OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MAR 29 2017

The Honorable Thad Cochran
Chairman
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report responds to section 723(d)(2) of the National Defense Authorization Act for Fiscal Year 2010 (Public Law 111–84), which requires the Secretary of Defense to submit a final report on the clinical trial assessing the efficacy of cognitive rehabilitation therapy (CRT) for members of the Armed Forces diagnosed with traumatic brain injuries (TBIs). It also requires that the Secretary of Defense submit a report on the efficacy of CRT in treating TBIs in members and former members of the Armed Forces; recommendations for increased access to safe, effective, and quality CRT; and the advisability of including CRT as a benefit under the TRICARE program.

While there is evidence to support the clinical efficacy of CR, the threshold for evidence required by TRICARE has not been met to date to authorize coverage. The Department of Defense is currently reviewing CRT using the hierarchy of reliable evidence. This review is expected to be completed in the summer of 2017 and will include the study that responds to section 723: "Cognitive Rehabilitation for Military Service Members with Mild Traumatic Brain Injury: A Randomized Clinical Trial," along with any new reliable evidence published since the last review in January 2015.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter has been sent to the chairpersons of the other congressional defense committees.

Sincerely,

A. M. Kurta
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Patrick J. Leahy
Vice Chairman

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MAR 29 2017

The Honorable John McCain
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report responds to section 723(d)(2) of the National Defense Authorization Act for Fiscal Year 2010 (Public Law 111–84), which requires the Secretary of Defense to submit a final report on the clinical trial assessing the efficacy of cognitive rehabilitation therapy (CRT) for members of the Armed Forces diagnosed with traumatic brain injuries (TBIs). It also requires that the Secretary of Defense submit a report on the efficacy of CRT in treating TBIs in members and former members of the Armed Forces; recommendations for increased access to safe, effective, and quality CRT; and the advisability of including CRT as a benefit under the TRICARE program.

While there is evidence to support the clinical efficacy of CR, the threshold for evidence required by TRICARE has not been met to date to authorize coverage. The Department of Defense is currently reviewing CRT using the hierarchy of reliable evidence. This review is expected to be completed in the summer of 2017 and will include the study that responds to section 723: "Cognitive Rehabilitation for Military Service Members with Mild Traumatic Brain Injury: A Randomized Clinical Trial," along with any new reliable evidence published since the last review in January 2015.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter has been sent to the chairpersons of the other congressional defense committees.

Sincerely,

A. M. Kurta
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MAR 29 2017

The Honorable William M. "Mac" Thornberry
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report responds to section 723(d)(2) of the National Defense Authorization Act for Fiscal Year 2010 (Public Law 111–84), which requires the Secretary of Defense to submit a final report on the clinical trial assessing the efficacy of cognitive rehabilitation therapy (CRT) for members of the Armed Forces diagnosed with traumatic brain injuries (TBIs). It also requires that the Secretary of Defense submit a report on the efficacy of CRT in treating TBIs in members and former members of the Armed Forces; recommendations for increased access to safe, effective, and quality CRT; and the advisability of including CRT as a benefit under the TRICARE program.

While there is evidence to support the clinical efficacy of CR, the threshold for evidence required by TRICARE has not been met to date to authorize coverage. The Department of Defense is currently reviewing CRT using the hierarchy of reliable evidence. This review is expected to be completed in the summer of 2017 and will include the study that responds to section 723: "Cognitive Rehabilitation for Military Service Members with Mild Traumatic Brain Injury: A Randomized Clinical Trial," along with any new reliable evidence published since the last review in January 2015.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter has been sent to the chairpersons of the other congressional defense committees.

Sincerely,

A. M. Kurta
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MAR 29 2017

The Honorable Rodney P. Frelinghuysen
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report responds to section 723(d)(2) of the National Defense Authorization Act for Fiscal YearFFiscalY2010 (Public Law 111–84), which requires the Secretary of Defense to submit a final report on the clinical trial assessing the efficacy of cognitive rehabilitation therapy (CRT) for members of the Armed Forces diagnosed with traumatic brain injuries (TBIs). It also requires that the Secretary of Defense submit a report on the efficacy of CRT in treating TBIs in members and former members of the Armed Forces; recommendations for increased access to safe, effective, and quality CRT; and the advisability of including CRT as a benefit under the TRICARE program.

While there is evidence to support the clinical efficacy of CR, the threshold for evidence required by TRICARE has not been met to date to authorize coverage. The Department of Defense is currently reviewing CRT using the hierarchy of reliable evidence. This review is expected to be completed in the summer of 2017 and will include the study that responds to section 723: "Cognitive Rehabilitation for Military Service Members with Mild Traumatic Brain Injury: A Randomized Clinical Trial," along with any new reliable evidence published since the last review in January 2015.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter has been sent to the chairpersons of the other congressional defense committees.

Sincerely,

AM Kurta

A. M. Kurta
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Nita M. Lowey
Ranking Member

# REPORT TO CONGRESSIONAL DEFENSE COMMITTEES

## Section 723 of the National Defense Authorization Act for Fiscal Year 2010 (Public Law 111–84), Clinical Trial on Cognitive Rehabilitative Therapy for Members and Former Members of the Armed Forces


**December 2016**

The estimated cost of this report or study for the Department of Defense is approximately $4,400.00 in Fiscal Years 2015-2016. This includes $0 in expenses and $4,400 in Department of Defense labor.
Generated on 2016Jul26 RefID 9-88D1461

This report responds to Section 723 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2010 (Public Law 111–84), which requires the Secretary of Defense (SECDEF) to provide for a clinical trial to assess the efficacy of cognitive rehabilitation therapy (CRT) for members and 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. In addition to the clinical trial, the SECDEF should provide congressional defense committees a report on procedures for Service members to access CRT services, qualifications for providers of CRT services, methodologies for reimbursement for CRT services, and the SECDEF's recommendation on including CRT as a benefit under the TRICARE program.

Background

The SECDEF submitted an initial report in November 2010 outlining planned steps to address the legislation. An interim report submitted in January 2016 provided the preliminary findings of the clinical trial mandated by this legislation, publication titled, "Study of Cognitive Rehabilitation Effectiveness (SCORE): A randomized control trial in a military population with mild TBI (mTBI) incurred during deployment to OEF/OIF."

The Department of Defense (DoD) defines TBI as a traumatically induced structural injury or physiological disruption of brain function that results from an external force. TBI is indicated by new onset or worsening of at least one of the following clinical signs immediately following the event: alteration in mental status (confusion, disorientation, slowed thinking, etc.); loss of memory for events occurring immediately before or after the injury; and loss of, or decreased, level of consciousness. TBIs are classified as mild, moderate, severe, or penetrating. From 2000 through June 30, 2016, there have been 352,619 first-time TBIs in military Service members. The majority of TBIs are mild (82.3 percent).

After TBI of any severity, cognitive deficits in the areas of attention, memory, and executive functioning are common and may affect Service members' daily activities, behaviors, and relationships. If not effectively addressed, these challenges can negatively affect Service members' well-being or ability to successfully reintegrate into work, family, and community roles.

CRT is an umbrella term. It refers to therapist-directed interventions ranging from cognitive retraining to cognitive compensation. CRT improves cognitive function. Recent studies assessed the effectiveness of various CRT interventions for individuals who have incurred a TBI.

Findings from the clinical trial, section 723 of the NDAA for FY 2010

The Defense Health Agency conducted a randomized control trial of CRT in a military population with TBI. The findings from this study were recently published in the Journal of Head Trauma Rehabilitation (Cooper et al., "Cognitive Rehabilitation for Military Service Members with Mild Traumatic Brain Injury: A Randomized Clinical Trial," Sept 2016). The primary outcome measures assessed in this study include the Paced Auditory Serial Addition Test (PASAT), Symptom Checklist-90 (SCL-90), and the Key Behavior Change Inventory.

The clinical trial enrolled 126 subjects randomized to one of four treatment groups offering six weeks of either: (1) psychoeducation, (2) computer-based CRT, (3) therapist-directed standardized CRT, or (4) integrated therapist-directed CRT combined with cognitive-behavioral psychotherapy (CBT). A total of 104 Service members completed the treatment.

Treatment dosage was constant (10 hours/week) for intervention arms 2 to 4. Analysis shows no significant differences between the groups on the PASAT or the SCL-90. Cooper et al concluded that "both therapist-directed CRT and integrated CRT with CBT reduced functional cognitive complaints in [Service members] following [mTBI] beyond psychoeducation and medical management alone." Computer-based CRT did not show statistical significance in this study.

An assessment of the efficacy of CRT in treating TBI

The aforementioned clinical trial adds to peer-reviewed literature supporting the clinical efficacy of CRT. Systematic reviews reveal a trend supporting the effectiveness of CRT after TBI. Since 2011, DoD has published five well-controlled studies of CRT with Service members and veterans. All five studies found that CRT had a positive benefit in mTBI and persistent post-concussion symptoms (Chen et al., 2011; Nelson et al., 2013; Novakovic-Agopian et al., 2011; Riegler et al., 2013; Twamley et al., 2014). These studies add to the body of knowledge supporting the clinical utilization of CRT after TBI.

The Cognitive Rehabilitation Task Force of the American Congress of Rehabilitation Medicine (ACRM) conducted three systematic reviews of the CRT literature, comprising an evaluation of 370 studies (Cicerone et al., 2000; Cicerone et al., 2005, Cicerone et al., 2011). The most recent ACRM review examines the effectiveness of CRT for TBI and stroke across 112 studies published from 2003 to 2008. The review concludes that substantial evidence supports the efficacy of CRT for TBI. Comparing CRT and conventional rehabilitation, CRT was more effective during the post-acute period. Studies of comprehensive multi-modal CRT provide the best evidence for improvements in health-related outcomes. An updated ACRM review of CRT is currently underway and expected to be published by late 2017.

In 2011, the DoD commissioned a study by the Institute of Medicine, now the National Academy of Medicine, to review the quality of evidence for the effectiveness of CRT for TBI. The study includes all severities of TBI (mild, moderate, and severe) and all phases of recovery (acute, sub-acute, and chronic). The study concludes that evidence supports the clinical application of some forms of CRT, but the evidence does not delineate which forms of CRT are best for subpopulations. The study outlines a research agenda for improvements in CRT study methodology. Limitations in the evidence notwithstanding, the study supports the clinical application of CRT for treatment of individuals with cognitive and behavioral deficits from TBI.

The Centers for Disease Control and Prevention collaborated with the National Institutes of Health in 2014 to conduct a systematic review of the literature to assess the status of TBI rehabilitation. The report concludes that modest evidence supports the efficacy of CRT interventions for individuals with moderate to severe TBI.

An international expert panel of researchers and clinicians conducted an analysis of clinical practice guidelines (CPGs) that searched five electronic databases from 2000 to 2011 and identified 11 CPGs for TBI. These CPGs were evaluated using the Appraisal of Guidelines for Research and Evaluation II instrument. Based on quality grading of published CPGs for moderate to severe TBI, the panel concluded that CRT should be offered to individuals with TBI

who have emerged from post-traumatic amnesia. The panel established treatment guidelines for each domain based on the systematic reviews of CRT for attention, executive function, memory, and language.

Adding to a large body of evidence supporting CRT after TBI, three evidence-based documents support standardization of CRT in patients with mTBI.

The Defense and Veterans Brain Injury Center's 2009 Clinical Guidance on Cognitive Rehabilitation for mTBI addresses the needs of Service members who are three or more months post-concussion. This evidence-based guidance describes CRT interventions having demonstrated efficacy and utility. It recommends implementing CRT into the care of Service members who have sustained mTBI.

The Department of Veterans Affairs (VA)/DoD CPG on Management of Concussion/mTBI, published in 2009 and revised in 2016, provides evidence-based recommendations for CRT in patients with a history of mTBI. The 2016 revision states, "Individuals with a history of mTBI who present with symptoms related to memory, attention, or executive function problems that do not resolve within 30-90 days and have been refractory to treatment for associated symptoms should be considered for referral to [CRT] therapists with expertise in TBI rehabilitation."

The literature review for the 2016 CPG revision used the Grading of Recommendations, Assessment, Development and Evaluation (known as GRADE) methodology for determining the strength of the evidence. Lacking published evidence for CRT in the Service member population, the strength of the evidence for this recommendation was "weak, in favor of." The CPG supports the clinical application of a short trial of CRT following mTBI. Notably, the clinical trial that responds to section 723 of the NDAA for FY 2010 was not yet published at the time of the VA/DoD CPG evidence review. Evidence from this trial may have favorably affected the CRT recommendation.

Finally, the mTBI Rehabilitation Toolkit, published by the Army Borden Institute states, "A review of the cognitive rehabilitation literature yielded substantial evidence to support interventions for attention, memory, executive function, and social communication skills" (Weightman et al., 2014).

Professional statements from the following associations endorse the clinical use of CRT for the treatment of cognitive deficits in people with TBI: American Speech Language and Hearing Association, American Occupational Therapy Association, and the National Academy of Neuropsychology.

Procedures for access to CRT

Currently, Service members and veterans access CRT primarily through TBI clinics at military treatment facilities (MTFs), in conjunction with speech-language pathology (SLP), occupational therapy (OT), physical therapy (PT), and neuropsychology services, often in an interdisciplinary manner. CRT is offered through a variety of delivery methods, including individual, group, and computerized CRT treatment models, to meet the identified needs of each patient. When Service members cannot access CRT locally at MTFs, DoD allows supplemental health care program waivers and referral to community providers.

Clinical outcomes of CRT are measured for patients using standard clinical cognitive evaluation and assessments. Clinical assessments allow providers to set outcomes of individual treatment plans, adjust treatment, and make recommendations for additional care and eventual discharge.

Clinical coding is an issue. There are ongoing efforts to ensure providers are accurately capturing clinical care codes to improve the ability to monitor utilization and outcomes related to CRT. Delineation of CRT treatment services after TBI using Common Procedural Terminology (CPT) code 97532 would assist in the accuracy of health surveillance data and better capture of outcomes related to CRT. Currently, under TRICARE coding, CPT code 97532 is infrequently used.

Qualifications and supervisory requirements for CRT Providers

Qualifications to deliver CRT are managed at the state level, ensuring clinicians have the skills and education through a professional licensure process. CRT is incorporated into the core curriculums of SLP, OT, PT, and neuropsychology training programs. The Military Health System relies upon state licensing agencies, national specialty boards, and professional accreditation agencies to credential individual health care providers providing TBI treatments, including CRT. National professional associations offer advanced training in CRT, which is recognized professionally. There is no standalone licensing or specialty board for CRT.

A methodology for reimbursing providers for CRT services

Current literature does not offer recommendations related to reimbursement methodology. Payers of healthcare services develop reimbursement procedures when the body of literature meets requirements to include new treatment recommendations in the healthcare benefit.

Recommendation for including CRT as a covered TRICARE benefit

Federal regulation requires that DoD use a hierarchy of reliable evidence to determine the medical effectiveness of a treatment or procedure for possible TRICARE coverage. The hierarchy of reliable evidence consists of:

(1) Well-controlled studies of clinically meaningful endpoints, published in peer-reviewed medical literature;

(2) Published formal technology assessments;

(3) The published reports of national professional medical associations;

(4) Published national medical policy organization positions; and,

(5) The published reports of national expert opinion organizations.

This listing of 1 through 5 is the order of the relative weight given to each source of evidence.

Conclusion

While there is evidence to support the clinical efficacy of CRT, the threshold for evidence required by TRICARE has not been met to date to authorize coverage. DoD is currently reviewing CRT using the hierarchy of reliable evidence. This review is expected to be completed in the summer of 2017 and will include the study that responds to section 723 of the NDAA for FY 2010: "Cognitive Rehabilitation for Military Service Members with Mild Traumatic Brain Injury: A Randomized Clinical Trial," along with any new reliable evidence published since the last review in January 2015.

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MAR 29 2017

The Honorable William M. "Mac" Thornberry
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report responds to section 723(d)(2) of the National Defense Authorization Act for Fiscal Year 2010 (Public Law 111–84), which requires the Secretary of Defense to submit a final report on the clinical trial assessing the efficacy of cognitive rehabilitation therapy (CRT) for members of the Armed Forces diagnosed with traumatic brain injuries (TBIs). It also requires that the Secretary of Defense submit a report on the efficacy of CRT in treating TBIs in members and former members of the Armed Forces; recommendations for increased access to safe, effective, and quality CRT; and the advisability of including CRT as a benefit under the TRICARE program.

While there is evidence to support the clinical efficacy of CR, the threshold for evidence required by TRICARE has not been met to date to authorize coverage. The Department of Defense is currently reviewing CRT using the hierarchy of reliable evidence. This review is expected to be completed in the summer of 2017 and will include the study that responds to section 723: "Cognitive Rehabilitation for Military Service Members with Mild Traumatic Brain Injury: A Randomized Clinical Trial," along with any new reliable evidence published since the last review in January 2015.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter has been sent to the chairpersons of the other congressional defense committees.

Sincerely,

A. M. Kurta
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MAR 29 2017

The Honorable Rodney P. Frelinghuysen
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report responds to section 723(d)(2) of the National Defense Authorization Act for Fiscal YearFFiscalY2010 (Public Law 111–84), which requires the Secretary of Defense to submit a final report on the clinical trial assessing the efficacy of cognitive rehabilitation therapy (CRT) for members of the Armed Forces diagnosed with traumatic brain injuries (TBIs). It also requires that the Secretary of Defense submit a report on the efficacy of CRT in treating TBIs in members and former members of the Armed Forces; recommendations for increased access to safe, effective, and quality CRT; and the advisability of including CRT as a benefit under the TRICARE program.

While there is evidence to support the clinical efficacy of CR, the threshold for evidence required by TRICARE has not been met to date to authorize coverage. The Department of Defense is currently reviewing CRT using the hierarchy of reliable evidence. This review is expected to be completed in the summer of 2017 and will include the study that responds to section 723: "Cognitive Rehabilitation for Military Service Members with Mild Traumatic Brain Injury: A Randomized Clinical Trial," along with any new reliable evidence published since the last review in January 2015.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter has been sent to the chairpersons of the other congressional defense committees.

Sincerely,

AM Kurta

A. M. Kurta
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Nita M. Lowey
Ranking Member