



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

NOV 23 2010

The Honorable Norm Dicks
Chairman, Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report responds to Section 723 (a) of the National Defense Authorization Act for Fiscal Year 2010 that requires the Secretary of Defense to provide for a clinical trial to assess the efficacy of cognitive rehabilitative therapy for members or former members of the Armed Forces who have been diagnosed with a traumatic brain injury (TBI) incurred in the line of duty in Operation Iraqi Freedom or Operation Enduring Freedom. The enclosed report provides the Department's plan for the studies. We are confident that with the Department of Defense's cognitive rehabilitation portfolio of studies, we will be able to answer the questions related to the efficacy of cognitive rehabilitation therapy for Service members diagnosed with TBI.

Thank you for your continued support of the Military Health System.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Peach Taylor, Jr.", written over a horizontal line.

George Peach Taylor, Jr., M.D.
Deputy Assistant Secretary of Defense
(Force Health Protection and Readiness)
Performing the Duties of the
Assistant Secretary of Defense
(Health Affairs)

Enclosure:
As stated

cc:
The Honorable C. W. Bill Young
Ranking Member



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

NOV 22 2010

The Honorable Ike Skelton
Chairman, Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

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cc:
The Honorable Howard P. "Buck" McKeon
Ranking Member



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HEALTH AFFAIRS

NOV 23 2010

The Honorable Carl Levin
Chairman, Committee on Armed Services
United States Senate
Washington, DC 20510

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cc:
The Honorable John McCain
Ranking Member



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

NOV 22 2010

The Honorable James H. Webb
Chairman, Subcommittee on Personnel
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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As stated

cc:
The Honorable Lindsey O. Graham
Ranking Member



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

NOV 23 2010

The Honorable Susan Davis
Chairwoman, Subcommittee on Military Personnel
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

The enclosed report responds to Section 723 (a) of the National Defense Authorization Act for Fiscal Year 2010 that requires the Secretary of Defense to provide for a clinical trial to assess the efficacy of cognitive rehabilitative therapy for members or former members of the Armed Forces who have been diagnosed with a traumatic brain injury (TBI) incurred in the line of duty in Operation Iraqi Freedom or Operation Enduring Freedom. The enclosed report provides the Department's plan for the studies. We are confident that with the Department of Defense's cognitive rehabilitation portfolio of studies, we will be able to answer the questions related to the efficacy of cognitive rehabilitation therapy for Service members diagnosed with TBI.

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Enclosure:
As stated

cc:
The Honorable Joe Wilson
Ranking Member



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

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HEALTH AFFAIRS

NOV 22 2010

The Honorable Daniel K. Inouye
Chairman, Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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Enclosure:
As stated

cc:
The Honorable Thad Cochran
Ranking Member



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The Honorable David R. Obey
Chairman, Committee on Appropriations
U.S. House of Representatives
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(Health Affairs)

Enclosure:
As stated

cc:
The Honorable Jerry Lewis
Ranking Member



**Report to Congress on the Studies of Cognitive
Rehabilitation Effectiveness for Traumatic Brain Injury in
Response to Section 723 of the National Defense
Authorization Act for Fiscal Year 2010**

September 2010

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 SEC. 723. CLINICAL TRIAL ON COGNITIVE REHABILITATIVE THERAPY FOR MEMBERS AND FORMER MEMBERS OF THE ARMED FORCES. **Error! Bookmark not defined.**

I. Background

This report summarizes progress to date on Section 723 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2010. The legislation mandates a clinical trial on cognitive rehabilitation therapy (CRT) for members or former members of the Armed Forces, with a particular emphasis on those diagnosed with traumatic brain injuries (TBIs) in Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF).

The Defense and Veterans Brain Injury Center (DVBIC) has partnered with investigators in the TBI Service at San Antonio Military Medical Center (SAMMC-North) to develop the research design for a study to evaluate the efficacy of CRT for Service members diagnosed with TBI who have persistent post-concussive symptoms. Investigators from the Department of Veterans Affairs (VA) Health System National Office are serving as consultants.

Funding was set aside in FY 2010 to support additional funding for clinical trials to assess the efficacy of CRT therapy with respect to (1) cumulative concussions; (2) mild, moderate, or severe TBI; (3) chronic symptoms of TBI; (4) use of information technology devices; (5) use of robotics, nutritional supplements, and timing of both outpatient and inpatient rehabilitation; and (6) strategies to reduce polytrauma leading to TBI. This effort is under the management oversight of the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of the Congressionally Directed Research Programs (CDMRP). It is expected that three studies will be funded through this process in 2011.

The National Academy of Sciences Institute of Medicine (IOM) is beginning a study in October 2010, of Military Health System (MHS) CRT treatment of TBI to identify specific CRT interventions with sufficient evidence base to support their widespread use in the MHS, including coverage through the TRICARE benefit. We anticipate the study running for 12 months.

II. Introduction

TBI is a leading cause of death and disability in the United States, with an estimated annual incidence of 1.5 to 2 million persons.¹ Across both civilian and military populations, approximately 75-90% of TBIs are mild, although true incidence is difficult

¹ Langlois, J.A., Kessler, S.R., Butler, K.E., Gotsch, R.L., Johnson, A.A., Reichard, K.W., Webb, V.G., Coronado, A.W., Selassie, A., & Thurman, D.J.(2003). Traumatic brain injury discharges. Results for a 14-state surveillance system. National Center for Injury Prevention and Control, CDC.

to estimate because many mild TBIs (mTBIs) are unreported.^{2,3,4} Although most individuals recover completely within days or weeks after a mTBI, up to 15% continue to experience chronic persistent symptoms known as post-concussion syndrome (PCS).⁵ Persistent deficits in objective cognitive functioning have been demonstrated in group studies of patients with persistent PCS.^{6,7} Although there is some question about the extent to which disability compensation recipients,⁸ diagnosed with depression^{9, 10} or post-traumatic stress may intentionally perform poorly on neuropsychological tests rather than risk losing their compensation.¹¹

Three reviews of studies have been published on psychological and/or neuropsychological treatments for adults with mTBI. They included studies published between 1980-2000,¹² between 1980-2003,¹³ and between 2004-2006.¹⁴ Findings across all reviews revealed significant methodological weaknesses in most of the research, with only tentative support for early educational approaches, including reassurance and support regarding symptom management and guidance regarding resumption of pre-injury roles. In the most recent review, only three of eight studies utilized rigorous methods, including randomization, blind outcome evaluations, and accounting for

² Kraus, J., McArthur, J., Silberman, T., et.al. (1996). Epidemiology of brain injury. In: Narayan, R.K., Wilberger, J.E., & Povlishock, J.T., Editors. Neurotrauma. New York: McGraw-Hill, 13-30.

³ Thornhill, S., Teasdale, G.M., Murray, G.D., McEwen, J., Roy, C.W., & Penny, K.I. (2000). Disability in young people and adults one year after head injury: Prospective cohort study. *British Medical Journal*. 320:1631-5.

⁴ <http://www.dvbic.org/TBI-Numbers.aspx>. Defense and Veterans Brain Injury Center, TBI numbers, accessed 6/11/2010.

⁵ Raskin, S., & Mateer, C. (2000). Neuropsychological management of mild traumatic brain injury. New York: Oxford University Press.

⁶ Geary, E.K., Kraus, M.F., Pliskin, N.H., & Little, D.M. (2010). Verbal learning differences in chronic mild traumatic brain injury. *J Int Neuropsychol Soc*; 16(3), 506-16.

⁷ Vanderploeg, R. D., Curtiss, G., Luis, C. A., & Salazar, A. M. (2007). Long-term morbidity and quality of life following mild head injury. *J Clin Exper Neuropsych*; 29: 585 – 598.

⁸ Lange, R.T., Iverson, G.L., Brooks, B.L., & Ashton Rennison, V.L. (2010, April 30). Influence of poor effort on self-reported symptoms and neurocognitive test performance following mild traumatic brain injury. *J Clin Exp Neuropsychol*; 1-12.

⁹ Chamelien, L., & Feinstein, A. (2006). The effect of major depression on subjective and objective cognitive deficits in mild to moderate traumatic brain injury. *J Neuropsychiatry Clin Neurosci*; 18: 33-38.

¹⁰ Iverson, G. (2006). Misdiagnosis of the persistent postconcussive syndrome in patients with depression. *Arch Clin Neuropsychology*; 21: 303-310.

¹¹ Langlois, J.A., Kessler, S.R., Butler, K.E., Gotsch, R.L., Johnson, A.A., Reichard, K.W., Webb, V.G., Coronado, A.W., Selassie, A., & Thurman, D.J. (2003). Traumatic brain injury discharges. Results for a 14-state surveillance system. National Center for Injury Prevention and Control, CDC.

¹² Borg, J., Holm, L., Peloso, P.M., Cassidy, J.D., Carroll, L.J., von Holst, H., Paniak, C., & Yates, D. (2004, Feb.). WHO Collaborating Centre Task Force on Mild Traumatic Brain Injury. Non-surgical intervention and cost for mild traumatic brain injury: Results of the WHO Collaborating Centre Task Force on Mild Traumatic Brain Injury. *J Rehabil Med*; (43 Suppl):76-83.

¹³ Comper, P., Bisschop, S.M., Carnide, N., & Tricco, A. (2005, Oct.). A systematic review of treatments for mild traumatic brain injury. *Brain Inj*. 19(11):863-80.

¹⁴ Snell, D.L., Surgenor, L.J., Hay-Smith, E.J., & Siegert, R.J. (2009 Jan.) A systematic review of psychological treatments for mild traumatic brain injury: an update on the evidence. *J Clin Exp Neuropsychol*; 31(1):20-38. Epub 2008 May 2. Review.

attrition. Only three of ten studies in two earlier reviews employed these rigorous methodologies.

Snell et al. (2009)¹⁵ provides a summary of the major findings for studies included in these reviews. Across all three reviews, 12 studies examined patient education approaches. One found no impact on reported symptoms three months after discharge from the emergency department with an information booklet about mTBI, although the patients reported feeling that it was helpful. Four other studies compared an enhanced follow-up with standard hospital care or no follow-up. Two of these studies found better outcomes in the treatment groups, compared to controls. The other two studies were randomized control trials (RCTs) and did not find a statistically significant benefit of treatment on self-reported measures of post-concussion symptoms, psychological distress, life satisfaction, and community integration, or on a neuropsychological test results. Only one unpublished study examined the effect of education on chronic mTBI symptoms, measured on average three to six years after injury.¹⁶ This study compared a brief group cognitive behavior therapy, a group education/support intervention, and a wait list control group. After treatment, participants in the two treatment groups showed greater improvement in self-reported, post-concussion symptoms than those in the wait-list control group.

Six studies evaluated the efficacy of more intensive cognitive rehabilitation approaches for the treatment of persistent post-concussive symptoms following mTBI. Although improvements were reported on a number of measures, including cognitive functioning, emotional adjustment, and functional status, methodological limitations prevent reliance on the findings. Specific limitations included absence of control groups, presence of practice effects on repeated measures of cognitive functioning, use of measures lacking sensitivity, and failure to monitor symptom validity or suboptimal effort.

Given the limited empirical basis for the efficacy of cognitive rehabilitation in mTBI, combined with the increased incidence of mTBI among Service members returning from deployment, a consensus conference on mTBI and cognitive rehabilitation was convened in April 2009. The 50 participants represented all Services of the Department of Defense (DoD), the VA and civilian subject-matter experts. The resultant report, published in 2009, provides a review of the existing literature and makes consensus-based recommendations for the treatment of cognitive sequelae after mild TBI.¹⁷ A major

¹⁵ Ibid.

¹⁶ Leonard, K. (2004). Cognitive-behavioral intervention in persistent post-concussion syndrome: a controlled treatment outcome study. Unpublished doctoral dissertation: University of Texas at Austin, USA.

¹⁷ Helmick, K., Batten, S., Beal, S., Bleiberg, J., Boccio, P., Boyd, T., Cicerone, K., Comper, P., Cooper, D.B., Cornis-Pop, M., Cozzarelli, T., Dickey, D., Doncevic, S., Ferland, K., Findling, E., French, L., Fortuin, N., Golden, J., Gonzalez, M., Gordon, W., Jones, D., Kass, F., Kelly, J., Kennedy, C., Kennedy, J., Kortte, K., Kreutzberg, K., Lowe, L., Malec, J., Mashima, P., Miller, C., Mouratidis, M., Prigatano, G., Roth, C., Russell, M., Schobitz, R., Scholten, J., Simmer, E., Sohlberg, M.M., Solomon, B., St. Laurent, M., Thomson, E., Tsao, J., Vanderploeg, R., Vogt, M., Walden, T., Williams, C., Wilmore, M., Woods, Y., & Xenakis, S. (2010). Cognitive rehabilitation for

conclusion was the need for well-controlled, randomized research studies in this area.

Establishing the effectiveness of cognitive rehabilitation is an important issue for reimbursement of clinical services within the healthcare industry. Currently, basic military healthcare for active-duty Service members does not cover cognitive rehabilitation for mTBI. This policy was based, among other things, on a meta-analysis of existing literature conducted by the Economic Cycle Research Institute (ECRI) for the Office of the Chief Medical Officer, TRICARE, confirming the efficacy of limited cognitive rehabilitative interventions for moderate and severe TBI, but not for mTBI. It was noted that the meta-analysis was negatively influenced by differences in outcomes assessed and by an insufficient number of studies addressing outcomes.

Section 732 of the NDAA for FY 2010, which states that “the Secretary of Defense shall provide for a clinical trial to assess the efficacy of cognitive rehabilitative therapy for members or former members of the Armed Forces diagnosed with a TBI incurred in the line of duty in OEF or OIF.” DVbic, as the primary TBI operational component of the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE), will conduct a clinical trial, entitled the “Study of Cognitive Rehabilitation Effects (SCORE): A randomized treatment trial in a military population with mild TBI incurred during deployment to OEF/OIF.”

III. DVbic SCORE Research Plan

Education provided to patients and their support systems about the nature and common manifestations of mTBI is a critical aspect of intervention, helping to manage patient expectations, and preventing the development of mTBI symptoms, or reducing their duration, number, and severity. The components of patient education after mTBI typically include education and normalization of symptoms, contact information and follow-up, and reassurance of positive expectation of recovery. It is generally recommended that the educational intervention occur at the time of diagnosing the mTBI, preferably in the acute post-injury period. However, there is evidence from a small three-arm RCT suggesting psycho-educational treatment can be effective in symptom reduction in chronic (three to six years post-injury) patient samples.¹⁸ Provision of patient education can take many forms, including individual and group formats, written handouts, and telephone contacts.¹⁹ In the study outlined here, patient education and symptom management will be provided to all subjects regardless of treatment

military personnel with mild traumatic brain injury and chronic post-concussional disorder: Results of April 2009 consensus conference. *Neurorehabilitation*; 26 (3), 239-255.

¹⁸ Leonard, K.N. (2004). Cognitive-behavioral intervention in persistent post-concussion syndrome: A controlled treatment study. Unpublished doctoral dissertation, University of Texas at Austin..

¹⁹ Bell, K., Hoffman, J., Temkin, N., Powell, J., Fraser, R., Esselman, P., Barber, J., & Dikmen, S. (2008). The effect of telephone counseling on reducing post-traumatic symptoms after mild traumatic brain injury: A randomized trial. *J Neurol Neurosurg Psychiatry*; 79: 1275-1281.

assignment.

SCORE will be an RCT, with subjects recruited from consecutive patient referrals to the TBI Service at SAMMC-North. Following consent to participate in the study, subjects will be randomly assigned to one of four, six week treatment arms: ((1) psycho-educational; (2) non-therapist directed (self-administered) computerized cognitive rehabilitation; (3) therapist-directed individualized cognitive rehabilitation; and (4) integrated interdisciplinary cognitive rehabilitation combined with cognitive behavioral psychotherapy). Psycho-educational materials, the only Class I evidence-based treatment recommended for individuals with mTBI, will be provided to participants in all four treatment conditions. Treatment intensity (i.e., number of hours of treatment per week) will be matched for individuals assigned to treatment arms 2, 3, or 4. Study evaluators will be blinded to treatment assignment, and participants will be evaluated prior to initiation of treatment, as well as at 3 weeks, 6 weeks, 12 weeks, and 18 weeks following the start of treatment.

A. Study Arm #1: Psycho-educational

Subjects assigned to this treatment arm ($n = 40$) will receive patient education materials (adapted from existing studies to address more persistent rather than acute symptom management), regularly scheduled follow-up each three weeks with a medical provider, and symptom-based treatment, such as medication trials for headache and co-occurring psychiatric disorders, physical therapy for vestibular complaints, and weekly counseling with a social worker.

B. Study Arm #2: Non-Therapist Directed Computerized Cognitive Rehabilitation

Subjects assigned to this arm ($n = 40$) will receive patient education materials, regularly scheduled follow-up every three weeks with a medical provider, and symptom-based treatment (as outlined above). Additionally, they will participate in computerized cognitive rehabilitation. Despite limited evidence for the utility of repetitive memory drills (i.e., memory as a muscle²⁰ or brain training²¹) in either brain-injured populations or normal controls, the use of computerized programs for cognitive rehabilitation continues to rise. Companies marketing computerized brain-injury software programs often target Service members and veterans with mTBI and software programs are distributed in large quantities to organizations serving the needs of wounded warriors for self-directed cognitive rehabilitation. To best address the issue of poor compliance and

²⁰ Rees, L., Marshall, S., Hartridge, C., Mackie, D., & Weiser, M. (2007). Cognitive interventions post acquired brain injury. *Brain Inj.*; 21: 161-200.

²¹ Owen, A.M., Hampshire, A., Grahn, J.A., Stenton, R., Dajani, S., Burns, A.S., Howard, R., & Ballard, C. (2010). Putting brain training to the test. *Nature*; 465: 755-758.

follow through with self-directed rehabilitation programs, the self-directed computerized treatment will be scheduled and proctored in the TBI Clinic to ensure patients' physical participation in this component.

C. Study Arm #3: Therapist-Directed Individualized Cognitive Rehabilitation

Subjects assigned to this arm ($n = 40$) will receive patient education materials, regularly scheduled follow-up every three weeks with a medical provider, and symptom-based treatment. Additionally, subjects will receive 10 hours per week of individual and group cognitive rehabilitation and homework directed by skilled rehabilitation therapists. While provision of psycho-educational materials is a cost effective way of alleviating chronic symptom development,²² there is evidence from two small-scale RCTs to suggest that multidisciplinary cognitive rehabilitation and emotional support improves outcomes for persons with PCS following mTBI²³ particularly in those with pre-injury psychiatric disorders. Given the need to determine if the treatment effect observed in the Tiersky, et al. (2005)²⁴ study was primarily due to specific cognitive rehabilitation interventions or more generalized effects of psychotherapy/emotional support, two treatment arms have been created for this study. In the therapist-directed cognitive rehabilitation arm, subjects will receive more intensive therapies but in a more condensed timeframe. By condensing the treatment to six weeks, we felt that it would facilitate external validity of the study by making replication of the treatment more feasible.

D. Study Arm #4: Integrated Interdisciplinary Cognitive Rehabilitation Combined with Cognitive Behavioral Therapy

Subjects assigned to this treatment arm ($n = 40$) will receive patient education materials, regularly scheduled follow-up every three weeks with a medical provider, and symptom based treatment (as outlined above). Additionally, subjects in this treatment arm will receive 10 hours per week of multidisciplinary cognitive rehabilitation and psychological interventions specifically designed to reduce PCS and co-occurring psychological conditions. This fourth treatment arm most closely resembles the treatment trial of Tiersky, et al.²⁵ As mentioned previously; the intensity of treatment will parallel previous studies, although the treatment will be condensed across a shorter time. Given the high incidence of psychiatric co-morbidities in post-deployment Service members with mTBI^{26, 27} and the potential effect of such conditions on maintenance of persistent

²² Mittenberg, W., Rotholz, A., Russell, E., & Heilbronner, R. (1996). Identification of malingered head injury on the Halstead-Reitan battery. *Arch Clin Neuropsychol* 11 (4): 271-281. doi: 10.1093/arclin/11.4.271 y.

²³ Ghaffar, O., McCullagh, S., Ouchterlony, D., & Feinstein, A. (2006). Randomized treatment trial in mild traumatic brain injury. *Journal of Psychosomatic Research*, 61, 153-160.

²⁴ Ibid.

²⁵ Ibid.

²⁶ Gaylord, K.M., Cooper, D.B., Mercado, J.M., Kennedy, J.E., Yoder, L.H. & Holcomb, J. (2008). Incidence of post-traumatic stress disorder (PTSD) and mild traumatic brain injury (mTBI) in burned service members: A

PCS^{28, 29} psychological treatments for reducing symptoms of combat stress and depression will be integrated into this treatment arm.

IV. CDMRP Fiscal Year 2010 Cognitive Rehabilitation for TBI Clinical Trial Awards

A total of \$10 million has been assigned to the USAMRMC CDMRP for management oversight of a funding opportunity for Cognitive Rehabilitation Clinical Trials. This funding mechanism is intended to encourage rapid implementation of clinical trials to assess the efficacy of cognitive rehabilitative therapy for TBI for members or former members of the Armed Forces. Principal investigators submitting to this grant mechanism will be encouraged to focus on (1) cumulative concussions; (2) mild, moderate, or severe TBI; (3) chronic symptoms of TBI; (4) use of information technology devices; (5) use of robotics, nutritional supplements, and timing of out/inpatient rehabilitation; and (6) strategies for polytrauma leading to TBI. Individual awards will have a maximum period of performance of four years with total direct costs not to exceed \$2 million. CDMRP anticipates funding three awards for FY 2010.

This award utilizes a two-step process, with invitations to submit a full proposal based on a pre-proposal screening conducted by a multi-Service, multi-agency PH/TBI Integration Panel (IP). On July 23, 2010, the IP reviewed a total of 89 pre-proposals. From these, the IP voted to invite 41 full proposals for submission, which were due September 7, 2010. A scientific review of the submitted full proposals occurred in October 2010. Programmatic review by the PH/TBI IP will occur in December 2010 and three proposals will receive funding in 2011.

V. IOM Study of Military Health System Treatment of TBI by Cognitive Rehabilitation Therapy

The IOM will conduct a study of MHS treatment of TBI by CRT. The goal is to identify specific CRT interventions with sufficient evidence to support their widespread use in the MHS, including coverage through the TRICARE benefit. The IOM study will include a comprehensive literature review of the studies conducted, including but not limited to studies conducted on MHS or VA wounded warriors. In addition, the study will include

preliminary report. *J Trauma: Inj Infect Crit Care.*; 64: 200-206.

²⁷ Vanderploeg, R.D., Belanger, H.G., & Curtiss, G. (2009). Mild traumatic brain injury and posttraumatic stress disorder and their associations with health symptoms. *Arch Phys Med Rehabil.*; 90: 1084-1092.

²⁸ Hoge, C.W., McGurk, D., Thomas, J.I., Cox, A.L., Engel, C.C., & Castro C.A. (2008). Mild traumatic brain injury in U.S. soldiers returning from Iraq. *New Eng J Med.*; 8; 358: 453-463.

²⁹ Schneiderman, A.I., Braver, E.R., Kang, H.K. (2008). Understanding sequelae of injury mechanisms and mild traumatic brain injury incurred during the conflicts in Iraq and Afghanistan: Persistent postconcussive symptoms and posttraumatic stress disorder. *Am J Epidemiol.*; 167: 1446-1452.

an assessment of current evidence supporting the effectiveness of CRT interventions in specific cognitive deficits associated with mild, moderate, and severe TBI. Finally, the study will assess the state of practice of CRT and if requirements for training, education, and experience for providers outside the MHS direct-care system with the delivery of the identified evidence-based interventions are sufficient to ensure reasonable, consistent quality of care across the United States.

VI. Conclusion

Cognitive rehabilitation is a long-standing and significant component of comprehensive rehabilitation for individuals with moderate and severe TBI. There is an accelerating, but still small, body of scientific literature supporting cognitive rehabilitation in mTBI. Because of DVBIC's access to the appropriate patient population and existing network of care, the SCORE research plan allows for fast-tracking scientifically rigorous cognitive rehabilitation for TBI research, specifically in Service members and veterans injured in combat. In conjunction with the Cognitive Rehabilitation for TBI Clinical Trial Award funds, the overall goal is to improve the health and quality of life for Service members who have sustained a mTBI through the development of empirically validated cognitive rehabilitation interventions. Finally, a rigorous review by the IOM of the current evidence will help further the field to determine whether CRT is an efficacious modality for use in returning Service members. Results from the studies included in this DoD cognitive rehabilitation portfolio will inform recommendations on the advisability of including CRT for TBI as a benefit under TRICARE.

APPENDIX 1
Timeframe for DVBIC Study Completion
(June 2010-November 2013)

Task (Date of Completion)	Short-term		Intermediate		Long-Term			
	Year 1*				Year 2		Year 3	
Beginning June 2010: Months	1-3	4-6	7-9	10-12	13-18	18-24	24-30	30-42
Steering Committee Workshop (June 10, 2010)								
Scientific Advisory Review (July 15, 2010)								
IRB Submission (Aug 1, 2010)								
Finalize Research Protocol (Aug 1, 2010)								
Treatment Manuals (Oct 30, 2010)								
Hire Staff (Jan 1, 2011)								
Train Staff on Protocol (Jan 1, 2011)								
Database for Data Entry (Dec 15, 2010)								
Enroll Participants (Jan 2011)								
Follow-up Data (May 1, 2013)								
Data Analysis								
Interim (Feb. 2012)								
Final (June 2013)								
Papers and Dissemination (July to Dec 2013)								