Contemporary Clinical Trials 40 (2015) 54–62

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

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

Kathleen R. Bell [a,*,1], 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,d], Nancy Temkin [a,d,i], Sonia Jain [j], Rema Raman [j], Murray B. Stein [f,j]

[a] Department of Rehabilitation Medicine, University of Washington, 1959 NE Pacific Street, Seattle, WA 98195, United States
[b] Department of Psychiatry and Behavioral Sciences, University of Washington, 1959 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] Clinical Psychology Doctoral Intern, Fielding Behavioral Health, 10200 132nd Street, Kirkland, WA 98034, United States
[i] Department of Biostatistics, University of Washington, F-600, Health Sciences Building, Box 357232, Seattle, WA 98195, United States
[j] Department of Family and Preventive Medicine, University of California, 9500 Gilman Drive, La Jolla, CA 92093, United States

ARTICLE INFO

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

ABSTRACT

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

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; EO, 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, 1959 NE Pacific Street, Seattle, WA 98195, United States. Tel.: +1 206 685 0935 (Office); fax: +1 206 685 3244.

E-mail addresses: krbell@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).

[1] 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.cct.2014.11.001

Military
Problem solving training
Telephone intervention
Telehealth

analysis of results. In particular, we provide details regarding the creation of a treatment that is manualized yet flexible enough to address a wide variety of problems and symptoms within a standard framework. The methods involved in enrolling and retaining an often hard-to-study population are also highlighted.

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 or without combat related concussion [2]. PPCS can impair 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)