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Use of a randomized clinical trial design to study cognitive rehabilitation approaches to enhance warfighter performance

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ABSTRACT

Within the military, cognitive readiness is essential to ensure the warfighter can return to highly demanding combat training and deployment operations. The warfighter must be able to make split second decisions and adapt to new tools and environments. After a traumatic brain injury, clinicians helping the warfighter must have techniques that address warfighter cognitive readiness. Current rehabilitation for cognitive complaints used in military medicine are modeled after civilian therapies which focus on remediating moderate to severe impairment through building compensatory strategies. This traditional approach to cognitive rehabilitation does not translate well to mild traumatic brain injury (mTBI) where impairments are subtle, nor does it meet the needs of our warfighters in deployed and combat training environments. Challenging our current methods is critical in adapting to the needs of this highly valued population to ensure that our warfighters are able to carry out mission critical decision making. Here we present a review of our best current practices for cognitive rehabilitation, describe the limitations our traditional approaches impose for mTBI in military personnel, and present an alternative treatment called Strategic Memory Advanced Reasoning Training (SMART) that can be adopted through a randomized clinical trial design. We propose directly comparing traditional treatment approaches with a novel cognitive rehabilitation strategy which has been well validated outside of the military setting. Procedures were developed to execute this clinical trial in a way that is most relevant to the study population by establishing ecologically valid outcome metrics.

1. Introduction

Cognitive complaints are common after a mild traumatic brain injury (mTBI) (Belanger, Curtiss, Demery, Lebowitz, & Vanderploeg, 2005). To treat these complaints, we have primarily relied on traditional cognitive rehabilitation interventions that focus on compensatory strategies for adaptive functional skills (e.g., cognitive mnemonics) and use of external aids. There is evidence of considerable effectiveness in the acute and sub-acute phase of recovery after severe TBI [1–3] but there is insufficient evidence that they improve rates of individuals returning to work, activities of daily living (ADL), community re-integration, or quality of life [4]. Cognitive rehabilitation for mild brain injury has shown only modest evidence of effectiveness. A number of recent studies have examined the use of compensatory strategies for individuals diagnosed with mild cognitive impairment from mTBI [5–7]. These interventions appear to be effective at reducing overall symptoms but not impacting cognitive performance or work-outcomes [6,8].

The efficacy of traditional cognitive rehabilitation may have more limitations for use with active duty military personnel. Unlike most civilians and veterans, all military personnel have set level of competency that they must maintain while serving in the military. The set of competencies is termed cognitive readiness. Like physical readiness, cognitive readiness of the warfighter is critical to ensure they can perform their duties effectively and safely. Specifically, they must be able to translate training into novel environments, adapt to new technological capabilities, and make split-second potentially life-threatening decisions [9]. Thus the goal of treatment in military medicine is not necessarily remediation of cognitive deficits but to obtain an acceptable level of cognitive performance required for operation in wartime environments. A recent cognitive rehabilitation study was conducted in active duty military personnel with mTBI and showed that traditional cognitive rehabilitation was far from optimal as only a small percentage of the sample had a meaningful improvement in functioning [10,11]. There is growing need to find alternative treatments to improve cognitive readiness of injured warfighters.

Strategic Memory Advanced Reasoning Training (SMART), an

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evidence-based manualized cognitive training protocol that focuses on enhancing top-down executive functioning may be particularly useful in treating warfighters. Particularly, SMART focuses on many of the cognitive domains that are key to cognitive readiness. In multiple clinical trials, SMART has shown to improve mental agility, strategic learning, problem solving, focus, and psychological well-being [12–17]. The SMART protocol has been shown to be superior to cognitive training of the same duration and dose of treatment [16,18]. Participants receiving SMART had greater gains compared to the control treatment across measures of cognition, psychological health, and real life outcomes. The cognitive gains were represented by improvements in complex reasoning and abstraction, switching, working memory, non-verbal reasoning and inhibition. Given these advantages, we have identified SMART as a potential solution to treat warfighters with cognitive complaints following mTBI.

This paper details the methodological approach to evaluate SMART through direct comparison with traditional cognitive rehabilitation for active duty military service members with chronic cognitive complaints following mTBI. The design merges classical methodology that examines changes on objective cognitive measures and symptoms with critical elements specific to the warfighter. First, the design emphasizes the unique demands of military occupation and assess change in military performance post treatment. Second the design takes into account the importance of warfighter availability by examining reduction in health care utilization post treatment.

2. Design and methods

2.1. Participants

This study is designed for an active duty military population with persistent cognitive complaints, present at least 6 months following a mTBI. Individuals undergoing treatment for mTBI at a military treatment facility will be recruited. There will be no limitations based on a service member's (SM) age, race, or ethnicity. Eligibility for participation will be determined exclusively by injury classification, and relevant exclusionary criteria such as neurological diagnoses other than mTBI including multiple sclerosis, cerebral vascular accident, brain tumor, neurodegenerative disease, and neuro-motor disorder. Other exclusions include mTBI history within the last 3 months or any history of moderate or severe TBI. Other exclusion criteria include current substance use disorder active suicidal or homicidal ideations.

2.2. Study design/procedures

This study will be a prospective randomized clinical trial with two study arms, SMART and traditional cognitive rehabilitation. After consenting, participants will complete a short screen for inclusion and exclusion criteria dictated for this study. Following screening and consent, a pre-treatment evaluation will be completed to determine baseline functioning. Treatment for both arms of the study will include individual and group appointments. Participants will be evaluated post-treatment to assess immediate treatment changes as well as 3 months post-treatment. Participants will be randomized into cohorts by week of enrollment and then therapists will be randomized by cohort to minimize the potential confounding effect of therapist by condition. This study will be performed by researchers at Camp Pendleton in collaboration with University of Texas Dallas Center for Brain Health.

2.3. Treatments

Traditional cognitive rehabilitation: Participants randomized to the traditional cognitive rehabilitation will participate in a clinician-directed intervention that provides manualized, traditional clinician-directed cognitive rehabilitation that was developed for the Study of Cognitive Rehabilitation Effectiveness (SCORE) trial [10]. Traditional cognitive rehabilitation is a functionally-oriented program. Performance is improved through repetition, errorless learning, and gradually increasing task stimuli and complexity in a structured systematic approach. This treatment consists of 6 weeks, 10 h per week, for a total of 60 h. Each week, the treatment will include 5, 1-h individual sessions, two of which will be focused on compensatory strategies and three of which will be focused on restorative strategies. There will also be 2, 1-h weekly group therapy sessions focused on compensatory strategies, and 3 h of weekly computer-based work with Attention Process Training-3 (APT-3) program [19]. All sessions will be proctored by clinic staff who record performance, and provide positive reinforcement of participation and effort.

SMART: Participants randomized to the SMART intervention will participate in two phases that total 20 h of therapy. The first phase, Strategy Education, reviews the three principle concepts of Strategic Attention, Integrated Reasoning, and Innovation (detailed below). These three core strategies will be trained in 5, 1-h sessions that will be done at week 1. The remainder of the 15, 1-h training sessions will consist of participants putting into practice the integration of these three core strategies in contexts relevant to their military responsibilities and personal lives. This entails 3, 1-h group sessions and 2, 1-h individual working sessions each week during weeks 2–4. Trainees receive feedback from the trainer not only relative to performance on in-session group interactions regarding complex cognitive activities, but also regarding their responses on applied activities. SMART focuses on three metacognitive strategies: Strategic Attention, Integrated Reasoning and Innovation. Strategic Attention is the ability to filter important information from less relevant data. Integrated Reasoning teaches individuals to rapidly combine separate streams of information and synthesize those aspects by abstracting the essence or prioritizing optimal action goals. Innovation encourages fluid and flexible thinking, perspective-taking and problem solving. Study therapists will be trained by the Brain Health Center clinicians on the SMART intervention prior to beginning treatment.

2.4. Measures

Cognitive Performance and Symptoms: Measures of cognition involve assessment of domains including attention, executive functioning, processing speed, learning, and verbal memory. To evaluate the domain of attention and executive functioning, measures assessing the ability to synthesize complex information into generalized concepts (i.e., Test of Strategic Learning, TOSL), attention processing (i.e., Paced Auditory Serial Addition Test, PASAT), mental flexibility and speed (i.e., Delis-Kaplan Executive Function System Trail Making, DKEFS TM), as well as inhibition and top-down brain control (i.e., Delis-Kaplan Executive Function System Color Word, DKEFS CW) will be used. Symbol Digit Modalities Test (SDMT) will be used to assess the domain of processing speed through a task requiring visual search and motor speed. For the domain of learning and memory, a measure of selective learning (i.e., Visual Selective Learning Task, VSLT) and verbal learning and recall (Hopkins Verbal Learning Test- Revised, HVLT-R) will be used. The Global Deficit Score (GDS), will be computed to interpret the overall performance on the cognitive measures [20]. GDS assigns increasing weight to individual test scores that are more discrepant from the normative mean which allows for detection of subtle and spotty impairment from multiple measures. Raw scores will be converted to T-scores which, in turn, will be translated into a deficit score (see Table 1). All deficit scores are then summarized into a total score, which is then divided by the total number of measures.

Assessment of symptoms will utilize self-report measures including the Pittsburgh Sleep Quality Index (PSQI), Combat Exposure Scale (CES), Neurobehavioral Symptom Inventory (NSI), Key Behaviors Change Inventory (KBCI), Post-Traumatic Stress Disorder Checklist (PCL-M), and Patient Health Questionnaire (PHQ-9). See Table 2 for a full list of measures and description of domains assessed.

Table 1
T-score conversion to deficit score.

T-score	Level	Deficit Score
>39	Normal	0
35–39	Mild Impairment	1
30–34	Mild to Moderate Impairment	2
25–29	Moderate Impairment	3
20–24	Moderate to Severe Impairment	4
<20	Severe Impairment	5

Health Care Utilization: Healthcare utilization will be measured using medical encounters with rehabilitation specialists (e.g., Speech Therapy, Occupational Therapy) and mental health professionals using data from electronic medical records. The number of encounters will be examined 3 months before treatment onset and 3 months post-treatment.

Warfighter Performance: Occupational performance will be determined as rated by a direct supervisor using a modified version of the Checklist of Military Activities of Daily Living (M-ADL). The M-ADL includes 15 items that are detailed in Table 3. Questions focus on reliability, efficiency of task completion, quality of work performance, independence on the job, as well as military readiness. In addition to the standard items, 3 items assessing cognitive performance at the workplace will be included. Each item is rated on a Likert scale from "0: Unable to Participate (medical/administrative waiver)" to "7: Complete Independence (timely, safely)". Total score will be used as the primary variable of interest. Surveys will be administered online via a secure email link sent to direct supervisors of participants. Assessments will be completed pre-treatment, at the end of treatment and 3 months post-treatment. At each assessment point, participants will also be queried about changes in their duty status to include limitations (e.g., Limited Duty Status) and specific duties they are completing with respect to their military occupational specialty (MOS) that is detailed in MOS Marine Corps Manual.

Study variables will be aligned with the Federal Interagency Traumatic Brain Injury Research Informatics System (FITBIR), a central repository for data from TBI studies built by the National Institutes of Health and the Department of Defense.

2.5. Statistical analyses

Based on the data from Refs. [16] that examined SMART intervention versus a traditional cognitive rehabilitation program and utilized a common data element with our own study design, with 1:1 random assignment and a 2 sided Van Der Waerden test with a significance level of 5%, a total sample size of 130 provides an 89% power to detect a true treatment difference in the outcome of interest by 0.5 SD. To allow for a 20% dropout rate, a minimum total of 162 participants will be enrolled.

Participants who do not pass the Rey 15-Item Memory Test will be removed from the data analysis. Criteria for passing the Rey 15- Item Memory Test will be a score of less than 20 [33]. The difference between treatment groups sample characteristics including demography, military information and co-variates will be evaluated using Student's t and chi-square tests for continuous and categorical variables, respectively. Wilcoxon Rank-Sum test will be used for two-group comparisons where continuous variables are non-normally distributed. Multilevel mixed-effect modeling will be conducted to assess group differences on the GDS (primary outcome), with the treatment modality (SMART vs. traditional cognitive rehabilitation) as the independent variable. The primary outcome will be assessed as change in cognitive scores over time. Secondary outcomes include healthcare utilization and work place performance. Multivariable linear regression will be used when looking at healthcare utilization between the two treatment groups. The functional outcome measurement will be the rate of healthcare utilization as measured by medical encounters in electronic medical records. Healthcare utilization will be assessed as a continuous variable and

Table 2
Study measures.

Test	Description
Selected Cognitive Measures to Calculate Global Deficit Score (GDS)	
Symbol Digit Modalities Test (SDMT)	Utilized to measure attention, visual searching and tracing, and motor speed [21]. The test is comprised of a coding key made up of nine abstract symbols. Each symbol has a corresponding number. The test-taker is asked to visually search the key and record the number that matches each symbol as quickly as they can. The test-retest reliability is 0.80 [22]). The SDMT has good concurrent validity with other tests of attention (r = .62-.78) (Bowler et al., 1992; [23, 24].
Test of Strategic Learning (TOSL)	The TOSL is a measure of an individual's ability to synthesize complex information into larger generalized concepts [25]. The test consists of three texts that vary in length (from 291 to 575 words) and complexity and then individuals are asked to provide a synopsis of each text. The TOSL measure has a manualized scoring system that tallies abstracted ideas for gist reasoning performance. The TOSL has acceptable test–retest reliability and is a validated measure in TBI with good sensitivity (84.7%) and specificity (71.1%) for TBI as well [16].
Paced Auditory Serial Addition Test (PASAT)	A serial addition task used to assess attentional processing in TBI by examining the role of immediate memory and attention [26]. During administration, a series of single digit numbers are presented where the two most recent digits must be summed. The PASAT has well-studied psychometric properties with good test-test reliability and validity [27].
Visual Selective Learning Task (VSLT)	The VSLT is a selective learning task in which the participant's ability to learn select information among other items is assessed [28,29]. It has been shown to be sensitive to changes in TBI and previous work investigating the SMART intervention have used

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Table 2 (*continued*)

Test	Description
	this metric to assess post treatment changes [15].
Hopkins Verbal Learning Test- Revised (HVLT-R)	The HVLT-R is used to assess verbal learning and memory [30]. It is a brief test with six alternate forms that can be easily administered in patients with varying cognitive disorders. The test consists of three learning trials with 12 nouns (targets) and includes a 25-min delayed free recall trial and recognition. In addition, the HVLT-R offers an embedded PVT which will be examined [31]. Participants with a Recognition Discrimination of ≤5 will be excluded from analysis.
Delis-Kaplan Executive Function System Trail Making (DKEFS TM)	The DKEFS TM is a paper-and-pencil test consisting of three trials assessing mental flexibility and processing speed [32]. It is a measure of psychomotor speed, visual search abilities, working memory, and cognitive flexibility. The score on each part of the TMT is determined by the time required to complete each trial. The test has been shown to have good reliability and validity when assessing acquired brain injury.
Delis-Kaplan Executive Function System Color Word (DKEFS CW)	The DKEFS CW is a measure of inhibition and top-down brain control [32]. The test has several conditions which require the participant to read words quickly, name colors, inhibit over-learned responses, and switch between competing tasks. The DKEFS CW task is widely utilized with good psychometric properties and validity for the assessment of individuals with TBI.
Test of Premorbid Functioning (TOPF)	The TOPF is used to determine premorbid intellectual functioning in adults (*Manual for the Test of Pre-Morbid Functioning (TOPF)*, 2009). When administering the TOPF, the participant is given a list of 50 words and asked to pronounce the words as best they can in consecutive. The TOPF allows for a direct estimated intelligence quotient before brain injury. The internal consistency for the TOPF is excellent, ranging from .90 to .97, and high test-retest reliability, .90-.94.
Rey 15-Item Memory Test	The Rey-15 Item Test measures exaggeration or pretending to have memory problems. The test-taker is given a sheet of paper that has no markings. A card with 15 items is presented to the examinee. The test-taker is allowed to look at the card for a total of 10 s. Following this time period, the examinee is asked to record as many items from the card onto the paper as he or she can. Following the initial recall trial, the recognition trial will be administered. Criteria for passing the Rey 15- Item Memory Test will be a score of less than 20 [33]. Test-retest reliability is not available for the Rey-15. Inter-rater reliability has found 95% agreement for items correct, and 97% agreement for rows correct. Validity with other effort measures (e.g. Test of Memory Malingering (TOMM), Dot Counting Test (DCT)) ranges from r = .19-.78.
Self-Report, Mental Health, and Military Specific Covariates	
Post-Traumatic Stress Disorder Checklist (PCL-M)	The PCL-M is a self-report questionnaire which includes 17 items that are designed to assess symptoms of PTSD [34]. The PCL-M is extensively used both in clinical practice and is frequently used in research investigating PTSD and MTBI in military populations [8,35]. Guidelines for assessment of changes for service members with mTBI have been published as well [36].
Patient Health Questionnaire (PHQ-9)	The PHQ-9 is the depression module of the self-administered version of the PRIME-MD diagnostic instrument; called the Patient Health Questionnaire. The PHQ-9 is an instrument whose 9 items are based on the DSM-IV diagnostic criteria for depression. Its validity and reliability as a diagnostic measure and monitor of treatment response are well-established [37]. It also has demonstrated reliability and validity for diagnosing depression in patients with mTBI [38].

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Table 2 (*continued*)

Test	Description
Neurobehavioral Symptom Inventory (NSI)	The NSI is a 22 item self-report questionnaire that assesses PCS [39]. The questionnaire is a preferred measure by the DoD and Veteran Affairs. It is well-validated in research studies on TBI and PTSD in military populations, it has known reliability and validity, as well as guidelines for assessment of change [36,40]. In addition, the NSI offers an embedded symptom validity measure. The Validity-10 scale [41] is a symptom validity test designed to detect symptom exaggeration when administering the NSI [42–46] A cut-off score of >22 will used to classify symptom exaggeration and participants will be excluded from analyses if they exceed this cut-off.
Key behaviors Change Inventory (KBCI)	The KBCI is a 64-item questionnaire that assesses behavioral areas such as lack of motivation, difficulties communicating, lack of insight into difficulties, and relationship problems [47]. The instrument has good content and construct validity and an internal consistency reliability of 0.82–0.91.
Pittsburgh Sleep Quality Index (PSQI)	A self-rated questionnaire which assesses sleep quality and disturbances over a 1-month time interval. It measures subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction over the last month [22,48].
Combat Exposure Scale (CES)	The Combat Exposure Scale is a 7-item measure used to assess the participants' exposure to combat stress such as enemy fire and in-theater life and death situations [49]. The 5-point scale for each item is weighted according to severity of exposure. The CES has a coefficient alpha of .85 and a 1-week test re-test of $r = .97$, $p < 0.0001$.
Blast Exposure Threshold Study (BETS)	The BETS is a self-report survey that was designed to assess occupational blast exposure from military personnel. The standardized measurement tool efficiently records and calculates cumulative, life-long exposure to potential sources of blast overpressure. The BETS development was supported by the JPC-5 Exposure Standards Working Group and will be included in our study in order to better understand blast exposure history relative to outcome from CR in mTBI.

Table 3
Checklist of military activities of daily living (M-ADL).

1. Military paper work completed on time	2. Showing up to place of duty/ formation on time
3. Adequate attention/concentration for work tasks	4. Operation/maintenance of equipment/tools
5. Communication with subordinates and superiors	6. Military appearance/bearing
7. Supply ordering	8. Uniform (appropriate wear, location of code)
9. Reading technical manuals/procedural guides	10. Weapon use
11. Military Training (online/in person)	12. Endurance for work assignments
13. Perform MOS/NEC specific job tasks	14. Complete military PT tests with passing score
15. Military duty (charge of quarters/staff duty)	16. Decision making
17. Remembering to complete assignments	18. Ability to stay organized during complex tasks

analyses will adjust for pre-treatment outcome (i.e., number of health-care utilization). Multilevel mixed-effect modeling will be conducted for assessment of work place performance between the two treatment groups. This approach will account for between-subject variable based on randomized group, and within-subject variance for repeated measures. The functional outcome measurement will be the level of occupational performance based on total score of the supervisor rated M-ADL. A significant p-value of 0.05 will be used to assess main effects.

3. Discussion

A scientifically driven approach to evaluating current treatment methods and including innovations from civilian practices is necessary to ensure that we are providing the most effective care possible in all rehabilitation domains including cognition. In fact, this is particularly necessary given the heightened awareness of the impact of concussions and repetitive blast exposures and the occupational demand placing the military population at risk. Here we described a randomized controlled trial comparing our traditional cognitive rehabilitation practices identified as best practices within the Department of Defense with a more novel treatment approach that has shown evidence for improvement of executive functioning. The novel treatment, SMART, was selected not only because of its evidence for improving cognition but also because it meets a gap in current treatment. Our traditional methods have had only modest success remediating mild cognitive complaints associated with mTBI. Another limitation of traditional therapist-directed treatment is that it's time intensive, with up to 10 h of intervention a week over the course of 6–10 weeks [10]. This impacts returning a warfighter back to duty and is challenging to execute in a military medical settings with limited resources.

SMART has the potential to over-come many of the limitations of traditional therapist-based cognitive rehabilitation when applied to treatment of mTBI in active duty SMs. The following are foreseeable advantages of this program: i) SMART has been shown to be effective in improving cognitive abilities in neurologically impaired individuals and healthy adults, ii) SMART is focused not on compensatory strategies for daily living but advancement of complex reasoning skills that are essential for warfighter readiness, iii) it has a shorter duration of treatment time than current treatments, iv) it may be administered by a wide-array of rehabilitation therapists (e.g., speech therapists, occupational therapists, psychologists), which are widely trusted across the military health system v) it is a behavioral intervention and suitable for utilization in remote military medical settings with limited resources.

The focus of this study is on patient outcomes following both treatment approaches, with utilization of multiple methods including self-report questionnaires, objective cognitive assessment, real world warfighter performance, and health care utilization. The incorporation of ecologically relevant outcome measures (i.e., health care utilization and workplace evaluations) allows for greater generalizability of treatments provided at a military treatment facility. This study optimizes knowledge translation and military relevance by working closely with operational units. The results of this study will inform military guidelines on best rehabilitation practices to address ongoing cognitive challenges following mTBI among active duty service members.

When determining optimal treatment for service members, it is important to recognize that a tenant of military medicine is to return injured warfighters to full-unrestricted duty status. The core components of cognitive readiness that are accepted across experts involve high-order cognitive reasoning: situational awareness, problem solving, metacognition, decision-making, adaptability, and creative thinking. The military has a longstanding desire to raise mental agility in their military operators. They also have a key goal for warfighters to return to duty, after the brain has been compromised, equipped with the cognitive readiness needed to effectively perform in the complex and unpredictable environment of modern military operations. Our service members deserve the best treatments to reinforce mental fortitude and resilience in the challenging contexts they operate.

In sum, methods and rationale have been described for a study evaluating cognitive rehabilitation methods for mTBI within an active duty military population. We have hypothesized that a novel treatment which incorporates higher order executive functioning training called SMART will show greater cognitive gains evidenced by objective assessment of cognition, self-report questionnaires, and work-place performance when compared to traditional treatment approaches. We have also outlined how these two treatment methods differ theoretically, with the traditional approach modeled after more severe deficits which are often not present in mTBI. The success of this study can aid in returning a warfighter back to duty status more quickly as well as overall improving the cognitive capacity of all service members even if no deficits are present. If successful, this study has the potential to set a pathway to new treatment interventions for our service members which is an important facet of treatment and care. Continuing to challenge ourselves as health care providers and looking for ways to improve standards of care is the optimal goal.

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