyze the mental health outcomes. This analysis included group assignment (PST vs UC) as the between-subjects factor, and time (baseline, 1-, 3-, 6-, and 12-month follow-up) as the within-subjects factor. Before data analysis began, distribution of the outcome variables and the effects of respondent bias (due to high rates of attrition from follow-up assessments) were examined. Statistical significance was set at  $p$ -values  $\leq .05$  (two tailed).

#### ***(Major Task 8: Data Analysis & Dissemination)***

### **3.D. Study Attrition**

A total of 17 caregivers (11% of the randomized sample) withdrew from the study after completing baseline surveys and before collecting follow-up data. A disproportionate number of those caregivers were assigned to the PST intervention group (Chi-square = 7.61,  $p = 0.006$ ). Fifteen (18%) of the caregivers in the PST group withdrew before receiving any PST training, and two (3%) of the caregivers in the UC group withdrew during the 12 to 14 weeks between baseline and one-month follow-up data collection. This resulted in a final sample of 132 military caregivers providing follow-up data, with 64 caregivers receiving full PST, 16 receiving partial PST, and 62 caregivers providing follow-up data only (UC group).

As illustrated in Figure 1 (Appendix A), this study experienced a high rate of missing follow-up data. Caregivers that missed one data collection point, often completed the next scheduled set of surveys. At the one-year follow-up point, 37 caregivers (44%) in the PST group, and 42 caregivers (66%) in the UC group, completed surveys. Examination of follow-up data completion rates shows high levels of missing data during the winter and spring holiday months (e.g., December, January, and April). Messages were sent electronically and telephone calls were

placed to remind participants to complete the follow-up surveys, but these attempts were often unsuccessful. Caregivers were compensated twenty dollars each time they completed the study surveys (\$100 for 5 surveys over 16 months). Respondent burden may have played a role in these attrition rates.

### **3.E. Study Participants**

Refer to Table 1 (Appendix) for characteristics of the caregivers enrolled in this study. Demographic and background characteristics were similar among caregivers in the two groups. A majority of the caregivers were female spouses. There was one male spousal caregiver and 19 parental caregivers enrolled in the study. The sample ranged in age from 23 to 71 years old, with an average age of 38 years old. Most of the caregivers were Caucasian, non-Hispanic, and had a college education. Nearly half of the sample acknowledged having a condition that limits their physical activities.

The length of the relationship between the caregiving dyad ranged from one to 35 years, with an average relationship length of 13 years. Although half of the caregivers endorsed an income over \$50,000/year, a similar proportion of caregivers indicated that their income was not adequate to meet their needs. Two-thirds of the sample endorsed being a full-time caregiver, and the remaining third of the sample was employed full- or part-time (in addition to being a caregiver). Three-quarters of the sample reported living with children (from one to eight children) in the home.

### **3.F. Care Recipient Characteristics**

All data regarding the care recipient was collected from the family caregiver's self-report. No care recipients (combat veteran with a TBI) or medical records were accessed to collect this data. Refer to Table 2 (Appendix) for characteristics of the care recipients (combat veterans). The care recipients were predominately Caucasian men ranging in age from 27 to 69 years old (with an average age of 40 years old). Most of the care recipients served in the Army and now are disabled Veterans or Service Members. Besides a TBI, most caregivers indicated that their

care recipients were also diagnosed with post-traumatic stress disorder (PTSD) and/or depression. Examination of the caregiver report of care recipient symptoms shows high rates of symptoms indicative of a TBI. Demographic and background characteristics were similar among care recipients in the two groups, with one exception. Caregivers assigned to the PST group endorsed that their care recipient experienced a “blast-related loss of consciousness” more frequently than caregivers assigned to the UC group.

### **3.G. Study Outcomes**

Study outcomes include caregiving burden, mental health quality of life (MHQOL), and depression symptoms levels. It was hypothesized that caregivers assigned to the PST group would show improvements in mental health outcomes over time, when compared to caregivers in the UC group. The outcome variables were normally distributed, and there were non-significant group differences in mean study outcomes at baseline (see Appendix, Table 3).

#### **3.G.1. Caregiving Burden (Primary Study Outcome)**

Caregiving burden was measured with the Montgomery’s Subjective Caregiver Burden Scale (caregiver burden scale). This scale includes a series of 13 questions to establish how the caregiver feels about caring for their family member with a TBI. The caregiver burden scale demonstrated sound psychometric properties in this study (Cronbach’s alpha = .95).

The study results support the hypothesis that caregivers in the PST-group would endorse improvements (reductions) in burden levels over one-year of follow-up, when compared to burden levels in caregivers in the UC-group. Results of the GLM-RM analysis for caregiving burden levels shows a non-significant main effect for treatment group assignment (PST or UC), although there was a significant main effect for time (1-, 3-, 6-, and 12-months post intervention) and a significant treatment group by time interaction effect ( $F = 13.68, p = .000$ ); this translated to an effect size of 1.0. Relative to caregivers randomized to UC, caregivers randomized to PST showed significant long-term improvements in caregiver burden scores. Results of the GLM, RM analysis are displayed in Table 4 and illustrated in Figure 2 (in the Appendix).

Examination of Figure 2 (treatment group means over time) shows a positive effect of PST on burden scores one-month after the intervention (crossing of the lines), and that positive effect remained relatively stable over the year of follow-up assessments. When we conducted an analysis of variance (ANOVA) in burden scores by treatment group, caregivers in the PST group endorsed significantly lower burden scores one-month ( $F = 10.64$ ,  $df = 107$ ,  $p = 0.001$ ), three-months ( $F = 10.46$ ,  $df = 108$ ,  $p = 0.002$ ), six-months ( $F = 18.36$ ,  $df = 107$ ,  $p = 0.000$ ), and 12-months after randomization ( $F = 12.94$ ,  $df = 114$ ,  $p = 0.000$ ), when compared to the burden levels of caregivers in the UC group. The ANOVA analysis suggests that PST had a positive effect on caregiver burden scores at each time point, but the sample size was not sufficient to detect significance differences in burden outcomes by treatment group assignment in the GLM-RM analysis.

### ***3.G.2. Caregiver Mental Health Quality of Life (QOL, Primary Study Outcome)***

Caregiver mental health QOL was assessed with the 12-item Medical Outcomes Survey (MOS) short form, version 2 (SF-12v2®) health survey, which is licensed and owned by the Medical Outcomes Trust and copyrighted by QualityMetric Incorporated. At this time, we are working with QualityMetric to renew our license to finish scoring the QOL data (primary outcome). The mental health QOL data will be analyzed and interpreted in a peer-reviewed publication of the main study outcomes in the near future.

### ***3.G.3. Caregiver Depression Levels (Secondary Study Outcome)***

Depression symptom levels were measured with Center for Epidemiological Studies - Depression Scale, Revised (CES-D-R). The CES-D-R is composed of 20 items, each response corresponds to the frequency of the symptom in the preceding week, higher score indicates more severe depressive symptoms. A cutoff score of 16 or greater is indicative of individuals at high risk for clinical depression. The CES-D-R demonstrated high internal reliability (Cronbach's alpha = .91).

PST effects on caregiver depression scores were very similar to the PST effects on their burden scores. The study results support the hypothesis that caregivers in the PST-group will endorse improved (reductions) in depression levels over one-year of follow-up, when compared to depression levels of caregivers in the UC-group. Again, results of the GLM-RM analysis for caregiving depression levels shows a non-significant main effect for treatment group assignment (PST or UC), a significant main effect for time (1-, 3-, 6-, and 12-months post randomization) and a significant treatment group by time interaction effect; this translated to an effect size of 0.85. Relative to caregivers randomized to UC, caregivers randomized to PST showed a positive treatment effect was significant when measured over time (positive long-term effects). Results of the GLM, RM analysis are displayed in Table 4 and illustrated in Figure 3 (in the Appendix).

Examination of the graph of treatment group means over time (Appendix, Figure 3) shows a positive effect of PST on depression scores one-month after the intervention (crossing of the lines), and that positive effect remained relatively stable over the year of follow-up assessments. ANOVA analyses of the depression scores by treatment group shows that the differences in depression scores are not statistically different at one-month follow-up ( $F = 3.54$ ,  $df = 109$ ,  $p = 0.062$ ), although they were significantly different at three-months ( $F = 3.76$ ,  $df = 111$ ,  $p = 0.005$ ), six-months ( $F = 12.80$ ,  $df = 107$ ,  $p = 0.001$ ), and 12-month after the intervention ( $F = 12.03$ ,  $df = 116$ ,  $p = 0.001$ ), when compared to the depression levels of caregivers in the UC group. The data supports the conclusion that PST had a positive effect on caregiver depression scores over time, yet those positive treatment effects did not occur until three-months after the intervention.

#### **4. Impact**

Preliminary results show that PST had a positive effect on military caregiver mental health outcomes. Specifically, 9-session problem solving training has a positive long-term (over one year) positive effect on caregiver burden and depression levels. Graphs of treatment group means at each time point show that the lines diverge as early as one-month, and that treatment

effect was maintained over the course of this study. This is an interesting finding since nearly 60% of the sample did not complete the one-month follow-up assessments (41% missing data in the PST group and 18% missing data in the UC group). Only when the data is collected longitudinally, do we see a positive treatment group by time effect on the caregiver burden and depression outcomes among military caregivers.

The caregivers in this study were highly distressed. One-third of the caregivers are employed full- or part-time while providing care to their spouse, and two-thirds of the sample care for one to eight children, in addition to caring for their spouse. Over one-half of the sample said their income was not adequate to meet their needs and nearly half of the sample has a condition that limits their activities. A comparison of burden and depression scores among military and family dementia caregivers also suggests that military caregivers are very distressed.

No established cutoff-scores have been established for the caregiver burden measure (Montgomery Subjective Caregiver Burden Scale, range = 13-65). When compared to a sample of 73 family dementia caregivers, the average burden scores of 149 military caregivers are slightly higher ( $39.46 \pm 7.47$  in military caregivers vs  $32.5 \pm 8.9$  in family dementia caregivers). This finding may be due to the screening questionnaire used to exclude military caregivers that were not burdened by caregiving (this was not done with the sample of family dementia caregivers). The depression measure, on the other hand, does have a cutoff-score for possible clinical depression (16 on the CES-D-R measure). A comparison of the depression scores (scale range 0-60) shows that military caregivers endorsed an high depression scores ( $29.64 \pm 13.80$ ), compared to an family dementia caregivers ( $10.08 \pm 10.0$ ). A large proportion of the military caregiver sample exceeded the cut score of 16, which indicates possible clinical depression. Regardless of treatment group assignment, the study PI attempted to contact each of these caregivers to provide them with contact information for mental health services in their

community and the National suicide hotline telephone number (for data-safety monitoring purposes).

The types of stressors endorsed by these caregivers appear very different than the stressors endorsed by family dementia caregivers. For example, dementia is a progressive neurodegenerative disease and caregiving stressors related to the care recipient's behaviors increase over time (until later stages of the disease). While we excluded military caregivers that endorsed "low burden" or "no burden on the screening questionnaire, military caregiver's distress levels do not appear to increase or decrease very much over time (as demonstrated by the group means of the caregivers in the attention-only or usual care condition). It will be important to describe and analyze these stressors to identify targets for future mental health intervention studies with this population.

The data generated from this study are one of the first steps towards providing evidence-based mental health service for distressed military caregivers. This study lays a foundation supporting PST as an evidence-based strategy to improve the burden and depression in family caregivers of combat veterans with a TBI. Today, there are many services and programs available to military families, although efficacy data regarding these programs are lacking. Also, there has been no consolidation of research regarding outcomes associated with military community support and the programs that currently exist to bolster family resiliency (Conforte et al., 2017, *Military Medicine*, 182, 5/6: 1572). This would address the DoD's goal of "supporting family well-being and readiness" and the Institute of Medicine's (2013) recommendation to increase the number of evidence-based services for post-9/11 combat veterans and their family members.

## **5. Changes/Problems**

This study has limitations, namely the relatively small sample size, attrition in the PST group, and high rates of missing data. Participant recruitment resulted in 357 caregivers being assessed for study eligibility and 169 consented to participate, suggesting a 50% recruitment

rate. Some caregivers consented to study participation, but they failed to complete the baseline surveys (n = 20, 12%). Conveying the importance of the survey information, and the amount of time required to complete the surveys needs to be discussed in more detail when obtaining informed consent with this population.

Regarding the retention of study participants in the PST group, there was not a sufficient number of certified PST Interventionists for the number of caregivers consenting to participate, especially at study start-up. Delays between baseline surveys and PST training may have resulted in some of the early attrition from the PST group. Initially, two clinical psychology students were certified in PST and delivered the intervention. Over the course of the study, five PST Interventionists were certified to deliver the experimental intervention and each Interventionist worked with a maximum of six caregivers at one time.

When it comes to participant retention, more needs to be done to keep the participants engaged with the study. This study required 16 months of the caregiver's time and caregivers assigned to the PST group also spend four months working with the PST Interventionist. This is a long period of time for caregivers that have other work-related and/or caregiving responsibilities. Since long-term follow-up data was critical in this study, it will be important to design future studies that focus on participant engagement (e.g., monetary compensation, periodic newsletters, periodic personal communication from study staff). We compensated the study participants \$20 for each set of surveys completed (\$100 total) and sent electronic birthday card to caregivers enrolled in this study, but it was not enough to keep the caregivers engaged.

## **6. Products**

The study design was presented orally by key personnel (La Rue, Project Manager) at Edinburgh Napier's university-wide Research Conference (June 13, 2017, Craiglockhart campus, Edinburgh, Scotland). An oral presentation was given by the PI (Garand, 12/8/2017) at the US Army Research and Materiel Command (USAMRMC) Congressional Directed Medical

Research Programs (CDMRP) Peer Reviewed Alzheimer's Research Program (PRARP) Fiscal Year 2017 (FY17) In-Progress Review (IPR) Meeting, Fort Detrick, Maryland.

A manuscript related to the problem-solving training intervention is currently under co-author review. Once the mental health QOL data is scored, analyzed, and interpreted, a manuscript reporting the study methods and main outcomes of this study will be written and submitted to a military journal (e.g., *Military Medicine*, *Military Psychology*) for peer review and publication,

In addition to emotional aspects of caregiver's QOL (i.e., caregiving burden, mental health QOL, depression levels), we also collected data to characterize the caregiver's level of vigilance and reaction to bothersome behaviors in the care recipient, physical aspects of QOL (such as new household and personal care responsibilities since the TBI), social aspects of QOL (quality of the marital relationship, perceived social support, and lifestyle constraints), and sociodemographic factors. We also collected data related to the caregiver's orientation to problems in life and problem-solving skills. Several manuscripts will be generated from this data. Not only will it be important to describe these military caregivers, comparisons will be made with family dementia caregivers. The results of this study suggest military caregivers, and the stressors they experience, are different from the stressors experienced by family dementia caregivers.

Lastly, we will determine which of a series of key caregiver sociodemographic factors most strongly moderate the efficacy of the PST- intervention on burden, mental health QOL, and depression outcomes in military caregivers, based on analysis of moderation effects. Candidate factors include caregivers' age, gender, education level, employment status, perceived adequacy of income to meet needs, perceived activity limitations, status as a parental vs. spousal caregiver, and whether the caregiver-care recipient dyad reside alone in their home or with children. If the sample size is sufficient, results of the moderation analysis will also be published. In addition to these publications, an abstract of the main study outcomes will be

submitted for an oral or poster presentation at the 2021 Annual Military Health System Research Symposium.

## **7. Participants & Other Collaborating Organizations:**

Nothing to report

## **8. Special Reporting Requirements:**

Nothing to report

## **9. Appendix: Study Tables & Figures**

Figure 1: Study Consort Flow Diagram (page 19)

Table 1: Military Caregiver Characteristics (page 20)

Table 2: Care Recipient Characteristics (page 21)

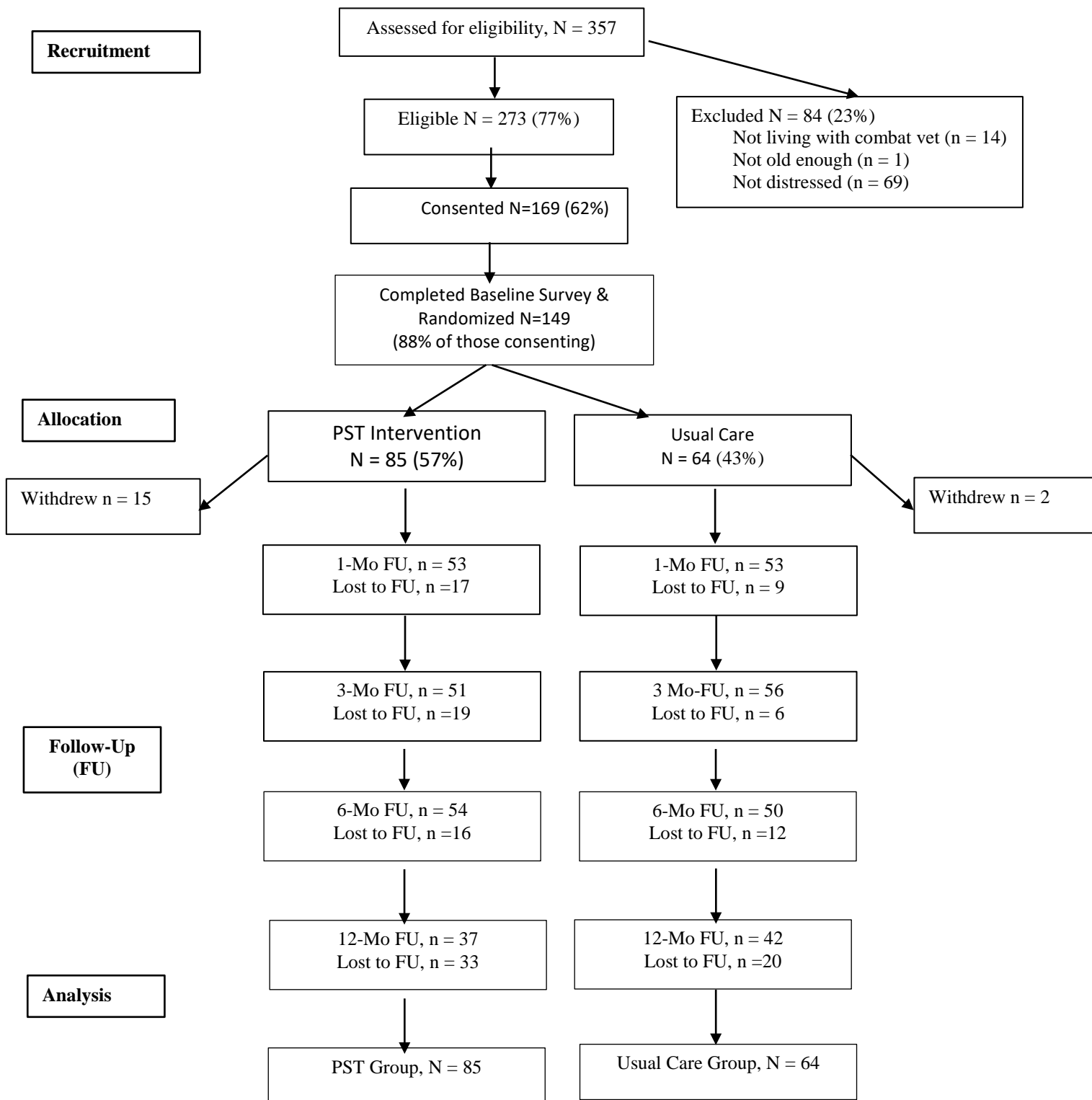
Table 3: Baseline Differences in Study Outcomes by Randomization Group (page 22)

Table 4: Effects of Randomization Group and Time on Study Outcomes (page 22)

Figure 2: Average Burden Levels by Randomization Group, Over Time (page 23)

Figure 3: Average Depression Levels by Randomization Group, Over Time (page 23)

**Figure 1: CONSORT FLOW DIAGRAM**



**Table 1: Baseline Caregiver Characteristics by Randomization Group [Mean (standard deviation) or Proportion (sub-sample size)]**

Variable	Total Sample N= 149	UC (n = 64)	PST (n = 85)	Test Statistic	Sig
<b>Age</b> (Yrs.) (Range: 23-71 Yrs.)	38.30 (± 8.87)	39.19 (± 9.38)	38.40(± 8.47)	.019	.89
<b>Female Sex</b>	99.3% (n = 148)	100% (n = 64)	98.8% (n = 84)		
<b>Marital Status</b>					
Married/Permanent relationship	98.0% (n = 146)	96.9% (n = 62)	98.9% (n = 84)	5.99	.20
Single/Separated/Divorced	2.0% (n = 3)	3.1% (n = 2)	1.1% (n = 1)		
<b>Relationship</b>					
Spouse/Partner caregiver	87.2% (n = 130)	93.7% (n = 60)	82.3% (n = 70)	3.78	.15
Parent caregiver	12.8% (n = 19)	6.3% (n = 4)	17.7% (n = 15)		
Years in the relationship Range: 1-35	12.57 (± 7.47)	13.31 (± 7.55)	11.92 (± 7.39)	1.17	.28
<b>Race</b>					
American Indian or Alaska Native	0.6% (n = 1)	1.6 % (n=1)	0% (n = 0)	3.37	.49
Asian	0.6% (n = 1)	1.6% (n = 1)	0% (n = 0)		
Black or African American	2.2% (n = 3)	1.6% (n = 1)	2.4% (n = 2)		
Native Hawaiian or Pacific Islander	0.6% (n = 1)	0% (n = 0)	1.2% (n = 1)		
White or Caucasian	93.3% (n = 142)	93.6% (n = 60)	96.4% (n = 82)		
American Indian or Alaska Native	0.6% (n = 1)	1.6 % (n=1)	0% (n = 0)		
<b>Ethnicity</b>					
Hispanic or Latin X, yes	2.7% (n = 4)	1.5% (n=1)	3.5% (n = 3)	.78	.37
<b>Educational Level</b>					
HS Diploma/GED	9.5% (n =15)	15.6% (n = 10)	5.9% (n = 5)	5.66	.34
Vocational/Technical	6.6% (n = 11)	6.2% (n = 4)	8.3% (n = 7)		
Some College	36.5% (n = 79)	50.0% (n = 32)	55.9% (n = 47)		
College Degree	28.5% (n = 42)	28.1% (n = 18)	28.6% (n = 24)		
Graduate Degree	18.9% (n =2)	1.5% (n = 1)	1.1% (n = 1)		
<b>Annual Income</b>					
Less than \$30,000	12.7% (n = 19)	18.9% (n = 19)	11.8% (n = 10)	4.08	.66
\$30,000 to \$50,000	34.3% (n = 51)	31.1% (n = 23)	32.9% (n = 28)		
More an \$50,000	53% (n = 79)	43.2% (n = 32)	55.3% (n = 47)		
Is your income adequate? Yes	46.3% (n = 69)	48.6% (n = 36)	38.8% (n = 33)	1.66	.19
<b>Employment Status</b>					
Full-time Homemaker/Caregiver	63.1% (n = 94)	62.5% (n = 40)	63.5% (n = 54)	5.28	.50
Employed Full-time	22.1% (n = 33)	21.9% (n = 14)	22.4% (n = 19)		
Employed Part-time	14.8% (n = 22)	15.6% (n = 10)	14.1% (n = 12)		
<b>Residence</b>					
Live with care recipient (CR) only	22.8% (n = 34)	20.3% (n = 13)	24.7% (n = 21)	.49	.78
Live with CR and children, (Range = 1 to 8 children)	73.2% (n = 109)	76.6% (n = 49)	70.6% (n = 60)		
Live with CR and other friends or relatives	4.0% (n = 6)	3.1% (n = 2)	4.7% (n = 4)		
<b>Overall Health</b>					
Do you have a condition that limits your activities? Yes	45.6% (n =68)	48.4% (n = 31)	45.5% (n = 37)	.21	.64
<b>Outcomes</b>					
Subjective Caregiving Burden	39.46 (7.47)	38.58 (7.85)	40.12 (7.15)	-1.24	.21
Depression Levels	29.64 (13.80)	27.94 (13.76)	30.93 (13.78)	-1.31	.19

Note: \*P < 0.05 (two-tailed), Independent sample t-test or Pearson Chi-Square, Care Recipient (CR), Usual Care (UC), Problem-Solving Therapy (PST), Subjective Caregiving Burden (Montgomery Caregiving Burden Scale), Depression Levels (Center for Epidemiological Scale - Depression, Revised)

**Table 2: Baseline Care Recipient Characteristics by Randomization Group [Mean (standard deviation) or Proportion (sub-sample size)]**

Variable	Total Sample N= 149	UC (n = 64)	PST (n = 85)	Test Statistic	P value
Age, Yrs. (Range = 27 to 69 Yrs.)	40.02 (± 9.7)	38.97 (±7.59)	39.46 (±8.66)	4.93	.48
Sex, Male	99.3% (n = 148)	100% (n = 64)	98.8% (n = 84)	.88	.34
<b>Race</b>					
American Indian/Alaska Native	1.3% (n = 2)	3.1% (n = 2)	0% (n = 0)	6.38	.17
Asian	1.3% (n = 2)	3.1% (n = 2)	0% (n = 0)		
Black or African American	2.7% (n = 4)	3.1% (n = 2)	2.3% (n = 2)		
Native Hawaiian or Pacific Islander	1.3% (n = 2)	0% (n = 0)	2.3% (n = 2)		
White or Caucasian	93.3-4% (n = 139)	87.5% (n = 58)	95.3% (n = 81)		
<b>Ethnicity</b>					
Hispanic or Latin-X, Yes	5.4% (n = 8)	7.8% (n = 5)	3.5% (n = 3)	.78	.37
<b>Educational Level</b>					
HS Diploma/GED	16.8% (n = 25)	18.7% (n = 12)	15.3% (n = 13)	4.78	.57
Vocational/Technical	6.7% (n = 10)	3.1% (n = 2)	9.4% (n = 8)		
Some College	41.6% (n = 62)	42.2% (n = 27)	41.2% (n = 35)		
College Degree	26.2% (n = 39)	29.7% (n = 19)	23.5% (n = 20)		
Graduate Degree	8.7% (n = 13)	6.2% (n = 4)	10.6% (n = 9)		
<b>Branch of Service</b>					
Army	71.9% (n = 107)	75% (n = 48)	69.5% (n = 59)	20.66	.27
Air Force	3.3% (n = 5)	4.7% (n = 3)	2.3% (n = 2)		
Marines	14.1% (n = 21)	14.1% (n = 9)	14.1% (n = 12)		
US Public Health Service	1.3% (n = 2)	0% (n = 0)	2.3% (n = 2)		
Multiple Branches	9.4% (n = 14)	6.2% (n = 4)	11.8% (n = 10)		
<b>Care Recipient's Diagnoses and Experiences</b>					
Diagnosed with a TBI, Yes	100% (n = 149)				
Diagnosed with PTSD, Yes	99.3% (n = 148)	100% (n = 64)	98.8% (n = 84)	2.89	.261
Diagnosed with depression, Yes	81.9% (n = 122)	89.0% (n = 57)	76.4% (n = 65)	.772	.85
Experienced a blast-related loss of consciousness, Yes	62.4% (n = 93)	59.3% (n = 38)	64.7% (n = 55)	<b>6.19*</b>	<b>.03</b>
Experienced a blast-related physical injury, Yes	62.4% (n = 93)	73.4% (n = 47)	54.1% (n = 46)	1.70	.19
Experienced other psychiatric and/or physical illness related to combat	95.3% (n = 142)	95.3% (n = 61)	80.0% (n = 68)	.93	.62
<b>Care Recipient's Symptoms</b>					
Headaches	94.2 % (n = 130)	78.4% (n = 58)	84.7% (n = 72)	4.60	.10
Sleep disturbance	98.5% (n = 136)	98.4% (n = 63)	85.9% (n = 73)	1.14	.28
Dizziness	79.7% (n = 110)	64.9% (n = 48)	72.9% (n = 62)	2.12	.34
Balance problems	86.2% (n = 119)	71.6% (n = 53)	77.6% (n = 66)	1.77	.41
Nausea & vomiting	45.6% (n = 63)	32.4% (n = 24)	45.8% (n = 39)	4.36	.11
Fatigue	94.2 (n = 130)	85.1% (n = 63)	78.8% (n = 67)	3.34	.18
Visual disturbances	69.5% (n = 96)	59.6% (n = 44)	61.1% (n = 52)	.313	.85
Light sensitivity	80.4% (n = 111)	64.8% (n = 48)	74.1% (n = 63)	3.91	.14
Noise sensitivity	83.3% (n = 115)	79.7% (n = 51)	75.3% (n = 64)	3.89	.14
Slowed thinking	92.0% (n = 127)	77% (n = 57)	82.3% (n = 70)	2.36	.30
Difficulty concentrating	89.1% (n = 123)	83.8% (n = 62)	85.9% (n = 73)	2.31	.31
Memory problems	98.5% (n = 136)	85.1% (n = 63)	85.9% (n = 73)	1.14	.28
Language difficulty	87.6% (n = 121)	75.7% (n = 56)	76.5% (n = 65)	.07	.96
Anxiety	96.3% (n = 133)	81.1% (n = 60)	85.9% (n = 73)	4.70	.09

Note: \*P < 0.05 (two-tailed), Independent sample t-test or Pearson Chi-Square, Care Recipient (CR), Usual Care (UC), Problem-Solving Therapy (PST), TBI = Traumatic Brain Injury, PTSD = Post Traumatic Stress Disorder

**Table 3: Baseline Differences in Study Outcomes by Randomization Group, N = 149, Mean ( $\pm$  SD)**

Variable	Total Sample N= 149	UC (n = 64)	PST (n = 85)	Test Statistic	P- value
Burden	39.46 (7.47)	38.58 (7.85)	40.12 (7.15)	-1.24	.21
Depression	29.64 (13.80)	27.94 (13.76)	30.93 (13.78)	-1.31	.19

Note: \*P < 0.05 (two-tailed), Independent sample t-test, PST = Problem-Solving Training, UC = Usual Care, Burden = Montgomery Subjective Caregiver Burden Scale, Depression Levels = CES-DR (Center for Epidemiological Studies - Depression Scale, Revised) score

**Table 4: Effects of Randomization Group and Time on Caregiver Burden, Mental Health Quality of Life, and Depression levels (N = 149)**

	Burden		Depression	
	F	Sig	F	Sig
Treatment Group (PST vs UC)	3.08	.085	4.84	.032
Time (1 Year of Follow-Up)	<b>4.92</b>	<b>** .001</b>	<b>3.29</b>	<b>* .012</b>
Treatment Group over Time	<b>13.68</b>	<b>** .000</b>	<b>6.15</b>	<b>** .000</b>

Note: Note: \* p < .05, \*\*p < .01 (two-tailed), General Linear Model, Repeated Measure Analysis, PST = Problem-Solving Training, UC = Usual Care, Burden = Montgomery Subjective Caregiver Burden Scale, Depression Levels = CES-DR (Center for Epidemiological Studies - Depression Scale, Revised) score

Figure 2: Average Burden Levels by Randomization Group, Over Time (PST n = 85, UC n = 64)

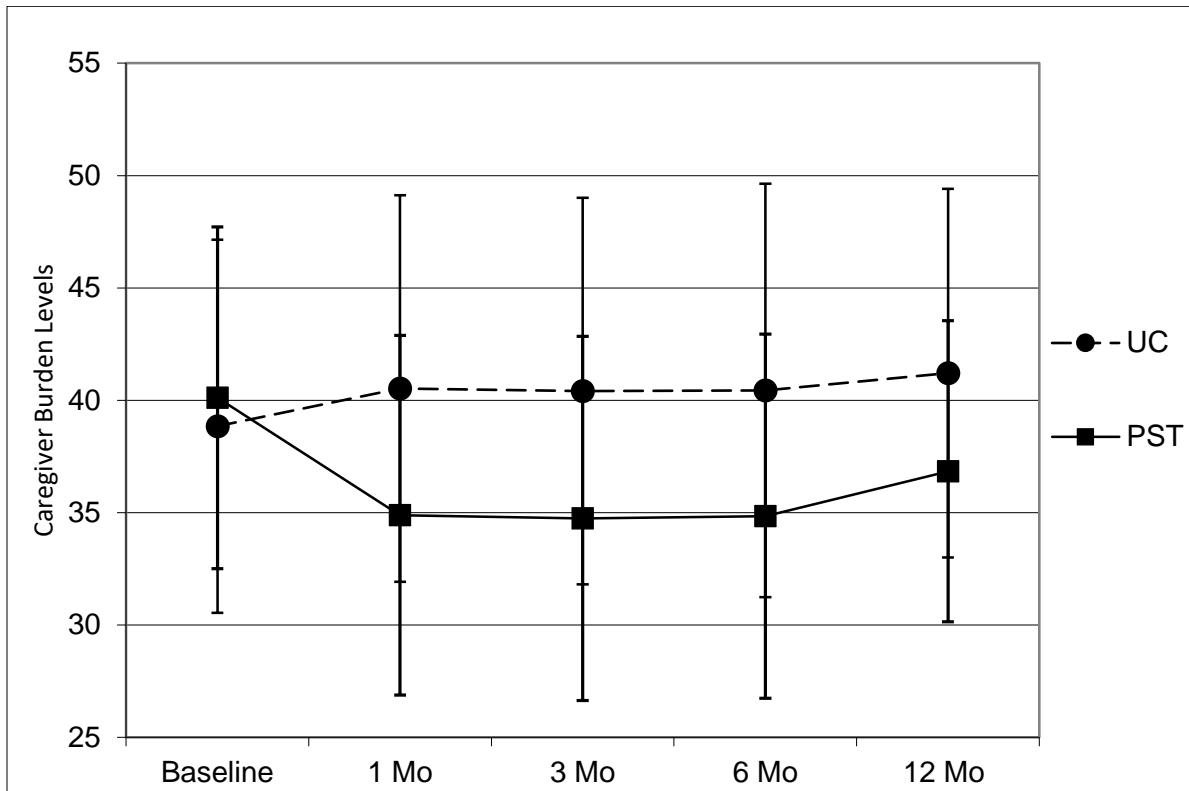


Figure 3: Average Depression Levels by Randomization Group, Over Time (PST n = 85, UC n = 64)

