Executive Functioning in TBI From Rehabilitation to Social Reintegration: COMPASS

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Title: Executive Functioning in TBI from Rehabilitation to Social Reintegration: COMPASS
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STUDY PROTOCOL

Study Summary

Traumatic brain injury (TBI) is a major health problem that leads to deficits in executive function, a term used for the cognitive operations responsible for planning, decision making, and other aspects of goal management. Executive functions are akin to the self-regulation processes by which humans manage their own thoughts, behaviors, and emotions in order to identify, prioritize, and meet goals.[1] After TBI, which often affects the frontal regions of the brain and their connections, self-regulation processes become disordered and behavior may lose its goal-directed quality.[2] This, along with other cognitive, physical, and behavioral deficits that follow TBI, contributes to injured Veterans' reduced ability to return to work or school and to regain satisfactory personal lives. Our understanding of the neurological disabling impact of TBI on executive function is necessary for both the accurate diagnosis of impairment and individual-tailoring of rehabilitation processes aimed at recovery of independent function in returning service members.[3]

Goal-setting and goal management concepts are part of the "natural language" of rehabilitation. However, collaborative goal-setting between clinician/case manager and client can be difficult because of the cognitive deficits that follow TBI, and because clients with TBI have heterogeneous problems and diffuse goals that are difficult even for experienced clinicians to address. It might be argued that re-training returning Veterans with TBI how to self-manage their goals, with appropriate help and support, would essentially treat deficits in executive function. Such treatment would have multiple benefits: Practical, real-life goals would be achieved, and injured Veterans would re-learn the skills needed to manage their own goals in the future. A structured approach to goal self-management would foster greater independence and self-efficacy, help clients to gain insight into goals that are realistic for them at a given time, and help clinicians and clients to work more effectively as true collaborators.

The COMPASS (**Com**munity **Pa**rticipation through **S**elf-Efficacy **S**kills Development) program aims at developing and testing a novel patient-centered intervention framework that can be utilized as a platform for VA community re-integration comparative effectiveness research. The COMPASS^{goal} intervention will be developed and implemented to meet these needs. COMPASS^{goal} will integrate principles and best practices of goal self-management. Goal setting is a core skill in self-management training by which persons with chronic health conditions learn to improve their status and decrease symptom impact.[4] One important mechanism of action of this program appears to be its positive effect on self-efficacy, or confidence in one's ability to attain goals and solve problems.[5]

The study goal is to gather data on the efficacy of a novel approach to psychosocial rehabilitation for Veterans with executive function impairment due to traumatic brain injury (TBI), and to explore over time, through relevant measures, Veteran responsiveness to intervention. Veterans with mild TBI will be randomized into two groups: the COMPASS (**Com**munity **Pa**rticipation through **S**elf-Efficacy **S**kills Development) goal-management intervention group and the supported discharge group.

110 participants with residual deficits in executive function due to TBI will be recruited at a minimum of 3 months post-injury from the TBI program at the DC VAMC over the three-year period of the study. The operational definition of executive dysfunction/ inclusion into the study is based on both clinical diagnosis by a study physician and a standardized executive dysfunction measure, the Frontal Systems Rating Scale (FrSBe score), such that a total score or any of the 3 subscale scores < 1 SD compared to the normative score would indicate executive dysfunction sufficient to include in the study. The treatment phase for the Veterans enrolled in the intervention group will continue for two consecutive months (8 weekly sessions). Each participant in the intervention and control group will be assessed at baseline (enrollment), post-intervention, and at 3 months post-treatment follow up.

The COMPASS patient-centered intervention framework then can be utilized as a platform for VA community reintegration comparative effectiveness psychosocial research.

SPECIFIC AIMS

The study main objective is to determine whether Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn (OEF/OIF/OND) Veterans with executive dysfunction due to traumatic brain injury (TBI) will benefit from a novel goal self-management intervention (Community Participation through Self-efficacy Skills Development, COMPASS^{goal}) compared to Veterans who receive case management support representing the current standard of care enhanced by an increased number of communication prompts as specified by the study protocol. 110 participants with residual deficits in executive function due to TBI will be recruited at least 3 months post-injury from the TBI program at the DC VAMC over the three year period of the study.

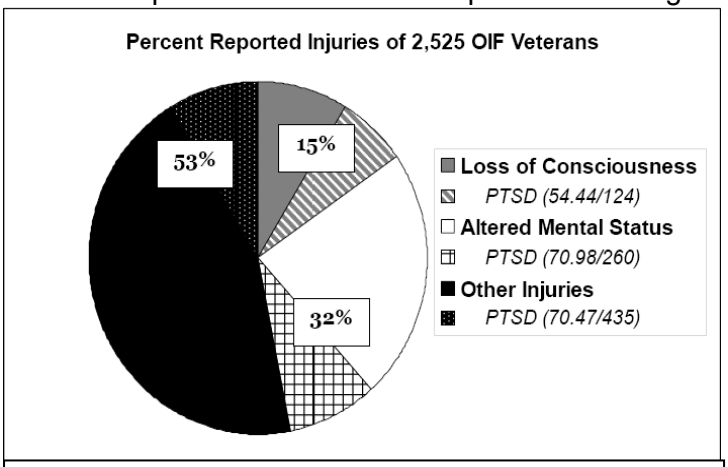
The specific aim and hypotheses of this project are:

Study Specific Aim 1: *To develop, implement, and evaluate a new goal self-management intervention (COMPASS) for Veterans with executive dysfunction due to mTBI, and to investigate how executive functioning is linked to the performance of everyday tasks and community functioning.*

Study Hypotheses:
Study Hypothesis 1: Participants in the COMPASS^{goal} group will have higher TBI self-efficacy and higher community integration scores over time than participants in the supported discharge group matched on executive dysfunction score;
Study Hypothesis 2: *Individual psychosocial profile (emotional status, resilience, and level of post-traumatic stress disorder, PTSD) will mediate the responsiveness to the COMPASS^{goal} intervention, measured through the standardized experimental performance of everyday tasks, in Veterans with impaired executive function due to TBI.*

Research Plan
BACKGROUND AND SIGNIFICANCE

BACKGROUND. Traumatic brain injury (TBI) is a direct cause of long-term cognitive disability in returning Veterans.[6] TBI is also an established risk factor for psychological health and community re-integration.[3,7] Studies emphasize the dramatic impact of neurological injuries among OEF/OIF/OND active duty troops (see **Figure 1**). There is mounting evidence to suggest that executive dysfunction due to central nervous system (CNS) insult causes both short-term and long-term consequences resulting in poor goal-directed behavior[8,9,10,11,12] and significant decrease in independent functioning in both soldiers and returning Veterans. Given the necessity for operational effectiveness in the battlefield environment, executive function symptoms become significant for the military because they jeopardize active duty troops' executive function for crucial decision making.[3,13,14] At the same time, while remaining undetected, neurological problems cause poor self-management skills resulting in maladjustment and low quality of life in returning military Veterans.[3,15] In this study we will use the Individuals with Disabilities Education Improvement Act of 2004 definition of the traumatic brain injury that describes it as "...an acquired injury to the brain caused by an external physical force, resulting in total or partial functional disability or psychosocial impairment, or both, that adversely affects a person's professional and educational performance in one or more areas, such as cognition; language; memory; attention; reasoning; abstract thinking; judgment; problem-solving; sensory, perceptual, and motor abilities; physical functions; information processing; and speech. The term does not



Hoge CW, McGurk D, Thomas JL, Cox AL, Engel CC, Castro CA. Mild traumatic brain injury in U.S. Soldiers returning from Iraq.*N Engl J Med*. 2008;358(5):453-63.

apply to brain injuries that are congenital or degenerative, or to brain injuries induced by birth trauma."[16] The exposure to stressors from combat including explosive blasts and loss or injury to self or comrades can lead to significant problems when translating back to civilian life post-combat.[17,18] Due to advances in medicine and body armor, soldiers are surviving blasts or explosions that may have previously resulted in severe injury or death during combat. Following the US defense causality report in November 2009, the Institute of Medicine updated its statistics to show that "casualty-to-wounded ratios have been found for OEF as 1:5.52 and for OIF as 1:7.[2318,19] compared with 1:2.6 in Vietnam and 1:1.7 in World War II18,[20]."

Many Veterans returning from the wars in Iraq and Afghanistan Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) may have experienced TBI,[21] the significance of which is underscored by a national study, undertaken by the RAND corporation commissioned by the Office of the Secretary of Defense for Health Affairs, to gage the impact of TBI on the lives of Veterans and their families.[22] Even if there are no other co-existing physical impairments, TBI and PTSD are enough to significantly hinder a Veteran's successful progression into active community participation and employment. Physical factors affecting community re-integration in Veterans with polytrauma and traumatic brain injury include pain, PTSD-related anger, and depression. Among psychosocial factors that affect community functioning in returning Veterans are social isolation, poor problem-solving of everyday difficulties, and lack of motivation to change.

EXECUTIVE FUNCTIONING SYSTEM IN TBI: A MULTIFACTORIAL MODEL

Executive dysfunction is the core condition underlying neurologic impairments resulting from central nervous system (CNS) insult such as traumatic brain injury,6 dual TBI-spinal cord injury9,[23] and stroke,[24] as well as a distinct feature of CNS degenerative disorders such as Parkinson's disease.[25] As a central clinical syndrome, executive functioning is defined as a network of processes that are responsible for initiating, guiding, and regulating psychomotor, cognitive, emotional, and behavioral functions, particularly, during active and novel problem-solving.[11,26,27]

EXECUTIVE SYSTEM: NEUROANATOMICAL - NEUROCOGNITIVE DIMENSION

Executive processes are thought of as part of the system that acts in a supervisory capacity in the overall brain hierarchy[28] and provide for purposeful, goal-directed behavior.[29,30,31] There is a plethora of neurologic and behavioral data demonstrating that individual performance processes are deeply involved with changes in what can be named the executive functional system (EFS) (see *Figure 2 below*).[32,33] Recent studies emphasize that executive processes do not have a single neuroanatomical representation in the central nervous system,[10,34] rather they present as patterns merging different brain structures (e.g., the brain's prefrontal zone and limbic system) and their peripheral counterparts (e.g., motor apparatus). Existing interlinkages in the brain-peripheral system are currently explored by measuring various aspects of executive functioning through standardized neuropsychological assessments, magnetic-resonance imaging (MRI) and a more precise assessment, diffusion tensor imaging (DTI).[35] The conceptual definition of the EFS proposes two major subsystems: the *central executive subsystem*,[36] that includes higher level processes such as selective attention, working memory, and decision-making capacity[10] and the *peripheral executive subsystem*, composed mainly of psychomotor processes associated with central executive performance.[37,38] Executive functioning can break down at any stage in the behavioral sequence be it volition control, planning, purposeful behavior, or effective performance.[39] Deficiencies in self-initiated behaviors may result from neurological damage to the frontal-subcortical or fronto-limbic circuitry (*see areas C and D, Figure 2*),[40,41] to the right hemisphere, or in diffuse neurologic conditions (*see area A, Figure 2*).[42] The dorsal prefrontal cortex is critical to allocating attentional resources involved with working memory tasks,[43] or to the attentional controller[44] – a system responsible for maintaining and switching attention.[45]

Cognitive and psychomotor goal-directed activity

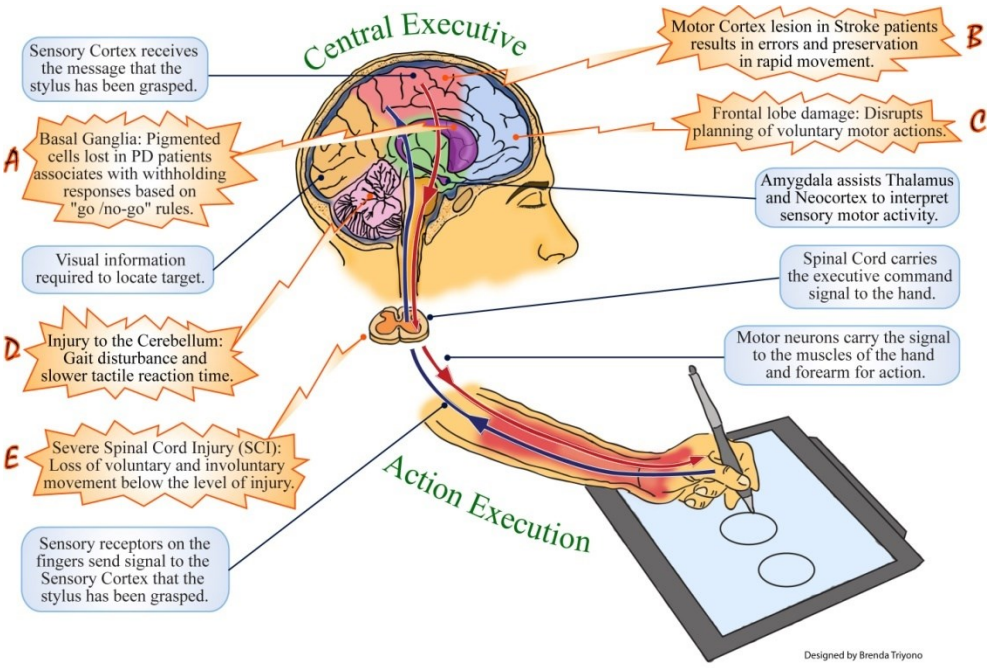


Figure 2. Central-Peripheral Dysregulation in Executive Functional System (EFS)

Motor performance is an instrumental component of the executive functional system.[32,33] In the classic methodology of motor examination tasks developed by Luria and his successors[45,46] the ability to copy hand movements paced by a metronome[47] was found to be sensitive to frontal damage and to temporal lesions (*see area C, Figure 2*). Inability to move rapidly through a repetitive or mixed-movement sequence, combined with errors and perseverations, was found to be characteristic of patients with left hemisphere lesions (*see area B, Figure 2*).[48] Motor regulation deficits are often associated with withholding responses,[49] based on a "go/no-go" rule where a subject should respond only to one of two presented signals (*see area A, Figure 2*).[31]

Patients with subcortical involvement display executive dysfunction that includes impairments in cognitive flexibility, memory recall, and psychomotor slowing.[50,51,52] Impairment of executive processes often presents the major challenge in individual ability to perform activities of daily living (ADLs),[53] management of disability,[54] and community reintegration.[55]

EXECUTIVE SYSTEM: TBI, PTSD AND COMMUNITY RE-INTEGRATION

There is an overlap of symptoms between TBI and PTSD. This issue is most pertinent in the chronic TBI population where there are higher rates of PTSD. Sustaining any kind of physical injury is known to increase a person's risk for PTSD.[56] There are several symptoms that are found in *both* PTSD and TBI, such as deficits in attention and memory, irritability, and sleep disturbance. However in the acute assessment of TBI, some of the distinguishing symptoms such as headache, dizziness, balance problems, and nausea/vomiting may help to elucidate TBI from PTSD. Another distinguishing factor is the history that is obtained from the patients about the course of events before, during, and after the traumatic event. Loss of consciousness (LOC) and post-traumatic amnesia are less common in PTSD and is the distinguishing historical factor to diagnose mild and moderate TBI.

Research has suggested a range of post-injury cognitive, somatic, and behavioral symptoms including headache, anxiety, dizziness, and memory difficulties immediately following TBI,[57,58,59] as well as decreased educational attainment and limitations in work performance.[60,61] The effects of cognitive and behavioral impairment on independence and societal participation following TBI is well established. At the same time the gaps between research and everyday life continue to exist. As the recent report on the needs of returning IOF/OEF Veterans, published by the U.S. Institute of Medicine, indicates, "little research has been conducted to evaluate whether service members who undergo third location decompression (that is, for service members to have time with their comrades and peers in a restful situation and prepare themselves for going back to their families and communities) have better outcomes than those who do not."[18]

Strengthening the community integration of Veterans with TBI requires a collaborative effort bringing together Veterans and their families, Veterans Health Administration case managers and social workers, and the broader research community to address barriers that prevent Veterans with serious injures such as TBI from

effectively pursuing opportunities in life that are available to others. In one of the first national surveys of OIF/OEF combat Veterans enrolled in the Department of Veterans Affairs health care system, Sayer and colleagues (2009)[62] explored the prevalence and types of community re-integration problems faced by Iraq and Afghanistan war Veterans, while assessing preferences for interventions to promote adaptation to civilian life. Stratified Poisson regression was used to determine whether the number of community reintegration problems and the number of services of interest were associated with the presence of probable PTSD, gender, or race. An estimated 25% to 56% of the population had some to extreme difficulty in social functioning, productivity, community involvement, and self-care domains. At least one third reported divorce, dangerous driving, increased substance use, and anger control problems since returning from deployment. An estimated 41% had probable PTSD and each type of reintegration problem was more prevalent among Veterans with probable PTSD. The vast majority (96%) of Iraq/Afghanistan veterans expressed interest in services to help them readjust to civilian life. The most commonly preferred ways to receive reintegration service or information was at a VA facility, through the mail, and over the internet. Interest in self-help techniques and yoga/meditation was particularly common.[63] Penk and colleagues (2010)[64] in their VHA comparative effectiveness study discussed the need for research that identifies ways to aid Veterans with dual diagnoses attain competitive jobs. Community re-integrations tools were found to be key to the effectiveness of employment programs providing Veterans not only with income-earning work but also with skills to help them secure employment.

INTERNATIONAL CLASSIFICATION OF FUNCTION, DISABILITY AND HEALTH (ICF)

In COMPASS^{goal}, we will consider function and disability, as well as activity and participation (including employment), based upon the widely-used International Classification of Function, Disability, and Health (ICF) framework[65] developed under the auspices of the World Health Organization . Through this inclusive approach, we will best be able to document the natural process of recovery in TBI, including the occurrence of accelerated recovery, thereby addressing the needs of people with chronic TBI and providing potential benefit. At each assessment time point, participants (and their families and/or caregivers, if appropriate) will complete validated, standardized scales that capture outcomes in four central domains as defined by the ICF model: function, health, participation, and employment. The ICF presents an interaction of several basic concepts in disability that is widely used as a methodological tool for studying physical disability in general and TBI in particular. Relevant to the present project's conceptual integration is the ICF proposed model of contextual (personal and environmental) factors as they relate to the individual health condition.[65]

OPERATIONAL DEFINITION OF EXECUTIVE FUNCTIONING

The operational definition of executive dysfunction/ inclusion into the study is based on both clinical diagnosis by a study physician and a standardized executive dysfunction measure, the FrSBe score, such that a total score or any of the 3 subscale scores < 1 SD compared to the normative score would indicate executive dysfunction sufficient to include in the study.

***SIGNIFICANCE*.** Studies emphasize the dramatic impact of neurological injuries among OEF/OIF active duty troops, as well as difficulties that such impairments present for returning service members.[3,6,13,17] An understanding of the neurological disabling impact on executive function is necessary for both the accurate diagnosis of impairment and individual-tailoring of rehabilitation processes aimed at recovery of independent function.[3,18,66]

Significance and Alignment with RR&D Priority Area: The proposed study directly supports the RR&D main goal to maximize functional recovery in Veterans as well as such additional goals as:

Topic area 1: integrating the Veteran back into work and society (**Hypothesis 1**)

Topic area 2: developing research that has strong potential for translation into clinical practice (**Hypothesis 2)**

The proposed goal self-management intervention COMPASS^{goal} promises to be effective for service members and their families, as well as for the civilian population, by timely detection of impaired decision-making due to executive dysfunction, facilitation of clinical behavioral monitoring, and promotion of the effectiveness of

neurorehabilitation and psychosocial procedures aimed at restoration of independent functioning and further community re-integration.

RESEARCH DESIGN AND METHODS

Overall Study Design

The proposed 3-year multi-phase study will test two inter-related hypotheses. Hypothesis 1 is explored through a randomized controlled trial (RCT) testing the efficacy of a newly developed intervention COMPASS^{goal} in 110 young to middle aged Veterans with mild TBI assigned to intervention goal self-management or supported discharge groups. Hypothesis 2 is aimed at studying the multilevel relationships between four set of variables (neurological, psychological, behavioral, and social) measured repeatedly for the duration of the project. Assessments for the Veterans with mTBI involved with the project will be performed at baseline (pre-intervention for the COMPASS^{goal} group), 2 months after enrollment (or post-intervention for the COMPASS^{goal} group), and 3 months post-intervention/follow up.

Overall Study Population

One hundred and ten Veterans with residual deficits in executive function due to mild TBI will be recruited from the TBI clinics at the DC VAMC over the three-year period of the study. Severity of TBI will be determined by the DC VAMC attending clinician using the VHA TBI Comprehensive Evaluation electronic template.[67] *The Frontal Systems Rating Scale (FrSBe) will be used to identify individuals with differing levels of executive dysfunction*. *The operational definition of executive dysfunction/ inclusion into the study is based on both clinical diagnosis by a study physician and a standardized executive dysfunction measure, the FrSBe score, such that a total score or any of the 3 subscale scores < 1 SD compared to the normative score would indicate executive dysfunction sufficient to include in the study.* Prior history of known bipoloar disorder, schizophrenia or severe psychiatric illness will be determined first by review of the medical history. If the potential participant's medical record has no documentation of mental health evaluation within the year prior to enrollment, the M.I.N.I. Neuropsychiatric Interview will be administered for exclusionary screening purposes..

We will make every effort to balance the sample by age, gender, and education following the study inclusion-exclusion criteria. Based on previous studies conducted with the VA population in the Greater Washington Area, we expect that approximately 10% of the study participants will be female, and 70% will be African-American. The total number of study participants (N = 110) accounts for a 20% attrition rate in a neurologically-disabled population due to their health condition and related problems.

Inclusion-exclusion criteria

One hundred and ten medically stable individuals with various levels of TBI severity who are not currently evaluated at weekly meetings by the Polytrauma Interdisciplinary team for TBI-related skilled therapy management will be enrolled into the study according to the following inclusion and exclusion criteria:

Table 1. Study inclusion-exclusion criteria

	Inclusion Criteria	Exclusion Criteria
COMPASS: community re-integration study	TBI of at least mild severity using criteria related to disturbance of consciousness (VHA TBI Comprehensive Evaluation screening tool)	Unable to provide informed consent and no proxy available
	Obtained informed consent	Severe impairment of language or day-to-day memory that would preclude participation in a verbally-based therapy
	Males or females of working age, between the ages of 18 and 55	Life expectancy of less than 36 months

Medically stable with physician approval to participate	Severe multiple trauma (as judged by the attending physicians and/or investigators that is too severe to participate in this study) such as severe burns, serious organ damage, amputations, multiple fractures.
Ability to comprehend and communicate in English at a 6th grade level	History of substance abuse severe enough to cause neurologic damage, pre-morbid history of neurologic disease (e.g., stroke)
Executive dysfunction as identified by Frontal Systems Rating Scale (FrSBe) and/or other study assessments (see Table 2)	Prior history of known bipolar disorder or schizophrenia or severe psychiatric illness as determined by clinical judgment and the medical record. The MINI assessment will be administered if no clinical judgment is on record within year prior to enrollment.

POWER AND SAMPLE SIZE CALCULATION

Sampling

During revision, we reversed our changes for the selection criteria following reviewers' suggestion to refocus our efforts on Veterans with mild TBI. The TBI clinic is held on a daily basis at the DC VAMC. This clinic evaluates 150-200 new Veterans per year who are identified with a positive TBI screen. Currently, the positive TBI diagnosis rate is approximately 50% for the DC VAMC site. In addition, other Veterans with known TBI are referred to the clinic resulting in additional 50-100 referrals per year. Frequency of follow-up visits is determined on an individualized basis. In addition to the Veterans with TBI who are hospitalized at the DC VAMC each year, many Veterans seen at the Richmond Polytrauma Rehab Center and discharged to the Washington DC Metro area are then seen in the DC VAMC TBI clinic. Everyone who consents to the study will be examined using the FrSBe. It is estimated that 50-75% of Veterans with mild TBI, have impaired decision-making/executive dysfunction and will be eligible and willing to participate in the study.

Power and sample size calculation

110 participants with executive dysfunction due to diagnosed TBI will be randomized into the COMPASS^{goal} intervention or supported discharge groups, as assessed via the VHA TBI Comprehensive Evaluation screening tool. Participants in the supported discharge group will not receive the intervention, but will receive usual care provided by case managers with increased intensity of communication prompts. Participants in the intervention group will receive 8 goal self-management sessions over a period of approximately 10 weeks. We don't expect a significant change from post-intervention to 3 month post-intervention, the sample size calculations are based on a t-test for comparisons of mean change in the Community Reintegration of Service members (CRIS) subscale from pre- to post-intervention between two groups.

Hypothesis:

H0: $\mu1 = \mu2$ where $\mu1$= mean change in CRIS subscale from time 1 to time 2 in self-management group and $\mu2$= mean change in CRIS subscale from time 1 to time 2 in supported discharge group
H1: $\mu1 \neq \mu2$

Power Calculation: PASS (Power Analysis and Sample Size Software, Kaysville, UT, 2008) was used for the power calculation. The primary outcome of this study is the frequency of social interactions measured via the Extent of Participation subscale of the CRIS.[6] The power calculation was performed based on the hypothesis listed above by using a two-sided t-test with assumption of normality. The level of significance was set at 0.05 and power was set at 90%. The effect size and standard deviation used for the power calculation were estimated based on a previous VA study and clinical judgment.[7] 44 subjects in each

group, for a total of 88 subjects will provide 90% power to test an effect size of 0.71 with a SD of 7 for difference in CRIS subscale score between groups with α=0.05 (two sided). After adjustment for 20% loss to follow-up, we will recruit 55 subjects in each group of this study, a total of 110 subjects.

COMPASS PROCEDURES AND IMPLEMENTATIONS

Study procedures will take place at the DC VAMC in Washington, DC either face-to-face or over the VA Telehealth System (see Study Algorithm, Figure 5). All research procedures, including assessments, may be completed over the phone, not including informed consent. Over the 3-year course of the COMPASS^{goal} project, we will screen, consent, and baseline 110 Veterans, aged 18-55 years, who have been diagnosed with MTBI. All participating Veterans will undergo a battery of tests measuring executive function, real-world performance, TBI self-efficacy, emotional status and PTSD resilience, community integration, and quality of life. Each will receive additional screening of TBI and executive dysfunction to determine intervention eligibility. COMPASS^{goal} investigators will discuss each participating Veteran with his/her VA case manager. Subsequently, Veterans will be randomized to intervention and control groups. The former will receive the COMPASS^{goal} self-management intervention developed to support vulnerable transitions identified during the first 6 months of the project. The latter will receive focused, but standard-of-care, support from the VA TBI Clinic team. Intervention group Veterans will receive 8, weekly, up to 90-minutes, one-on-one goal management sessions over a period of 2 months. Goal sessions with coaches, as well as control group interactions and assessments, will be audio recorded to better inform the researchers about the effectiveness of the interventions. These sessions may occur in person or over the phone. Veterans in both the intervention and control groups will receive assessments pre-, post-, and 3 months following completion of the COMPASS^{goal} intervention or supported discharge process. Data will be modeled longitudinally and on multiple levels to identify vulnerable transitions and predictors of community integration/participation outcomes. Findings will form the basis for clinical practice guidelines.

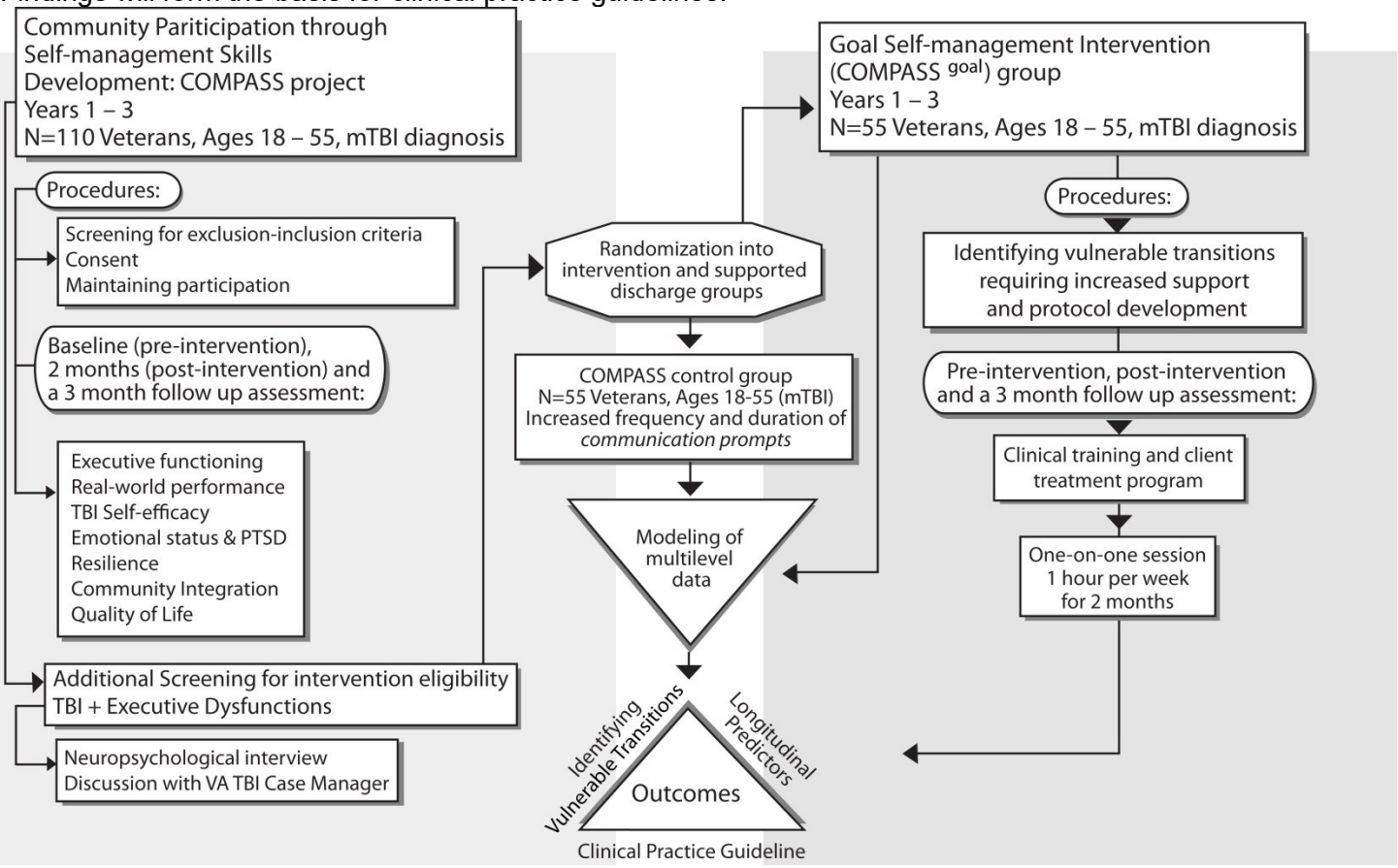


Figure 5. COMPASS Study Algorithm

Recruitment Process

Participants will be recruited from DC VAMC by Dr. Alexander Libin (PI), Dr. Joel Scholten (Co-PI; Polytrauma Clinic Director, and their clinical associates. Consecutive patients approaching discharge from multi-disciplinary care who meet the inclusion/exclusion criteria will be notified of the study and approached for informed consent. If necessary, participants will be recruited using recruitment flyers. Following consent procedures, individuals agreeing to participate in the study will be asked a series of screening questions to ensure that they have met all inclusion/exclusion criteria. In addition, study investigators will take special precautions to ensure that potential study participants fully understand the consent form and authorization for the release of Protected Health Information (e.g., by reviewing the consent form and answering any questions the individual may have - see details in the Human Subjects section).

Screening for exclusion-inclusion criteria

Potential participants will be approached at least three months after TBI for informed consent. The results of the **VHA TBI Comprehensive Evaluation electronic template** will be reviewed following IRB approved and HIPAA compliant data collection procedures. The first data collection will take place within the first 14 days after screening and enrollment into the project.

Informed Consent Process

Upon identifying a potential subject in the DC VAMC TBI database or through the TBI Case Manager, the study PI and Co-PI (Dr. Scholten) or treating physician will speak with the TBI patient and family, as appropriate to each Veteran's circumstances, about the study. In addition, the treating physician will introduce the research team to the families of patients. Special care will be taken to explain the nature of the study and all risks/benefits to the individual in language that is appropriate for his/her comprehension level. Once written consent has been obtained, subjects will be assigned a de-identified study number for data collection purposes by the PI.

Testing setting

For both standard and computerized testing, participants will be provided with a quiet room, a desk, and a chair. We will make every effort to standardize testing conditions. Assessments will be audio recorded for quality control purposes.

Patient retention and PI prior recruiting experiences

Based on the PI's prior experiences, we are confident in the success of study recruitment and retention procedures. In addition, we will be using a motivational technique that previously proved to be very useful in participant recruitment and retention. An IRB approved Certificate of Participation (Thank You letter) template will be used to provide participants and family members with appreciation for participation in the study in comprehensible, "layman" language. This will not only keep participants engaged with the study, but will also potentially create a study atmosphere that will motivate them to bring other potential participants to the study to benefit from the same experience.

To encourage ongoing patient engagement between assessment sessions T2 and T3, Veterans will receive IRB-approved Engagement Templates as reminders of COMPASS participation. This will remind participants that they are enrolled in the COMPASS study without providing information that may influence study variables. Further, participants who initially engaged with the study team, but are lost to follow-up will also receive an IRB-approved Follow-up Letter asking them to contact the study team to confirm continued participation in the study. See Appendix 4 for the letter templates.

Overall rationale for the assessment model

While assembling the study assessment battery we considered the following rules: a) relevance of the proposed measure to the study Specific Aim and Hypotheses; b) the balance of the proposed measures by

modes of expression and assessment quality (self-reported assessment vs. experimental technique vs. observation by a clinician or a family member); c) the possibility of premorbid executive functioning evaluation and sequential charting of executive function over time as it returns to the estimate; and d) possibility of linking performance at the baseline with executive performance over time, using reliable change models to determine if the change meets criteria for some a priori "recovery threshold".

Included in Table 2 below and Appendix 1 (*Assessment Schedule*), core TBI measures were suggested by the TBI Common Data Elements work group and/or were used in community integration TBI studies while implementing a multilevel approach to data analysis. **The National Institute of Neurological Disorders and Stroke (NINDS), the Department of Veterans Affairs (VA), the National Institute on Disability and Rehabilitation Research (NIDRR), the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE), and the Defense and Veterans Brain Injury Center (DVBIC) have co-sponsored this scientific initiative to develop common data elements (CDEs) for TBI research.**

In accordance with the study Specific Aim, we also considered psychosocial individual assessments that capture the subjective aspects of recovery including resilience, amount of stress (PTSD), functional capacity, emotional status (including depression and anxiety levels), TBI self-efficacy, coping, and life satisfaction. These measures have proved external validity and are commonly used in TBI studies (see Table 2, Assessment Schedule). The behavioral assessment focuses on individual performance of real-world tasks. The community integration measures focus on different aspects of societal participation and individual productivity including educational attainment and employment. These measures also have good construct validity, test-retest reliability, and importantly, they are sensitive to change. Most measures employ alternate forms or demonstrate low practice effect which makes them appropriate for repeated administration. We are also aware that the types of measures included are complementary such that "recovery" on the objective measures might not reflect "recovery" on the subjective measures.

STUDY ASSESSMENT SCHEDULE

Assessments will be performed at baseline (termed as "pre-intervention" for the COMPASS^{goal} group), 2 months (or post-intervention for the intervention group), and 3 months follow up for both intervention and supported discharge groups. Participants involved with the COMPASS^{goal} intervention (see relevant section below) will receive 8 goal self-management sessions over a 2-month period. The data will include demographics, level of TBI severity as confirmed by duration of post-traumatic amnesia and alteration of consciousness based on the VHA TBI Comprehensive Evaluation screening tool, executive dysfunction, PTSD, resilience, emotional status, coping, TBI self-efficacy, real-world tasks, and community integration. Family members will be invited to participate and answer the family-report FrSBe assessment either in person or over the telephone after being contacted through an IRB-approved letter.

Table 2: Multifactorial Executive Functioning, Psychological, Behavioral, and Community Integration Measures (for a detailed description see *Appendix 1, Assessment Schedule*)
NOTE. Table 2 was significantly revised; therefore changes are not italicized.

Domain	Test	Description	Study Protocol	Time
Cognitive functioning and TBI severity	TBI screening (VHA TBI Comprehensive Evaluation screening tool)	Reliable measure for detecting cognitive impairment in service members. If the Veteran does not have a CTBIE available in the medical record, questions 6-8 will be collected by an IRB-	Screening for exclusion	*

Domain	Test	Description	Study Protocol	Time
		approved member of the Polytrauma team.		
Executive dysfunction	FrSBe** [80, 82]	Frontal systems Behavioral Scale, 46-items. Both self-report and Family-report.	Executive dysfunction due to TBI	10 min
Demographic Information	Patient Information Form	8 questions about demographics	Collected once during exclusionary screening	5 minutes
Mental Health	**MINI International Neuropsychiatric Interview (MINI) 7.0.0**[68]	Reliable measure of Mental Disorders from DSM-V, including depression, suicidal ideation, manic and hypomanic episodes, panic disorder, agoraphobia, social phobia, obsessive-compulsive disorder, post traumatic stress disorder, alcohol dependence/abuse, substance dependence/abuse, psychotic and mood disorders, anorexia nervosa, bulimia nervosa, generalized anxiety disorder, and antisocial personality disorder.	Determination of mental health disorders in absence of clinical judgment within past year.	15 min
Executive dysfunction	TMT Trail Making Test	Trail Making Test (Part A and B) This is a measure of cognitive processing speed, mental sequencing, visual search and motor speed and consists of two components: Part A and Part B. Part A requires the subject to connect 15 encircled numbers that are randomly arranged on a page in numerical order. Part B requires	Executive dysfunction due to TBI	5 min

Domain	Test	Description	Study Protocol	Time
		the subject to connect 15 encircled numbers and letters in alternating order. The score provided is time required to complete the task.		
Executive dysfunction	COWAT Controlled Oral Word Association Test	Controlled Oral Word Association Test (COWAT) This is a measure of word generation and is considered an executive functioning measure. Letter Fluency requires the person to generate words that start with a specific letter. Category Fluency requires generation of words from within a specific category (e.g., animals). Each trial lasts for one minute and the score is based on the number of words provided.	Executive dysfunction due to TBI	5 min
TBI Self-efficacy	**TBI Self-efficacy Questionnaire**	**15-item TBI-specific scale of self-efficacy with regard to trauma**	**Measure of individual abilities to manage TBI consequences**	**5 min**
Emotional status and resilience	*BSI-18 assessment*	*Paper-and-pencil scale that consists of* 18 items; 5-point rating scale *and is part of the Common Data Elements set*	*Measures depression, anxiety, somatic concerns, and general distress*	5 min
	Post-traumatic Stress Disorder Checklist (PCL)	Presence of PTSD symptoms. PCL is a 20 item self-report scale, updated for DSM-V.	Stress signs: intrusive thoughts, avoidance behavior, arousal symptoms	5 min
	Community Reintegration for Service Members	107 – items assessing Extent of Participation, Perceived Limitation in	Veteran-specific measure utilizing 3 unidimensional	25 mins

Domain	Test	Description	Study Protocol	Time
	(CRIS, Fixed Form; Resnik L.) [81, 82,83,84**]	Participation, and Participation Satisfaction	scales	
	Social participation via ICF qualifiers: return to work and/or to school as defined by the ICF framework	Work status/educational attainment confirmed by a family member/immediate caregiver or other reliable source.	Categorical variables	*

*Tests performed by attending clinician or as part of the routine care at the DC VAMC
** If patients participate in the recruitment assessment within 1 month of participating in clinical trial, the test will not be repeated.

RANDOMIZATION OF THE COMPASS PARTICIPANTS

Randomization of the study participants will occur after all the baseline data are collected. The mTBI diagnosis including operational definition of executive dysfunction will be determined by the study Co-PI, Dr. Joel Scholten, Director of the TBI Program at the DC VAMC with the participation of the DC VAMC neuropsychologist as part of the routine evaluation of Veterans referred with suspected TBI. Staff performing all outcome assessments will be blinded to group assignment throughout the study, and participants will be asked at each assessment not to reveal their group assignment to data collectors.

GOAL SELF-MANAGEMENT INTERVENTION (COMPASS^{goal}) DEVELOPMENT

The purpose of the study is to develop and implement an innovative treatment program called COMPASS^{goal} which will teach goal self-management to Veterans with executive dysfunction due to TBI. This will include a systematic, written protocol for therapists and "user-friendly" materials for clients, to be used in individual treatment with clients with TBI. This treatment protocol will be used to guide Veterans and their therapists in the process of defining, setting, and tracking progress towards goals throughout the study timeframe.

As an aid to developing the intervention materials, focus groups and semi-structured interviews will be held with Veterans with mTBI who come from a variety of backgrounds. The purpose of these interviews and focus groups is to assure that the content and format of the COMPASS intervention is broadly relevant to both Veterans' goals in the context of their lived experiences.. The focus groups and interviews will be audio recorded. Focus group/interview scripts are found in Appendix 2.

As another aid to developing the intervention materials, focus groups and semi-structured interviews will be held with VA clinicians from practices representative of how the VA delivers services nationwide. The purpose of these interviews and focus groups is to assure the content and format of the COMPASS intervention in broadly relevant to the constraints of clinicians' practice across VA service environments. The focus groups and interviews will be audio recorded. Focus group/interview scripts are found in Appendix 2.

In addition to the modifications described above, we will conduct a recruitment assessment prior to implementing the intervention. This portion of the study will not be audio recorded. The assessment will be part of routine clinical treatment and participation is mainly a release of records. In this assessment, we will document the approximate number (and thus, proportions) of new patients presenting for clinic services (without keeping personal identifiers associated with those data). Among this consecutive series of new patients, we will use an informed consent process to invite participation in a single, brief testing session, for those who screen positive for mild TBI, but do not have documented serious mental health co-morbidity (e.g., schizophrenia, major depressive disorder, clinically significant PTSD). Thus, these latter participants will grossly resemble those who might be invited into the COMPASS trial on discharge from rehabilitation team

treatment. Following informed consent, these participants will be given the main measure used for inclusion in the intervention study, the FrSBe, the primary outcome measure, the CRIS, and a short interview. Total participation is expected to take no more than 30 minutes and may be done either in person or by phone at the convenience of the Veteran (these 2 modes of administration have been shown to be psychometrically equivalent.[69] In addition to consenting to answering the questions on these 2 measures, participants will be asked to consent to have their routine clinical data (age, gender, presenting symptoms, severity of TBI, records from the current episode of treatment) used as needed to correlate with the psychometric findings (without personal identifiers attached).

The rationale for this recruitment assessment is as follows. The FrSBe is a self-report measure of executive dysfunction that was developed originally to measure neurobehavioral symptoms in dementia. It has been carefully validated and normed, and has favorable psychometric characteristics. Despite being selected as a relevant measure for TBI by the TBI Common Data Elements Outcome Measures Working Group, it has been used little in studies of *mild* TBI in *Veterans*, which is the target population of the investigation. One study (Schiehser et al., 2011) administered the pre- and post-onset versions of the FrSBe to 71 non-combat military personnel who were <3 months post mild to moderate TBI. On average, the pre-injury ratings were within normal limits but post-injury scores were elevated, especially on apathy and executive dysfunction. However, on average, even the elevated scores were within the *normal or borderline ranges*.[70] This reinforces the need to examine the distribution of FrSBe scores in a sample of Veterans with remote mTBI and to relate specific score elevations to other sources of symptom report. The only other study examining FrSBe scores exclusively in mild TBI sustained in adulthood did show scale elevations in a non-military convenience sample of 76 persons presenting with symptomatic, self-reported mild TBI years after injury; actual TBI severity could not be determined in most cases and symptom exaggeration could not be ruled out.[71] Thus, from prior literature we cannot predict with certainty (1) whether our current inclusion criterion of ≥ SD on any FrSBe subscale is overly restrictive, overly inclusive, or appropriate for this population; nor can we judge (2) the proportion of available participants who would meet this criterion, which has important implications for our ability to meet recruitment benchmarks within the study time frame. The proposed assessment will enable us to determine the sensitivity of the FrSBe to mild TBI sustained months or years prior to intervention and, by revealing the approximate proportion of clinic patients who would meet inclusion criteria, will help us to plan how to recruit adequate numbers of Veterans into the trial.

The CRIS, our primary outcome measure, is equally important to assess in this sample in order to address the following objectives: (1) Determine the time needed to administer the measure, which is quite lengthy. Recently, the CRIS was converted to a computer-adapted (CAT) version which may substantially reduce participant burden.[72] Before starting the assessment, we will contact the primary author of the measure to determine if the CAT and/ or validated short forms are available; (2) Verify that this measure, too, is sensitive to the community integration problems experienced by those with *mild* TBI. The CRIS has been validated thus far on Veterans with severe, mixed type injuries; homeless Veterans; and those with mental health diagnoses such as depression and PTSD, but not in our target population; (3) Derive preliminary data on the relationship, if any, between the FrSBe and the CRIS measures. Reid-Arndt et al. (2007) found that the FrSBe predicted community integration only weakly.[73] However, that study used the Community Integration Questionnaire, a measure with known psychometric difficulties.

Conceptual Framework

The proposed new interventional framework, COMPASS^{goal}, aims at addressing unmet needs of OIF/OEF Veterans for successful return to civilian life.[3,8-14] Employing the proven elements from self-management training and other goal management programs successfully implemented with civilian clinical populations, COMPASS^{goal} will guide participating Veterans, their families, and rehabilitation specialists through the process of negotiating goals, establishing hierarchies of long-, mid-, and short-range goals, and developing individualized, measurable ways of tracking progress. A skill that will be emphasized is the ability to break distal, or long-term goals, into proximal or short-term goals, and to use one's performance on proximal goals to modify the distal ones as necessary.[74] Other specific components to be incorporated into the COMPASS^{goal} protocol include three over-arching self-regulation strategies that have been shown in meta-analyses to be effective: goal manipulations; arousal management (both relaxation and increasing arousal/ motivation); and

cognitive self-regulation, which includes self-monitoring, evaluating, and adjusting performance to meet a selected standard.[75] A meta-cognitive technique called "mental contrasting"—simultaneously considering both the positive aspects of the goal state with the negative aspects of one's current state—will also be employed.[76] Finally, self-monitoring skills will be incorporated as these also have a strong evidence base.[77]

Procedures and Implementation

The COMPASS^{goal} intervention will be developed with the assistance of the study *Chief TBI Rehabilitation Research Consultant,* Tessa Hart, PhD. Dr. Hart is a recognized expert on executive function/ dysfunction after TBI, and its treatment.[78,79,80,81,82,83,84,85,86,87,88,89,90,91,92,93,94] She is also an expert in the process of developing treatment manuals,[95,96] and is leading an NIH-funded 3-center study to test a treatment protocol for anger self-management in TBI. Dr. Hart also recently published a review of the literature on goal and self-regulation theories applied to TBI rehabilitation.[97] She will be primarily responsible for organizing the COMPASS treatment manual and will also assist with solving the inevitable challenges that emerge in the process of implementing a rigorous trial in a clinical setting.[98] Researchers will work as an integral part of the DC VAMC TBI clinic in partnership with *Dr. Joel Scholten, Director, VA TBI case manager*. Dr. Scholten specializes in TBI rehabilitation and has previously served as Medical Director of the Brain Injury Rehabilitation Program and the Polytrauma Network Site Director at James A. Haley Veterans Hospital in Tampa, FL. Dr. Scholten is currently the Associate Chief of Staff for Rehabilitation Services at the DC VA Medical Center.
The project team will participate in VA TBI clinic weekly meetings discussing potential participants, Veterans nearing discharge, to approach for informed consent.
Each client in the intervention group will receive up to 90 minutes per week of treatment, called goal self-management intervention, which will follow the written protocol. This treatment will be conducted by trained research staff. In the course of these weekly sessions, each client will develop his or her goal planner. The planner is conceived as a portfolio containing the written materials generated during goal planning with various tabs for long- mid-, and short-term goals and activities relating to them -- and all the materials designed collaboratively with each client for goal tracking. Depending on the individual client's comfort with and access to technology, materials may be managed through a secure online portal. The goal planner will be updated weekly during intervention sessions.

Significant others (spouses or other close friends/ relatives) will be invited to participate in the assessments and the sessions at the discretion of each participant, in order to provide support outside of treatment for implementing the procedures learned in each session. They will also be asked to answer the FrSBe Family-Rating questionnaire on the behalf of their family member/significant other. If family members/significant others are not physically present to consent and answer the FrSBe family member assessment, the Veteran will be asked to provide a mailing address and phone number for a family member/significant other. The family member/significant other will be mailed a letter with the contact information for the study team, asking him or her to call the study team. The letter will also state that the family member/significant other will receive a call from the study team in 2-3 weeks if he or she does not contact the team. An opt-in/opt-out form will be included in the letter to be returned to the study team. A waiver of informed consent and HIPAA waiver have been submitted to the IRB for approval.

Note about the Manual: The COMPASS Advisor will have a certain amount of flexibility when it comes to implementing the manual in order to tailor the program to participants and individualize the approach. The following are appropriate adaptations that the COMPASS Advisor is authorized to implement:

1. Flexibility in presenting information while maintaining structure to fit the natural flow of the sessions. For example, because this is a verbally-based therapy, the Advisor may find that an individual Veteran directs the session toward discussing the brain graphic before discussing the COMPASS graphic. This represents a change the order of the information presented in the sessions, but not a change in the protocol or structure of the manual. The same information will be provided each time, albeit in a different order. If the Advisor finds he or she consistently has to change the order in numerous sessions, the change will be implemented for all participants and this will be reported to the IRB.
2. If the Advisor and the participant run short on time in a session, parts of the session may be covered in the first few minutes of the next session. For example, if the participant has to leave Session 2 early and the Advisor cannot introduce the Objective Planning and Evaluation sheet, this will be addressed in

the beginning of Session 3. This is necessary because, based on clinical experience, Veterans may show up late to sessions or have a family emergency that requires them to leave early.

3. The Advisor will not be required to read the manual word-for-word in the session. It will be difficult to connect with the Veteran if the Advisor spends time reading word-for-word. The interventions will be recorded for quality improvement purposes to ensure the same protocol is followed in every case.
4. In the same vein, wording changes in the text of the manual that best suits the participant can be implemented in the meetings. For example, if the COMPASS Advisor finds a Veteran reacts better to the term "goal" as opposed to "objective," the Advisor can use the words that are most appropriate to the situation throughout the intervention with that particular Veteran. If the Advisor finds that a series of Veterans react more positively to particular words that differ from the wording in the manual, the change will be implemented for all participants and this will be reported to the IRB.

Updates to forms and homework sheets for the Veteran will be submitted to the IRB before being implemented in the manual. If changes to the manual are so significant to change the nature of the intervention, the manual will be submitted to the IRB as well. Cumulative changes will be submitted to the IRB upon request.

Integration of the COMPASS^{goal} Intervention with the VA Individualized Rehabilitation and Community Re-Integration Care Plan

To successfully implement the proposed intervention as a complementary service to participating Veterans with TBI, the study staff will employ the framework developed in the VHA Handbook[5] 1172.04, Physical Medicine and Rehabilitation: Individualized Rehabilitation and Community Re-Integration Care Plan (2010). This Veterans Health Administration (VHA) Handbook defines procedures for development and implementation of the Individualized Rehabilitation and Community Reintegration Care Plan for Veterans and military Service members who receive inpatient or outpatient rehabilitative care for functional deficits or needs related to Traumatic Brain Injury (TBI) and polytrauma. The COMPASS^{goal} protocol will interplay at each phase of development and implementation with the procedures for Individualized Rehabilitation and Community Integration Care Plans specified by the VHA Handbook and carried out at the DC VAMC.

Research staff will undergo intensive training during months 9-11 of Year 1 and receive ongoing relevant education. Supervision of the COMPASS^{goal} *staff involved with the intervention delivery* is the responsibility of the PIs and study consultant, who will also provide mentoring regarding specific medical, family, and community issues as needed. Initially, daily meetings among the research team will be held to address operational, procedural, and scheduling issues. These meetings will decrease to weekly consultations to address difficult cases and share successful management strategies and new resources. Data collection will be regularly verified and audited by the study coordinator.

Supported Discharge (Control) Group activities

Participants randomized into the supported discharge group, serve as controls for the intervention group and will not receive the COMPASS^{goal} intervention. *It was suggested by the reviewers to increase both the intensity and duration of interactions between the Veterans involved with the COMPASS control group to offset the possible effects of the additional time and attention devoted to participants in the COMPASS group models.*

To address this issue, we held a special meeting at the DC VAMC with the TBI Case Managers, Social Worker, and the study's newly added PI (Joel Scholten, MD). The result of the meeting was a proposal to structure communication procedures for the Veterans involved with the COMPASS control group through the increase and standardization of the intensity and duration of their interactions with the research team acting as Case Managers. Each control group participant will receive additional prompts to address just-in-time concerns as documented in their treatment plans. This strategy will result in increased frequency of the phone calls and other means of contact.

Veterans enrolled in the control group will be contacted by the study team every two weeks over the eight week period corresponding with their counterparts randomized to the intervention arm. During the point of contact, the Veteran in the supported discharge group will answer the Mayo-Portland Adaptability Inventory-4

Participation Index (M2PI). The test will be a self-report by the person with TBI. The M2PI is currently used by the DC VAMC TBI clinic team when the Veteran is initially evaluated in team meeting, when the Veteran is discharged from team treatment, and 6 months post-discharge. Thus, the administration of the M2PI will mimic interactions with a case manager. The M2PI will function as a checklist for the research team and will fulfil the role of increased interactions with a case manager. It encourages Veterans to reflect upon their community integration and will offset the possible effects of the additional time and attention devoted to participants in the COMPASS group models. The M2PI will be administered through one of two means. The default means to contact the Veteran will be through a Secure Message asking to set-up a time to answer the M2PI over the phone. If the Veteran does not respond within a week, the study team will call the Veteran to either collect the M2PI or set up a time to collect the M2PI. If the Veteran does not have Secure Messaging, he or she will only be contacted through a phone call, which will be audio recorded to enable discourse analysis as in the intervention group. If the Veteran feels more comfortable interacting through secure messaging and is enrolled in myHealtheVet, he or she will receive a secure message with the M2PI at the same time intervals as the phone call. In addition control subjects will receive case management support as requested upon initiation by the Veteran (standard practice). Please see Appendix 3 for the M2PI and study team email/phone call script.

Data Collections and Storage

Data will be collected into an Access Database and analyzed through SPSS on the VINCI server. If data is downloaded from VINCI to share with non-VA collaborators, the data will be deidentified. VINCI will be used to upload and store data, but no data will be requested from the national databases supplied through VINCI. The following information comes from VINCI:

"*VA Informatics and Computing Infrastructure (VINCI)*

The VA Informatics and Computing Infrastructure (VINCI) is a major informatics initiative of the Department of Veterans Affairs (VA) that provides a secure, central analytic platform for performing research and supporting clinical operations activities. It is a partnership between the VA Office of Information Technology (OI&T) and the Veterans Health Administration Office of Research and Development (VHA ORD). VINCI includes a cluster of servers for securely hosting suites of databases integrated from select national VA data sources. VINCI servers for data, applications and virtual sessions are physically located at the VA Austin Information Technology Center (AITC), located in Austin, Texas. This secure enclave with 105 high-performance servers and 1.5 petabytes of high-speed data storage has multiple layers of security and disaster recovery to prevent data loss.

To ensure the protection of Veteran data, VINCI maintains compliance with the guidelines set forth by Veterans Health Administration (VHA) Handbook 1200.12, Use of Data and Data Repositories in VHA Research, and all other applicable VA and VHA policies and regulations. In addition, VINCI has undergone all security certification activities in support of obtaining an Authorization to Operate (ATO). Access to VINCI resources are approved in accordance with the requirements of National Data Systems (NDS), VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research, and all other applicable VA and VHA policies and regulations. All data transferred from VINCI is subject to audit for compliance.

VA-credentialed research or operations staff are granted access to study-specific data along with tools for analysis and reporting in the secure, virtual working environment through a certified VHA network computer within the VA. If not working within a VA or VHA hosted office environment containing VA network access, researchers may apply for and then access VINCI through an approved Virtual Private Network (VPN) and Remote Desktop application. The remote computing environment enables data analysis to be performed directly on VINCI servers, offering a number of advantages: uniform security standards for access; a common point of entry for all investigators who use the data; tools for analysis and reporting; tighter and more consistent control of data quality; and the ability to standardize and update terminology and format as technology and methodology improve.

Data Collection

VA provides care to Veterans at over 1,400 points of care. At the core of virtually all care processes is a broadly scoped and extensively used electronic health record system known as the Veterans Information System Technology Architecture (VistA). VistA provides a longitudinal view for patients receiving care nationwide including diagnoses, procedures, medications, labs, physiologic measurements, and text notes and reports. VA

uses 130 VistA implementations to provide electronic health record services nationwide for just over 20 million Veterans historically. The aggregate content of these 130 VistA systems includes 2.3 billion documents (e.g., Progress Notes, Discharge Summaries, Reports) accumulating at a rate of 696,000 each day; 6.2 billion lab values (+1.5 million each day), 3.4 billion orders (+845,000 each day), and 1.7 billion medication administrations and prescription fills (+390,000 each day).

Data are aggregated from individual VistA systems to the VA Corporate Data Warehouse where it is modeled and prepared for use. Data published by the VHA Decision Support System (DSS), Inpatient and Outpatient Medical SAS (MedSAS), VA Health Economics Resource Center (HERC) cost data, Vital Status and VA-CMS linked data files maintained by VA Information Resource Center (VIReC), CDC National Death Index VA-linked data, and several other specialty data sets can be requested through VINCI. VA National Data Services and other data stewards regulate the right to use the data, but VINCI facilitates the process. When study requests are approved, project-specific data are extracted from source databases and placed in SQL tables accessible only to the research team and VINCI data managers.

Storage of Study Data
Study data will be kept in accordance with the Department of Veterans Affairs Record Control Schedule 10-1 (RCS 10-1). Storage and transfer of any Personally Identifiable Information (PII) or Protected Health Information (PHI) must be done in accordance with applicable VA and VHA policies and directives, state and federal regulations, and applicable statutes including the Health Insurance Portability and Accountability ACT (HIPAA). Unless explicitly requested and approved by data stewards, all sensitive patient data must remain on VINCI project servers and only aggregate data without PII / PHI may be transferred from VINCI. Any desired change in data storage location or transfer requires amending the original data request with an updated of disposition of study data. The amendment must be approved by all data stewards before data may be transferred.

Violations of data policy or approved use of data will be subject to full penalty of law, which may include suspension of access privileges, reprimand, suspension from work, demotion, removal, and criminal and civil penalties.

Upon completion of the research project, the study principal investigator in conjunction with the VA Information Security Officer (ISO), and in accordance with VA policy, will ensure that, study data containing sensitive, confidential information will be returned to the VA, sanitized and removed from all servers, desktops, removable storage devices, etc.

Data Access
Only study team personnel explicitly authorized by data stewards will have access to project data. The study principal investigator has the responsibility for security of study. VINCI data managers and VA OI&T personnel not under the purview of the study principal investigator control the servers, network, processors, firewall and software in the VINCI environment, including access rights granted to study personnel.

When study personnel are no longer part of the research team, the study principal investigator will amend the data access request to terminate that person's access to all study data and notify the VA Information Security Officer of such action. No sensitive patient data may be shared with anyone who does not have a VA appointment. All study team personnel with access to sensitive patient data must stay current on required VA information security and privacy policy trainings.

Data Storage Location
Study data stored on VINCI servers is located at the Austin Information Technology Center, 1615 Woodward St., Austin, TX 78772-0001. The specific server where the data are stored within the VINCI environment will be chosen by VINCI personnel. The server name and location within the Austin Information Technology Center may be changed at any time at the discretion of VINCI personnel.

Specialized Software
All software used to access sensitive patient data, whether provided by VINCI, or developed by the study team, will run in virtual desktop sessions on VINCI servers within the Austin Information Technology Center."[99]

STATISTICAL ANALYSIS PLAN

Overview

For this project, we plan to collect three major types of data assessed at times 1-3 (baseline/pre-intervention, 2 months/post-intervention, and 3 months follow up): community integration parameters including educational attainment and employment, individual characteristics such as PTSD; TBI self-efficacy, emotional status, coping, performance of real-world tasks, resilience and life satisfaction, and neuropsychological parameters including overall cognitive and executive functioning. Though we have removed the physical function assessments from future data collection, previously collected data on physical function may still be used for data analysis and subsequent publication and presentation purposes. The primary outcome will be the change in the three major types of parameters from pre- to post-intervention. Depending upon the hypothesis being tested (see Specific Aims section), participants will be stratified according to level of executive functioning, severity of conditions secondary to TBI (PTSD, level of functioning, emotional status), or degree of societal participation. Dependent variables will include TBI-self-efficacy, community integration indices, educational or work attainment as defined by the ICF qualifiers, and life satisfaction. Both objective (e.g. executive performance) and subjective (e.g., perceived TBI self-efficacy) data will then be obtained based on repeated measures over the three-year period. Multiple regression models will be fitted to explore continuous primary and secondary outcomes differentiating between groups at each time point and changes at the intra-individual and inter-individual levels over time. For categorical outcomes (e.g., low/high executive performance, or work status such as unemployed/employed, part-time/full-time), unconditional logistic and/or multinomial regression models will be implemented.

The basic testing of the hypotheses will involve ANOVA test and repeated measures ANOVA test. Bonferroni adjustments will be made to account for multiple testing.

Hypothesis 1: Outcome Variables Main Effects for Community Re-integration Factors

This algorithm is based on the assumption that an interaction between the intervention group and control groups can be modeled as a fixed effect. An LMM will then be used to evaluate whether the intervention had an effect at any time point or whether the intervention influenced change (growth, trajectory) in the outcome over the course of the study. The following will be considered for the analytical strategy:

- ANOVA, Repeated-measures ANOVA as well as MANCOVA will be used to compare the effect of the COMPASS^{goal} intervention vs. supported discharge group determined via baseline assessment. ANOVA will be used to compare the change from pre- to post-intervention between the two groups. Furthermore, in order to analyze the main effect of the COMPASS^{goal} intervention over time, a two-way repeated measures parametric ANOVA, as well as a non-parametric repeated measures Friedman ANOVA, will be performed, using the baseline time point, levels of TBI self-efficacy, or real-world tasks performance as the dependent variables. The levels of the repeated measures factor correspond to the number of assessments: baseline (pre-intervention) and 2 months post-intervention. The between-groups factor will be the intervention group vs. the supported discharge group. MANCOVA analysis will focus on the contrast in TBI self-efficacy between the intervention and supported discharge groups while accounting for a specified covariate: level of executive impairment as defined by FrSBE. In the case of non-normal residuals, we will use a nonparametric repeated measures approach. In the case of missing data, an LMM, which uses a maximum likelihood estimate to correct for unequal number of measures per subject, will be employed.
- *We will use Linear mixed models to control for potential confounding variables and baseline values will be utilized as a covariate. These models will allow for the additional control of potential within subjects clusters. These clusters, though not part of the formal hypothesis testing but byproducts of these models, will allow for conceptualization of additional future hypotheses.*

Hypothesis 2: Psychosocial Profile as Mediator of the Reponsiveness to the Intervention Over Time Course

To explore Hypothesis 2, we will utilize a multistage analytic strategy. Because of the possibility of missing data due to non-responses, missed visits, attrition, and mortality over the course of the study, the statistical analysis presents certain challenges. At the first stage, a linear mixed model[100] will be used to incorporate all available data, evaluate trends, and estimate change of outcome variables without discarding cases that have missing data points. Furthermore, linear mixed models (LMM) control for confounding effects of other repeatedly measured covariates while accounting for the correlation among repeatedly measured outcomes. SAS PROC MIXED will be used to estimate a LMM for each outcome of interest. For categorical outcomes, generalized estimating equations (GEEs) will be used to evaluate trends over time while accounting for the dependency among the repeatedly measured outcomes. GEEs will be solved using SAS PROC GENMOD.

Also for **Hypothesis 2** analysis the following will be considered:

- Linear mixed models (LMM) will be used to control for confounding effects of other repeatedly measured covariates while accounting for the dependency among the repeated measured outcomes and covariance matrix.
- We will construct a model which only includes the repeated measures variables to obtain means, variances, and covariances.
- We will add time-invariant variables such as treatment group into the multi-level model (MEME) to predict the change over time in executive dysfunction and associated real-life task performance. Therefore, this method will allow us to address individual growth, identify latent trajectories of growth, relate the observed changes to pre-existing differences between TBI subjects, and determine treatment effects.

Then, we will use linear growth curves to assess individual differences as well as group differences by following a two-stage LGM. At the second stage, we will construct a model that only includes the repeated measures variables to obtain means, variances, and covariances. At stage three, we will add time-invariant variables such as age, gender, and education into the model to predict change over time in executive function and real- world performance. We will also be able to refine our model at any level by assessing the fit after additional variables are inserted. The obtained covariance structure will allow us to draw inferences with regards to linear increases or decreases in executive dysfunction and real-world performance over time. Therefore, this method will allow us to address individual growth, identify latent trajectories of growth, and finally, relate the observed changes to pre-existing differences between TBI subjects.

Missing Data

Rigorous methods to **address loss to follow-up and missing data** will also likely be of importance. As in many studies with vulnerable populations, participant dropout or censoring may be informative. For example, sicker patients and those with sub-optimal treatment results may opt to discontinue participating or providing samples or questionnaire responses. Thus, the probability of missing outcome data may be dependent on covariate data and, hence, "non-ignorable." To assess the probable type of missing data, baseline covariates among patients with and without missing data will be compared. If missing data are judged as Missing Completely at Random (MCAR), the typical strategy will be to conduct a complete case analysis, recognizing a loss of precision. The exception to this strategy will be when considerable data (i.e. >15%) are missing on a particular covariate that is judged to be critical for inclusion in the analysis. In this instance, imputation by unconditional or conditional mean imputation will be used; these simple approaches perform well when the overall percent of missing data is low. In rare instances when the percentage of missing data is not low (i.e. >15%), more sophisticated multiple imputation methods may be employed. Imputation methods will not be used to fill in values for missing outcome data.

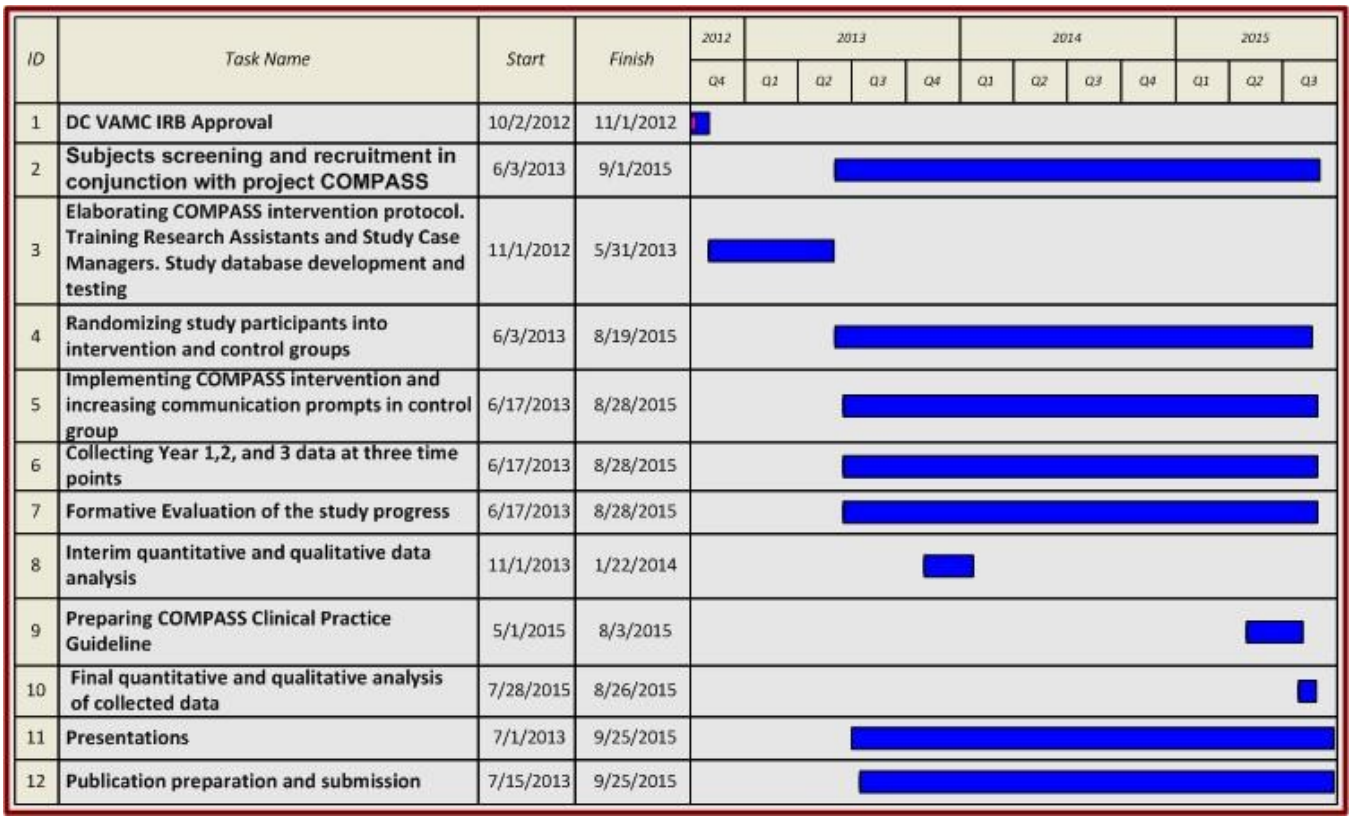
COMPASS PROJECT TIMELINE AND EVALUATION

Program evaluation (Years 1-3)

Ongoing program evaluation will begin in Year 1 and continue through Year 3. Monthly project meetings will continue among project staff for the duration of the project so that issues can be addressed and evaluated, and solutions can be implemented as a team. In addition, yearly project reports will be submitted to DC VAMC IRB to approve continuation of the project. Any modifications to this protocol will be submitted to DC VAMC IRB for approval. A Veteran Advisory Panel will also be formed during Year 1 and will be kept abreast of program

progress on a bi-annual basis, to ensure that feedback from Veterans with TBI will be considered in the ongoing evaluation and implementation of the program. Year 3 will be dedicated to refining the COMPASS program and working towards implementation of the program outside of the DC VAMC and the greater Washington, DC community (see Figure 7).

ID	Task Name	Start	Finish
1	DC VAMC IRB Approval	10/2/2012	11/1/2012
2	Subjects screening and recruitment in conjunction with project COMPASS	6/3/2013	9/1/2015
3	Elaborating COMPASS intervention protocol. Training Research Assistants and Study Case Managers. Study database development and testing	11/1/2012	5/31/2013
4	Randomizing study participants into intervention and control groups	6/3/2013	8/19/2015
5	Implementing COMPASS intervention and increasing communication prompts in control group	6/17/2013	8/28/2015
6	Collecting Year 1,2, and 3 data at three time points	6/17/2013	8/28/2015
7	Formative Evaluation of the study progress	6/17/2013	8/28/2015
8	Interim quantitative and qualitative data analysis	11/1/2013	1/22/2014
9	Preparing COMPASS Clinical Practice Guideline	5/1/2015	8/3/2015
10	Final quantitative and qualitative analysis of collected data	7/28/2015	8/26/2015
11	Presentations	7/1/2013	9/25/2015
12	Publication preparation and submission	7/15/2013	9/25/2015



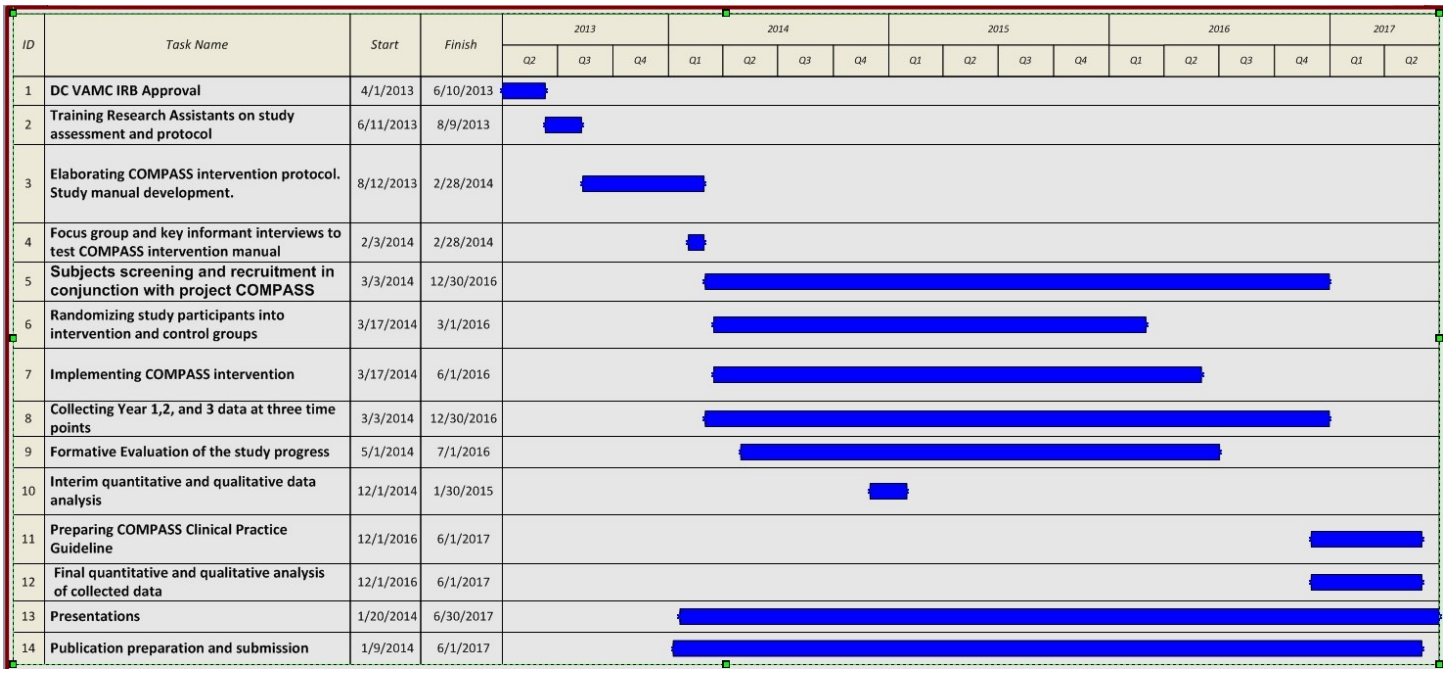


Figure 7. COMPASS Project Timeline

Discussion of the Timeline phases

The first 6 months of the study constitute a preparative phase. During this time we will secure IRB approval, train project staff, develop the COMPASS[goal] intervention and build the study database. Recruitment, implementation of the intervention, data collection, and formative evaluation of the project will take place during the subsequent 26 months. An interim analysis of data (both qualitative and quantitative) will take place 13 months into the project. Presentations and publications, based initially on interim data and finally on summative data, will be produced for the duration of the project following the preparative and early intervention phases (approximately 8 months into the study). A Clinical Practice Guideline will be a deliverable completed during the final quarters of the last year of the COMPASS[goal] project.

Knowledge Translation: Dissemination and Utilization of Study Results

COMPASS staff and the DC VAMC public relations office will work together to ensure that objectives are met and information gained from this study is translated directly back to clinical services at DC VAMC through a variety of mechanisms. Appropriate Knowledge Tools for the given audience will be determined and will include, but not be limited to 4 peer-reviewed publications, 4 national presentations, and integration into existing websites. All of this information will be shared with the Psychological Health and Community Integration office at the VA RR&D in Washington, DC.

Potential Utilization of COMPASS findings for MyHealtheVet application

MyhealtheVet. (www.MyHealthe.va.gov), a self-help/management tool has been available but very much underutilized. One of the reasons for this is that MyHealtheVet, the online, VA personal health record (PHR), is still in a developmental stage with new functionality accruing in an incremental fashion. At present, MyHealtheVet allows Veterans to download self-entered health information to share with both VA and non-VA providers as a print or electronic text file. If a Veteran has authenticated his or her identity in person at a VA Medical Center, portions of his/her VA (VistA) medical record that have been "abstracted" to MyHealtheVet can also be downloaded. This information is referred to as the "Blue Button" data set. There is no mechanism for Veterans to "delegate" (e.g., share electronically in a secure manner) their MyHealtheVet information to health care providers and other trusted individuals. They are, therefore, on their own if they want to leverage the benefits of MyHealtheVet for health surveillance and coordination of care. Survey data collected from the general public, [101]a randomized controlled trial of PHR effectiveness[102] and the experience of a large managed care provider[103] show that interaction with care providers motivates individuals to use available personal health

tools. At present, MyHealtheVet does not provide interactive self-management functions. COMPASS^{goal} differs from MyHealtheVet in that it is a guided intervention in which health care providers engage Veterans, offer goal management exercises and provide personalized feedback. The Department of Veterans Affairs Innovation Initiative (http://www.va.gov/vai2/) issued a request for proposals in the spring of 2011 to enhance MyHealtheVet with such functionality as the ability to import outside data into the PHR space, and to access applications that leverage that data to help in Veteran health decision-making and self-management. COMPASS^{goal} is, potentially, one such application. To assure that COMPASS^{goal} develops in such a way as to facilitate interworking with MyHealtheVet, we have added Manon Schladen MSE EdS, to the project staff (at no increase to budget). Ms. Schladen is a doctoral candidate in computing technology in education exploring use of technology to enhance self-management and engagement of health teams to promote continuity of care. She is presently MedStar National Rehabilitation Hospital's knowledge translation and disparities fellow and chairs the Knowledge Translation and Training Committee at NARRTC.

Future steps and plans for continuing support

The proposed project may be regarded as a first stage project in which the efficacy of the method is demonstrated, and the efficiency of each component is tested. The next phase, which will follow this study, would involve the development of several projects aimed at exploring the mechanisms underlying successful vs. non-successful adaptation of Veterans to everyday life, as well as routes for transferring the ongoing delivery of intervention to the daily routine of community dwelling Veterans with TBI.

The proposed study will prepare the field of creating supportive care environments for necessary future studies on the utilization of best clinical practice guidelines for the everyday life of Veterans and their families. Clinical and applied research will concentrate on the utility of goal self-management interventions in routine care in both home and institutional settings, such as VA hospitals and community centers. These studies will also examine the cost benefits of this approach, which are expected to be substantial because the approach will lessen the time health service providers (e.g., TBI case managers or TBI social workers) must devote to their clients. In the basic research venue, studies need to explore the links between neuroanatomical structure, executive function, and everyday problem-solving in the context of both comparative effectiveness interventional research. This research would help not only to improve quality of life for Veterans with TBI and other neurological deficits, but would also have important social benefits, such as training relatives and immediate caregivers on how to engage their loved ones in meaningful, healthy, and productive activities. The methodology proposed could be utilized with technology-based and other non-pharmacological interventions to better understand the needs and preferences of different clinical populations with chronic illnesses, or physical, cognitive, and behavioral disabilities (i.e., persons with PTSD, substance abuse, disturbing behaviors, etc.). This particular extension may elucidate the commonalities and differences among various clinical groups, and provide additional tools to improve individual care of returning Veterans.

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