Concussion treatment after combat trauma: Development of a telephone based, problem solving intervention for service members

Kathleen R. Bell a,⁎, Jo Ann Brockway a, Jesse R. Fann b, Wesley R. Cole c, Jef St. De Lore d, Nigel Bush e, Ariel J. Lang f, Tessa Hart g, Michael Warren h, Sureyya Dikmen a,⁎, Nancy Temkin a,⁎, Sonia Jain j, Rema Raman l, Murray B. Stein f

a Department of Rehabilitation Medicine, University of Washington, 1595 NE Pacific Street, Seattle, WA 98195, United States
b Department of Psychiatry and Behavioral Sciences, University of Washington, 1595 NE Pacific Street, Seattle, WA 98195, United States
c Defense and Veterans Brain Injury Center, General Dynamics Information Technology, Department of Brain Injury Medicine, WAMC, Fort Bragg, NC 28310, United States
d Department of Neurological Surgery, University of Washington, 325 9th Avenue, Seattle, WA 98104, United States
e National Center for Telehealth and Technology, 9933 West Hayes Street, Joint Base Lewis McChord, Tacoma, WA 98431, United States
f Department of Psychiatry, University California San Diego, 9500 Gilman Drive (MC 0855), La Jolla, CA 92093, United States
g Moss Rehabilitation Research Institute, 50 Township Line Road, Elkins Park, PA 19027, United States
h Department of Biostatistics, University of Washington, F-600, Health Sciences Building, Box 357232, Seattle, WA 98195, United States
i Department of Family and Preventive Medicine, University of California, 9500 Gilman Drive, La Jolla, CA 92093, United States
j National Center for Telehealth and Technology, 9933 West Hayes Street, Joint Base Lewis McChord, Tacoma, WA 98431, United States

A R T I C L E   I N F O

Article history:
Received 25 August 2014
Received in revised form 31 October 2014
Accepted 1 November 2014
Available online 8 November 2014

Keywords:
Concussion
Brain Injury

A B S T R A C T

Military service members (SMs) and veterans who sustain mild traumatic brain injuries (mTBI) during combat deployments often have co-morbid conditions but are reluctant to seek out therapy in medical or mental health settings. Efficacious methods of intervention that are patient-centered and adaptable to a mobile and often difficult-to-reach population would be useful in improving quality of life. This article describes a new protocol developed as part of a randomized clinical trial of a telephone-mediated program for SMs with mTBI. The 12-session program combines problem solving training (PST) with embedded modules targeting depression, anxiety, insomnia, and headache. The rationale and development of this behavioral intervention for implementation with persons with multiple co-morbidities is described along with the proposed implementation with persons with multiple co-morbidities.

Abbreviations: AUDIT, Alcohol Use Disorders Identification Test; BA, Behavior activation; B-IFE, Brief Inventory for Functioning Evaluation; BSI, Behavioral Symptoms Inventory; CBT, Cognitive behavioral therapy; CDC, Centers for Disease Control and Prevention; CD-RISC, Connor–Davidson Resilience Scale; CSQ-8, Client Satisfaction Questionnaire; C-SSRS, Columbia Suicide Severity Rating Scale; ED, Education only; GAD-2, Generalized anxiety disorder-2 item; GSI, Global Severity Index; HIT-6, Headache Impact Test; MAMC, Madigan Army Medical Center; MACE, Military Acute Concussion Evaluation; mTBI, Mild traumatic brain injury; OEF, Operation Enduring Freedom; OIF, Operation Iraqi Freedom; PCL-M, PTSD Checklist-Military Version; PHQ-9, Patient Health Questionnaire-9; PHQ-2, Patient Health Questionnaire-2; PM&R, Physical medicine and rehabilitation; PPCS, Persistent post-concussive symptoms; PSQI, Pittsburgh Sleep Quality Index; PST, Problem solving training; PTSD, Post-traumatic stress disorder; RCT, Randomized control trial; RPSQ, Rivermead Post-Concussion Symptom Questionnaire; SF-12, Short Form-12; SMs, Service members; VA, Veteran Affairs; WAMC, Womack Army Medical Center.

Sources of support: The research reported in this article was supported by the U.S. Army Medical Research and Materiel Command (USAMRMC), USAMRMC Funding Mechanism: Contract # W81XWH-08-2-0159. Supplemental funding for development of the treatment manual and fidelity assessment system was provided by the National Institute on Disability and Rehabilitation Research, grant # H133G070143.

⁎ Corresponding author at: Department of Rehabilitation Medicine, Box 356490, University of Washington, 1595 NE Pacific Street, Seattle, WA 98195, United States.
Tel.: +1 206 685 0935 (Office); fax: +1 206 685 3244.

E-mail addresses: krebell@uw.edu, Kathleen.Bell@UTSouthwestern.edu (K.R. Bell), brockja@uw.edu (J.A. Brockway), fann@uw.edu (J.R. Fann), wesley.r.cole.ctr@mail.mil (W.R. Cole), saint@uw.edu (J.S. De Lore), nigel.e.bush.civ@mail.mil (N. Bush), ajlang@ucsd.edu (A.J. Lang), thart@einstein.edu (T. Hart), mwarren@email.fielding.edu (M. Warren), dikmen@uw.edu (S. Dikmen), temkin@uw.edu (N. Temkin), sojain@ucsd.edu (S. Jain), reraman@ucsd.edu (R. Raman), mstein@ucsd.edu (M.B. Stein).

⁎⁎ Present address: University of Texas Southwestern, Department of Physical Medicine and Rehabilitation CS2.122 5323 Harry Hines Dallas, TX 75390-9055, United States.
Tel.: +1 214 648 2240; fax: +1 214 648 9207.

http://dx.doi.org/10.1016/j.jct.2014.11.001
1551-7144/© 2014 Elsevier Inc. All rights reserved.
1. Introduction

Since 2000, over 260,000 traumatic brain injuries (TBI) have been diagnosed among US service members (SMs), with most (76%) categorized as mild TBI (mTBI) [1]. Although most persons recover well from mTBI, some experience persistent post-concussive symptoms (PPCS) such as headache, memory impairment, and light and sound sensitivity. Particularly for SMs returning from combat deployments, depression, anxiety, and/or posttraumatic stress disorder (PTSD), with attendant sleep difficulties, may complicate the picture. Depression and PTSD can account for a PPCS-like presentation among SMs with sleep difficulties, may complicate the picture. Depression and PTSD can impact personal quality of life, and more broadly, troop readiness. Current treatment guidelines for mTBI focus on acute physical and mental rest, education and symptom management, and multidisciplinary rehabilitation programs, often without the ability to work or engage in daily activities, negatively impacting personal quality of life, and more broadly, troop readiness. Current treatment guidelines for mTBI focus on acute physical and mental rest, education and symptom management, and multidisciplinary rehabilitation programs, often without research-based clinical guidelines [3–6]. Additionally, treatment of PPCS is complicated by the need to treat associated psychiatric disorders, requiring different evidence-based approaches.

SMs returning from deployment with PPCS may be difficult to treat because they are mobile and hard to reach, and/or concerned about the stigma of treatment. As few as one in three SMs with post-deployment adjustment problems seek treatment [7,8]. Transportation, taking time off duty, and financial resources are barriers to care [8–11]. Personal acceptance of having a mental health problem may be an even greater barrier [7]. As many as 61–70% of SMs believe admitting to a mental health problem and seeking treatment will harm their military career [12,13].

Telehealth may be useful for overcoming some of these barriers [14]. Cell phones are now used by 90% of American adults [15], and one-third of SMs not willing to seek in-person counseling services report willingness to engage in technology-based services [16]. Telephone-based healthcare interventions often result in high satisfaction [16,17] as well as efficacy [18–21].

For the current study we designed a telephone-based treatment flexible enough for the diverse symptoms of PPCS, capable of addressing associated conditions such as depression and insomnia, and focused on teaching self-management skills [22,23]. As a general framework we used problem solving treatment (PST), in which patients learn a flexible algorithm of steps for planning, implementing, and evaluating solutions to problems of daily life. PST is effective for treating general distress [24], depression [25], suicidality [26], anxiety disorders [27,28], and other conditions. PST has been successfully delivered by telephone [21,31] and similar algorithms have been learned by people with cognitive impairment due to TBI [32–34]. Our group has successfully used telephone-delivered self-management interventions in populations with mild and moderate to severe TBI [18,19,35–37]. In two large Veteran Affairs (VA) randomized controlled trials (RCTs), treatments incorporating problem solving strategies were effective and better tolerated than trauma-focused psychotherapies for military-related PTSD [29,30]. PST features externally oriented, action-based strategies, typically preferred by veterans [38]. Finally, PST is intuitive and can be effectively implemented by a wide range of health care providers such as nurses, psychologists, social workers or licensed counselors [18,37,39].

The purpose of this paper is to describe 1) the development and structure of this PST-based telephone therapy and 2) the methodology of a RCT testing the efficacy of the treatment in reducing the symptoms of PPCS and concurrent conditions in SMs sustaining mTBI during recent deployments to Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF). We present the design rationale and how methodological challenges and encountered decision points were resolved, in particular those relating to manualization of a complex intervention and recruitment of active duty service members.

2. Design and methods

2.1. Overview and design

The study described below is a randomized, controlled trial of a manualized problem-solving treatment delivered by telephone as compared to an education-only (EO) treatment delivered by mail or email.

2.2. Participants

Participants are active duty SMs and/or National Guard/Reserve who have returned from an OEF/OIF deployment within the past 2 years and are identified as likely sustaining one or more mTBIs on that deployment. We recruit SMs from TBI Clinics at Madigan Army Medical Center (MAMC) on Joint Base Lewis-McChord and Womack Army Medical Center (WAMC) on Fort Bragg. Qualifying mTBIs are determined by (a) an affirmative response to screening at a post-deployment health examination, and (b) an affirmative response to questions on the “2 + 10 TBI Screening Questionnaire” (this questionnaire has two questions regarding the mechanism of injury and 10 questions regarding the characteristics of the injury and associated symptoms) or the Military Acute Concussion Evaluation (MACE) [40], which correspond to the critical sections of the Centers for Disease Control and Prevention (CDC)
Table 1

TBI screening questionnaires used to evaluate eligibility for study. "2 + 10" is used at MAMC’s TBI Clinic. MACE is used at WAMC’s TBI Clinic.

<table>
<thead>
<tr>
<th>&quot;2 + 10&quot; TBI questionnaire (items 1, 2, and 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. While deployed, were you exposed to or near a blast, IED explosion, car bomb, suicide explosion, or exposed to any other combat event that caused a blow or jolt to your head?</td>
</tr>
<tr>
<td>2. While deployed, were you involved in a motor vehicle accident, a fall, a sports accident, or any other event that caused a blow to your head or that resulted in a neck whiplash?</td>
</tr>
<tr>
<td>6. Do you have a loss of memory for what happened right after (and/or before) the event?</td>
</tr>
</tbody>
</table>

Military Assessment of Concussion (MACE) (selected items)

1c. Were you dazed, confused, “saw stars”? |
4. Amnesia Before: Are there any events just BEFORE the injury that are not remembered? |
5. Amnesia After: Are there any events just AFTER the injuries that are not remembered? |
6. Does the individual report loss of consciousness or “blacking out”?

MAMC = Madigan Army Medical Center; WAMC = Womack Army Medical Center; IED = improvised explosive device.

operational definition of mTBI [41] (see Table 1). This affirmative screening had to be confirmed by formal evaluation by the clinical staff (usually psychologists and neurologists) for inclusion. We exclude SMs with moderate to severe TBI requiring hospitalization, those with significant mental health disorders (psychoses, depression with active suicidal ideation, at the time of screening), or any subjects entered into an intensive TBI treatment program at either medical center. Typically, these treatment programs involve a scheduled and defined series of in-person educational, counseling, and other therapy sessions. We do not exclude subjects who are receiving other outpatient medical or mental health treatment. We are projecting to enroll approximately 400 subjects between the two military bases. We purposefully have minimally restrictive criteria for enrollment into this study. Medical documentation of mTBI in theater was lacking early in the OEF/OIF conflicts and there is no consistent method of diagnosing mTBI among the various military clinics. In addition, we believe including individuals receiving other treatments concurrent with the study better reflects the active duty military population, and that randomization will result in even allocation of those SMs to experimental groups.

2.3. Assessment schedule

At the time of enrollment, demographic and contact information are obtained in person by the research staff at the TBI clinics. The remaining baseline measures are obtained by an examiner via telephone at the same time of enrollment or within 1–2 days thereafter. Baseline measures include all of the outcome measures listed below in Section 2.5 except for the Cornell Service Index and the Client Satisfaction Questionnaire. After baseline testing was completed, the subjects were given sealed binders that contained their assignment, educational material received by both groups, and gift cards to reimburse the subjects for anticipated telephone minutes. We conduct subsequent assessments by telephone at completion of the intervention for the primary outcome (6 months) and again at 12 months to examine maintenance of effect. Examiners, who administer assessments at baseline and 6-month and 12-month follow up interviews, are blinded to randomization assignment. For SMs who were deployed again to combat operations during participation, we have a secure website for self-administration of the outcome measures as telephone contact is often unavailable. When contacting a subject regarding their follow up interview, examiners complete the primary outcome measures on first contact before scheduling an official appointment for the complete outcome interview; this is proving effective as most participants will then complete the entire set of measures on the first contact.

2.4. Randomization

After the baseline evaluation is completed, subjects are randomly assigned by the research coordinator to one of two groups (PST plus Education, or EO), using a centralized, secured, web-based data management system. The randomization is stratified on active duty/National Guard or Reserve status, presence/absence of significant psychological distress (Global Severity Index, GSI > 60), and enrollment site. All demographic information and baseline assessments are obtained prior to assignment of treatment status to eliminate bias in treatment allocation. The use of a stratified randomly permuted block allocation procedure will also prevent imbalance in the groups on variables that are known to influence treatment effects. Based on clinical information, we believe that there are distinct differences in the availability of resources to active duty and National Guard/Reserve status personnel as well as a distinct pathway after initial evaluation that is likely to influence outcome. Similarly, emotional distress has a high likelihood of impacting outcome.

2.5. Outcome measures

Because of the significant symptom overlap between mTBI and mood disorders such as depression and anxiety, we chose two co-primary outcome measures: The Rivermead Post-Concussion Symptoms Questionnaire (RPSQ) and the 18 item Brief Symptom Inventory (BSI-18) (see Table 2). The RPSQ examines the presence and severity of 16 common post concussive symptoms seen after mTBI [42]. The BSI-18 is a brief screen of psychological distress with a Global Severity Index (GSI), and three clinical subscales: somatization, anxiety, and depression [43].

Secondary measures include the following instruments, with hypotheses concerning them listed in Table 2. We elected to cast a wide net of secondary analyses to capture the range of outcomes that might be affected by a general improvement in problem-solving ability. Considering the large number of analyses that are entailed, we consider these to be exploratory in nature.

1) EuroQol [44]—a measure of health status; 2) PTSD Checklist-Military Version (PCL-M) [45]—a widely used screening measure for PTSD that might be expected to co-occur with mTBI;

The table below lists the outcome measures used in the study:

<table>
<thead>
<tr>
<th>Measure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EuroQol</td>
<td>18-item measure of health status</td>
</tr>
<tr>
<td>PCL-M</td>
<td>20-item measure of PTSD severity</td>
</tr>
<tr>
<td>BSI</td>
<td>18-item measure of psychological distress</td>
</tr>
<tr>
<td>RPSQ</td>
<td>18-item measure of post-concussive symptoms</td>
</tr>
</tbody>
</table>

1. EuroQol [44]—a measure of health status; 2. PTSD Checklist-Military Version (PCL-M) [45]—a widely used screening measure for PTSD that might be expected to co-occur with mTBI;
medical care, regardless of their randomization assignment. PST is a manualized intervention comprising 12 biweekly telephone calls over a 6-month period. PST includes symptom-related education, training in problem solving, and focused behavioral strategies for participant-identified problems that commonly occur with mTBI and is discussed in greater detail below. The EO intervention, provided to both groups, consists of 12 informational brochures on topics addressing common problems associated with mTBI and problems common after 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. Brochures were adapted from peer-reviewed civilian educational literature and were reviewed for military content and appropriateness by the Educational Coordinator at the MAMC TBI Clinic. We provide the brochures in a study packet to all subjects at enrollment and then either mail or email additional copies to each SM every 2 weeks during the study duration (one brochure per mailing).

2.7. PST-based intervention

SMs randomized into PST learn and practice the steps of problem solving, summarized in the acronym ABCDEF, as applies to their own problems: Assess (assessing and defining the selected problem and establishing realistic and achievable goals); Brainstorm (developing potential solution alternatives); Consider (weighing the positive and negative aspects, or pros and cons, of the potential solutions, ranking the solutions with a prediction of the success and potential barriers of each), and Choose (selecting an action plan); Do it (developing the detailed action plan and trying the planned actions); Evaluate (reviewing the outcome of the action plan and reflecting on what was successful or not and why); and Fight on (reworking the problem if the desired outcome does not result).

The telephone Concussion Support Specialist, referred to as a counselor, in this paper, provides didactic information and examples germane to each step and then coaches the SM on selecting one problem at a time to address using the approach. A structured worksheet designed for this study is used to capture the SM’s self-identified problems and aid in selecting the first and subsequent problems to address throughout the intervention (see Appendix). The counselor does not select the issue to be addressed in the intervention but rather guides the SM to help identify a challenge or problem they want to address. When needed, guidance is provided on how to break the selected problem down into more manageable parts, or if the first identified problem is not feasible to achieve an early experience of successful application, a second problem is identified. The pre-selection worksheet is also helpful in identifying the relationships among different problems so that, when possible, a “core” issue may be selected to achieve a wider impact in other areas of functioning. Motivational Interviewing is used as needed to promote engagement in the intervention, to resolve ambivalence, to help the SM identify important areas of potential change, and to encourage initiation of changes that are of greatest concern to the SM.

Counselors are trained to use modules embedded in the core framework of PST which include assessment, education, and therapeutic strategies for (1) depression, (2) anxiety/PTSD symptoms, (3) insomnia, and (4) headache, which were chosen

<table>
<thead>
<tr>
<th>Table 2 Study objectives and hypotheses.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary objectives</strong></td>
</tr>
<tr>
<td>Hypothesis for Primary Objective 1: PST will be associated with lower levels of post-concussive symptoms (compared to EO) at 6-month follow up (Outcome: Rivermead Post Concussion Symptoms Questionnaire—Total Score).</td>
</tr>
<tr>
<td>Hypothesis for Primary Objective 2: PST will be associated with lower levels of emotional distress (compared to EO) at 6-month follow up (Outcome: Brief Symptom Inventory-Global Severity Index).</td>
</tr>
<tr>
<td><strong>Secondary objectives</strong></td>
</tr>
<tr>
<td>Hypothesis for Secondary Objective 1: Compared to EO, PST will be associated with higher levels of functioning, quality of life, and resilience, and lower levels of symptoms and impairment at 6-month follow up (Outcomes: EuroQol, CD-RISC, PHQ-9, PCL-M, B-IFE, PSQI, AUDIT, Sheehan, SF-12, Life Events Checklist, CSI, CSQ-8).</td>
</tr>
<tr>
<td>Hypotheses for Secondary Objectives 2 and 3: Response to the intervention will differ depending on minority versus non-minority racial and ethnic endorsement (Secondary Objective 2) and active duty military versus National Guard/Reserve status (Secondary Objective 3).</td>
</tr>
<tr>
<td>Hypothesis for Secondary Objective 4: PST will be superior to EO on primary and secondary outcome measures at 12-month follow up (Outcome: Client Satisfaction Questionnaire).</td>
</tr>
<tr>
<td>Hypothesis for Secondary Objective 5: PST will be superior to EO on client and significant other satisfaction with care at 6 and 12 months (Outcome: Client Satisfaction Questionnaire).</td>
</tr>
</tbody>
</table>

PST = Problem Solving Treatment, EO = Education only, CD-RISC = Connor Davidson Resilience Scale, PHQ-9 = Patient Healthy Questionnaire, PCL-M = Brief Inventory for Functioning Evaluation, PSQI = Pittsburgh Sleep Quality Index, AUDIT = Alcohol Unit Disorder Identification Test, Sheehan = Sheehan Disability Scale, SF-12 = Short Form-12 Version 2, CSI = Cornell Service Index, CSQ-8 = Customer Service Questionnaire.
due to the frequency with which these complaints occur in this population. These condition-specific modules are designed to last two to four sessions only.

During the course of the intervention, SMs can choose to focus on one or more problem-focused modules. The modules build on Behavioral Activation (BA) and Cognitive Behavioral Therapy (CBT) as well as PST to address thoughts, beliefs, and maladaptive responses associated with each topic. We use BA in the depression and anxiety/PTSD modules, components of CBT in the insomnia module, and psychoeducation and relaxation techniques in the headache module. We provide the previously described problem-specific educational packets and worksheets and monitor symptoms using validated instruments (e.g., PHQ-9 [47] for depression, HIT-6 [59] for headaches).

At the completion of each module, based on treatment response, the counselor discusses with the SM whether a referral for further treatment is indicated. The counselor continues to monitor and provide care management for the problem during the course of the program. While PST is used to structure conversations with SMs and help them improve their self-management skills, there are times when SMs are directed towards specific local resources and services, especially for urgent problems or emergencies. Prior to the program’s implementation, we assembled a list of local and national resources for use in the sessions. We also developed protocols to help the counselor determine the level of action that should be administered based on the severity of the issue (see Fig. 1). After each telephone contact, the counselor would refer to the decision tree protocol and document any urgent and/or emergent concerns that require referrals and/or clinical supervision assistance. Most issues are expected to fall under the non-urgent category and will be addressed using the PST intervention with referral to community resources, if needed.

---

**Fig. 1.** CONTACT assessment and decision tree.
Circumstances that would trigger urgent concerns might include a progressing medical problem; those that would trigger an emergent response would include suicidality or potential violence or threats to others.

2.8. Therapist training and fidelity assessment

The counselors have Master’s level training in mental health fields. They received approximately 8-weeks of specific training on the study procedures before being cleared to engage in the study intervention. Subject matter experts educated the counselors about the effects of mTBI on symptoms, cognition, and behavior, and trained them to help SMs address common TBI-related problems. Using in-person and remote modalities, study clinicians, with the assistance of consultants, trained the counselors in PST, BA, Motivational Interviewing, and best practices in participant engagement. They also received thorough training in the special problems of administering the study intervention via telephone, how to monitor response to treatment, how to deal with psychiatric and medical emergencies, and how to use the session recording database while engaged on the phone. This training included a total of approximately 60 h of didactic instruction and role-play. The counselors spent 20 h learning both the content and the process of the intervention via reading the manual, didactic sessions, and preliminary practice calls with investigators and others acting as proxy participants, simulating responses and providing feedback. Finally, before being allowed to formally implement the intervention with study participants, another 40 h of training was devoted to each counselor’s performance on recording a series of practice calls that were reviewed and approved by study clinicians.

Supervision sessions initially occurred three times a week for 1–1.5 h with the counselors and supervision team (licensed psychologist, physiatrist, psychiatrist, research coordinator) to review cases, listen to audiotapes of sessions, and discuss difficult clinical situations. Over the course of the intervention, supervision decreased to twice weekly as counselors became more experienced, and then to weekly.

With the consent of SMs, we record all telephone sessions and store the audio-files on a secure server (backed up on discs stored in a locked location). We monitor the structural fidelity of the intervention program (number of telephone calls, duration of sessions, and completion of recommended assessments) using procedure checklists. To ensure ongoing content fidelity of the interventions, counselors follow and document detailed session-by-session checklists. The first 10 calls by each counselor were reviewed for fidelity by the supervision team. Thereafter, 10% of randomly selected sessions receive detailed review and corrective feedback provided to counselors by the supervision team. Recordings are also reviewed for training new staff and during supervision meetings.

2.9. Content of PST calls

Each PST phone call is expected to last between 30 and 45 min; the duration of each call will depend on its content. The content of each call depends upon the self-identified problems of the SM. Calls include three elements: (1) screening for depression/anxiety/distress using the PHQ-2 [60], the GAD-2 [61,62], and a 0–10 general distress score [63]; (2) reviewing the previous call and related action plans; and (3) identifying the current problem and developing the plan using the steps of PST; or, for those engaged in specific modules, continuation of Depression/Anxiety/Headache/Insomnia module activity.

PST is introduced to SMs in the first two phone calls of the intervention. On the initial phone call, the counselor describes the outline for each future call, introduces the PST concepts, and asks the SM to commit fully to PST. During the second call, the counselor completes the assessments for mood disturbances, uses the structured worksheet to help the SM develop a problem list, and then works with the SM to prioritize a problem to work on. Following the steps of PST with coaching from the counselor, the SM works on the problem through one or more telephone calls until the outcome is satisfactory to the SM. The SM then chooses another problem to work on during subsequent calls and the process is repeated. During the course of the intervention, subjects work on at least two problems but may address more, depending on the complexity of the problem and the success of the actions decided on and taken by the subject. The intervention is flexible and subject-centered. After each telephone session, the counselor forwards a personalized follow-up letter or email to the SM that provides encouragement and summarizes key concepts and mutually agreed-upon plans for between-session tasks. If applicable to the issues discussed during the session, the letter also includes one of the previously described educational brochures. Letters were included as attachments only, sent on a protected server. No personal information was included in the texts or emails.

2.10. Distress monitoring

As noted, during each telephone call, SMs are asked to rate their level of distress on a scale of 0–10 and to complete the Patient Health Questionnaire-4 combining the PHQ-2 and GAD-2 depression and anxiety screens [64]. Scores of ≥ 5 or increases of ≥ 3 from distress scale baseline initiate a structured approach by the counselor to explore the cause of the distress. Scores of ≥ 3 trigger further assessment with the full PHQ-9 or the BSI-18 [43,65–67]. Ratings on the PHQ-9 or BSI-18 indicating clinically significant depression or anxiety trigger a discussion about the need for further treatment (e.g., entry into the depression or anxiety module) and care management or referral to other resources. Motivational Interviewing strategies (i.e., eliciting change talk, asking open-ended questions, etc.) are used to ensure that study participants are engaged in planning for more intensive treatment referrals when necessary. Evidence of suicidal ideation is addressed by the counselor immediately with a standard protocol. All rating scores are monitored on a weekly basis by a member of the supervision team.

2.11. Process measures

Finally, we collect process measures, including the time spent in the call, the content area of the problem discussed (i.e., mental health, physical function, work issues, etc.), and the extent to which planned strategies discussed in previous calls were implemented based on SM report.
3. Proposed statistical analyses

3.1. Overview

Primary and secondary outcomes are assessed at 6- and 12-months by an examiner blinded to group assignment. The two co-primary outcome variables are post-concussion symptom severity, measured by the RPSQ, and severity of emotional distress, using the BSI-18, at 6 months follow-up. Secondary outcomes include overall day-to-day functioning, quality of life, pain, sleep, depression, health status, posttraumatic stress, health services use, and resilience, measured with the AUDIT, EuroQol, Sheehan Disability Scale, SF-12, BIF-E, PSQI, PHQ-9, PCL-M, Life Events Checklist, Cornell Service Index, and CD-RISC. Participant satisfaction with treatment will be measured with the CSQ-8.

3.2. Power and sample size justification

During the initial course of the trial, the sample size was re-estimated from an n = 800 to an n = 400 due to slow accrual. Additionally, this intervention was originally planned to be preventive for the development of persisting symptoms and emotional distress. It became clear after the first months of enrollment that, in fact, the nature of injury while deployed and the time interval to evaluation in the TBI clinics resulted in an unlikely clinical scenario for prevention. The re-calculation took into account the lower sample size necessary for a treatment intervention as compared to a preventive intervention. A final sample size of 200 per group with 90% follow-up rates would give the study over 85% power to detect an effect size that is equal to that observed in a previous study of telephone-delivered PST in civilians with mTBI [19]. This power is based on a two-sample t-test with a two-sided significance level of 0.025 (= 0.05/2) after a Bonferroni correction due to two measures used for the co-primary outcome. This sample size was deemed feasible given the current available population at the enrollment sites with a planned refusal rate of 50% and an exclusion rate of 15%, both of which are higher than expected, over an enrollment period of 18 months. We have enrolled 356 subjects; enrollment began to taper significantly after the completion of OIF and the draw-down of troops in Afghanistan.

3.3. Statistical analysis plan

In general, analyses will incorporate the intent-to-treat principle by including all randomized participants in the analyses. To evaluate the effect of the intervention on the co-primary outcome scores, we will use a two-sided significance level of 0.025 for each of the primary analyses, so the overall risk of erroneously concluding the intervention is effective is <0.05. No adjustments for multiple comparisons will be made for secondary analyses, and a p-value of 0.05 will be considered statistically significant. We will use the Mann–Whitney and Fisher’s exact tests to compare the PST and EO groups on demographics, injury characteristics, and pre-randomization functioning to ensure the randomization has yielded comparable groups.

The primary objective of the study is a comparison of change between the treatment arms in the two primary outcomes, RPSQ and BSI-18, between baseline and 6 months. A mixed-effects regression model will be conducted separately on each of the primary outcome measures to determine if the PST group will produce improved RPSQ and BSI-18 scores compared to the EO group at treatment end (i.e. 6 months after enrollment). This model will include the outcome score as the dependent variable, and time, arm and time-by-arm interaction terms as independent effects, and a random intercept and slope using an unstructured variance-covariance structure. Time (Months 0, 6) will be treated as a categorical variable. In addition, stratification factors (site, active military/National Guard or reserve status, presence/absence of significant psychological distress), as well as any baseline covariate that is simultaneously unbalanced at baseline (univariate p < 0.10) and associated with the outcome (univariate p < 0.15) will be included in the model as observed confounders. A significant treatment effect will be concluded if the p-value for the 6-month time-by-treatment interaction contrast in either of the primary analyses models is ≤0.025.

The effect of treatment arm on 12-month change in the two primary outcomes will be analyzed using an MMRM (mixed model repeated measures) approach. The model will include the change in outcome from baseline at each post-baseline visit as the dependent variable. Independent variables in the MMRM analyses will include arm, visit, arm-by-visit interaction, and baseline score. Visits (Months 0, 6, 12) will be treated as a categorical variable. An unstructured variance-covariance structure will be used. In addition, stratification factors (site, active military/National Guard or reserve status, presence/absence of significant psychological distress), as well as any baseline covariate that is simultaneously unbalanced at baseline (univariate p < 0.10) and associated with the outcome (univariate p < 0.15) will be included in the model as observed confounders.

Mixed effects regression models and MMRM analyses analogous to the primary analysis methodology will be applied for secondary and exploratory analyses and the per-protocol population. There are no planned interim analyses for this study.

4. Discussion

We have described an RCT of a patient-centered, telephone-based PST for SMs with mTBI. This treatment was also designed to address multiple common co-morbid conditions. The development of this treatment is in response to the often complex nature of mTBI, especially in military populations exposed to combat. Experiences of SMs involved in the conflicts in Iraq and Afghanistan have highlighted the complex nature of mTBI, with many injuries often accompanied by stress, mood disorders, sleep disturbances, and pain syndromes. This complicated picture is also often mirrored in civilians sustaining mTBI, and therefore this study will likely have implications beyond the military. While a number of interventions for mTBI or concurrent conditions have been studied separately, there are few RCTs to date, and none that investigate an intervention designed to address mTBI as well as concurrent conditions in a military population. We believe using an intervention that addresses a broad range of symptoms and concerns will result in better treatment outcomes, especially in military personnel. Use of telephone-based treatment delivery may also increase service
utilization for individuals without ready access to TBI care centers or members of populations where stigma is attached to seeking treatment.

This study has a number of strengths in that it will be one of the largest, behaviorally based interventions to be studied in a military population. We believe that the results will be generalizable to the larger population of SMs diagnosed with mTBI as we have few exclusions for participation. The intervention itself is deceptively simple with well-defined treatment options for the most common problems seen in this population. However, these types of studies by themselves will not answer questions of whether another type of telephone-supported intervention (e.g., supportive counseling or other technique) might be equally helpful. If results are positive, we can try to identify the active ingredient(s). More research will be needed to determine which populations might be most responsive to this approach. Even pending this information, if it is learned that this intervention is more effective than usual care plus education, it will offer another option in addition to in-person care for treating this challenging and highly mobile population.

Certainly, there are challenges in designing this type of study. First, it is difficult to strictly control the intervention since it involves the interaction of a counselor and an SM. There are likely to be differences in difficult-to-measure interaction factors: engagement, alliance, and follow-through. To address this, we “overtrained” the counselors, added mandatory computer prompt responses to ensure that the intervention was appropriately stepped, and had substantial supervision. It is unlikely that this degree of preparation would be necessary for the clinical implementation of this model. Additionally, it is difficult to design analyses for a single outcome or treatment effect when the intervention addresses more than one symptom or diagnosis (e.g., depression and insomnia, or irritability and headache). We chose to address this by having two primary outcome measures, one focusing on the presence and severity of symptoms and one on emotional distress. This may, however, impact detecting a smaller effect.

We have not required any specific level of symptoms in order to enroll in this study. This may serve to decrease the likelihood of proving a significant difference between the study groups. However, this population has been shown to have a high number of symptoms on return from theater [2,68] than soldiers without mTBI. We cannot know whether there will be any differences in accessing other medical and mental health services between the PST and control groups. Because of this, we are collecting data via the Cornell Services Index to better describe any associations with increased or decreased use of care outside of this intervention.

We anticipate some difficulties with enrollment of subjects in this particular cohort of SMs returning from OEF/OIF deployment but think that enrollment staff embedded in the TBI clinics will help with this. Due to Department of Defense regulations, we are unable to provide financial compensation for participation. However we are able to reimburse participants for telephone minute use by the use of gift cards which will decrease some burden on the subjects and may enhance willingness to participate. These gift cards are included in the blinded study packets given to the subjects after enrollment. Other methods employed to sustain recruitment included frequent updates and presentations to the clinical staff and familiarity of the clinical staff with the enrollment staff.

We hope to demonstrate that telephonically delivered PST results in improvements in post-concussive symptoms and emotional distress in SMs injured during combat deployment. This type of intervention would be relatively easy to implement in both military and veteran populations and offers the promise of effective intervention for tailoring an intervention to the individual needs of service members.

Disclaimer: 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.

Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.cct.2014.11.001.

References
