Research Protocol
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Title: Neurobehavioral Measurement of Substance Users in an Outpatient Treatment Setting
Principal Investigator: James M. Bjork, Ph.D.
Coordinator: James M. Bjork, Ph.D.

1. Purpose and Objectives:

This protocol does not include any administration of medication or other interventions. This protocol will record cognitive performance and decision-making behavior in Veterans who seek mental health services in the substance use disorder intensive outpatient program (IOP). The goal is to identify the neurobehavioral effects of a structured, brief cognitive-based psychotherapy currently being conducted in the IOP along with other supportive, unstructured, treatments. The benefit of this study will be to obtain a better understanding of neurobehavioral changes occurring from evidence-informed treatments.

Aim 1: To determine if measurable neurobehavioral function in the domains of problem solving, decision making, and motoric impulsivity is predictive of treatment success and adherence outcomes (e.g. Urinary Drug Screen/Breathalyzer Analysis results, appointment no shows, early drop out, recidivism).

Exploratory Aim: To determine if there are between group differences in neurobehavioral function as a result of treatment modality being received as standard of care in the substance use outpatient setting.

2. Background, Significance, and Scientific Rationale:

It is established that impulsivity is a tremendous risk factor for the development of addiction (Bickel et al., 2007) and for treatment failure (Loree, Lundahl, & Ledgerwood, 2015). Impulsivity is a multi-faceted trait that has been conceptually divided into a more decision-based domain and rapid “acting without thinking” motoric domain(Swann, Bjork, Moeller, & Dougherty, 2002), where greater impulsivity in both domains has been found in patients addicted to stimulants in particular (Ahn & Vassileva, 2016). Trait personality measures of impulsivity typically capture some elements of both domains and frequently correlate poorly with individual task metrics of impulsivity. Therefore, comprehensive assessment of cognitive change (as it may underlie improvements in mental perseverance and thus changes in substance use) should include objective behavioral measures of both decision-making and motoric impulsivity. The addition of focused neurocognitive tasks holds potential to *identify mechanisms* of psychotherapy effects, such as whether a structured cognitive behavioral therapy may reduce substance use by promoting mindful attention generally, or whether it influences future-orientation specifically.

There are currently multiple treatments being conducted in the IOP clinic as standard of care, with a particular psychotherapy of interest for this study being a brief, structured cognitive-based treatment, called the Mind Freedom Plan (MFP). This treatment is one of two treatments being administered, with the other being a supportive, unstructured treatment that is also provided as standard of care. The aim of the MFP treatment is to improve problem solving abilities, increase engagement in pleasurable activities, and teach the patient to identify and change maladaptive thoughts. Structured worksheets for each session have been developed for

the purpose of achieving these goals. An exploratory aim of the current study will be to identify whether there are neurobehavioral differences in subjects as a result of the treatment modality being conducted during their treatment regimen. This is novel due to the lack of studies previously examining neurobehavioral impulsivity tasks as a metric for exploring differences in treatment modality.

The VA has an increasing need for brief, efficacious interventions to assist Veterans in reducing alcohol and substance abuse. The emphasis on brief therapies is partly due to VA initiatives and ongoing access concerns that have limited the number of sessions providers are allotted with patients. Additionally, there are significant efforts to roll out and integrate evidence based practices across the VA. This exploratory aim will be an effort to meet the intersection of these demands by examining a brief evidence-informed therapy for substance users in outpatient treatment. The focus of this aim will be to determine whether this treatment results in measurable changes in neurobehavioral performance shown to be aberrant in addiction. These behaviors might serve as *early-indicator proxy markers* for improvement in cognitive domains relevant to addiction, which could in turn result in longer-term benefits of alcohol or drug abstinence.

3. Study Design:

This protocol will recruit approximately 35 Veterans once they enroll in the McGuire VA Medical Center Substance Abuse Treatment Program (SATP) IOP to complete two sessions of questionnaires and neurobehavioral measures, lasting approximately 3 hours in total. Each subject will meet initially with research staff after their SATP intake (conducted as standard of care), but prior to initiating treatment for the first session. Subjects will then meet with research staff again approximately one month later following their completion (or potentially incompletion) of the treatment. Following this meeting, research staff will complete a targeted CPRS medical chart review to collect information on appointment no shows, early termination of services, and results of Urinary Drug Screen (UDS) and Breathalyzer collections, and results of the Beck Depression Scale and Quality of Life Inventory administered during the SATP intake. 90 days following this chart review, a second chart review will occur to collect the same information, if available, for the post-treatment time period, along with information about whether they have re-entered treatment.

4. Methods:

a. Procedures:

The study will take place at the Substance Abuse Rehabilitation Program-Intensive Outpatient Program (IOP) of the Richmond VA Medical Center (RICVAMC). To minimize subject burden, consent and the first visit testing procedures will take place in the same visit to RICVAMC if possible. The study entails two visits with study staff. The first visit will include retrieving informed consent, and once enrolled, the completion of several questionnaires (see below). This visit is expected to last 60-90 minutes. The subject will then be scheduled for a follow up visit in to be conducted after he/she completes the intensive outpatient substance use program. This visit will last approximately 2 hours, and will involve questionnaires and desktop performance based tasks (see below)

CPRS Chart Review. CPRS records will first be reviewed by research study staff (research assistants) for intake and progress notes pertaining to the entry into IOP. When a Veteran is

identified to be entering the program and is determined to not have legal involvement from examining the intake, the Veteran will be contacted by research staff in a face-to-face encounter in the SATP clinic to explore his/her interest in participating in the current study. If interested, an appointment will be scheduled to meet to complete informed consent and the initial self-report tests. For the purposes of this study, legal involvement will be defined as a current legal issue identified during the clinic screening that mandates the completion of a substance use treatment program.

Once a subject has consented and is confirmed eligible to participate in the protocol, he or she will be assigned a five-digit ID number for this protocol. The subject will be identified by this number on all study forms, questionnaires, and surveys. The file that links a subject's name and other personally-identifiable information to this ID code number will be an electronic excel file on a password-protected virtual drive furnished by VA.

CPRS will also be used to complete a review following the second visit with subjects to collect information on appointment no shows, early termination of services, results of Urinary Drug Screen (UDS) and Breathalyzer collections, and results of the Beck Depression Inventory and Quality of Life Inventory administered during the SATP intake. 90 days following this chart review, a second chart review will occur to collect the same information, if available, for the post-treatment time period, along with information about whether they have re-entered treatment.

b. Data

The study features a series of questionnaires in the initial visit, and a combination of questionnaires alternating with desktop behavioral tests during the second visit. Below are the descriptions of each measure:

Visit One:

The following self-report measures (questionnaires) will be administered with paper-and-pencil:

Brief Addiction Monitor (BAM) – The BAM is a 17-item self-report questionnaire that assesses the recent occurrence and frequency of various substances, including marijuana, cocaine, stimulants, and opiates. It additionally has items for the rater to respond to recent health (excellent, very good, good, fair, poor), and recent engagement in risky situations or treatment. Lastly, it has several items asking about symptoms of substance use disorder, such as cravings and difficulties related to substance use (Cacciola et al., 2013). We hypothesize subjects with more reported substance use and less engagement in treatment resources will have poorer treatment adherence. This measure will take approximately 10 minutes to complete.

Barratt Impulsiveness Scale (BIS-11) - The BIS-11 is a reliable and valid self-report measure of attentional, motor, and non-planning impulsivity composed of 30 items rated on a 4 point Likert scale from rarely/never to almost always/always (Patton, Stanford, & Barratt, 1995). We hypothesize subjects with higher impulsivity will be more likely to have poorer treatment adherence. This measure will take approximately 10 minutes to complete.

PTSD Checklist 5 - This is a VA-distributed measure of 20 PTSD-related symptoms (each scored from 0-4) that align with DSM-5 PTSD criteria. It is administered in addition to the SCID itself in order to provide a continuous variable of PTSD symptom severity (Bovin et al., 2016). This measure is being used to account for potential confounding symptomology that may lead to treatment adherence issues. This measure will take approximately 10 minutes to complete.

Beck Anxiety Inventory - This is a tally of the subject's self-reported experience of 21 different anxiety-related symptoms in the past week-including the day of testing, where each item is rated on a scale from 0-3 (A. T. Beck, Epstein, Brown, & Steer, 1988). This measure is being used to

account for potential confounding symptomology that may lead to treatment adherence issues. This measure will take approximately 10 minutes to complete.

Visit Two:
The following self-report measures (questionnaires) will be administered with paper-and-pencil:

Barratt Impulsiveness Scale (BIS-11) – See above for description

Quality of Life Inventory (QOLI) – The QOLI assesses the importance of 16 life domains on a 3-point rating scale, as well as current satisfaction of each domain (6-point scale). The scores are summed to determine quality of life. This is a quick self-report questionnaire that has been normed in a community sample of adults. Higher scores indicate better quality of life. We hypothesize that those with better treatment adherence and less evident impulsivity on neurobehavioral measures will indicate better quality of life (Frisch, Cornell, Villaneuva, & Retzlaff, 1992). This measure takes approximately 10 minutes to complete.

Beck Depression Inventory-II (BDI-II) - The BDI-II is a 21-question, multiple-choice self-report questionnaire that is widely used in clinical and research practice for the purposes of measuring reported symptoms of depression. This has been widely established as a reliable and valid measure (Aaron T. Beck, Steer, & Brown, 1996). This measure takes approximately 10 minutes to complete.

The following tasks will be completed via administration by research staff:

Delis-Kaplan Executive Function System (DKEFS) Tower Test – The DKEFS Tower Test is a neuropsychological measure examining the executive functioning ability, specifically the ability to plan and sequence behavior. The test consists of two boards with pegs and several beads with different shapes. The test requires the individual to complete a timed-task requiring planning and sequencing in order to move the pegs in an instructed manner. We hypothesize errors on the Tower Test will be significant associated with poorer performance on neurobehavioral measures (as evident by more errors and faster reaction times) and with poorer treatment adherence. Time and errors are considered for scoring. The task requires approximately 10 minutes to complete.

The following laboratory performance measures will be conducted on a desktop computer:

Adjusting Delay Discounting (DD) Task - This decision task assesses how a subject de-values a hypothetical money reward the longer he or she would have to wait to receive it ("delay-discounting"). The participant chooses between immediate adjusting rewards (e.g., ''$5 now''), and delayed rewards (e.g., ''$10 in 1 week''). Participants are exposed to a series of choices where the future reward magnitudes are $10, $25, $100, $250, $1000 or $2500 (for delayed rewards) at delay periods of 1 day, 1 week, 1 month, 6 months, 1 year, 5 years or 25 years. The computer program varies the choices available across trials according to an algorithm that rapidly converges on an indifference point for each delay interval for every reward amount. These indifferences points enable calculation of a single constant ("k") that characterizes the severity of DD for that subject. The task ends once indifference points have been determined for each magnitude at each delay, usually within four minutes. Two different question series will be administered, one series involving smaller dollar amounts (per above), and another series involving much higher amounts (e.g. $50,000) in order to assess individual differences in the reduction of delay-discounting severity typically observed when subjects consider very high hypothetical reward magnitudes. We hypothesize that subjects who do not adhere to treatment will devalue delayed rewards more severely, and will not show as great a reduction in discounting

when very large hypothetical rewards are presented. This task requires approximately 15 minutes.

Stop-Signal Task (SST) - In this rapid-response impulsivity task, participants view a series of go stimuli ("X" or "O") in the center of the screen and are told to press the keyboard left arrow button when they saw an "X" and to press the right arrow button when they see an "O". On a subset of trials, a stop-signal (a 500 Hz tone presented for 250ms) is presented as a short delay after the go stimulus. Participants are instructed to respond as quickly and accurately as possible, but to withhold their response on Stop trials (on trials with the tone). The delay of the onset of the stop-signal is dynamically titrated by 50 ms intervals to promote a 50% rate of successful stops. The Stop Signal Reaction Time (SSRT) will be calculated as the interval between "go" and subsequent "stop" signals at which the subject can stop half the time. We hypothesize that subjects who do not adhere to treatment will show a faster SSRT, meaning that their response style is more "ballistic," and difficult to stop once-launched. This task requires approximately 12 minutes.

The Emotional Go-NoGo Task – This task presents a series of facial stimuli with either no facial expression, or with expression of an emotion, for 500 ms each, atop a black screen. A white fixation crosshair is displayed between Face stimuli. Facial stimuli are composed of sets of multiple faces of each of several actors/models, across neutral and different emotions. The subject is to respond with a keyboard or mouse press when he or she sees either a neutral face (neutral blocks) or an emotional face (emotion blocks). Blocks of trials are set in pairs, where at the start of one block, subjects are instructed on-screen that the emotional face is the target (to which to respond) and the neutral face is the non-target, and at the start of the counterpart block, the reverse instruction holds true in the other block. Attentional capture by either positive or negative emotions will be indexed by the rate of commission errors to emotion non-target faces relative to commission errors to neutral non-target faces. The task lasts roughly 14 minutes, including self-paced rest breaks between blocks.

Project timeline (Day 0 is the first day of IOP)		
Timeline	**Study activities**	**Measures**
Day -7 – Day -1	- Contact withpotential subjects for recruitment during a face to face meeting when they are in the SATP clinic - Consent and pre-treatment baseline assessment	Brief Addiction Monitor (BAM), Barrett Impulsivity Scale-11 (BIS-11), Posttraumatic Checklist-5 (PCL-5), Beck's Anxiety Inventory
Day 0 – Day 28	- Participants engage in either MFP or TAU treatment during their IOP engagement	N/A
Day 29 – Day 35	- Post-treatment assessment - Chart review: treatment engagement (appointment no shows, early drop out) and Breathalyzer/UDS results, results of Beck Depression Inventory and Quality of Life Inventory.	BIS-11, Delay Discounting Task, Stop-Signal Task, Emotional Go-NoGo task, Quality of Life Inventory
Day 120	- Chart Review: recidivism (treatment re-entry) and Breathalyzer/UDS results	N/A

Data Analysis

The analytic plan includes conducting an independent-group t-test of each of the following continuous dependent variables, or chi-square for categorical dependent variables: 1)

proportion drug-free urines; 2) retention in program (Chi-Square); 3) Quality of life score on the QOLI; 4) Delay discounting constant k; 5) Stop signal reaction time (SSRT) on the stop-signal task; 7) Reaction time in the Emotional Go-NoGo task, 8) errors in the DKEFS Tower Test.

A repeated-measures design will be used to examine the within-subjects effects of the treatments on state depression and quality of life, as well as for a group X treatment interaction effect. Although we do not expect an intervention of this time scale of to alter trait impulsivity, we will also analyze within-subject changes in BIS11 scores as an exploratory analysis. Lastly, a between-group design comparing the MFP group vs. TAU group for substance use primary outcomes of symptomology and neurobehavioral measures for problem solving and impulsivity. Individual differences in PTSD and anxiety measures and other symptomatology will be included as covariates to account for confounding factors in the analyses.

c. Facilities and Resources

The consent procedures and behavioral testing of this protocol will take place in the new second-floor Mental Health services facility at RICVAMC. Written informed consent procedures and clinical interviewing will take place in private interview rooms of this new second-floor RICVAMC wing. Questionnaires and laboratory behavioral tasks will be administered at dedicated research task workstations installed in testing rooms.

d. Staff Qualifications

James M. Bjork, Ph.D. will be the Principal Investigator of this protocol. Dr. Bjork has a 5/8 VA appointment and a joint (faculty) appointment as Associate Professor of Psychiatry at Virginia Commonwealth University. He has extensive experience in the laboratory testing of impulse control and decision-making in addicted inpatients, outpatients, and at-risk human subjects. He is also known for his successful design and execution of protocols to examine the neurocircuitry of motivation and self-control in addicted and adolescent at-risk populations. He has over 50 peer-reviewed publications and book chapters, 48 of which are available in PUBMED.

Thomas Burroughs, Ph.D. is the co-designer of this protocol, and will play a role in data interpretation and analysis. He has extensive experience conducting neuropsychological tests and structured clinical interviews for DSM-IV at RICVAMC in the course of his graduate school fellowship.

5. Risk/Benefit Assessment:

The procedures proposed herein are limited to computerized psychological tasks and symptomatology questionnaires. This protocol is considered to be minimal risk.

Risks:

5.a. Psychological distress due to performance of cognitive tasks or completion of questionnaire instruments on depression and PTSD.

There is a small possibility that a subject may feel uncomfortable in endorsing symptoms of depression, PTSD, or anxiety. In addition, subjects may perceive lack of self-efficacy or cognitive skill when performing the desktop computerized tasks.

Risk mitigation steps: Research staff are trained to be encouraging of the subjects and their efforts, and to not comment negatively on performance, other than the automatically-generated "please try harder" feedback of the CEDT, which is required to help ensure that the subject tries his/her best.

Either the study PI or a designated mental health clinician from the suicide response team of the Mental Health Service Line will be on the Richmond VAMC campus while the participants are completing the questionnaires and assessments. The research staff will have updated contact information available for the PI, designated mental health clinician (if different that day from the PI), the Richmond VAMC Urgent Care Clinic (aka, SOS Clinic), and the Veterans Suicide Hotline (aka Veterans Crisis Line, 1-800-273-8255).

Upon obtaining written informed consent, we will also provide subjects with resource materials for mental health services and contact numbers for suicide prevention should their symptoms become acute at any point during/after the protocol.

5.b. Disclosure of sensitive information

There is a small possibility of an unauthorized party gaining access to sensitive research-collected information in conjunction with personally-identifiable information (PII) or protected health information (PHI) contained in the CPRS database.

Risk mitigation steps: This risk is mitigated by secure information-technology (IT) procedures (see "Data Safety Monitoring" below) for CPRS, coupled with the sequestration of PII/PHI from research data by using anonymous subject ID numbers assigned by this protocol. The document that enables linkage of research data (protocol ID number) with PII is not electronic, and is kept physically secured.

Benefits:

There are no medical benefits for participation in this protocol.

Risk/Benefit Assessment: This protocol is minimal risk. The investigative team contends that the benefits of this study in terms of generalizable neurobehavioral and psychiatric knowledge outweigh the risks to subjects.

Importance of knowledge to be expected: It is important to understand the effect of treatments being conducted in clinical settings here at McGuire VA Medical Center. This study has the opportunity to establish that a brief cognitive-based intervention is effective in treating patients with substance use disorders. Additionally, this study can expand our understanding of neurobehavioral effects of treatment on impulsivity and substance use outcomes.

Subject Compensation:

All subject compensation will come in the form of a direct deposit payment issued by the McGuire VAMC. The original grant funding source for this study was the Durham VA Mental Illness, Research, Education, and Clinical Center (MIRECC). These funds have been transferred to the McGuire VA Medical Center, and will be paid to participants directly from the VA. Subjects who consent to participate in the current study will be compensated $20.00 for the first meeting (approximately 60-90 minutes), and $30.00 for the second meeting (90 minutes).

6. Data Safety and Monitoring:

Data Sharing

This protocol will not create a data repository and is not a multi-site study. It is not anticipated that data will be shared with an entity outside of this facility. If this is to occur, IRB approval will be sought and any shared data will be completely de-identified, per VA regulation (1605.1 Appendix B).

Data-Safety Monitoring Plan (DSMP):

DSMP Element 1: Handling of Unexpected or Adverse Events

Veteran participants will only be scheduled for testing during business hours, when a clinician of the suicide response team is always on call at RICVAMC. Should a participant express suicide ideation, the research assistant will first call or page the PI (Bjork) to notify him, then will summon the SOS Crisis Team that is operated by the Mental Health Service, where responders will include an MSW or clinical psychologist to further evaluate the subject. As a backup, the research team will contact the RICVAMC Suicide Prevention Coordinator, and/or a study staff member will escort the participant to the RICVAMC emergency department and wait with the participant until assessed by a mental health clinician. Following the intervention and complete disposition of the subject, the research staff member and Clinicians will fully document the incident.

If the subject does not agree to undergo clinical evaluation, and the (SOS Crisis Team clinician meeting with the subject determines that it is appropriate to initiate the civil-commitment process consistent with state law, the clinician and/or the research staff member may initiate direct contact

with the subject's family members, friends, local magistrate, and/or local law-enforcement authorities in order to assure appropriate evaluation and treatment. Information collected as part of this clinical evaluation will become part of the subject's mental-health record. Thus, the identified clinician will communicate details of the intervention to the subject's outpatient mental-health-care provider or primary-care provider, as appropriate, to assure safety and continuity of clinical care.

With respect to after-hours suicidal or other psychiatric reactions in outpatients or community subjects that do not take place during testing at RICVAMC, subjects will have been provided with both a VA suicide hotline information card, as well as a copy of the signed consent form, on which after-hours numbers for the PI (Bjork) are available. Should a subject call with a mental health crisis, they will be referred to the national VA suicide hotline, and a member of the research team will notify clinical staff at RICVAMC as appropriate, and will follow up with the subject.

For all adverse events, the IRB will be notified in writing by the PI within five days with all the details of the incident.

DSMP Element 2: Data Storage and Confidentiality

This protocol will yield a mixture of electronic and paper data. All study records, database information containing subjects' data, and their identities will be kept confidential as required by HIPAA standards. All paper questionnaire response forms will be secured in a locked cabinet that has limited access. As electronic data from computerized behavioral tasks are collected at the McGuire VAMC, data will be transferred as needed using encrypted VA-issued thumb drive and stored on the secure RICVAMC virtual (U) drive with access limited to the PI and his designees, through use of a shared folder. Individual data files, such as spreadsheets for statistical analysis import will be individually password-protected. Finally, the RICVAMC virtual drive itself is also password- and PIV-card- protected.

Except when required by law, approved through a separate IRB protocol, or authorized by a HIPAA authorization or other approved mechanism (e.g., limited dataset, data use agreement, etc.), we will not identify subjects by name, social security number, address, telephone number, or any other personal identifier in study records outside the Richmond VAMC. For records disclosed outside RICVAMC, subjects will be assigned a unique protocol code number. The subject ID code file (i.e. linking each subject's protocol ID number/code his/her PII/PHI and medical record) will be maintained in an excel electronic file on the PI's VA-issued virtual drive. This code file will be a separate from any data-analysis file that would contain results of any testing, psychiatric interviews or questionnaires.

7. Recruitment:

Recruitment: This project will recruit Veterans enrolled in the Substance Abuse Intensive Outpatient Program (IOP). The IOP includes five different groups over three days of the week for four weeks. Veterans are also randomly assigned to meet with a provider for four weekly individual sessions. Currently, Veterans either meet with one of two providers to complete the Mind Freedom Plan treatment, or they meet with a different provider to receive supportive, unstructured, therapy.

For the study, Veterans will be identified in their medical chart as being enrolled in IOP following the clinic intake and prior to beginning treatment. Research staff will contact Veterans face to face when they present to the SATP clinic to provide information about the study and explore if they are interested in participating. If they express interest, staff will schedule an appointment to meet with the potential participant to introduce the study, review and sign consent, and complete the baseline assessment self-report measure before they begin treatment.

Subject groups (inclusion and exclusion criteria):

Inclusion criteria:

- Enrollment in the Substance Abuse Treatment Program – Intensive Outpatient Program
- Currently meets criteria for an Alcohol or Substance Use Disorder per SUD clinic intake

Exclusion criteria:

- Unable to read and speak English
- Currently active-duty military
- Current engaged with legal involvement that is mandating the completion of the substance use program.

Collection of written informed consent:
The capacity to provide informed consent may be impaired in some patients, and we will not enroll decisionally-impaired individuals. Therefore, we will pay special attention to mental capacity and ability to provide informed consent. The determination of such capacity rests in a few key items:

- The subject should be able to understand the general procedures of the experiment and what is expected of him/her during participation.
- The subject should be able to understand the risks and benefits associated with the study.
- The subject should be able to understand that he/she can decline the study or withdraw from the study at any time after entering the study.

We will confirm that all participants understand the informed consent process by asking them to summarize the key points in their own words. The consent form will convey that confidentiality is limited in situations where the subject is assessed to be a threat in harming self or others. Subjects will be provided with a written copy of the consent form. The research staff will point out the contact numbers listed on the consent form for the PI Bjork (for questions, comments, or concerns). Finally, as a safety precaution, each subject will be provided with a VA suicide hotline information card.

8. Consultants: none

9. Curriculum Vitae: Principal Investigator's CV is on file with other projects, but can be provided if requested.

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