Mindfulness for Alcohol Abusing Offenders
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Protocol: Mindfulness for Alcohol Abusing Offenders
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V Research Methodology and Procedures:

The primary goals of this study are to test the efficacy of mindfulness-based relapse prevention against standard relapse prevention as well as two control groups (waitlist and treatment as usual) in a full-scale, randomized, controlled study among incarcerated offenders; and further, to elucidate the neural mechanisms supporting cognitive and behavioral changes resulting from these interventions. Volunteers seeking treatment who meet inclusion criteria will be randomly assigned to mindfulness-based relapse prevention or standard relapse prevention (see "Intervention" below, for details). Once the initial treatment cells are filled, additional volunteers seeking treatment will be assigned to a waitlist group. Volunteers who do not seek treatment will be assigned to the treatment as usual group.

Each treatment course will last eight weeks. We will administer the courses in conjunction with pre-, midpoint-, and post-intervention behavioral and MRI testing. The entire protocol that each treatment participant completes lasts approximately 28 to 44 hours (16 hours of treatment, follow up sessions every three months following the baseline phase of the study lasting one hour each, 3-6 MRI scans one hour each, and 6-12 hours of clinical interviews, cognitive tests, and other forms/questionnaires) and is spread out over several appointments (usually two hours maximum). Participants in the control groups will complete all study procedures (including MRI scans and follow up sessions) except the treatment sessions.

Intervention

The interventions to be used in this study were initially developed and tested by our study team in both community and incarcerated samples. The full protocol has been published (*Bowen, S., N. Chawla, and G.A. Marlatt, Mindfulness-based relapse prevention for addictive behaviors: A clinician's guide. 2011: Guilford Press.*).

The mindfulness-based relapse prevention (MBRP) course consists of eight modules. Each module will be presented in a weekly two-hour group meeting (one facilitator with 8-12 inmates). Sessions include guided meditation and discussion. The groups will be led by facilitators who are trained and supervised by professional mindfulness teachers with experience teaching mindfulness in state prisons. The mindfulness modules are designed to foster a number of inter-related cognitive skills to prevent relapse, including awareness of urges and cravings; tempering reactions to urges and cravings; identifying triggers for relapse and other high-risk situations; processing difficult emotions without habitually reacting (executive control of action); assessing the risk of typical daily activities; identifying helpful people and alternatives to using alcohol; building a support system; and cultivating a regular mindfulness practice. Participants will perform individual mindfulness practice outside the group setting.

The relapse prevention (RP) course follows the same structure as the MBRP course in terms of time commitment, group format, and schedule; however, this program will not include mindfulness meditation training. Rather, the RP control course will follow cognitive behavioral principles and well-established protocols that have been developed elsewhere (Daley, DC, & Marlatt, GA (2006). Overcoming your Alcohol or Drug Problem: Effective Recovery Strategies (2nd edition). New York, NY: Oxford University Press; *Marlatt, G.A., Parks, GA, & Witkiewitz, K. (2002). Clinical Guidelines for Implementing Relapse Prevention Therapy.* Peoria, IL: Behavioral Health Recovery Management Project; Monti, PM, et al. (2002). Treating Alcohol Dependence A Coping Skills

Training Guide (2nd edition). New York, NY: Guilford. The RP course focuses on teaching participants to assess high-risk situations for relapse, building cognitive and coping skills for managing cravings, goal-setting, problem solving, social support, and a balanced lifestyle. Again, our team members have experience implementing both forms of treatment among incarcerated individuals from prior NIH-supported research efforts. Adherence and competence measures developed specifically for the RP and MBRP interventions will be utilized in both conditions for ongoing assessment of fidelity in intervention delivery across sites.

Both MBRP and RP groups will also complete daily skill-building homework assignments (approximately one hour per day for the eight weeks of treatment) designed to reinforce the skills learned during the therapy sessions. This includes listening to audiotaped exercises and paper and pencil homework assignments. These will be taken to the participants' prison cell to complete the week following therapy and before the next therapy session. Homework assignments will be labeled with a participant code only and participants will be instructed not to write their names or any other identifying information on them. We will provide a secure box in the participants' unit at the facility where they can place the completed assignments daily.

Similar to previous studies, we may provide food and beverage to participants at the end of treatment sessions. When food and beverages are provided, we would plan to provide food that is suitable to the time of day that treatment sessions end. For example, if the treatment session ends in the morning, we may provide breakfast-type foods and water or juice for the participants. If the treatment sessions end in the afternoon, we may provide pizza and beverages may include water or soda. It is not anticipated that all sessions will have food and beverages provided. These will be planned in advance based on facility permission and other logistics. When food and beverages are able to be given to participants, they will be provided at the end of the treatment session. If the participant attends a treatment session where food and beverages are provided on that day, then they will receive food and beverage when the treatment session is over. However, if the participant does not attend the treatment session, withdraws from treatment, or leaves the session early, they will not be present when the food and beverages are available.

Clinical/MRI data collection

In addition to treatment, the study involves the collection of brain data (non-invasive MRI) and clinical information from each participant. The experimental procedures include three to six MRI scans, a series of psychiatric and neuropsychological assessments and interviews, collection of demographic and self-report personality data.

Incarcerated participants will complete all baseline study procedures (clinical assessments, treatment, MRI scans) at their prison facility where we currently staff research offices. They will also complete follow up visits every three months following the baseline phase of the study at the Mind Research Network or the University of Wisconsin-Madison (or alternate location/method if travel to MRN/UW is not possible). If any individuals are still incarcerated at the time of follow up, we will complete the follow up assessments in the prison facility.

All brain imaging data will be collected on an FDA approved MRI system. The FDA has specified the MRI (without contrast agents) as a minimal risk device. The Siemens 1.5T Avanto is a secure mobile MRI unit that will be parked within the perimeter of the correctional facilities and monitored by the correctional officers on staff. In addition to anatomical MRI and resting state functional MRI (fMRI) scans, fMRI scans will be conducted while participants perform tasks assessing response inhibition and error monitoring (Go/No-go task), and in which participants view images with and

without alcohol-related cues and indicate whether the images contain alcohol-related content. The MRI protocol will last approximately 1-1.5 hours.

Protocol Assessments

We will administer a self-report screening questionnaire to assess age, history of neurological illness or head injury, medications, MRI safety, scheduled release (from incarceration) date, and other information relevant to study eligibility. Socioeconomic Status (SES) will be evaluated using the Hollingshead SES questionnaire and/or zip code indexes. Collateral file review will also be used. Institution files, which usually consist of medical, psychiatric, and criminal history, will be accessed through the participating correctional institution. These files are scanned to encrypted laptops and uploaded by staff to our secure network at the end of the day.

Clinical assessments will be administered by trained clinical research assistants. *DSM-5* diagnosis (e.g., alcohol use disorder/AUD, psychosis, personality disorders) is established using the Structured Clinical Interviews (SCID). The substance use modules will be used to identify alcohol use disorder (required for study eligibility). All SCID interviews will be videotaped and stored within our secure database.

The Hare Psychopathy Checklist-Revised (PCL-R) will be used to assess psychopathy in all participants. The PCL-R assessment requires extensive review of file information (i.e., social workers statements, psychological assessments, forensic reports, etc.) in addition to self-reported information via interview. These interviews are videotaped and stored similar to the SCID. A random sample of PCL-R and SCID interviews are double rated to ensure consistence and reduce rater drift over time. The interviews usually take approximately two hours.

Other protocol assessments are summarized below.

Cognitive/Neuropsychological function (45-60 minutes):

- *Edinburgh Handedness Inventory*: Participants indicate, for 10 everyday actions (e.g., writing, opening the lid of a jar), their hand preference for completing the action (right (strong preference), right, both, left, left (strong preference)). The responses are used to calculate a laterality quotient indicating right or left handedness (or neither).
- *Wechsler Abbreviated Scale of Intelligence (WASI):* IQ test. An abbreviated version of the Wechsler Adult Intelligence Scale.
- *Wide Range Achievement Test (WRAT3):* reading test. Participants are required to read 30 words aloud.
- *Delis-Kaplan Executive Functions System (D-KEFS):* is a battery of standard neuropsychological tests. Examples include listing as many words participants can generate that begin with a particular letter for three different letters, identifying the meaning of eight proverbs, and using a pencil to draw a trail that connects numbers and letters in sequential order (1-13 and A-L).
- *Post Head Injury Symptoms Questionnaire (Modified from Rivermead Questionnaire):* asks participants to describe any past head injuries, details of injury (e.g., age, whether under influence of alcohol or drugs at time of injury), and any 'secondary symptoms' experienced (e.g., nausea, light sensitivity), and their severity and duration.
- *Ohio State University Traumatic Brain Injury Identification Method (OSU TBI-ID):* The OSU TBI-ID is a structured interview that is part of the NIH/NINDS Common Data Elements

(CDE) for TBI studies. The OSU TBI-ID assessment includes the number, age, cause, symptoms, and severity of past TBIs.
- Structural MR scans will be reviewed by a radiologist for the presence of white matter hyper intensities or other clinical neuropathology that may indicate alcoholic encephalopathy or drug-related health consequence (i.e., ischemia), and secondarily affect cognitive task performance.

Assessment of substance use and abuse (20 minutes):

- *Modified Substance Abuse Questionnaire:* Participant is asked if they have ever used alcohol or drugs and, if so, the severity, duration, and method of use for each applicable substance (e.g., did you use alcohol more than three times a week? For how many years?).
- *Fagerstrom Nicotine Dependence Assessment:* Participant is asked if they have ever smoked and, if so, the extent and duration of use (e.g., How many cigarettes would you smoke per day?) Used to assess tobacco use.
- *Alcohol Use Disorders Identification Test:* Self-report and interview questions about alcohol use and severity, designed to evaluate the severity of participants' use and problems with alcohol consumption. 20 items (e.g., "How often do you have six or more drinks on one occasion"?) scored on Likert scales of varying ranges across items.
- *Drug Use Disorders Identification Test:* Self-report and interview questions about drug use and severity, designed to evaluate the severity of participants' use and problems with drugs. 22 items (e.g., "How often do you have six or more drinks on one occasion"?) scored on Likert scales of varying ranges across items.
- *Circumstance, Motivation, Readiness Scale for Substance Abuse Treatment:* The CMR is designed to assess a participant's feelings towards treatment, which may predict how well they will respond. Includes subscales that assess their feelings about their current circumstances, and their motivation and readiness for treatment. 18 items (e.g., "I feel if I don't change, my life will get worse"), scored on a 1 (strongly disagree) – 5 (strongly agree) scale.
- *Follow-back Substance use before treatment questionnaire (FBSUBT)*: Participants are asked about their drug and alcohol use prior to treatment and what their use was prior to their current incarceration.

Self-report questionnaires (60 minutes):

- *Penn Alcohol Craving Scale:* The PACS, adapted to focus on alcohol craving, is a 5-item, self-report measure assessing frequency, intensity, and duration of craving, and overall rating of craving for the previous week. The PACS will be administered immediately before (pre), at the midpoint (mid-) and immediately after (post-) eight sessions of treatment, as well as at follow up.
- *Five Facet Mindfulness Questionnaire:* Designed to assess participants' dispositional/trait tendencies toward five facets of mindfulness. 39 items (e.g., "I'm good at finding words to describe my feelings"), scored on a 1 (never or very rarely true) to 5 (very often or always true) scale. The FFMQ will be administered immediately before (pre), at the midpoint (mid-) and immediately after (post-) eight sessions of treatment, as well as at follow up.
- *Multidimensional Personality Questionnaire-Brief Form:* A questionnaire designed to measure variation in normal personality traits. 155 items (e.g., "I usually like to spend my leisure time with friends rather than alone"), scored in true/false format.

- *Externalizing Spectrum Inventory:* A self-report-based method for indexing a range of correlated problem behaviors and traits in the domain of deficient impulse control. 100 items (e.g., “I've told lies about someone who upset me”), scored true/mostly true/mostly false/false.
- *Balanced Inventory of Desirable Responding (BIDR):* Evaluates the participant’s tendency to answer questions disingenuously, i.e., the way they think they should or the researcher expects them to. (e.g., ‘I don’t care to know what others really think of me’) scored from 1 (not true) to 7 (very true). 40 items.
- *Childhood Trauma Questionnaire:* 28-item self-report retrospective inventory intending to measure childhood or adolescent abuse and neglect. A 5-point frequency of occurrence scale is utilized: (1) never true, (2) rarely true, (3) sometimes true, (4) often true, and (5) very often true. Contains five subscales, three assessing abuse (Emotional, Physical, and Sexual) and two assessing neglect (Emotional and Physical). Each subscale score ranges from 5 (no history of abuse or neglect) to 25 (very extreme history of abuse and neglect).
- *RAND 36-Item Health Survey (SF-36):* 36-item measure which assesses physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions. In addition, it includes a single item which assesses the patient's perceived change in health. The SF-36 will be administered immediately before (pre), at the midpoint (mid-) and immediately after (post-) eight sessions of treatment, as well as at follow up.
- *PTSD Checklist for DSM-5 (PCL-5):* 20-item self-report measure which assesses the presence and severity of PTSD symptoms. A 5-point Likert scale is utilized to rate how bothered the patient has been by each item in the past month: (0) not at all, (1) a little bit, (2) moderately, (3) quite a bit, and (4) extremely. PTSD severity can be determined by adding the score for each item together to get a total score. The range is 0-80, with a total score of 33 or higher indicating that the patient needs further assessment to confirm a PTSD diagnosis. The PCL will be administered immediately before (pre), at the midpoint (mid-) and immediately after (post-) eight sessions of treatment, as well as at follow up.
- *WHO Quality of Life-BREF (WHOQOL-BREF):* 26-item measure which assesses the patient's perceptions in the context of their culture and value systems, and their personal goals, standards, and concerns. Physical health, psychological health, social relationships, and environment are measured. The *WHOQOL-BREF* will be administered immediately before (pre), at the midpoint (mid-) and immediately after (post-) eight sessions of treatment, as well as at follow up.

Anxiety/depression measures (15-30 minutes):

- *Spielberger State-Trait Anxiety scale:* Participants indicate the extent to which statements reflecting anxiety experience (e.g., ‘I feel tense’) describe them on a 1 (‘not at all’) to 4 (‘very much so’) scale.
- *Beck Depression Inventory:* Participants indicate the extent to which words representing depression experience (e.g., ‘Pessimism’) describe them on a 0 (does not apply) to 3 (applies very much) scale. The BDI is checked for suicidality immediately after completion. BDI will be administered immediately before (pre), at the midpoint (mid-) and immediately after (post-) eight sessions of treatment, as well as at follow up.
- *Clinician Administered PTSD Scale for DSM-5 (CAPS-5):* The CAPS-5 is a 30-item structured interview that can be used to make current, past, or lifetime diagnosis of PTSD, and/or assess PTSD symptoms over the past week. In addition to assessing the 20 DSM-5 PTSD symptoms, questions target the onset and duration of symptoms, subjective distress, impact of symptoms on social and occupational functioning, improvement in

symptoms since a previous CAPS administration, overall response validity, overall PTSD severity, and specifications for the dissociative subtype (depersonalization and derealization).

Other assessments (35 minutes):

- *Medication Form:* Participants are asked to provide information regarding the dosages and frequency of any medications they are taking.
- *COVID-19 Questionnaire:* 16-item questionnaire that evaluates the participants' experiences with COVID-19. Most questions are presented in 'yes' or 'no' format.
- *Menopause Questionnaire:* 3-item questionnaire (subset of HBEM questions) which inquires about menopausal status and symptoms.
- *Crime Inventory:* Participants are asked about the number of times they have committed and/or been charged/convicted of multiple crime types (e.g., theft, assault, robbery, murder).
- *Confidential Information Form.* This form gathers the address and contact information for the participant for use in contacting the participant for follow-up assessments post-release. It also gathers Facebook and other social media identifiers (see below for details), the names, addresses and phone numbers of four other individuals who would assist the research team in locating the participant should we lose contact with the participant. The information on this form will be updated with the participant at an appointment prior to their release date to ensure the most recent information for contacting the participant is available. The form is optional, and if the participant declines to provide some or all contact information they will still be allowed to participate. The participant is free to withdraw permission for the use of this information at any time. This information will be kept secure a separate locked cabinet in a separate locked room from any research data.
- *Trauma Checklist (TCL)*: The TCL is an expert-rater checklist of trauma items. This instrument was recently published by our team and was developed to minimize concerns related to reliance on self-report for assessing trauma history, lack of understanding of trauma symptoms/experiences in forensic populations. It combines a brief interview with coding data from institutional files, resulting in a score of 0 (none) - 2 (serious or prolonged trauma) for several types of childhood (at or prior to 18 years old) trauma ranging from abuse to neglect to exposure to violence.
- *Columbia-Suicide Severity Rating Scale (C-SSRS):* Participant is questioned about suicidal ideation (5 items, e.g., "wish to be dead", rated yes or no), intensity of ideation (5 items, e.g., "controllability", rated on a 1-5 scale), suicidal behavior (5 items, e.g., "aborted attempt", rated yes or no along with number of instances recorded), and lethality of suicide attempts (rated on a 1-5 scale). Note that the C-SSRS is only given if the participant checks '2' or '3' on the BDI (indicating suicidal ideation), and the evaluator, after further questioning, determines that a structured evaluation of suicidal ideation/intent is necessary to evaluate risk of harm to self.
- *Baseline Interview:* Participants are video recorded and asked open-ended questions regarding their thoughts about treatment.
- *Endpoint Interview:* Participants are video recorded and asked open-ended questions about their thoughts regarding treatment and their experience participating in the study. Participants will also be asked questions regarding how much they have practiced the skills they learned in treatment.
- *Pre-Scan Menstrual Cycle Assessment (MCA):* Collects information regarding menstrual cycle (e.g., first day of last cycle, typical length of cycle) immediately prior to the MRI scan.

Follow up assessments (One hour):

- *Time-Line-Follow-Back for substance use*: Participants report their daily use of substances over the duration of the reporting period in a follow-back format using a calendar.
- *Follow-Up Interview*: Participants are video recorded and asked open-ended questions about their thoughts regarding treatment and their experience participating in the study. Participants will also be asked questions regarding how much they have practiced the skills they learned in treatment.
- *Abstinence Self-Efficacy Scale:* Evaluates how tempted the participant found themselves to drink under various circumstances. 40 items (e.g., "When I am excited or celebrating with others", scored on a 0 (Not at all) to 4 (Extremely) scale.
- *Crime Inventory supplement:* Participants are asked about crimes committed since the last time they took the Crime Inventory.
- *PTSD Checklist for DSM-5 (PCL-5; see above)*
- *Penn Alcohol Craving Scale (see above)*
- *WHO Quality of Life-BREF (WHOQOL-BREF; see above)*
- *RAND 36-Item Health Survey (SF-36; see above)*
- *Five Facet Mindfulness Questionnaire (see above)*
- *Beck Depression Inventory (see above)*

Various psychological instruments (i.e., personality tests, etc.) are often updated/changed as new versions are developed. We update the above instruments regularly.

We will also collect the participants' Correctional Department ID Number. The Correctional Department ID number will not be used to label research data. This is essential for us in order to pay them for their participation as their account is listed under this unique number.