Telephone Problem Solving for Service Members with Mild Traumatic Brain Injury: A Randomized, Clinical Trial

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Abstract

Mild traumatic brain injury (mTBI) is a common injury for service members in recent military conflicts. There is insufficient evidence of how best to treat the consequences of mTBI. In a randomized, clinical trial, we evaluated the efficacy of telephone-delivered problem-solving treatment (PST) on psychological and physical symptoms in 356 post-deployment active duty service members from Joint Base Lewis McChord, Washington, and Fort Bragg, North Carolina. Members with medically confirmed mTBI sustained during deployment to Iraq and Afghanistan within the previous 24 months received PST or education-only (EO) interventions. The PST group received up to 12 biweekly telephone calls from a counselor for subject-selected problems. Both groups received 12 educational brochures describing common mTBI and post-deployment problems, with follow-up for all at 6 months (end of PST), and at 12 months. At 6 months, the PST group significantly improved on a measure of psychological distress (Brief Symptom Inventory; BSI-18) compared to the EO group ($p=0.005$), but not on post-concussion symptoms (Rivermead Post-Concussion Symptoms Questionnaire [RPQ]; $p=0.19$), the two primary endpoints. However, these effects did not persist at 12-month follow-up (BSI, $p=0.54$; RPQ, $p=0.45$). The PST group also had significant short-term improvement on secondary endpoints, including sleep ($p=0.01$), depression ($p=0.03$), post-traumatic stress disorder ($p=0.04$), and physical functioning ($p=0.03$). Participants preferred PST over EO ($p<0.001$). Telephone-delivered PST appears to be a well-accepted treatment that offers promise for reducing psychological distress after combat-related mTBI and could be a useful adjunct treatment post-mTBI. Further studies are required to determine how to sustain its effects. (Trial registration: ClinicalTrials.gov Identifier: NCT01387490 <https://clinicaltrials.gov>)

Keywords: mild traumatic brain injury; problem-solving treatment (or training or therapy); service members (or military); telehealth

Introduction

MILD TRAUMATIC BRAIN INJURY (mTBI) is considered the “signature injury” of the recent military conflicts in Iraq and Afghanistan.¹ Whereas many people recover completely from mTBI

within a few months, others experience persistent physical and psychological post-concussive symptoms (PCS), which often overlap with, or are influenced by, psychological problems such as post-traumatic stress disorder (PTSD), depression, and anxiety.^{2,3} PCS and psychological distress can result in significant functional disability and poor

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quality of life. Unfortunately, there are no standardized treatments for PCS, and service members' treatment can be challenging because of barriers to care (e.g., duty requirements, getting to clinics, and child-care), restricted access attributed to distance or preference, and the perceived stigma of receiving mental health care.⁴

To self-manage their post-deployment readjustment difficulties, most returning Veterans state a preference for education- and coaching-based interventions over treatments more focused on self-exploration.⁵ Problem-solving treatment (PST) appears to be well suited to helping individuals manage PCS. PST directly targets initiation of active coping strategies that may counteract the passivity often associated with chronic problems. Because of this, interventions designed to promote resiliency and recovery after trauma exposure often incorporate PST as a component of prevention and early intervention efforts.⁶ Rather than a focus on "feelings," PST features externally oriented, action-based strategies, which address barriers to achieving goals, and are intuitive and concrete. Problem-solving treatment can be used to address a wide range of practical problems, such as financial and occupational stressors (e.g., employment), interpersonal conflicts, and role limitations attributed to physical/cognitive impairments. Moreover, because PST does not require the participant to engage in complex cognitive processing, the treatment may be more accessible to persons with cognitive difficulties. Finally, PST is well accepted by military and Veteran populations.⁷ PST uses a client-centered model that promotes self-efficacy by allowing the participant to drive the work of the treatment and gain mastery over problems. An advantage of PST that may be particularly far reaching is that it can be effectively implemented by health care providers with a variety of skills and specialties. PST is an effective component of treatment for a range of psychological problems, including depression^{8,9} and mood disorders secondary to chronic medical conditions.¹⁰

A promising modality of treatment delivery for service members with PCS is telephone-based treatment (telehealth), which may overcome access-to-treatment barriers, allowing for more-flexible scheduling than in-person visits and reducing the stigma of receiving treatment. Leveraging centralized counselors and subject matter experts through telephone-based PST may be a viable approach for reaching large, geographically diverse military populations. Moreover, we know that telehealth treatments are acceptable and sometimes preferred by civilian and military populations.¹¹ We have previously studied the use of telehealth interventions in civilian populations with mTBI, as well as moderate-to-severe TBI, and have established their feasibility and efficacy, even in individuals with cognitive impairment.¹²⁻¹⁶

In the current study, we conducted a trial of telephone-delivered PST in active duty service members who sustained mTBI while deployed to a combat setting. Our primary hypothesis was that PST in addition to treatment as usual (TAU) would result in greater improvement in PCS and symptoms of psychological distress at 6- and 12-month follow-up compared to TAU plus an education-only (EO) intervention. Secondary objectives included evaluating the effects of PST on daily functioning, quality of life, resilience, depression, PTSD, alcohol use, and insomnia.

Methods

Participants

We enrolled active duty service members from the TBI clinics of two military medical centers; all participants were allowed to continue with TAU during the trial. Inclusion criteria involved clinically confirmed mTBI sustained during deployment to Iraq or

Afghanistan during Operations Iraqi Freedom, New Dawn, or Enduring Freedom within the previous 2 years. Subjects who screened positive for possible TBI on return to one of two domestic military bases after completion of deployment were referred to the military hospitals' TBI clinics. They were then evaluated by the clinic team, which included experienced neuropsychologists and physicians who confirmed mTBI using standard self-report clinical criteria. This included assessment for period of confusion as well as presence and length of retrograde and/or post-traumatic amnesia. In-theater evaluation of concussion was not standard procedure for part of this cohort, and combat medical records were not available to TBI clinic or study personnel at any time during the study. Enrollment in the study was based on diagnosis of mTBI by the military hospital's TBI clinic. Subjects were excluded for moderate-to-severe TBI requiring hospitalization, psychosis, active suicidal ideation at the time of screening, or participation in a formal TBI treatment program on base.

Measures

At baseline, we conducted a structured interview in person to obtain demographic information, injury history, and medical history. We administered all other measures by telephone at baseline and at 6 and 12 months post-enrollment. The two primary outcomes were psychological distress and PCS, evaluated by the Brief Symptom Inventory-18 (BSI-18) and the Rivermead Post-Concussion Symptoms Questionnaire (RPQ), respectively. The BSI-18 yields a Global Severity Index (GSI), which is converted to a T-score (adjusted for age and sex), with higher scores indicating more-severe symptoms; it has excellent validity and reliability in TBI patients.¹⁷ The RPQ examines the presence and severity of 16 common PCS with scores from 0 to 64, with higher being worse.¹⁸

Additional measures included: 1) EuroQol,¹⁹ a measure of quality of life; 2) PTSD Checklist-Military Version (PCL-M),²⁰ a measure for PTSD symptom severity anchored to events that occurred during service; 3) Pittsburgh Sleep Quality Index (PSQI),²¹ a measure of sleep disorders and sleep quality; 4) Patient Health Questionnaire-9 (PHQ-9),²² a measure of depression based on Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition criteria; 5) Connor-Davidson Resilience Scale-10 (CD-RISC)²³; 6) Brief Inventory for Functioning Evaluation (B-IFE),²⁴ a measure of social functioning designed for military populations; 7) Alcohol Use Disorders Identification Test (AUDIT)²⁵; 8) Sheehan Disability Scale (SDS),²⁶ a measure of functional impairment in the work, social life, and family life domains; 9) 12-item Short Form Health Survey (SF-12),²⁷ a commonly used measure of functional health status; and 10) the Client Satisfaction Scale.²⁸

Procedure

The study utilized a two-group parallel design. After enrollment and baseline assessment, study participants were randomly assigned to either the PST group or the EO group, with a 1:1 ratio, using blocked randomization stratified on active duty versus National Guard or Reserve status, level of psychological distress (BSI-18 GSI >60 vs. ≤60), and enrollment site. Outcomes were assessed by examiners blinded to participant assignment, and participants were instructed to not reveal their treatment condition while speaking with examiners.

Interventions

The PST and EO interventions are described in detail elsewhere.²⁹ After baseline assessment, all participants received a study binder, which included group assignment, a list of resources, and the contact information for the study coordinator. The binder also included 12 educational brochures addressing problems

common to mTBI and military readjustment after return from deployment (stress, substance abuse, pain and headache, sleep disorders, anger, depression, cognitive problems, relationships, money and finances, post-traumatic stress, physical recovery, and returning to work). The EO group also received a second copy of the brochures, one mailed every other week throughout the study. The PST group received 12 scheduled biweekly calls. Master's-level counselors conducted the phone treatment after extensive training and practice and were supervised in a weekly group led by study investigators (J.A.B., J.R.F., and K.R.B.). All intervention calls were placed from the University of Washington (Seattle, WA) site. PST participants self-selected problems to work on from a list generated during the first or second call and were emailed a call summary after each call. The problem-solving steps for participant-selected problems (Table 1) were frequently reviewed, with participants gradually taking on more independence in following the steps.

Study oversight

The protocol was approved by the institutional review boards at each study site and by the Army Human Rights Protection Office. The study was conducted in accord with the Declaration of Helsinki and the International Conference on Harmonization Guidelines for Good Clinical Practice. Informed consent was obtained from all participants before entering the study. The investigators were responsible for the design and oversight of the study, development of the protocol, data collection, and the analysis. The study was funded as part of a Department of Defense-funded consortium, called INTRuST (Injury and Traumatic Stress: Posttraumatic Stress and Traumatic Brain Injury Clinical Consortium). The INTRuST data safety monitoring board reviewed all study data quarterly. All statistical analyses were conducted by the consortium biostatisticians (R.R., S.J., and K.E.), separate from the clinical or supervising sites.

Statistical analysis

We conducted all statistical analyses using statistical software R (version 3.1.1; <http://www.r-project.org>). Our analyses followed the intent-to-treat principle. Summary statistics and comparisons between intervention groups were provided for demographics and injury-related variables. We used a mixed-effects regression model separately on each of the primary outcome measures to determine

whether the PST group had improved BSI-18 or RPQ scores, compared to the EO group, at treatment end (i.e., 6 months after enrollment) and at follow-up (12 months after enrollment). This model included the outcome score as the dependent variable, and time, treatment, and time-by-treatment interaction terms as independent effects, and a random intercept and slope using an unstructured variance-covariance structure. We treated time (0, 6, and 12 months) as a categorical variable, and we included stratification factors in the model, as well as observed confounders defined as any baseline covariate simultaneously unbalanced at baseline (univariate, $p < 0.10$) and associated with the outcome (univariate, $p < 0.15$). We considered a significant treatment effect if the p value for the 6-month time-by-treatment interaction contrast in either of the two primary analyses was ≤ 0.025 . Size of the treatment effect was estimated from the coefficients for the 6-month time-by-treatment interaction.

We conducted a sensitivity analysis to examine any imbalance between those followed and those with a missed assessment. We used a mixed-effects regression model analogous to the primary analysis, additionally including any baseline variables found to be imbalanced between those followed and those missed. We applied mixed-effects regression models analogous to the primary analysis methodology for secondary and exploratory analyses. Another sensitivity analysis we conducted for the primary outcomes was to compare the original model with the time-variable model including only months 0 and 6. We made no adjustments for multiple comparisons for secondary analyses, and we defined $p < 0.05$ as our minimum threshold for statistical significance.

We used the Reliable Change Index (RCI) for the GSI to estimate whether the change observed was greater than that which is attributable to the reliability of the instrument. The test-retest reliability of GSI score is set as 0.9.^{30,31} Subjects were categorized based on the RCI as the following: Improvement: $\text{RCI} < -1.96$; Worsening: $\text{RCI} > 1.96$; and No Change: otherwise.

Finally, we conducted regression analyses to examine the potential factors that might influence the response to the CONTACT intervention. We used the BSI score at 6 months as the dependent variable, and race, ethnicity, number of concussions, time since return from last deployment, baseline PCL-M, baseline PHQ-9, and baseline CD-RISC scores as independent variables.

Results

Participants

Of 1274 soldiers screened, 356 were eligible and were randomized to two groups (PST, EO) of 178 each (Fig. 1). Across both groups, 304 (85.4%) completed their 6-month follow-up (PST group, 138; EO group, 166) and 299 (83.9%) completed their 12-month assessments (PST group, 142; EO group, 157). Those not followed at either the 6- or 12-month assessment were considered dropouts. There were no significant differences between groups in their baseline demographics or injury characteristics (Table 2). Those successfully contacted at 6 months for follow-up were older and better educated ($p = 0.020$; $p = 0.030$). Additional sensitivity analyses were performed to account for these differences and are reported under Outcomes.

Safety

Overall, there were 33 reported adverse events (AEs) in 26 participants during the course of the study. There was a trend toward a higher rate of participants experiencing at least one AE in the PST group (10% vs. 4%; $p = 0.070$). There were 23 serious adverse events (SAEs) in 18 participants. The SAE rate did not differ between groups. There were three deaths (two in the PST

TABLE 1. CONTACT PROBLEM-SOLVING STEPS

A. Assess	Analyzing the selected problem and setting realistic and achievable goals
B. Brainstorm	Developing solution alternatives
C. Consider and choose	Weighing the pros and cons of the potential solutions, ranking the solutions with a prediction of the success and potential barriers of each, and choosing one
D. Do it	Developing a detailed action plan to enact the selected solution and carrying it out between sessions
E. Evaluate	Reviewing the outcome of the action plan and reflecting on what was successful or not, and why
F. Fight on	Reworking the plan if the desired outcome did not result and committing to continued actions if successful

FIG. 1. CONSORT diagram. CONSORT, Consolidated Standards of Reporting Trials; PST, problem-solving treatment.

group—one suicide and one accidental drug overdose—and one combat-related fatality in the EO group; all three deaths were deemed unrelated to the study). Additionally, 6 participants in each group were hospitalized at least once. AEs were all considered to be unrelated to the interventions. It should be noted that there were more occasions for PST participants to report AEs over EO participants.

Outcomes

The mean number of sessions completed by the 178 participants assigned to the PST group was 6.6 ± 4.6 (range, 0–12; median, 7). Of 12 possible telephone sessions over 6 months, 119 participants (67%) completed four or more sessions. The mean duration of sessions was 44.7 minutes (range, 2–120, median, 45).

The assessment of the two primary outcomes of the study at 6 months showed that PST was associated with greater improvement in psychological distress compared to EO on the BSI-18 GSI

($p=0.005$; treatment difference, 3.03; 95% confidence interval [CI], 0.91, 5.16; Table 3), but not on the RPQ ($p=0.19$; treatment difference, 1.89; 95% CI, −0.94, 4.73). RCI analysis for the GSI score supported the finding for improvement in psychological distress ($p=0.048$). Compared to the EO group, we also noted significant positive effects of the PST group on secondary outcomes, PHQ-9 ($p=0.030$; treatment difference, 1.36; 95% CI, 0.14, 2.58), PSQI ($p=0.010$; treatment difference, 1.30; 95% CI, 0.27, 2.32), PCL-M ($p=0.04$; treatment difference, 2.89; 95% CI, 0.16, 5.62), and the SF-12: Physical Component Summary ($p=0.030$; Table 4; treatment difference, −3.06; 95% CI, −5.76, −0.35). There were no differences noted on secondary outcomes for the AUDIT-C, B-IFE, CD-RISC, EuroQol Health State, SDS, or the SF-12: Mental Component Summary (Table 4). However, none of these effects were found to persist at the 12-month assessment. The protocol-specified analyses and sensitivity analyses all gave results similar to these, with no changes in treatment differences considered to be significant. We did not find any factors (race, ethnicity,

TABLE 2. DEMOGRAPHIC AND INJURY CHARACTERISTICS OF PARTICIPANTS

<i>Variable</i>	<i>All randomized subjects (n = 356)</i>	<i>Randomized to PST (n = 178)</i>	<i>Randomized to education only (n = 178)</i>	<i>p value</i>
Recruitment site				
Madigan AMC, <i>n (%)</i>	110 (31)	55 (31)	55 (31)	>0.99
Womack AMC, <i>n (%)</i>	246 (69)	123 (69)	123 (69)	
Age, years				
Mean (SD)	29.35 (7.23)	29.25 (7.20)	29.44 (7.27)	0.76
Range	(20, 54)	(20, 54)	(20, 53)	
Sex, <i>n (%)</i>				
Male	332 (93.26)	166 (93.26)	166 (93.26)	>0.99
Race, <i>n (%)</i>				
Black or African American	29 (8.15)	15 (8.43)	14 (7.87)	>0.99
White	274 (76.97)	137 (76.97)	137 (76.97)	
Other	53 (14.89)	26 (14.61)	27 (15.17)	
Ethnicity, <i>n (%)</i>				
Hispanic or Latino	65 (18.26)	36 (20.22)	29 (16.29)	0.70
Non-Hispanic or Latino	289 (81.18)	141 (79.21)	148 (83.15)	
Unknown	2 (0.56)	1 (0.56)	1 (0.56)	
Education				
Mean (SD)	13.4 (1.81)	13.47 (1.84)	13.34 (1.78)	0.69
Range	(9, 20)	(10, 20)	(9, 20)	
Military status, <i>n (%)</i>				
Regular	332 (93.26)	167 (93.82)	165 (92.7)	0.83
Other	24 (6.74)	11 (6.18)	13 (7.3)	
Deployments to combat zone				
Mean (SD)	2.44 (1.82)	2.47 (1.91)	2.41 (1.72)	0.851
Range	(1, 10)	(1, 10)	(1, 9)	
Circumstances of TBI*, <i>n (%)</i>				
Blast	304 (85)	149 (84)	155 (87)	0.453
Vehicular	82 (23)	46 (26)	36 (20)	0.257
Fragment	27 (8)	13 (7)	14 (8)	>0.99
Struck	127 (36)	73 (41)	54 (30)	0.046
Fall	96 (27)	47 (26)	49 (28)	0.905
Thrown	144 (40)	82 (46)	62 (35)	0.040
Training	32 (9)	15 (8)	17 (10)	0.853
Assault	11 (3)	5 (3)	6 (3)	>0.99

*Possible multiple responses selected by participants.

AMC, Army Medical Center; SD, standard deviation; TBI, traumatic brain injury; PST, problem-solving treatment.

TABLE 3. PRIMARY OUTCOME MEASURES SCORES

	<i>Overall</i>		<i>PST group</i>		<i>EO group</i>		<i>Significance*</i>
	<i>N</i>	<i>Mean (SD)</i>	<i>N</i>	<i>Mean (SD)</i>	<i>N</i>	<i>Mean (SD)</i>	
BSI-18 GSI							
Baseline	356	57.2 (9.9)	178	57.3 (10.1)	178	57.2 (9.8)	
6-month	304	56.1 (11.8)	138	54.5 (12.5)	166	57.4 (11.1)	0.005
12-month	298	56.7 (11.8)	142	56.4 (12.8)	156	56.9 (10.9)	0.543
RPQ							
Baseline	355	26.5 (13.3)	177	26.2 (13.4)	178	26.8 (13.2)	
6-month	304	24.2 (14.8)	138	22.8 (15.3)	166	25.4 (14.4)	0.190
12-month	299	23.4 (15.0)	142	22.4 (15.6)	157	24.2 (14.5)	0.453

*Each *p* value is the time-by-treatment interaction in the mixed-effects model and corresponds to the group difference in the change in score from baseline.

BSI-18 GSI (Behavioral Symptoms Inventory-18 Global Severity Score): lower score is better.

RPQ (Rivermead Post-Concussion Symptoms Questionnaire): lower score is better.

SD, standard deviation; PST, problem-solving treatment; EO, education only.

number of concussions, time since return from last deployment, baseline PCLM, baseline PHQ-9, and baseline CD-RISC scores) to be predictive of response to the CONTACT intervention.

As expected, participants receiving the PST intervention rated the received services at 6 months as better for the quality ($p < 0.001$), type ($p < 0.001$), and amount of help ($p = 0.010$) re-

ceived than did EO participants. They were also more likely to report that the assistance helped them solve problems more effectively ($p < 0.001$), and that they would recommend this type of treatment to a friend ($p = 0.040$). There were no differences between groups on whether needs were perceived to have been met or whether participants would seek help in this type of program again.

TABLE 4. SECONDARY OUTCOME MEASURES SCORES

	Overall		PST group		EO group		Significance*
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	
AUDIT-C							
Baseline	355	3.5 (2.6)	177	3.6 (2.5)	178	3.4 (2.6)	
6-month	285	3.1 (2.4)	127	3.0 (2.3)	158	3.2 (2.5)	0.106
12-month	270	3.0 (2.5)	129	2.8 (2.1)	141	3.2 (2.8)	0.061
B-IFE							
Baseline	355	2.4 (1.2)	177	2.3 (1.2)	178	2.4 (1.2)	
6-month	275	2.1 (1.3)	123	2.1 (1.3)	152	2.2 (1.2)	0.895
12-month	258	2.0 (1.2)	123	2.0 (1.3)	135	1.9 (1.2)	0.489
CD-RISC							
Baseline	355	30.2 (6.7)	177	30.5 (6.5)	178	30.0 (6.9)	
6-month	284	31.9 (6.5)	126	32.6 (6.1)	158	31.4 (6.7)	0.366
12-month	265	31.5 (7.1)	127	30.6 (7.5)	138	32.4 (6.6)	0.004
EuroQol Health State							
Baseline	355	69.9 (16.0)	177	70.2 (16.3)	178	69.6 (15.8)	
6-month	284	70.3 (18.2)	126	73.1 (17.0)	158	68.1 (18.8)	0.071
12-month	269	70.3 (18.0)	128	70.0 (18.0)	141	70.6 (18.2)	0.389
PCL-M							
Baseline	356	41.5 (14.2)	178	41.3 (14.2)	178	41.6 (14.2)	
6-mMonth	292	40.5 (16.6)	132	38.7 (17.2)	160	42.0 (16.1)	0.038
12-month	271	40.2 (16.6)	130	39.5 (17.3)	141	40.7 (15.9)	0.593
PHQ-9							
Baseline	355	10.0 (5.4)	177	10.1 (5.4)	178	10.0 (5.3)	
6-month	284	8.5 (6.0)	126	7.6 (6.2)	158	9.2 (5.7)	0.030
12-month	266	8.3 (6.1)	128	8.2 (6.4)	138	8.4 (5.8)	0.841
PSQI							
Baseline	352	12.5 (4.3)	175	12.5 (4.5)	177	12.6 (4.1)	
6-month	276	11.0 (4.9)	122	10.1 (5.0)	154	11.8 (4.7)	0.013
12-month	255	10.8 (5.2)	120	10.7 (5.5)	135	10.8 (4.9)	0.947
SDS							
Baseline	355	11.5 (7.2)	177	11.7 (7.1)	178	11.3 (7.3)	
6-month	284	8.8 (7.5)	126	8.0 (7.6)	158	9.4 (7.4)	0.120
12-month	270	9.0 (7.7)	129	9.1 (8.0)	141	8.9 (7.5)	0.906
SF-12 MCS							
Baseline	355	44.7 (11.9)	177	45.1 (11.7)	178	44.3 (12.1)	
6-month	262	47.8 (12.1)	116	48.5 (12.3)	146	47.3 (12.0)	0.883
12-month	206	48.1 (11.6)	96	47.7 (12.8)	110	48.5 (10.6)	0.404
SF-12 PCS							
Baseline	355	43.4 (11.7)	177	43.4 (11.5)	178	43.4 (11.9)	
6-month	262	43.6 (11.8)	116	45.7 (11.4)	146	41.9 (11.9)	0.027
12-month	206	43.2 (11.3)	96	44.0 (11.1)	110	42.5 (11.5)	0.533

*Each p value (except Client Satisfaction Questionnaire [CSQ-8]) is the time-by-treatment interaction in the mixed-effects model and corresponds to the group difference in the change in score from baseline.

AUDIT-C (Alcohol Use Disorders Identification Test): lower score is better.

B-IFE (Brief Inventory for Functioning Evaluation): lower score is better.

CD-RISC (Connor Davidson Resilience Scale): higher score is better.

EuroQol: lower score is better.

PCL-M (PTSD Checklist–Military Version): lower score is better.

PHQ-9 (Patient Health Questionnaire–9 Item): lower score is better.

PSQI (Pittsburgh Sleep Quality Index): lower score is better.

SDS (Sheehan Disability Scale): lower score is better.

SF-12 MCS (Short Form-12 Mental Health Composite Scale): lower score is better.

SF-12 PCS (Short Form-12 Physical Composite Scale): lower score is better.

SD, standard deviation; PST, problem-solving treatment; EO, education only.

Discussion

In this study of active duty service members who were clinically diagnosed with mTBI and were receiving treatment as usual, the addition of education and a telephone-delivered PST intervention was more effective than the provision of educational materials alone in reducing symptoms of psychological distress, but not more effective in reducing PCS. Participant satisfaction with the services including the PST intervention was higher in most respects than for services including education alone. From these results, it appears that PST administered by telephone was associated with significant improvement in the short-term for post-deployment emotional distress and, possibly, physical functioning, and that PST by phone was well received by active duty service members. This study, which had a large sample size and high follow-up rate, is the first to show that manualized, telephone-delivered PST can be delivered by a diverse group of care providers and is effective for decreasing psychological distress in active duty service members with mTBI. However, the positive findings did not persist to a 12-month follow-up (i.e., conducted 6 months after completion of the intervention).

In addition to reducing psychological distress, this intervention had a positive effect on a number of comorbid conditions that are known to be particularly vexing to this population. Depression, PTSD, and sleep disorders are among the most common complaints noted to be associated with combat-associated mTBI.^{32–34} Further analysis will be necessary to determine whether these effects were specific to subject-chosen areas for problem solving or whether improved problem solving resulted in a more-generalized feeling of emotional control.

This is one of the largest intervention studies to date in service members with mTBI. We kept the inclusion/exclusion criteria minimally restrictive to allow us to evaluate efficacy in a representative population of active duty service members with mTBI. The final diversity of our study sample collected from two sites reflected the demographic makeup of the general army population (<http://www.armyg1.army.mil/hr/docs/demographics/FinalFY14ArmyProfileReport.pdf>). Our ability to retain participants for treatment and outcome assessment compared favorably with other studies of this population, one that can be difficult to enroll and retain.³⁵ In addition to a well-documented reluctance to participate in treatment (or studies) involving emotional health, duty participation conflicts and base transfers have often resulted in difficulties in recruiting and retaining subjects in research studies. For example, in systematic reviews of studies of military populations with

PTSD (a similar, although not identical, population), sample sizes ranged from 8 to 180 with dropout rates of 9–47% for primary and secondary endpoints and high nonresponse rates.^{36–38}

As noted, results from our secondary analyses indicated that physical well-being, depression, PTSD, and quality of sleep were particularly responsive to the PST intervention, although the effect did not persist. Given the positive results on the emotional scales, it was somewhat surprising that physical well-being (on the SF-12 measure) improved in the PST group over the EO group, but that mental well-being did not. A content analysis of the problems addressed during the PST or a further item analysis of the SF-12 responses may help explain this finding. Because exercise was a common solution selected by service members to address a variety of physical and emotional problems, it may have resulted in an improved sense of physical well-being and less fatigue.

The lack of significant difference between treatment groups on reported PCS symptoms may be attributed, in part, to the fact that the RPQ contains a wide variety of items reflecting somatic, emotional, and cognitive symptoms. Given the flexibility of the PST intervention, some participants focused on problems addressed by the RPQ, whereas others focused on problems completely unrelated to PCS (e.g., financial or employment problems). Further analysis of items or content clusters on the RPQ may elucidate this result.

It is striking that there is a difference in the persistence of PCS and levels of emotional distress (Fig. 2). Both groups improved steadily over a 12-month period, as measured by the RPQ. The trajectory for emotional distress was different. Whereas the PST group demonstrated improvement in emotional symptoms at the completion of the intervention, each group had an equally high level of emotional distress at baseline and 12 months, indicating a possible difference in trajectory for post-concussion and emotional symptoms in a military population with mTBI. This has implications for designing treatment programs for active duty service members; emotional distress was likely to persist without ongoing treatment and was more resistant to sustained improvement over time.

Taken together, our overall findings suggest that although telephone PST may be effective during the course of treatment, the positive effects may not persist. Few studies of PST and other cognitive-behavioral interventions have been evaluated past the termination of treatment. A few studies of populations with specific emotional targets for PST (e.g., anxiety, depression) have demonstrated maintenance of effects.^{39,40} There are relatively few reports of behavioral interventions for PCS. A systematic review

FIG. 2. Primary outcome measures. BSI, Brief Symptom Inventory-18; PST, problem-solving treatment; RPQ, Rivermead Post-concussion Symptoms Questionnaire.

documented studies with many methodological limitations and gave some limited evidence to support effectiveness of cognitive-behavioral approaches, but little information on long-term outcomes.⁴¹ Additionally, there are only a few large trials that have focused on active duty military populations. For populations exposed to stressful combat situations, it is not clear what the duration of treatment or amount of follow-up “booster” treatment should be.³⁸

Several study limitations should be noted. Our loss to follow-up at 6 and 12 months was higher in the PST group and even included some who completed most of the intervention calls. This difference in follow-up at 6 months may have biased the outcome in either direction. Subjects in the PST group completed an average of 6.6 of 12 scheduled calls. Subjects in the PST group may have chosen to reduce contact because they were tired of receiving telephone calls or because the calls did not help, or because they were feeling better and did not need further intervention. Subjects who were negative about participation in the study and who dropped out of the telephone intervention arm may have been less likely to respond to the outcome assessment call than similarly negative subjects who had not received telephone calls. All of these situations could have biased the outcome as well as client satisfaction scores. Additionally, because participants were not required to demonstrate a minimum level of symptomatology (e.g., psychological distress, PCS) in order to participate, there may have been a “floor effect” that potentially attenuated the magnitude of improvement. Minimum levels of symptomatology may also have resulted in subjects without perceived problems choosing to not complete the full number of calls scheduled.

In addition, while allowing subjects to choose the problems discussed in PST sessions fostered more patient-centered care, it may have allowed some participants to avoid discussion of challenging emotional issues, limiting the longer-term effectiveness of PST for those areas for those subjects. Last, these results cannot be generalized to an acute civilian or military concussion population because of the delayed identification and treatment of these subjects. Whereas this is the norm for active duty service members with mTBI acquired in combat situations later returning to the continental United States for treatment, these subjects had concussions months to 2 years before enrollment into this study.

In conclusion, PST delivered by telephone was acceptable and offers promise in the short term in reducing symptoms of psychological distress in active duty service members diagnosed with mTBI. PST also decreased depression, PTSD, and sleep problems and improved health-related physical functioning over 6 months of active treatment. The results of this study demonstrate that this intervention does offer a means of delivering effective intervention to a population that has historically been difficult to engage in treatment, particularly treatment involving behavioral health intervention, and may offer an alternative or be used as adjunct to traditionally delivered therapy. An important next step is to determine how to improve the maintenance of gains after the termination of therapy and identify those service members that would be most likely to benefit from this type of brief intervention.

Acknowledgments

The authors thank Michael Warren, Sara Fey-Hinckley, Jocelyn Savage, Jason Barber, Elisa Thomas, Frederick Flynn, DO, Emily Fantelli, Karyna Boykin, Danielle Feldman Benton, Sara Wellnitz, Laurie Peabody, Erica Wasmund, Leila Forbes, Simona Vuletic, the participants, and the AMC staffs.

This study was supported by the U.S. Army Medical Research and Materiel Command (USAMRMC; contract no.: W81XWH-08-2-0159). Supplementary support was provided by the National Institute on Disability and Rehabilitation Research (grant no.: H133G070143).

The views expressed herein are those of the author(s) and do not reflect the official policy of the Department of the Army, Department of Defense, or the U.S. government.

Author Disclosure Statement

Dr. Stein is a member of the scientific advisory board of Oxeia Biopharmaceuticals.

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