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

PERSONNEL AND
READINESS

The Honorable Richard C. Shelby
Chairman
Committee on Appropriations
United States Senate
Washington, DC 20510

APR 30 2018

Dear Mr. Chairman:

The enclosed report is in response to section 725(f)(2) of the National Defense Authorization Act for Fiscal Year (FY) 2010 (Public Law 111–84), Chiropractic Clinical Trials, which requires the Secretary of Defense to support a series of chiropractic clinical trials by the National Institutes of Health or an independent academic institution.

The RAND Corporation, along with collaborating institutions Palmer College of Chiropractic and Samueli Institute, was awarded $7.5M for the proposal titled "Assessment of Chiropractic Treatment for Low Back Pain, Military Readiness and Smoking Cessation in Military Active Duty Personnel," or ACT. Three clinical trials were planned in response to the requirement: ACT 1, the results of which were detailed in a report submitted on February 2, 2018; ACT 2, the results of which are detailed in this report; and ACT 3, the results of which will be submitted in September 2019.

ACT 2 sought to test whether chiropractic manipulation therapy (CMT) can improve reaction and response times in combat ready, asymptomatic Special Operations Forces (SOF) personnel. The trial found that while a sustained, long-term improvement in reaction or response times was not associated with a short course of CMT, a single session had an immediate effect of reducing the time for asymptomatic SOF personnel to complete a complex motor response test.

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

Sincerely,

Stephanie Barna
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Richard J. Durbin
Vice Chairman

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

PERSONNEL AND
READINESS

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

APR 30 2018

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Sincerely,

Stephanie Barna
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

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

APR 30 2018

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Sincerely,

Stephanie Barna
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

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

APR 30 2018

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Sincerely,

Stephanie Barna
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 IN RESPONSE TO SECTION 725(f)(2) OF THE NATIONAL DEFENSE AUTHORIZATION ACT FOR FISCAL YEAR 2010 (PUBLIC LAW 111–84)

"CHIROPRACTIC CLINICAL TRIALS"

May 2018

SUBMITTED BY THE OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

The estimated cost of this report or study for the Department of Defense is approximately $4,920 in Fiscal Years 2017 - 2018. This includes $4,4000 in expenses and $520 in DoD labor. Generated on 2018Mar16 RefID: 4-B58CC13

BACKGROUND

Since 1985, the Department of Defense (DoD) has conducted several demonstration projects designed to examine the cost and feasibility of chiropractic health care services for its beneficiaries. The results of these projects have generally concluded that it is feasible to implement chiropractic services as a military health care benefit, and the resulting patient satisfaction is higher than that seen with traditional medical care.[1,2] Following results of the demonstration projects, section 725 of the Floyd D. Spence National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2001 (Public Law 106-398), mandated that DoD develop and implement a plan to make a chiropractic benefit available to all Active Duty personnel in the U.S. Armed Forces. The resulting Chiropractic Care Program established chiropractic care to Active Duty Service members at 49 military clinics and hospitals, later expanded to a total of 60 locations by the NDAA for FY 2009 (Public Law 110-417). Currently, chiropractic care is offered at a total of 66 military clinics and hospitals.[3] At this time, the service is not available at the remaining Military Health System (MHS) health care facilities, nor is it available to all MHS health care beneficiaries. Chiropractic care is only available to Active Duty Service members and activated Guard/Reserve members.

The NDAA for FY 2010 (Public Law 111-84), provided for additional research on the outcomes of chiropractic treatment in the MHS, while continuing the chiropractic benefit available at select MHS health care facilities. The legislation required that the Secretary of Defense provide for the conduct of chiropractic clinical trials, in accordance with the requirements of section 725. In May 2010, the Chiropractic Clinical Trials requirement was assigned by the Assistant Secretary of Defense for Health Affairs (ASD(HA)) to the U.S. Army Medical Research and Materiel Command and to the Congressionally Directed Medical Research Programs (CDMRP) for execution.

The CDMRP initiated the execution of the NDAA for FY 2010 Chiropractic Clinical Trials requirement in accordance with its accepted execution management processes. The ASD(HA) allocated a total of $7.5 million (M) from FY 2010 Defense Health Program funds to support the Chiropractic Clinical Trials. A program announcement was released by the CDMRP on May 12, 2010, and full proposal receipt occurred in August 2010. The responses were externally peer reviewed by subject matter experts in chiropractic care, chiropractic research, and musculoskeletal research, as well as consumer representatives (military Service members with orthopedic conditions who utilized chiropractic care). Funding recommendations were made in September 2010 by a programmatic review panel composed of the Joint Program Committee Chairs from the Military Operational Medicine Research Program, Combat Casualty Care Research Program, and Clinical and Rehabilitative Medicine Research Program; a representative from the Office of the Army Surgeon General; a representative from the Office of the ASD(HA); a chiropractic practitioner within the DoD; and a consumer representative. One proposal was recommended for funding, and the award was issued in February 2011, as detailed below.

The RAND Corporation, along with collaborating institutions Palmer College of Chiropractic and Samueli Institute, was awarded $7.5M for the proposal titled "Assessment of Chiropractic Treatment for Low Back Pain, Military Readiness and Smoking Cessation in Military Active Duty Personnel," or ACT. The ACT is a multi-institutional effort with several military sites and is designed to carry out the following objectives, which align with the requirements laid out in

section 725 of the NDAA for FY 2010: (1a) Compare pain and functional outcomes of chiropractic manipulation therapy plus usual medical care (UMC) to UMC alone in a randomized, controlled trial of Active Duty military personnel ages 18-50 years with non-surgical acute, sub-acute, or chronic low back pain; (1b) Measure and compare changes in smoking behavior after participation in a smoking cessation program offered with chiropractic manipulation therapy plus UMC or with UMC alone; (2) Assess the effect of chiropractic manipulation therapy on military readiness, by comparing pre- and post-treatment differences in reflexes and reaction times in Special Operations Forces (SOF); (3) Determine differences in strength, balance, and likelihood of re-injury between combat-ready troops receiving either chiropractic manipulation therapy or sham manipulation.

Three clinical trials were planned, with objectives 1a and 1b addressed in an initial clinical trial (ACT 1), a second trial to address objective 2 (ACT 2), and a third trial to address objective 3 (ACT 3). The results from ACT 1 were submitted to Congress on February 2, 2018. This report details the results of ACT 2. ACT 3 is currently ongoing; results will be submitted to Congress in September 2019.

ACT 2 INTRODUCTION

Chiropractic care is utilized most frequently to treat disorders or injuries of the neuromusculoskeletal system, such as low back pain and neck pain. Preliminary research studies have shown that in addition to offering pain relief, chiropractic manipulation therapy (CMT) may provide the benefit of improving reaction times. A pilot study from the New Zealand School of Chiropractic found an almost 15 percent improvement in mental task reaction times following an upper cervical adjustment compared to control participants, while two other pilot studies showed significantly improved movement times following chiropractic adjustments to areas of joint dysfunction compared to the control groups.[4, 5, 6] In addition, pre-competition chiropractic adjustment has been positively associated with improved performance in athletics.[7]

SOF are elite, highly trained units within the U.S. military that carry out complex, sensitive missions that often rely on quick thinking and reflexes. In light of the aforementioned pilot studies linking chiropractic treatment and reaction times, the ACT 2 study team sought to test whether CMT can improve reaction and response times in combat ready, asymptomatic SOF personnel.

ACT 2 METHODS

ACT 2 was designed as a prospective, randomized, controlled clinical trial, and was conducted at the Blanchfield Army Community Hospital in Fort Campbell, Kentucky. Active Duty SOF volunteers aged 20 years or older participated in the study. Exclusion criteria included self-reported pain at an intensity of 4 or greater (Patient Reported Outcomes Measurement Information System (PROMIS) scale) at the initial screening visit, recent spinal fracture or other bone/joint pathology contraindication, concurrent treatment for traumatic brain injury, and recent (within last 30 days) chiropractic care. The study design is detailed in a 2016 publication and is summarized in brief below.[8]

Participants were allocated to one of two groups: (a) CMT, or (b) wait-list control. Participants allocated to the CMT group had a total of five study visits. After the first visit to determine

eligibility and enroll in the study, CMT participants returned for a second visit, where they undertook five biomechanical tests both before and after a session of CMT. They then returned for two separate CMT sessions, during which no biomechanical testing was conducted. During their final visit (#5), the participants again undertook the same five biomechanical tests before and after a session of CMT. In total, the CMT group participants received four sessions of CMT over a 2-week period, and reaction/response times were measured before and after the first and fourth CMT sessions (or visits #2 and #5, respectively). CMT was administered by two doctors of chiropractic that provide chiropractic services at the Blanchfield Army Community Hospital. Each participant received spinal manipulation therapy individualized by the provider following clinical evaluation of the participant.

Participants allocated to the wait-list control group had a total of three study visits. After the first visit to complete screening and enrollment, the wait-list control participants returned for a second visit, where they undertook the same five biomechanical tests as the CMT group both before and after a 10-minute rest. The 10-minute rest served as a substitute for the CMT session provided to the CMT group participants. The wait-list control participants returned two weeks later for a final study visit, where they again performed the biomechanical tests twice with a 10-minute rest period in between the testing. Upon study conclusion, the wait-list control participants were offered the opportunity to receive four sessions of CMT.

The five biomechanical tests assessed were: 1) Simple reaction time of the dominant hand – involves reactions times measured by the press of a button in response to visual cues; 2) Simple reaction time of the dominant foot – involves reaction times measured by the press of a pedal in response to visual cues; 3) Choice reaction time – involves reaction times measured by the press of a specific button or pedal by either hand or foot in response to specific visual cues; 4) Response time involving the dominant hand (the Fitts' law test) – involves measuring response times via use of a computer mouse to select pairs of targets that change in size and orientation during the test; and 5) Response time involving whole body movement (t-wall®) – involves measuring the response times by pressing individual touch pads arrayed along a wall as they light up. Reaction time was defined as the length of time occurring between a prompt and the pressing of the button/pedal in response to that prompt. Response time was defined as the length of time occurring between a series of prompts and the actions to complete the given task (involves both reaction and movement time).

ACT 2 RESULTS

ACT 2 study enrollment began in September 2014 and was completed in May 2016. There were 174 individuals screened and 120 Active Duty SOF enrolled in the study. A majority of the participants were referred by physical therapists or other health care providers; the remainder learned of the study through advertising efforts. Demographics (age, race, body mass index, PROMIS measures) were similar between the intervention and control groups. During the course of the study, four adverse events were reported, none of which was related to the study intervention or procedures.

During the first biomechanical assessment (visit #2 for both CMT and control groups), where the biomechanical tests were conducted before and after a single session of CMT (or a 10-minute rest for the control group), there were no differences between the control group and CMT

intervention group when looking at immediate changes in pre- and post-treatment reaction or response times for four of the five biomechanical tests assessed. The exception was the t-wall® response time test, where participants in the CMT group saw a significantly greater improvement in response times than the control group participants. During the second biomechanical assessment (visit #5 for the CMT group and visit #3 for the control group), results were consistent with the first assessment, with no significant differences in immediate pre- and post-treatment reaction or response times between the two groups for four of the five biomechanical tests. As before, the exception was the t-wall® test, where CMT group participants experienced a significantly larger immediate post-treatment reduction in response times than the control group. No significant long-term differences were seen in comparing reaction and response times between the first and second biomechanical assessments for any of the five biomechanical tests.

ACT 2 DISCUSSION AND SUMMARY

The RAND Corporation and its partners completed the second of three clinical trials in accordance with section 725 of the NDAA for FY 2010. The ACT 2 trial is the first randomized, controlled study to examine the impact of a brief course of CMT on the reaction and response times of Active Duty SOF personnel. The trial has resulted in one publication, which describes the study protocol in detail.[8] A second manuscript outlining trial results is in preparation.

The investigators found no statistically significant differences in reaction and response times between the two study groups over the 2-week study period, nor were there significant immediate pre-post differences (comparing test results immediately before and after CMT or a 10-minute rest) for four of the five biomechanical tests that were assessed. However, t-wall® test pre-post response times were significantly different, with the CMT group showing a greater reduction in response time immediately following CMT than the control group displayed immediately following a 10-minute rest. The investigators noted that the t-wall® test measured the longest continuous response time of the five biomechanical tests assessed, which suggests that CMT may influence complex tasks that require longer continuous periods of time to complete.

There are some potential limitations of the study which could impact the ability to detect a greater effect of the intervention. SOF personnel are highly trained with high-level physical conditioning, which may make it more difficult to detect any significant improvement in reaction or response time, regardless of intervention. The investigators suggest that non-SOF personnel or SOF personnel with musculoskeletal symptoms/injuries might be more positively impacted by CMT. Furthermore, the CMT provided was a relatively short course of chiropractic care. The number of sessions was chosen to ensure busy SOF personnel would be able to complete the study, but may not be a long enough course to induce a measureable, sustained improvement in reaction or response times in the study population.

In summary, the ACT 2 trial successfully addressed the NDAA for FY 2010 requirement for an interventional trial on the effect of chiropractic treatment on the reaction times of SOF. While a sustained, long-term improvement in reaction or response times was not associated with the short course of CMT provided, a single session had an immediate effect of reducing the time for asymptomatic SOF personnel to complete a complex motor response test.

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1. Birch & Davis Associates, Inc. 2000. *Final Report: Chiropractic Health Care Demonstration Program*, Falls Church, VA.

2. Muse & Associates, Inc. 2000. *Report on the Department of Defense Chiropractic Health Care Demonstration Project.* Results of independent study conducted by Department of Defense contracted agency. Washington, D.C.

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8. DeVocht JW, Smith DL, Long CR, et al. 2016. The effect of chiropractic treatment on the reaction and response times of special operation forces military personnel: study protocol for a randomized controlled trial. *Trials* 17(1):457.