Official Title: Enhanced Problem-Solving Training (E-PST) to Improve Recovery From mTBI

ClinicalTrials.gov ID: NCT03759223

Document date: 11-30-21

Objectives, Design, and Methods

The purpose of this line of research is to adapt an enhanced version of PST-PC (E-PST) that can be delivered to Veterans with history of mTBI by generalist providers in VA primary care-mental health settings. In phase 1, we will deliver the intervention to a group of eligible Veterans, and gather feedback on their experiences receiving E-PST. Quantitative and qualitative data will be gathered in order to help us evaluate the feasibility and acceptability of this intervention before we advance to further testing or modifications of the protocol. This will allow us to ensure patient-centeredness in the intervention, and to make final adjustments to E-PST modules. In phase 2, we will conduct a pilot RCT of the E-PST protocol in order to a) estimate a preliminary effect size (ES) for the primary outcome measure; b) determine the feasibility of the assessment plan; and c) establish feasibility of recruitment and retention in order to guide the design of a future multisite efficacy trial.

Phase 1 Approach

General study flow is summarized by the following process and depicted in Figure 1:

1. Electronic medical record review will be used to identify potential candidates.

2. Recruitment letters will be sent to potential candidates, followed by a recruitment phone call. Up to 40 candidates will then be invited to attend either an in-person or telehealth/telephone consent session which will include administration of screening/baseline measures. In the case of telehealth/telephone consent sessions, verbal consent will first be gathered, and signed consent forms will be returned by mail.

3. Eligible participants who provide consent to participate will then engage in the following major study activities:

    a. Receive the E-PST intervention that incorporates mTBI education, compensatory cognitive skills-training, and the core set of problem-solving and goal-setting skills that currently exists as part of VA's nationally-implemented PST-PC.

    b. Complete brief semi-structured interview after each treatment session to gather data on the acceptability of E-PST treatment components.

    c. Complete a post-intervention assessment using standard behavioral health measures as outlined below.

4. All study participants will continue in primary care TAU for any necessary medical management of symptoms. Should participants evidence elevated risk for suicidal or homicidal behavior during study procedures, they will be referred for crisis intervention.

5. Quantitative data will be summarized with descriptive statistics. Study staff will monitor trends in recruitment and retention to guide evaluation of treatment feasibility. While the E-PST intervention includes up to six treatment sessions, attendance at fewer than six sessions will not be recorded as a protocol deviation, as a primary aim of this study is to evaluate whether a six session intervention is feasible and acceptable. Qualitative data will be analyzed via rapid analysis.

Phase 1 Participants, Recruitment, and Enrollment. Potential candidates will primarily be identified using the EMR, which contains information such as patient demographics, coded encounters, and clinic stop codes. Based on prior CIH work, a conservative estimate of a 30% response rate has been assumed for this study. Thus, up to 40 primary care patients who meet pre-screening criteria (see below) will be screened in order to achieve a target enrollment of up to 12 Veterans. Using previously effective recruitment methodology, candidates will be mailed introductory letters that describe the study, how to volunteer, and how to opt out. Veterans who do not opt out will be considered eligible for recruitment phone calls. A trained RA will conduct recruitment phone calls to verify Veterans' age and contact information; establish capability of communicating in English; provide additional information about the study; and conduct further screening for TBI and relevant psychiatric history. Eligible and interested Veterans will subsequently be offered times to attend an in-person or telehealth/telephone meeting to complete informed consent procedures and their screening/ baseline assessment. In the case of telehealth/telephone consent, copies of consent forms and relevant surveys/ study measures will be provided by mail; verbal consent will be gathered, and signed consent forms (including copies for participants' records) will be returned by mail. Follow-up phone contact will take place on an as-needed basis (e.g., to schedule/ re-schedule study visits, respond to participant questions, clarify the nature missing or ambiguous responses on study measures, deliver telehealth/telephone sessions). In the event that a participant is lost to follow-up, we will send a letter if attempts at phone contact are unsuccessful.

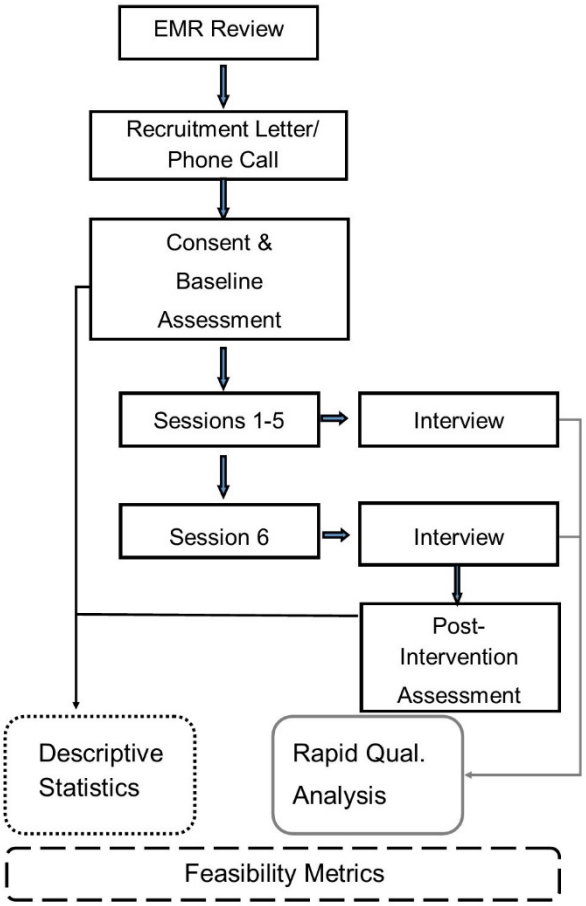

Figure 1. Study Flow Process.

Phase 1 Inclusion Criteria:

a) OEF/OIF/OND Veteran; b) ≥ age 18; c) enrolled in VA primary care (appointment within last 12 months); d) history of mTBI (as measured by the *Ohio State Traumatic Brain Injury Identification Method-Short Form;* OSU TBI-ID; Corrigan & Bogner, 2007); e) persistent post-concussion-like symptoms (as measured by the NSI; Cicerone & Kalmar, 1995); f) BSI-18 (Derogatis, 2001) GSI T-score > 53; g) English speaking, able to read and write, and able to comprehend study materials.

Phase 1 Exclusion Criteria:

a) Prior, current, or pending enrollment in a cognitive rehabilitation program or other specific TBI rehabilitation program; b) moderate to severe TBI or other major neurocognitive disorder; c) psychotic disorder (e.g., schizophrenia spectrum disorder, delusional disorder, schizotypal personality disorder, bipolar or depressive disorder with psychotic features); d) acute suicidal ideation; e) inpatient psychiatric hospitalization within the past 12 months; f) any other illness or condition that would preclude or predictably influence ability to appropriately engage in study visits, as determined by the study team; g) active receipt of other mental health services during enrollment or active intervention period, except for stable psychotropic medications (≥ 1 month with no dose or medication changes).

Given high documented rates of MH comorbidity among Veterans with history of mTBI, individuals with current depression or PTSD symptoms will be permitted to enroll, as long as symptoms are not so functionally-impairing that they would preclude study participation. Exclusion criteria **a-d** are similar to those reported in a previous trial of full-length PST (Bell et al., 2017). Criteria **e-f** were added to narrow the target sample to the most likely candidates for PC-MHI, as opposed to specialty MH treatment, programs. The purpose of criterion **g** is to improve the likelihood that observed treatment effects are due to participation in the

intervention as opposed to other mental health services. Relative to exclusion criterion **a**, participants who have previously completed a cognitive assessment for research or clinical purposes, or who have received general clinical feedback on cognitive performance will be permitted to enroll as these are considered routine care and not cognitive rehabilitation.

Phase 1 Measures and Materials.

Measures are described below and summarized in Table 1.

a) Study Pre-Screening: Will be conducted via EMR review to establish service era status, primary care enrollment, and age (inclusion criteria **a-c**), and chart data points that signal probable mTBI history (see below) or possible exclusion criteria.

b) Study Screening/ Baseline Assessment: Screening and baseline assessment will consist of the following measures that are estimated to require 15-30 minutes:

- Demographic Survey: The demographic survey will collect basic information on participants such as age, racial and ethnic background, gender, vocational, and socioeconomic status. Additional questions will inventory any PST-related and/or compensatory skills that Veterans may independently endorse prior to beginning study interventions.

- *OSU TBI-ID* (Corrigan & Bogner, 2007): A brief, structured screen designed to determine lifetime history of TBI by identifying possible head/neck injuries and associated loss or alterations of consciousness. Scores of 2 or 3 indicate a likely history of mTBI and will be used to establish inclusion criterion **d**. The OSU TBI-ID is a NINDS CDE.

- *NSI* (Cicerone & Kalmar, 1995): A 22-item checklist of common affective, cognitive, and somatosensory symptoms commonly reported after concussion. Sample items pertain to dizziness, headaches, and forgetfulness. This measure is commonly used in VA's second-level TBI evaluations, and is a NINDS CDE. An embedded Validity-10 index (Vanderploeg et al., 2014) estimates the likelihood of symptom exaggeration. Scores of 2 (moderate) or higher on at least one cognitive, affective, and somatic symptom will indicate possible persistent post-concussion-like symptoms (inclusion criterion **e**).

- *BSI-18* (Derogatis, 2001)*:* The BSI-18 is a brief measure of psychological distress brought about by common somatic and affective symptoms. It has been validated for use in patients with history of TBI (Meachen et al., 2008) and is appropriate for use in primary care (Lang, 2005). BSI-18 GSI T-scores will be used to gauge inclusion criterion **f**. A score > 0 on Item 17 will serve as a signal to conduct further suicide risk assessment per the protocol specified below.

- PHQ-9 (Kroenke et al., 2001): A standard measure of depression symptoms validated for use in primary care. A score > 0 on Item 9 will serve as a signal to conduct further suicide risk assessment per the protocol specified below.

- PCL-5 (Bovin et al., 2015): A standard measure of post-traumatic stress symptoms.

- Coronavirus Anxiety Scale (CAS) (Lee, 2020): A brief mental health screen for coronavirus-related anxiety.

c) Mid-Intervention Measures:

- Behavioral Health Measure-20 (BHM-20; Kopta & Lowry, 2002): A brief measure of emotional distress and life functioning, normed for use in primary care (Bryan et al., 2014). It consists of 3 subscales that measure general well-being, MH symptoms, and life functioning. The 4-item life functioning subscale (which evaluates work/ school and relationship functioning, as well as general quality of life) will be administered during each session attended during the open trial for routine outcome monitoring.

- Qualitative Interview: A brief (~5-item) semi-structured interview designed to gather patient feedback on each individual treatment session. Participants will be asked to provide details on the acceptability of each treatment component and perceived value of the skills that were reviewed (Proctor et al., 2011). The interview is designed to be flexible to allow for follow-up to participant responses; a tentative schedule is included with this submission. We estimate that interviews will require 15 minutes, though additional time will be allotted in the event that Veterans wish to elaborate further on any aspect of the interview.

d) Post-Intervention Measures (see descriptions above): BSI-18 (primary clinical outcome); NSI, PHQ-9, PCL-5, CAS (secondary clinical outcomes).

Table 1. Phase 1 Measurement/ Assessment Schedule.

	Chart Pre-Screening	Baseline Assessment	Individual Sessions	Post-Intervention
EMR Review	●			
Demographic Survey		●		
OSU-TBI-ID		●		
NSI		●		●
BSI-18		●		●
PHQ-9		●		●
PCL-5		●		●
CAS		●		●
BHM-20 (Life Functioning Subscale)			●	
Qualitative Interview			●	
Feasibility Measures	**Staff will monitor throughout the study**			

e) Study Feasibility Measures:

- *Feasibility of recruitment* will include the following descriptive statistics: the relative proportion of Veterans excluded per pre-screening criteria *vs*. screen-eligible Veterans; the relative proportion of screen pass *vs*. screen failures; reasons for screen failures; the number of participants enrolled per week; total time to sample accrual; and the proportion of the intent-to-treat sample with clinically-significant depression, and/or PTSD.

- *Feasibility of retention* will include the following descriptive statistics: the number of sessions attended per participant; mean and range of number of sessions attended overall; the relative proportion of participants who complete all 6 possible sessions *vs*. drop out of treatment; and reasons for treatment completion and dropout (as measured by qualitative interview described above).

- *Feasibility of measurement* will include assessment retention and completion rates, time estimates for each study measure and homework assignment, and recording participant questions, comments (e.g., requests for clarification, level of burden, items left blank).

- *Patient-level treatment fidelity* will be evaluated by determining Veteran rates of completion of at-home assignments (e.g., Veterans are asked to practice specific E-PST and compensatory skills, record practice).

- *Therapist-level feasibility and fidelity indicators* will include documentation and review of training required for study therapist(s) (i.e., time, intensity); session length; therapist protocol adherence (i.e., proportion of essential actions completed on a fidelity checklist); remedial actions required (i.e., frequency, type); and time required to complete review of session tapes and rating forms. Rating forms will be developed to use for therapist training and supervision purposes, with content coinciding with the E-PST intervention manual (e.g., session content, coverage, frequency, and duration).

Phase 1 Procedures.

Chart Pre-Screening. Study staff will review local primary care clinic lists for Veterans who have mTBI-related diagnoses listed in their EMRs (i.e., problem lists, corresponding ICD-9 or ICD-10 diagnostic codes); meet the

age, service-era, and primary care enrollment criteria; and whose EMRs do not include evidence of any exclusion criteria listed above. An identical procedure will be utilized to review charts for the age and exclusion criteria for individuals who are directly referred by warm handoff from their primary care/ primary care-mental health provider. Recruitment letters will then be sent to veterans who pass the pre-screening procedure.

Recruitment Phone Calls. Veterans who pass pre-screening procedures and who do not opt-out will be contacted by phone to discuss the study and gauge interest. Interested candidates will then be scheduled for an in-person or telehealth/telephone consent appointment and baseline assessment.

Screening/ Baseline Assessment & Selection. Veterans who provide consent will be formally screened using the measures outlined above. Veterans who meet criteria will be invited to stay in the study; those who do not will be informed of their disposition and thanked for their time.

Intervention. The E-PST intervention will be administered to all participants in this open trial by a trained, therapist (Master's level-equivalent or higher). E-PST will consist of up to 6, 30-minute sessions focused on: a) reducing psychological distress by enhancing specific problem-solving skills; and b) developing specific cognitive and behavioral skills that target common cognitive inefficiencies reported in Veterans with mTBI history. The current therapist guide and participant workbook are included with this submission. We anticipate that sessions will be scheduled biweekly, but will afford flexibility in scheduling to aid in our assessment of feasibility of this planned approach. Psychological distress data (BHM-20 life-functioning subscale) will be collected during treatment sessions as part of routine outcome monitoring. Sessions will be audio-recorded for training and supervision purposes.

Qualitative Interview. Following completion of each E-PST session, study staff will conduct a brief semi-structured interview with participants to gather data on their opinions of the intervention. Interviews will be conducted in-person following treatment sessions or else later by phone. A trained RA will take notes on participant comments via a flip chart/ spreadsheet to facilitate rapid qualitative analysis (see below). Interviews will be recorded to serve as part of the audit trail. Flip chart data will be reviewed by the RA, under the PI's supervision, and cross-referenced with audio to ensure accuracy prior to analysis.

Post-Intervention Assessment. Clinical outcome measures (BSI-18, NSI, PHQ-9, PCL-5) will be administered following the final treatment session. Veterans who discontinue early will be invited to complete clinical outcomes at a time (e.g., 12-week mark) when they otherwise would have completed the final session.

Participant Payment. Participants will be provided a maximum $75 stipend at the conclusion of the study according to the following schedule: $10 for completion of each post-session study interview (up to 6 visits) and a $15 stipend at screening/ baseline assessment.

Risk Management. RA's will monitor for signals of clinical need at study assessment time points (e.g., participant statements of concern, ratings of suicidal ideation), and study therapist(s) will monitor such signals at intervention visits. New or worsening ratings that pertain to suicidal ideation will be addressed using the procedure outlined below. Adverse events will be monitored and reported according to institutional protocols.

Phase 1 Quantitative Data Analysis

Feasibility: As this trial will provide us with feasibility information in preparing for our pilot RCT, we will describe the number of participants screened and enrolled per month, proportion of screened participants who are eligible to enroll, completion rates of treatment sessions, patient attrition rate and other relevant variables. Recruitment will be displayed by plotting the cumulative number of patients enrolled into this study and compared to the anticipated rate of recruitment. Graphs will also be utilized to display rates of intervention and assessment retention at each measurement time. Descriptive statistics will be calculated for each of the feasibility and fidelity indicators described above (e.g., measurement, treatment fidelity). Study therapist fidelity will be described quantitatively with the mean number of items endorsed in fidelity checklists. Items with relatively low fidelity will inform revisions to the training curriculum that will be designed for E-PST therapists in our pilot RCT.

Clinical outcomes: Given the small sample, we are precluded from conducting an advanced quantitative analysis of these data. We will however use an appropriate level of descriptive analysis to explore the clinical effect of E-PST. Descriptive statistics will be calculated and reviewed for relevant participant demographic variables. Individual line graphs of pre-post BSI scores will be generated, and mean differences in BSI-18 scores will be compared. We will also calculate the percentage of participants who report a clinically-significant change on the BSI-18 will be calculated. Additionally, BHM-20 data will be reviewed for each participant after each session. Trends of changes in scores will be visually inspected over time to evaluate evidence of a preliminary clinical effect.

Phase 1 Qualitative Data Analysis

Acceptability: Veteran feedback on acceptability of E-PST will primarily be analyzed via rapid qualitative analysis (Beebe, 2001) of interview data. This approach will facilitate our ability to quickly incorporate patient feedback in making final revisions to the treatment manual that will be used in our future RCT. If our analyses reveal consistent concerns related to E-PST, we will make any necessary adjustments prior to finalizing the manual that will be used in the subsequent RCT. For example, if ≥20% of Veterans describe difficulty interpreting content of a treatment module, we will conclude that there is sufficient consistency across participants to suggest the need for modification in that domain in our future trial. The team will meet to evaluate the feasibility and appropriateness of a change in content, and consider options such as adjusting language to reflect a more lay approach to terminology, re-organizing session content to improve session flow and interpretability, or removing potentially confusing content. If larger changes are required as a result of Veteran feedback, we will seek follow-up consultation and feedback from subject matter experts before changes to the protocol are finalized.

Phase 1 Sample Size Justification

Our primary goal for this study is to gather preliminary feedback from Veteran stakeholders in order to establish evidence that the proposed intervention is both feasible and acceptable, with a secondary goal of evaluating the potential clinical effect of E-PST. Previous work has shown that our target sample of up to 12 participants will be adequate to glean sufficient breadth of stakeholder opinions (Guest et al., 2006; Palinkas et a., 2015). A more comprehensive evaluation of feasibility and treatment satisfaction will later be conducted as part of the RCT. As the small sample size precludes robust statistical analyses, we will focus our quantitative observations solely on descriptive data.

Phase 1 Data Attrition

As this is an adapted intervention, we do not presently have robust estimates of the level of sample and data attrition expected for this open trial. However, our intended sample (up to n = 12 Veterans) is intentionally small. We are prepared to sample with replacement should we need to enroll more than 12 Veterans to achieve the minimum sample of treatment participants necessary to reach qualitative data saturation, and will amend the study as necessary if additional participants are needed.

Phase 1 Study Timeline

We expect that one to two participants will be enrolled per month over a 6-month period, which is reasonable given our experience of recruitment in other PC-MHI studies. Because we are gathering data from such a small sample (i.e., target of up to 12 participants) and will employ a rapid analytic approach, we do not anticipate significant delays.

Following completion of this study, our team will move to conduct a pilot RCT of this protocol in the next study phase. This will prepare us to submit a future application designed to test the intervention in a full-scale RCT.

Phase 2 Approach

General study flow is summarized by the following process and depicted in Figure 2:

1. Electronic medical record review will be used to identify potential candidates.

2. Recruitment letters and consent summaries will be sent to potential candidates, followed by a recruitment phone call. Up to 127 candidates will then be invited to attend a verbal consent session which will include administration of screening/baseline measures.

3. Eligible participants who provide consent to participate will then engage in the following major study activities completed through telehealth:

    a. Receive either the test (E-PST) or control (Healthy Living Messages) per random assignment.

    b. Complete a post-intervention assessment using standard measures/interviews as outlined below.

    c. Complete a follow-up assessment using standard measures outlined below.

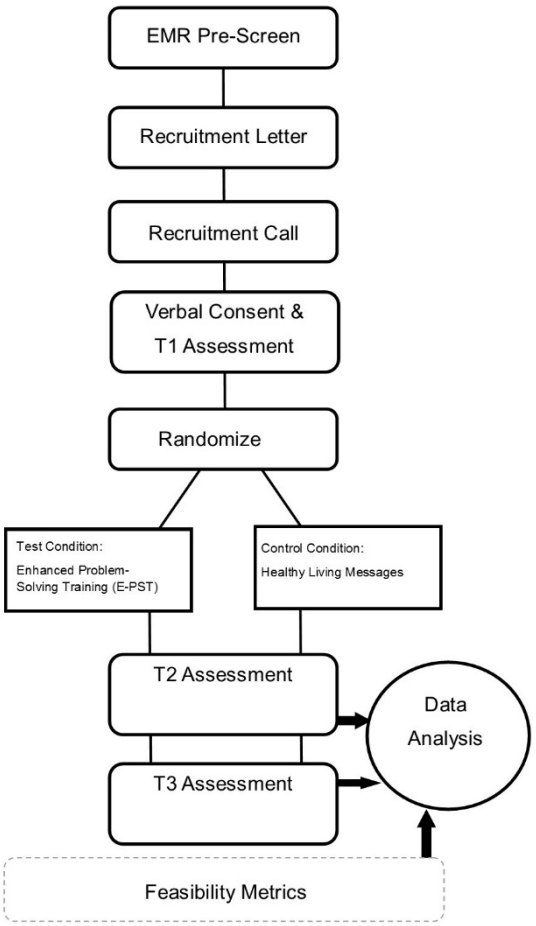

Figure 2. Pilot RCT Study Flow

4. Participants will continue in usual primary care for any necessary medical management of symptoms. Treatment as usual is not a study condition. Should participants evidence elevated risk for suicidal or homicidal behavior during study procedures, they will be referred for any necessary crisis intervention, including referral to the VA Crisis Line.

5. Quantitative data will be summarized using descriptive statistics and graphic displays, with a post-test ES calculated to describe the standardized difference between treatment conditions. Qualitative data will be summarized using a rapid analysis process. Because primary aims of this pilot study involve evaluation of feasibility, attendance at fewer than the intended number of treatment sessions, or participant noncompliance with assessment regimens will not be recorded as protocol deviations. Further, flexibility in scheduling and the timing of participant contact will be offered to evaluate the feasibility of the recruitment and retention plans for our future trial. Ultimately, data gathered in this study will help us to determine the optimal scope, study logistics, and recruitment and retention timelines for our future work.

Phase 2 Participants, Recruitment, and Enrollment.

Potential candidates will primarily be identified using EMR data (i.e., CPRS, Corporate Data Warehouse/VA Informatics and Computing Infrastructure [VINCI]), including patient demographics, coded encounters, and clinic stop codes. Based on prior CIH work, a conservative estimate of a 30% response rate has been assumed for this study. Thus, up to 127 primary care patients will be solicited in order to achieve a maximum randomization of 38 Veterans (n = 19 per arm). While we ultimately seek to gather treatment data from 32 Veterans (n = 16 per arm), we have adjusted our enrollment projection upward to improve the precision of our confidence interval (CI) estimates. To ensure an adequate mix of participants, we seek to oversample females

as well as racial and ethnic minorities if the study sample is skewed from the local patient demographic (i.e., ≤10% female; ≤ 16% racial/ethnic minority). Using previously effective recruitment methodology, candidates will be mailed introductory letters that describe the study (including an informed consent summary), how to volunteer, and how to opt out. Veterans who do not opt out will be considered eligible for recruitment phone calls. A trained RA will conduct recruitment phone calls to verify Veterans' age and contact information; establish capability of communicating in English; and provide additional information about the study. Interested candidates will then be offered time(s) to attend a remote (i.e., phone, telehealth) meeting to complete verbal informed consent procedures, that will include review of a detailed written summary of study procedures, and a screening/ baseline (T1) assessment. Candidates will have a copy of the consent summary in-hand as they review materials with staff. Eligible candidates will then be randomized 1:1 to the test or control condition. Follow-up contact (e.g., phone, mail, encrypted Azure email, video telehealth appointment) will take place on an as-needed basis, for instance, to schedule/ re-schedule study visits, respond to participant questions, clarify the nature missing or ambiguous responses on study measures, deliver telehealth/telephone sessions, distribute relevant handouts/ workbook materials, conduct participant outreach. Participants will have an option to directly enter patient-reported outcome data in the VA Qualtrics platform. A secure link to the data entry portal will be shared using secure communication methods outlined above. These multiple avenues for participant engagement are necessary as phase 2 study procedures will be conducted remotely.

Phase 2 Inclusion Criteria:

a) OEF/OIF/OND Veteran; b) ≥ age 18; c) enrolled in VA primary care (appointment within last 12 months); d) history of mTBI (as measured by the *Ohio State Traumatic Brain Injury Identification Method-Short Form;* OSU TBI-ID; Corrigan & Bogner, 2007); e) persistent post-concussion-like symptoms (as measured by the NSI; Cicerone & Kalmar, 1995); f) BSI-18 (Derogatis, 2001) GSI T-score > 53; g) English speaking, able to read and write, and able to comprehend study materials.

Phase 2 Exclusion Criteria:

a) Pending, current, or prior 24-months enrollment in a cognitive rehabilitation program or other specific TBI rehabilitation program; b) moderate to severe TBI or other major neurocognitive disorder; c) psychotic disorder on problem list (e.g., schizophrenia spectrum disorder, delusional disorder, schizotypal personality disorder, bipolar or depressive disorder with psychotic features); d) acute suicidal ideation; e) inpatient psychiatric hospitalization within the past 12 months; f) any other illness or condition that would preclude or predictably influence ability to appropriately engage in study visits, as determined by the study team; g) active receipt of concurrent mental health services during active intervention period, except for stable psychotropic medications (≥ 1 month with no dose or medication changes).

Given high documented rates of MH comorbidity among Veterans with history of mTBI, individuals with current depression or PTSD symptoms will be permitted to enroll, as long as symptoms are not so functionally-impairing that they would preclude study participation. Exclusion criteria **a-d** are similar to those reported in a previous trial of full-length PST (Bell et al., 2017). Criteria **e-f** were added to narrow the target sample to the most likely candidates for PC-MHI, as opposed to specialty MH treatment, programs. The purpose of criterion **g** is to improve the likelihood that observed treatment effects are due to participation in the intervention as opposed to other mental health services. Relative to exclusion criterion **a**, participants who have previously completed a cognitive assessment for research or clinical purposes, or who have received general clinical feedback on cognitive performance will be permitted to enroll as these are considered routine care and not cognitive rehabilitation.

Phase 2 Measures and Materials.

Measures are described below and the proposed assessment schedule is summarized in Table 1. T1 and T3 assessments are estimated to require ≤70 minutes. As T2 assessments also include a brief qualitative interview, we estimate an approximate 90-minute time commitment for Veterans assigned to the E-PST arm.

a) Study Pre-Screening: Will be conducted via EMR review to establish service era status, primary care enrollment, and age (inclusion criteria **a-c**), and chart data points that signal probable mTBI history (see below) or possible exclusion criteria.

b) Study Measures:

- Demographic Survey: The demographic survey will collect basic information on participants such as age, racial and ethnic background, gender, vocational, and socioeconomic status. Additional questions will inventory any PST-related and/or compensatory skills that Veterans may independently endorse prior to beginning study interventions.

- *OSU TBI-ID* (Corrigan & Bogner, 2007): A brief, structured screen designed to determine lifetime history of TBI by identifying possible head/neck injuries and associated loss or alterations of consciousness. Scores of 2 or 3 indicate a likely history of mTBI and will be used to establish inclusion criterion **d**. The OSU TBI-ID is a NINDS CDE.

- *Neurobehavioral Symptom Inventory* (*NSI*; Cicerone & Kalmar, 1995): A 22-item checklist of common affective, cognitive, and somatosensory symptoms commonly reported after concussion. Sample items pertain to dizziness, headaches, and forgetfulness. This measure is commonly used in VA's second-level TBI evaluations and is a NINDS CDE. An embedded Validity-10 index (Vanderploeg et al., 2014) estimates the likelihood of symptom exaggeration. Scores of 2 (moderate) or higher on at least one cognitive, affective, and somatic symptom will indicate possible persistent post-concussion-like symptoms (inclusion criterion **e**). Changes of ≥ 8 points indicate clinically-significant change (Belanger et al., 2016).

- *BSI-18* (Derogatis, 2001)*:* The BSI-18 is a brief measure of psychological distress brought about by common somatic and affective symptoms. It has been validated for use in patients with history of TBI (Meachen et al., 2008) and is appropriate for use in primary care (Lang, 2005). BSI-18 GSI T-scores will be used to gauge inclusion criterion **f** and will serve as the primary outcome measure. A score > 0 on Item 17 will serve as a signal to conduct further suicide risk assessment per the attached protocol.

- PHQ-9 (Kroenke et al., 2001): A standard measure of depression symptoms validated for use in primary care. This item is included in VA's Mental Health Assistant and is a supplemental NINDS common data element. A score > 0 on Item 9 will serve as a signal to conduct further suicide risk assessment per the attached protocol.

- *PTSD Checklist for DSM-5 (PCL5*; Bovin et al., 2015): A 20-item measure of DSM-5 symptoms related to trauma, organized over re-experiencing, avoidance, hyperarousal, and cognitive/mood domains. Participants will be asked to identify a specific traumatic event (i.e., criterion A event) prior to providing symptom ratings.

- Coronavirus Anxiety Scale (CAS; Lee, 2020): A brief mental health screen for coronavirus-related anxiety.

- *Applied Cognition-General Concerns-Short Form (ACGC-8a*; Lai et al., 2014; Saffer et al., 2015): An 8-item checklist of general cognitive concerns over the past week. Items were generated and validated as part of the National Institute of Health's Patient-Reported Outcome Measurement Information System (PROMIS).

- *Applied Cognition-Abilities-Short Form (ACA-8a*; Lai et al., 2014; Saffer et al., 2015): An 8-item checklist of self-perceived cognitive abilities (e.g., my mind has been sharp") over the past week developed as part of the NIH PROMIS project.

- *Hopkins Verbal Learning Test-Revised (HVLT-R*; Brandt & Benedict, 2001): A brief test of verbal learning, recall, and recognition. Participants are read a word list over 3 learning trials and are asked to recall as many words as possible after a 25-minute delay. Normative data are available for ages 16-92. Alternate forms are used for repeat administrations to curtail practice effects.

- *Trail Making Test Parts A and B (TMT-A, TMT-B*; Reitan, 1958): The TMT is a timed sequence of tests that requires participants to connect a series of circles in a particular sequence. TMT-A gauges visual

attention/ processing speed, and TMT-B gauges task-switching ability. Normative data are available for individuals ages 18-89 (Tombaugh, 2004). This test is an optional addition for participants who are able to engage, as administration via telehealth may not be feasible for all participants.

- *Wechsler Adult Intelligence Scale- Fourth Edition (WAIS-IV) Digit Span* (Wechsler, 2008): A brief verbal attention test. Participants are presented with a sequence of digits and asked to repeat them forward and backward.

- *Behavioral Health Measure-20* (BHM-20; Kopta & Lowry, 2002): A brief measure of emotional distress and life functioning, normed for use in primary care (Bryan et al., 2014). It consists of 3 subscales that measure general well-being, MH symptoms, and life functioning. The 4-item life functioning subscale (which evaluates work/ school and relationship functioning, as well as general quality of life) will be administered during each session attended during the open trial for routine outcome monitoring

- *Alcohol Use Disorders Identification Test (AUDIT;* Bradley et al., 2007): A measure of the frequency and severity of alcohol intake over the past year included in VA's Mental Health Assistant package.

- *Brief Addictions Monitor-Revised (BAM-R;* Cacciola et al., 2013)*:* A 17-item measure of substance misuse and associated functional impairment included in VA's Mental Health Assistant software package.

- *Pain Symptom Survey (PEG;* Krebs et al., 2009): A 3-item pain assessment that has been validated for use in VA patients. Respondents are asked to report their average level of pain, the average impact of pain on their ability to enjoy life, and the average level of interference on daily activities on a scale of 0 to 10.

- *Patient Global Impressions of Change (PGIC;* Hurst & Bolton, 2004): The PGIC is a 7-point scale that asks patients to rate their overall impression of response to treatment. Ratings range from "no change" to "a great deal better."

- *Client Satisfaction Questionnaire* (*CSQ*; Larsen et al., 1979): A brief survey of client experiences and satisfaction in a therapy program.

- *World Health Organization Quality of Life - BREF (WHOQOL-BREF*; WHOQOL Group, 1998): A 26-item abbreviated version of the full-length WHOQOL (WHO, 1998) measure that evaluates disability and quality of life in several different domains such as social relationships, physical and MH, and satisfaction with person-environment interactions.

- General Self-Efficacy Scale (GSES; Schwarzer & Jerusalem, 1995): A 10-item measure of subjective self-efficacy in general life areas.

- Qualitative Interview: A brief semi-structured interview designed to gather patient feedback on EPST at the conclusion of treatment. E-PST participants will be asked to provide details on their satisfaction with the treatment experience, acceptability of treatment components, perceived benefits of treatment, and reasons for treatment completion and/ or dropout. A tentative interview schedule is included as an attachment.

c) Feasibility data will be internally monitored. Because feasibility is a study aim, missing items/ assessments and alterations in scheduling will not be reported as protocol deviations, but will be treated as specific study data points. Examples of evaluation metrics include:

- *Feasibility of recruitment statistics*: the relative proportion of Veterans excluded per pre-screening criteria *vs*. screen-eligible Veterans; the relative proportion of screen pass *vs*. screen failures; reasons for screen failures; the number of participants enrolled per week; total time to sample accrual; and the proportion of the intent-to-treat sample with clinically-significant depression, and/or PTSD.

- *Feasibility of retention statistics*: the number of sessions attended per participant; mean and range of number of sessions attended overall; the relative proportion of participants who complete all six possible sessions *vs*. drop out of treatment; and reasons for treatment completion and dropout (as measured by qualitative interview described above).

- *Feasibility of measurement statistics*: completion rates, time estimates for each study measure and homework assignment, and recording participant questions, comments (e.g., requests for clarification, level of burden, items left blank).

- *Patient-level treatment fidelity statistics*: Veteran rates of completion of at-home assignments (e.g., Veterans are asked to practice specific E-PST and compensatory skills, record practice).

- *Therapist-level feasibility and fidelity indicator statistics:* training required for study therapist(s) (i.e., time, intensity); session length; therapist protocol adherence (i.e., proportion of essential actions completed on a fidelity checklist); remedial actions required (i.e., frequency, type); and time required to complete review of session tapes and rating forms. Rating forms will be revised to use for therapist training and supervision purposes, with content coinciding with the E-PST intervention manual (e.g., session content, coverage, frequency, and duration).

Phase 2 Procedures.

Chart Pre-Screening. Study staff will review VISN2 primary care clinic lists for Veterans who have mTBI-related diagnoses listed in their EMR data (e.g., problem lists, corresponding ICD-9 or ICD-10 diagnostic codes); meet the age, service-era, and primary care enrollment criteria; and whose EMRs do not include any obvious evidence of exclusion criteria listed above. Recruitment letters and informed consent summaries will then be sent to veterans who pass the pre-screening procedure.

Recruitment Phone Calls. Veterans who pass pre-screening procedures and who do not opt-out will be contacted by phone to discuss the study and gauge interest. Interested candidates will then be scheduled for a verbal consent appointment and baseline assessment.

Screening/ Baseline Assessment & Selection. The written informed consent summary will be reviewed with candidates. Candidates will have a copy of the consent summary in-hand as they review materials with staff. Veterans who provide verbal consent will be formally screened for eligibility using the T1 measures outlined above.

Randomization. Following completion of the T1 assessment, eligible participants will be randomized in equal proportions to the test (E-PST) or control using a stratified permuted block design. Block designs ensure treatment balance of participants by randomly assigning the same number of participants to each treatment condition within blocks (e.g. ABBA, ABAB, etc.). A stratified design ensures treatment balance across 1 or more prognostic factors. We plan to implement a stratified permuted block design using blocks of size 4 within low and high levels of the baseline psychological distress as measured by the BSI-18: 1) “mild to moderate” (BSI-18 GSI T-score 54-62); and 2) “severe” (BSI-18 GSI T-score ≥ 63). Our block design maintains treatment balance within levels of baseline psychological distress while ensuring that the overall imbalance is not too great. Since we expect that an overall small number of female participants will be enrolled in the RCT, the treatment groups might be imbalanced by gender (i.e., because randomization is more effective with larger *n*’s). To account for this possible gender imbalance, we will also equalize the treatment groups according to gender, which will minimize the chance of gender confounding the treatment effect.

Table 2. Phase 2 Assessment Schedule

Measure	Chart Pre-Screen	T1	Mid-Intervention	T2	T3
Chart Pre-Screening Tool	●				
Demographic Survey		●			
Ohio State Traumatic Brain Injury Identification Method-Short Form (OSU TBI-ID)		●			
Neurobehavioral Symptom Inventory (NSI)		●		●	●
Brief Symptom Inventory-18 (BSI-18)		●		●	●
Patient Health Questionnaire-9 (PHQ-9)		●		●	●
PTSD Checklist for DSM-5 (PCL5)		●		●	●
Coronavirus Anxiety Scale (CAS)		●		●	●
Applied Cognition-General Concerns-Short Form (ACGC-8a)		●		●	●
Applied Cognition-Abilities-Short Form (ACA-8a)		●		●	●
Hopkins Verbal Learning Test-Revised (HVLT-R)		●		●	●
Trail Making Test Parts A and B (TMT-A, TMT-B)		●		●	●
Wechsler Adult Intelligence Scale- Fourth Edition (WAIS-IV) Digit Span		●		●	●
Alcohol Use Disorders Identification Test (AUDIT)		●		●	●
Brief Addictions Monitor-Revised (BAM-R)		●		●	●
Pain Symptom Survey (PEG)		●		●	●
World Health Organization Quality of Life - BREF (WHOQOL-BREF)		●		●	●
General Self-Efficacy Scale (GSES)		●		●	●
Patient Global Impressions of Change (PGIC)				●	●
Client Satisfaction Questionnaire (CSQ)				●	●
Qualitative Interview				●	
Behavioral Health Measure-20 (BHM-20) Life Functioning Subscale			●		
Feasibility Metrics		●	●	●	●

Intervention. The test (E-PST) or control intervention will be administered to participants by a trained, therapist (Master's level-equivalent or higher). Psychological distress data (BHM-20 life-functioning subscale) will be collected during treatment sessions as part of routine outcome monitoring. Sessions will be audio-recorded for training and supervision purposes.

- *Test intervention (E-PST).* E-PST consists of 6, approximately 30-minute sessions focused on: a) reducing psychological distress by enhancing specific problem-solving skills; and b) developing specific cognitive and behavioral skills that target common cognitive inefficiencies reported in Veterans with mTBI history. The current therapist guide and participant workbook are included with this submission. We anticipate that sessions will be scheduled approximately biweekly but will afford flexibility in scheduling to aid in our assessment of feasibility of this planned approach.

- Control intervention (Healthy Living Messages). Healthy Living Messages includes up to six, 15 to 30-minute sessions of a supportive intervention that includes health coaching and symptom monitoring. Each of the healthy living messages included in this condition are evidence-based, already available for use in VA (Department of Veterans Affairs, 2017) and consistent with primary care goals. In order to deliver these messages as part of the attention control condition, 6 of 9 possible messages were selected for control sessions: 1-*Be Involved in Your Health Care*, 2-*Get Recommended Screening Tests and Immunizations*, 3-*Be Physically Active*, 4-*Eat Wisely*, 5-*Strive for a Healthy Weight*, and 6-*Be Safe.* One message (*Manage Stress*) was excluded because materials from VA's PST program are directly referenced; two others (*Limit Alcohol* and *Be Tobacco Free*) were excluded as they might not apply uniformly to participants. We anticipate that sessions will be scheduled approximately biweekly but will afford flexibility in scheduling to aid in our assessment of feasibility of this planned approach.

Patient Outcome Measurement. Post-intervention (T2) and follow-up assessments (T3) will be completed. At each study time point, participants will complete a series of common MH self-report measures and a standard battery of brief cognitive measures. Participants will be encouraged to complete each assessment regardless of whether they choose to continue attending intervention sessions or discontinue treatment at any point. At T2, E-PST participants will be asked to complete a brief qualitative interview to query their experiences with the intervention. Interviews will be recorded in order to allow for quality assurance efforts by study staff working under supervision of the PI.

Payment. Participants will be provided a maximum $150 stipend for completing study assessments according to the following schedule: $35 for T1; $50 for T2; $35 for T3; and a $30 bonus to those who complete all assessments.

Risk Management. RA's will monitor for signals of clinical need at study assessment time points (e.g., participant statements of concern, ratings of suicidal ideation), and study therapist(s) will monitor such signals at intervention visits. New or worsening ratings that pertain to suicidal ideation will be addressed using the attached risk management procedure. This procedure has been successfully implemented in several prior studies. Adverse events will be monitored and reported according to institutional protocols.

Phase 2 Data Analysis

As noted above, this study is designed to achieve 3 goals: a) estimate a preliminary ES for our primary outcome measure (i.e., psychological distress as measured by the BSI-18); b) determine the feasibility of the assessment plan; and c) establish the feasibility of recruitment and retention in order to plan for a future multisite efficacy trial. We will employ a sequential explanatory mixed-methods approach (i.e., quantitative data collection, followed by qualitative data collection) to address these research questions.

a) Quantitative Data Analysis:

Primary analyses will focus on detecting post-treatment change in psychological distress as measured by the BSI-18's GSI T-score. We will test the preliminary hypothesis that E-PST (*vs*. control) will be associated with reduced psychological distress as measured by BSI- 18. BSI-18 data will be described with means, standard deviations and CIs at each time point and condition. To show central tendency, variation and potential trends over time, means and 95% CIs will be plotted across time for each condition. Additional line plots connecting means across time will overlay the CIs to help illustrate trends. To assist in developing a larger trial, an ES will be calculated at post treatment to describe the standardized difference between conditions. The ES will be calculated by dividing the difference in the mean BSI-18 score between conditions at post-treatment by the pooled standard deviation. Then, the upper limit of a one-sided 80% CI under the null hypothesis of no difference between groups (ES = 0) will be compared to the observed ES by using the non-central *t*-distribution method discussed by Cumming & Finch (2001). We opted for a one-sided CI because we are interested in progressing toward a larger trial based on some evidence of effectiveness. The lower end of the CI is not informative in this pilot as the progression towards a larger trial would not occur even if the control condition was marginally more effective than E-PST. While a standard 95% CI provides greater coverage of the population difference, it also requires a larger sample of patients and associated increases in cost and time. Therefore, we propose an 80% interval that provides reasonable assurance of making the correct decision to move on to a larger trial (Cocks & Torgerson, 2013) While primary analyses focus on psychological distress, post-treatment ES's will also be calculated for secondary outcomes, and a correlation matrix will be built to describe the degree of correspondence among all outcomes. Our goal is to calculate a preliminary ES estimate that is representative of the true population using the ITT principle. Thus, all patients who are complete a baseline assessment and are randomized will be included in our analysis. We plan to utilize two sophisticated methods with the first being Maximum Likelihood Estimation (MLE), and Multiple Imputation (MI) as the second. A multi-level model (MLM) will be developed using MLE to calculate means and standard errors that will be used in the formation of an ES. MLM provides unbiased parameter estimates under a missing at random (MAR) assumption without resorting to listwise deletion of patients due to missing data. While the validity of MAR cannot be fully determined from the data, the reason for the missingness may depend on observed co-variates. If the latter case is true, MI (see below) is a viable and powerful option for imputing

missing values and satisfying the MAR assumption. We plan to conduct a sensitivity analysis to determine the effect of the missingness by comparing MI to MLE estimation via MLM.

Evaluation of feasibility will focus primarily on descriptive statistics. For instance, means and standard deviations will be calculated for time estimates for each primary and secondary measure and homework assignment. The study team will also record and review frequencies of completed vs. incomplete measures, and any relevant participant comments that pertain to lack of clarity or undue burden of measures. Recruitment over time will be displayed by plotting the cumulative number of patients enrolled into this study and compared to the anticipated rate of recruitment. Any intervention elements with relatively low fidelity will subsequently inform the future training curriculum that will be designed for EPST therapists in our full-scale RCT.

Qualitative feedback on experiences with E-PST (i.e., acceptability treatment satisfaction) and reasons for completion/ dropout will be analyzed via rapid qualitative analysis (Beebe, 2001). Rapid qualitative analysis will facilitate our ability to quickly incorporate patient feedback in planning our future RCT.

Phase 2 Sample Size Justification

a) *Quantitative Methods*: Using previously published ES data on the effect of PST in mTBI10 and the method described by Cocks and Torgerson (2013) we calculated the sample size to adequately employ an 80% one-sided CI to estimate the upper limit of the ES under the null hypothesis of no difference (ES=0) between conditions. The one-sided CI was calculated so that 32 patients allow for the upper limit of an 80% CI to exclude 0.3, or a difference of 0.3 standard deviations, between conditions. While 32 total participants are required to meet these parameters of CI estimation, we will seek to randomize a total of 38 Veterans to increase the precision of our estimate while accounting for the possibility of missed visits (see data attrition section below).

b) *Qualitative Methods:* Diversity in opinion is paramount to promoting cultural and content validity, as well as comprehensibility of our newly-generated intervention. A sample of at least 12 is typically required to achieve saturation of opinions in qualitative work (Guest et al., 2006). Therefore, our maximum enrollment of 19 Veterans per group will provide an adequate mix of feedback and protect against loss of critical information due to attrition.

Phase 2 Data Attrition

Because E-PST is being adapted and initially tested over this line of funding, and delivered to a niche population of Veterans, we do not have a precise estimate of an expected level of attrition for this pilot trial. However, the evaluation of study feasibility, including that of recruitment and retention, is a core aspect of this pilot RCT. Therefore, data on participant dropout and missing data will be collected, analyzed, and figured into our plans for the future Merit application. As a point of reference, we calculated rates of attrition for recent intervention trials led by co-investigators and approximated 6% participant attrition over a 12-week window, and just 20% attrition over 6-months. Conservatively, the latter figure (20%) was selected as an expected upper limit of data attrition for planning the present pilot RCT. Because our proposed ITT analyses account for the possibility of missing data, we do not estimate that this will substantively hinder our analytic plan.

Phase 2 Plan to Address Missing Data

We will use MI to manage missing quantitative data (Berglund & Heeringa, 2014). In order to predict missing values, regression models are used in the imputation process on existing data. The predicted values, called imputes, replace the missing values, thus resulting in a fully analyzable data set. This process is performed multiple times, resulting in many data sets; each data set is then analyzed to produce multiple sets of results. The results are then summarized to produce a single solution. The advantage of MI over other methods (e.g., last observation carried forward, mean substitution, expectation maximization) is that it preserves associations with other variables, adds variability during the imputation process, and accounts for variability due to multiple imputes, which results in efficient and unbiased parameter estimates (Berglund & Heeringa, 2014). Valid critiques of MI pertain to the variables used to fill-in the missing values, which may differ among analysts and can lead to biased parameter estimates (Kim et al., 2006). To address this criticism, we plan to use

VanBuuren's (2012) recommendations as well as practical guidelines in our imputation model. Our guideline encompasses inclusion of all items from the respective measure, variables that are correlated with the analysis variable, and variables that predict missingness.

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Official Title: Enhanced Problem-Solving Training (E-PST) to Improve Recovery From mTBI

ClinicalTrials.gov ID: NCT03759223

Document date: 3-11-20

Research Informed Consent Document

Department of Veterans Affairs

VA Western New York Healthcare System, Buffalo, New York

PARTICIPANT NAME:	**DATE:**
PRINCIPAL INVESTIGATOR:	*Paul King, PhD*
TITLE OF RESEARCH STUDY:	*Open Trial of Enhanced Problem-Solving Training*

SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether or not to volunteer for a research study being funded by the VA Office of Rehabilitation Research and Development service about a new behavioral health treatment that our team developed to improve recovery after a concussion. This summary is intended to give you key information to help you decide whether to participate. We have included detailed information after this section. Ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn what Veterans think about this treatment. Your participation in this research will last about 12 weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may choose to volunteer for this study if you experienced a concussion in the past and would like to: a) learn more about concussions and recovery; b) learn new organizational and memory skills; or c) learn new stress, mood, and symptom management skills.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

This study will require you to attend up to 6 in-person or telehealth treatment appointments at the VA Western New York Healthcare System. You should not participate if you will not be available to attend these appointments. We also ask that you avoid using other mental health therapy during the study. You may continue taking any psychiatric medications you are prescribed but avoid changing the dose during the study. You should not participate if you feel that this treatment would interfere with your mental health care. For a complete description of alternate treatments, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

It is important to tell the study team if you are taking part in another research study.

IRB Approval Stamp

Western New York VA Health Care System (WNYHS) IRB
Effective Date: April 7, 2021
Expiration Date: April 23, 2022

Research Informed Consent Document

Department of Veterans Affairs

VA Western New York Healthcare System, Buffalo, New York

PRINCIPAL INVESTIGATOR: *Paul King, PhD*

TITLE OF RESEARCH STUDY: *Open Trial of Enhanced Problem-Solving Training*

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Paul King, PhD of the VA Center for Integrated Healthcare, located at the VA Western New York Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is: 716-862-6038.

DETAILED CONSENT

WHAT IS THE PURPOSE OF THIS STUDY?

Our research team has developed a new behavioral health treatment to help Veterans recover from a concussion. Before we develop this treatment further, we want to learn what Veterans think of it. Because this treatment is using a new combination of cognitive and behavioral skills training, Veteran feedback is needed to help us understand aspects of the treatment that might work well, as well as those that we should change.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 2 years. Your individual participation in the project will take about 12-14 weeks.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 40 people will participate in this research study at the VA Western New York Healthcare System.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

This study involves the following research activities:

a) Completion of a brief interview and a series of surveys. These activities will help us determine if you are eligible to participate. This will require about 30 minutes.

b) Attendance and participation in up to 6 in-person or telehealth treatment appointments. Appointments will last for about 30 minutes each. Aspects of this treatment have been used in usual clinical care before. This research is testing whether Veterans find this new combination to be acceptable and useful.

c) Completion of a brief interview after each treatment appointment. These interviews are to learn about your experiences during treatment. They will require about 15 minutes each.

d) Completion of a series of surveys after your last treatment appointment, that will take about 10-15 minutes.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

During the rest of today's appointment, which will take about 30 minutes, a study staff member will ask you to complete a brief interview about any head injuries you may have experienced. Then, we will ask you to complete some questionnaires and surveys regarding:

Research Informed Consent Document

Department of Veterans Affairs
VA Western New York Healthcare System, Buffalo, New York

PRINCIPAL INVESTIGATOR:	*Paul King, PhD*
TITLE OF RESEARCH STUDY:	*Open Trial of Enhanced Problem-Solving Training*

- Your background, demographics, and health care use
- Symptoms you may have experienced after a head injury
- General stress you may be experiencing
- Symptoms related to your mood or traumatic experiences you may have had

Our team will then review your responses to determine if you are eligible to proceed in the study. We will let you know once we have reviewed your responses.

If you are eligible, you will be asked to participate in up to 6 treatment appointments with staff from the VA Western New York. This treatment teaches cognitive and behavioral skills to improve problem-solving and stress management, and ways to manage symptoms that sometimes occur following a concussion. Appointments will last about 30 minutes each and be scheduled about once every one to two weeks. We will work with you to accommodate your schedule if need be. If we are not able to schedule your first appointment today, a member of our team will follow-up with you by phone.

During treatment appointments, you and your study therapist will discuss any problems or symptoms you may be experiencing, and ways to address them. A brief checklist will be used to help track how you are doing. Appointments will be audio-recorded for supervision and training purposes.

Following each treatment appointment, you will be asked to participate in a short interview so that you can share your opinions about the treatment. These interviews can be completed in-person with study staff after each treatment appointment, or else later by phone. We expect that interviews will take about 15 minutes each. Interviews will be audio-recorded for data quality control purposes.

After your final treatment appointment, we will ask you to take about 10-15 minutes to complete some of the same surveys mentioned above.

We ask your permission to review your medical record to identify any treatment that you may have received for your concussion or other related medical or mental health diagnoses. Your privacy will be carefully protected (see below). Your own reports and the information we get from your medical records are important ways of tracking study outcomes.

While you are enrolled in the study, we will monitor your chart for any new medical or mental health developments that are relevant to your safety or eligibility to continue participating. We will monitor your progress while you are receiving the treatment. We will alert you about any problems related to the treatment if they occur. Your regular medical providers (e.g., primary care providers) will continue to provide and oversee your medical care whether you are enrolled in the study or not.

While participating in this research study, we ask the following:

- Complete surveys and interviews as instructed. You are free to skip any questions that you would prefer not to answer.

Research Informed Consent Document

Department of Veterans Affairs

VA Western New York Healthcare System, Buffalo, New York

PRINCIPAL INVESTIGATOR:	*Paul King, PhD*
TITLE OF RESEARCH STUDY:	*Open Trial of Enhanced Problem-Solving Training*

• Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.

• Do not start a new mental health treatment or change your psychiatric medication while you are in the study. After the final treatment and survey appointment(s), you and your health care providers can make any changes you feel are necessary. If you would rather seek other mental health services instead of completing the study, please let us know. We will help make referrals that may be necessary.

• Do not take part in any other research project without approval from the investigators. This is to protect you from possible injury and to prevent treatment interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

• Ask questions about the study or procedures when you think of them.

The surveys, interviews, and treatment described above will be performed for research purposes only by members of the study team. Dr. King (a licensed psychologist) will oversee the study team.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

• **Surveys and interviews.** Some people become uncomfortable at being asked questions about their physical and mental health. If, for any reason, you wish not to answer specific questions, or you wish to terminate the appointment, you will be able to do so. You will also be able to take breaks as needed.

• **Treatment appointments.** There are no known risks associated with this treatment. While aspects of the treatment have been used during routine care, to our knowledge, they have not been used in the same order or format that we have proposed. It is possible that you might not feel this treatment is a good fit for you, or that you would prefer to seek other services. If that is the case, please let us know and we will help make other referrals. Other possible risks may include feeling uncomfortable when talking about sources of life stress, mood, and symptoms you may be experiencing. Your study therapist will work with you if you experience any discomfort. In the event of a mental health crisis or personal emergency, licensed mental health professionals and mental health emergency services are available to assist you.

• **Scheduling and logistics.** You may find it inconvenient to travel to the hospital for treatment appointments, or to make time for telehealth or phone contact. We will make efforts to arrange treatment appointments and other contact at a time that works for your schedule.

• **Audio recording of treatment appointments and interviews.** Some people feel uncomfortable knowing that their voices will be recorded. This recording is necessary for the supervision and training of study therapists, and to ensure quality control for interview data. The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recording(s) to be made of you by the study team while you are participating in this study.

Research Informed Consent Document

Department of Veterans Affairs
VA Western New York Healthcare System, Buffalo, New York

PRINCIPAL INVESTIGATOR:	*Paul King, PhD*
TITLE OF RESEARCH STUDY:	*Open Trial of Enhanced Problem-Solving Training*

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded and may rescind your consent for up to a reasonable time before the voice recording is used.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include

- Learning more about concussions and recovery
- Learning new organizational and memory skills
- Learning new stress, mood, and symptom management skills

It is also possible that the information we get from this study might help others with your condition(s).

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If this is your decision, there are other choices such as continuing with your current treatment or medication regimen or seeking other care. Options for other care may include seeking behavioral health services to help manage life stress or symptoms of depression or post-traumatic stress; cognitive rehabilitation services to find new thinking and organizational strategies; or talking with your medical providers about medications to help manage headaches or other physical health concerns you may have.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Information obtained about you in this study will be treated as confidential and will be securely stored. Hard copies of study data will be stored in a locked file cabinet at the VA Western New York Healthcare System. Electronic data will be stored on a secure VA network.

We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are. Only approved study staff or the inspectors outlined below will have access to your identifiable information, including but not limited to:

- **The VAWNYHS Medical Center Research and Development Committee and its Subcommittees**
- **VAWNYHS Research Staff and Research Compliance Officer**
- **The Office for Human Research Protections (OHRP)**
- **VA Office of Research Oversight (ORO)**

Research Informed Consent Document

Department of Veterans Affairs
VA Western New York Healthcare System, Buffalo, New York

PRINCIPAL INVESTIGATOR:	*Paul King, PhD*
TITLE OF RESEARCH STUDY:	*Open Trial of Enhanced Problem-Solving Training*

- **Office of the Inspector General (OIG)**

The study team may include additional information about your study participation in your medical record if it becomes necessary. For instance, if you opt for or require additional mental health treatment during or following the study or experience a personal crisis. It is possible that additional disclosures may be required by law, for instance if evidence of elder abuse or child abuse emerges, or evidence emerges that you pose a danger to yourself or another person.

Identifiers might later be removed from the identifiable private information that are collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical and mental health history, drug or alcohol use or treatment, and behavioral health treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. King and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Research Informed Consent Document

Department of Veterans Affairs

VA Western New York Healthcare System, Buffalo, New York

PRINCIPAL INVESTIGATOR: *Paul King, PhD*

TITLE OF RESEARCH STUDY: *Open Trial of Enhanced Problem-Solving Training*

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I BE PAID FOR PARTICIPATING?

You can receive up to $75 for participating in this study:

- You will receive $15 for completing the interview and surveys that will help us determine if you are eligible.

- You will receive $10 for each interview you complete following a treatment appointment. If you complete all 6 interviews, you will receive $60.

Should you choose to withdraw, or be withdrawn from the study, you will be paid for the portion of procedures you complete.

Payments will be scheduled following each completed study visit, and will be made by check, direct deposit, or debit card. Identifying information, including your Social Security Number, is needed to make these payments. If you are paid by check, those payments will be generated from VA Western New York. Direct deposit or debit card payments will be processed from a central location. Study staff will review these options with you at the end of today's assessment and assist with processing your payment.

An Internal Revenue Service (IRS) Form 1099 may be generated as a result of your payment. This payment is considered taxable income. If you owe money to the government, this payment may be to satisfy the debt.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA Western New York Healthcare System) will provide necessary medical treatment at no cost to you for research related injury in accordance with applicable federal regulations (38 CFR 17.85). No additional compensation is available should an injury occur.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call Dr. King at 716-862-6038 during normal business hours. Emergency and ongoing medical treatment will be provided as needed.

Research Informed Consent Document

Department of Veterans Affairs

VA Western New York Healthcare System, Buffalo, New York

PRINCIPAL INVESTIGATOR:	*Paul King, PhD*
TITLE OF RESEARCH STUDY:	*Open Trial of Enhanced Problem-Solving Training*

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary. Refusing to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you are also a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress.

You may withdraw from the study at any time without any penalty or loss of benefits.

If you withdraw, you will still receive the same standard of care that otherwise would have received. Our team may continue to review and use data that were collected prior to your withdrawal but will not collect further information.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION (Include if applicable)

Even if you want to stay in the study, there may be reasons we will need to take you out of it. For example, you may be taken out of this study if:

- You are not deemed eligible to participate following completion of today's interview and surveys.
- New circumstances arise that make you ineligible to continue in the study. For example, if you require new mental health care, including emergency mental health services, or changes in mental health medication during the study.
- We find out it is not safe or in your best interests for you to stay in the study. For example, if your physical or mental health worsens.
- You are not coming for your study visits when scheduled or completing study tasks as needed.
- The funding for the study is stopped.

If we feel that it is necessary for you to withdraw from the study, we will let you know. We are not aware of any adverse effects of discontinuing this treatment early. We will instruct you how to stop the treatment and help make referrals for any necessary follow-up mental health care.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions, complaints, or concerns about the research or related matters, please contact one of the following individuals:

- Dr. King, Principal Investigator, at 716-862-6038.
- The Research Compliance Officer, at 716-862-3218.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Human Research Protections

Research Informed Consent Document

Department of Veterans Affairs

VA Western New York Healthcare System, Buffalo, New York

PRINCIPAL INVESTIGATOR: *Paul King, PhD*

TITLE OF RESEARCH STUDY: *Open Trial of Enhanced Problem-Solving Training*

Program Coordinator at 716-862-6523 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA AND RE-CONTACT

Data collected as part of this study may be retained for future research. Any relevant hard copies of study data will be stored in a locked file cabinet in the office of the VA Center for Integrated Healthcare, located at the VA W stern New York Healthcare System. Relevant electronic data will be stored on a secure VA network.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. King, or his designee, has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

I voluntarily consent to participate in this study. I have been told that I will receive a copy of this consent form.

I agree to participate in this research study as has been explained in this document.		
Participant's Name	Participant's Signature	Date
Participant's DOB	Participant's last 4 Social Security	

Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Official Title: Enhanced Problem-Solving Training (E-PST) to Improve Recovery From mTBI

ClinicalTrials.gov ID: NCT03759223

Document date: 7-13-21

Study Overview

Principal Investigator: Paul R. King, PhD

Title of Research Study: Open Trial of Enhanced Problem-Solving Training

Sponsor: This study is being sponsored by the VA Rehabilitation Research and Development service. There are no conflicts of interests to report.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether or not to volunteer for a research study being funded by the VA Rehabilitation Research and Development service about behavioral health treatments to improve recovery after a concussion. This summary is intended to give you key information to help you decide whether to participate. We have included detailed information after this section. Ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

This study will compare two behavioral treatment options. By doing this study, we hope to learn whether a new brief treatment is better than another available option. Your participation in this research will last about 26 weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may choose to volunteer for this study if you experienced a concussion in the past. Your participation in this study will help us understand what type of integrated primary care approaches are helpful to veterans who have experienced a concussion. All study appointments can be completed over the phone or through video telehealth. In-person appointments will be offered when it is safe to do so.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

This study will require you to attend up to 9 study appointments with staff from the VA Western New York Healthcare System. You should not participate if you will not be available to attend these appointments. We also ask that you avoid using other mental health therapy during the study. You may continue taking any psychiatric medications you are prescribed but avoid changing the dose during the study. You should not participate if you feel that this treatment would interfere with your mental health care. Responding to questions during study assessments may cause distress. Examples of distress include anxiety symptoms (e.g., shortness of breath, fear) or feeling down. For a complete description of risks, refer to the detailed summary. If you choose not to participate, study staff can refer you to regular VA services for any health concerns you have. For a complete description of alternate treatments, refer to the detailed summary below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. It is important to tell the study team if you are taking part in another research study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Paul King, PhD of the VA Center for Integrated Healthcare, located at the VA Western New York Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is: 716-862-6038.

DETAILED SUMMARY

WHAT IS THE PURPOSE OF THIS STUDY?

This study compares two types of brief, primary care-based behavioral treatments. With this research, we hope to learn if one treatment is more effective than the other. Both treatments involve meeting with a behavioral health provider up to 6 times over approximately 12 weeks.

- The first treatment is called Enhanced Problem-Solving Training (E-PST). This treatment involves a combination of cognitive and behavioral skills training.

- The second treatment is called Healthy Living Messages. This treatment involves health coaching for common concerns among primary care patients.

Participants will be randomly assigned to one of these two treatments. You have a 50/50 chance of being in either treatment, like the flip of a coin.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 3 years. Your individual participation in the project will take about 26 weeks.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 127 people will participate in this research study at the VA Western New York Healthcare System.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

This study involves the following research activities:

a) Completion of a brief interview and a series of surveys. These activities will help us determine if you are eligible to participate. This will require about 75 minutes.

b) Attendance and participation in up to 6 treatment appointments, which will require about 15-30 minutes each.

c) Completion of a series of surveys and interviews after your last treatment appointment, that will take about 70-90 minutes.

d) Completion of a series of surveys about 3 months after your last treatment appointment, that will take about 70 minutes.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

During the initial appointment, which will take about 75 minutes, a study staff member will ask you to complete a brief interview about any head injuries you may have experienced. Then, we will ask you to complete some questionnaires and surveys regarding:

- Your background, demographics, and health care use

- Symptoms you may have experienced after a head injury

• General stress you may be experiencing

• Symptoms related to your mood or traumatic experiences you may have had

Our team will then review your responses to determine if you are eligible to proceed in the study. We will let you know once we have reviewed your responses.

If you are eligible, you will be assigned to one of the two treatment conditions using a process like flipping a coin. You will then be asked to participate in up to 8 additional appointments with staff from the VA Western New York as outlined above. We will work with you to accommodate your schedule if need be. If we are not able to schedule your first treatment appointment today, a member of our team will follow-up with you by phone.

During treatment appointments, you and your study therapist will discuss ways you may address common problems or symptoms you may be experiencing. A brief checklist will be used to help track how you are doing. Appointments will be audio-recorded for supervision and training purposes.

After your final treatment appointment, we will ask you to take about 75-90 minutes to complete the same surveys and interviews mentioned above. There will also be an additional follow-up assessment 3 months later that will take about 70 minutes to complete.

We ask your permission to review your medical record to identify any treatment that you may have received for your concussion or other related medical or mental health diagnoses. Your privacy will be carefully protected (see below). Your own reports and the information we get from your medical records are important ways of tracking study outcomes.

While you are enrolled in the study, we will monitor your chart for any new medical or mental health developments that are relevant to your safety or eligibility to continue participating. We will monitor your progress while you are receiving the treatment. We will alert you about any problems related to the treatment if they occur. Your regular medical providers (e.g., primary care providers) will continue to provide and oversee your medical care whether you are enrolled in the study or not.

While participating in this research study, we ask the following:

• Complete surveys and interviews as instructed. Please know that answers to certain questions are required to determine your eligibility to participate. You are however free to skip any questions that you would prefer not to answer.

• Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.

• Do not start a new mental health treatment or change your psychiatric medication while you are attending study treatment sessions. If you would rather seek other mental health services instead of completing the study, please let us know. If you would like to initiate other mental health services after completing your final treatment session, please also let us know. We will help make referrals that may be necessary.

• Do not take part in any other research project without approval from the investigators. This is to protect you from possible injury and to prevent treatment interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

• Ask questions about the study or procedures when you think of them.

The surveys, interviews, and treatment described above will be performed for research purposes only by members of the study team. Dr. King (a licensed psychologist) will oversee the study team.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks listed. Rare, unknown, or unexpected risks also may occur.

• **Surveys and interviews.** Some people become uncomfortable at being asked questions about their physical and mental health. If, for any reason, you wish not to answer specific questions, or you wish to terminate the appointment, you will be able to do so. You will also be able to take breaks as needed.

• **Treatment appointments.** There are no known risks associated with either treatment in this study. While aspects of each treatment have been used during routine care, to our knowledge, they have not been used in the same order or format that we have proposed. It is possible that you might not feel this treatment is a good fit for you, or that you would prefer to seek other services. If that is the case, please let us know and we will help make other referrals. Other possible risks may include feeling uncomfortable when talking about sources of life stress, mood, and symptoms you may be experiencing. Your study therapist will work with you if you experience any discomfort. In the event of a mental health crisis or personal emergency, licensed mental health professionals and mental health emergency services are available to assist you. In the event that you report intention or plan to harm yourself, or become suicidal, a warm transfer to a crisis representative may take place.

• **Scheduling and logistics.** You may find it inconvenient to make time for study contact. We will make efforts to arrange treatment appointments and other contact at a time that works for your schedule.

• **Audio recording of treatment appointments and interviews.** Some people feel uncomfortable knowing that their voices will be recorded. This recording is necessary for the supervision and training of study therapists, and to ensure quality control for study data.

By providing your consent to participate in this study, you voluntarily and without separate compensation authorize voice recording(s) to be made of you by the study team while you are participating. You will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded and may rescind your consent for up to a reasonable time before the voice recording is used.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include:

• Learning more about concussions and recovery

• Learning new organizational and memory skills

• Learning new stress, mood, and symptom management skills

• Learning new health behaviors

It is also possible that the information we get from this study might help others with your condition(s).

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If this is your decision, there are other choices such as continuing with your current treatment or medication regimen or seeking other care. Options for other care may include seeking behavioral health services to help manage life stress or symptoms of depression or post-traumatic stress; cognitive rehabilitation services to find new thinking and organizational strategies; or talking with your medical providers about medications to help manage headaches or other physical health concerns you may have.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Information obtained about you in this study will be treated as confidential and will be securely stored. Hard copies of study data will be stored in a locked file cabinet at the VA Western New York Healthcare System. Electronic data will be stored on a secure VA network.

We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are. Only approved study staff or the inspectors outlined below will have access to your identifiable information, including but not limited to:

- **The VAWNYHS Medical Center Research and Development Committee and its Subcommittees**
- **VAWNYHS Research Staff and Research Compliance Officer**
- **The Office for Human Research Protections (OHRP)**
- **VA Office of Research Oversight (ORO)**
- **Office of the Inspector General (OIG)**

The study team may include additional information about your study participation in your medical record if it becomes necessary. For instance, if you opt for or require additional mental health treatment during or following the study or experience a personal crisis. It is possible that additional disclosures may be required by law, for instance if evidence of elder abuse or child abuse emerges, or evidence emerges that you pose a danger to yourself or another person.

Identifiers might later be removed from the identifiable private information that are collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I BE PAID FOR PARTICIPATING?

You can receive up to $150 for participating in this study:

- You will receive $35 for completing the interview and surveys that will help us determine if you are eligible.

- You will receive $50 for completing the interview and surveys after completing your final treatment session (post-test)

- You will receive $35 for completing the interview and surveys at your 3-month follow-up.

- You will receive a $30 bonus for completing all of these assessments.

Should you choose to withdraw, or be withdrawn from the study, you will be paid for the portion of procedures you complete.

Payments will be scheduled following each completed study visit, and will be made by check, direct deposit, or debit card. Identifying information, including your Social Security Number, is needed to make these payments. If you are paid by check, those payments will be generated from VA Western New York. Direct deposit or debit card payments will be processed from a central location. Study staff will review these options with you at the end of today's assessment and assist with processing your payment.

An Internal Revenue Service (IRS) Form 1099 may be generated as a result of your payment. This payment is considered taxable income. If you owe money to the government, this payment may be to satisfy the debt.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA Western New York Healthcare System will provide necessary medical treatment at no cost to you for research related injury in accordance with applicable federal regulations (38 CFR 17.85). No additional compensation is available should an injury occur.
If you should have a medical concern or get hurt or sick as a result of taking part in this study, call Dr. King at 716-862-6038 during normal business hours. Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary. Refusing to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you are also a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress.

You may withdraw from the study at any time without any penalty or loss of benefits.

If you withdraw, you will still receive the same standard of care that otherwise would have received. Our team may continue to review and use data that were collected prior to your withdrawal but will not collect further information.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Even if you want to stay in the study, there may be reasons we will need to take you out of it. For example, you may be taken out of this study if:

• You are not deemed eligible to participate following completion of our initial interview and surveys.

• New circumstances arise that make you ineligible to continue in the study. For example, if you require new mental health care, including emergency mental health services, or changes in mental health medication during the study.

• We find out it is not safe or in your best interests for you to stay in the study. For example, if your physical or mental health worsens.

• You are not coming for your study visits when scheduled or completing study tasks as needed.

• The funding for the study is stopped.

If we feel that it is necessary for you to withdraw from the study, we will let you know. We are not aware of any adverse effects of discontinuing this treatment early. We will instruct you how to stop the treatment and help make referrals for any necessary follow-up mental health care.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you would like more information about this study, please call [RA Name] at [RA Phone Number].

If you have any questions, complaints, or concerns about the research or related matters, please contact one of the following individuals:

• Dr. King, Principal Investigator, at 716-862-6038.

• The Research Compliance Officer, at 716-862-3218.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Human Research Protections Program Coordinator at 716-862-6523 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA AND RE-CONTACT

Data collected as part of this study may be retained for future research. Any relevant hard copies of study data will be stored in a locked file cabinet in the office of the VA Center for Integrated Healthcare, located at the VA W stern New York Healthcare System. Relevant electronic data will be stored on a secure VA network.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. King, or his designee, has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By providing your verbal consent, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. A copy of this summary has been provided to you.

For Research Staff Only:

- *Do you agree to participate in this study?*
- *Do we have your permission to contact you about future studies you may be eligible for?*