SMART: Project 3, Pilot Trial of Interventions

Manual of Procedures

June 14, 2021

Table of Contents

1. PREFACE

The purpose of this document is to provide a Manual of Operating Procedures (MOP) for Project 3 of SMART (Pilot Test of Contingency Management [CM] and Brief Motivational Interviewing + Substance Free Activity Session Interventions + Mindfulness-Based Adherence Promotion [BSM]). The role of the MOP is to facilitate consistency in protocol implementation and data collection across participants and study staff. Use of the MOP increases the likelihood that the results of the study will be scientifically credible and provides reassurance that participant safety and scientific integrity are closely monitored.

2. AWARD AND IRB INFORMATION

2.1. Study Title

Full Title: Pilot Test of Contingency Management vs. Brief Motivational Interviewing + Substance Free Activity Session + Mindfulness-Based Adherence Promotion

Working Title: SMART Project 3.

2.2. Award Information

Funding Agency: National Center for Complementary & Integrative Health (NCCIH)

Award number: R61AT010604-01

Grant Title: Testing the Effects of Contingency Management and Behavioral Economics on Buprenorphine-Naloxone Treatment Adherence Using a Sequential Multiple Assignment Randomized Trial (SMART) Design

Grant Years:
R61: 2019-2021
R33: 2021-2024

Grant Amount: $3,358,258

Program Director: Clinical Research – Peter Murray, PhD
Division of Extramural Research
National Center for Complementary & Integrative Health (NCCIH)
6707 Democracy Boulevard, Suite 401 Bethesda, Maryland 20892-5475

Phone: 301-496-4054 Email: peter.murray@nih.gov

2.3. IRB

Project number: 20-07418-XP

The University of Tennessee Health Science Center IRB (FWA00002301) approved this study on 6/30/20. The IRB Reference number is 20-07418-XP UM. IRB approval is provided in Appendix A.

2.4. Clinical Trials Registration

This study is now registered with clinicaltrials.gov, registration number, it's NCT04464421.

3. OVERVIEW

3.1. Forward

The SMART Project 3 manual includes concepts, strategies and materials that have been used in previous substance use intervention, abstinence, and medication adherence trials, including the interventions that were previously designed by our Co-PI's and their current and former colleagues. Their contribution is acknowledged with thanks to the investigators and staff involved.

It is essential that staff adhere to the Manual of Procedures (MOP) as closely as possible. This MOP is the official reference for how the SMART Project 3 study should be conducted. Familiarize yourself with these materials. The Principal Investigator, or Project Manager can answer questions you have about the study and its implementation.

It should be noted that Interventionists have some flexibility in implementing the treatment protocol to tailor the intervention to participant needs. However, Interventionists should not modify the protocol in significant ways and should always notify the Project Manager of protocol modifications, deviations, or violations.

3.2. Objectives

Our goal with this research is to examine the feasibility, satisfaction rates, and efficacy of two interventions, Contingency Management (CM) and Brief Motivational Intervention + Substance Free Activities + Mindfulness-Based Adherence Promotion (BSM), to improve buprenorphine-naloxone adherence during the treatment initiation phase (first 5 physician visits). Once feasibility, satisfaction, and efficacy are acquired, Project 4 (the randomized clinical trial associated with the R33 award phase) will be conducted.

Feasibility in this trial is defined as the ability to recruit, treat, and follow up participants within the target timeline and costs. Recruitment, intervention, and retention actuals (vs. goals) will be evaluated by investigators and the Data Safety Monitoring Board (DSMB) which will be convened every 6 months.

Satisfaction will be measured with a measure developed from previous research.

Efficacy will be evaluated in terms of participant adherence to buprenorphine-naloxone treatment: Showing up to scheduled appointments with their physician at the Center for Addiction Science AND the presence of buprenorphine in the participant's urine screen, conducted as a part of buprenorphine treatment.

3.3. Design and Outcomes

This project will use a randomized design to compare treatment satisfaction and effectiveness of Contingency Management (CM) and Brief Motivational Intervention + Substance Free Activities Session + Mindfulness-Based Adherence Promotion (BSM) for medication adherence in patients who are initiating buprenorphine-naloxone treatment at our Center for Addiction Science (N=40). The interventions will take place across the first 4 physician visits of buprenorphine-naloxone treatment, starting after treatment intake.

Primary outcomes will include feasibility and satisfaction at the fourth weekly intervention visit, and an efficacy comparison of intervention group differences in buprenorphine-naloxone treatment adherence, defined as (1) attendance at physician visit AND (2) buprenorphine-naloxone presence in urine toxicology.

3.4. Duration

3.4.1. CM Group Course and Session Duration

Participants assigned to the CM arm will have contact with study staff at their first physician visit (intake visit at the Center for Addiction Science) and then at the following 4 physician visits that are scheduled as a regular buprenorphine-naloxone treatment course. These visits are often scheduled at 1 week, 2 weeks, 4 weeks, and 8 weeks following intake (see Figure 1). However, this varies with some patients, thus participation could potentially last 4 months as a result of them being seen on a monthly basis. Participation at each intervention session is expected to last for 10minutes for the assessment and 2 minutes for the intervention ("number wheel" gift card picker).

3.4.2. BSM Group Course and Session Duration

Participants assigned to the BSM arm will have contact with study staff at their first physician visit (intake at the Center for Addiction Science) and then at the following 4 physician visits that are scheduled as a regular treatment course. These visits are often scheduled at 1 week, 2 weeks, 4 weeks, and 8 weeks following intake (see Figure 1). However, this varies with some patients, thus participation could potentially last 4 months as a result of them being seen on a monthly basis. Participation is expected to last 10 minutes for the assessment and 30 minutes for the psychosocial intervention.

3.4.3. Final Assessment (Participant)

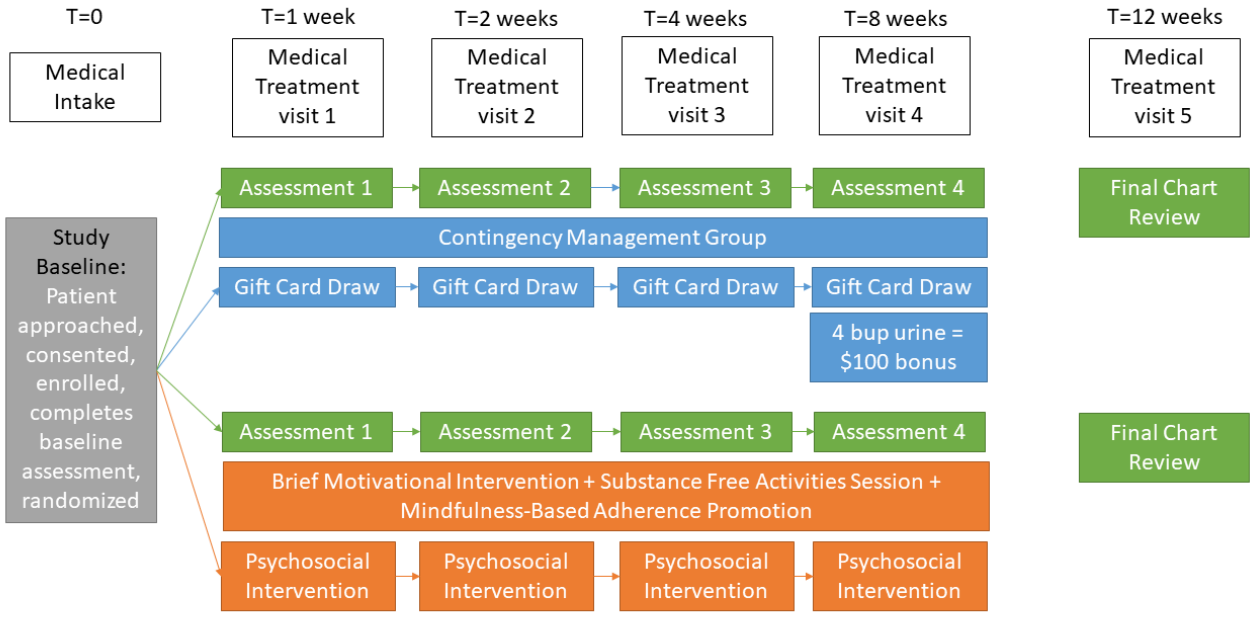
All participants will complete a blinded treatment satisfaction follow-up assessment shortly after completing Session 4 Part 1. Session 4 Part 2 assessment is to be conducted by an assessor blind to study conditions.

3.4.4. Final Chart Review

To examine treatment efficacy, we will also collect treatment attendance and urine toxicology information 30 days after S4 is completed (or the S4 window closes for those who do not complete the S4 intervention).

3.4.1. Figure 1.

Figure 1. Study Duration and Participant Medical vs. Study visits



3.5. Sample Size and Population

Approximately 40 participants will be recruited from UTHSC's Center for Addiction Science (CAS) for this study. We will randomize 20 participants to the CM group, and 20 participants to the BSM group.

3.5.1. Randomization

Participants are individually assigned to a study arm by block randomization (1:1 allocation, block length of 4).

3.5.2. Inclusion/Exclusion

Participants must be 18 years of age or older and presenting for buprenorphine-naloxone treatment. Patients must be eligible to receive buprenorphine-naloxone medication (e.g., Suboxone, Bunavail, Zubsolv) during their visit at CAS. This study is open to all eligible participants.

Notably, due to the nature of medical treatment, approximately 5% of new patients will not follow the "regular" intake course of buprenorphine due to previous treatment and/or treatment initiation using injectable depot buprenorphine administration (which requires fewer physician visits). Because all patients initiating treatment are at risk for drop out/low adherence, we wish to enroll these participants if at all possible under the stringent timelines for this study. We will therefore enroll unusual buprenorphine-

naloxone initiation timelines on a case by case basis, dependent upon the ability to complete study procedures within the study timeline.

3.6. Cascade of Events

3.6.1. Baseline Visit

1. Explain study to participants to see if they are interested in participating
2. Obtain informed consent
3. Screening for inclusion/exclusion criteria
4. Complete baseline assessment questionnaires (20 minutes)
5. Measures of buprenorphine-naloxone dose prescribed at this visit will be acquired from the medical record
6. Randomization

3.6.2. Sessions1-4: Intervention Treatment

1) Assessment questionnaires with interventionist
   a) Assessment questionnaires completed (10 minutes)
2) Engage in either CM (2 minutes) or BSM (30 minutes)
   a) BSM:
      i) All BSM sessions will be audio-recorded in order for the study staff to evaluate treatment fidelity. Participants will be informed when the recording device is on, and permission to record will be obtained as soon as the recording device is started. Participants may refuse to have the session recorded and still participate. Audio recordings will be de-identified and labeled with a Study ID number stored on an encrypted computer.
   b) CM:
      i) A number wheel (pickerwheel.com) with varying levels of gift cards (ranging from $25 to $100) will be available.
      ii) Urine toxicology will be obtained from the chart to assess presence of buprenorphine in urine (criteria for reward).
      iii) Participants will be informed of the buprenorphine toxicology result.
         (1) IMPORTANT: IT IS BUPRENORPHINE IN URINE THAT RESULTS IN A GIFT CARD WIN.
         (2) We ARE NOT providing feedback to the participant about the use of illicit substance presence in urine as this is not criteria for reward.
      iv) For those who have buprenorphine in urine, they will be allowed to spin the wheel in order to determine the amount of gift card earned.
      v) For those who DO NOT have buprenorphine in urine, no wheel spin will be done.
3) Chart Review Following Intervention

a) Information about buprenorphine-naloxone dose, all urine screen results (13 panel), and other substance use disorder diagnosis will be copied from the participant's medical chart.
b) Opioid prescriptions will be obtained from prescription drug monitoring database.

3.6.3. Visit 4 ONLY: Follow-up Call (Blinded)

Assessments and treatment satisfaction questionnaire with Research Assistant blinded to treatment condition (25 minutes)

3.6.4. Final Chart Review

At 30 days following the last intervention visit, we will conduct a chart review to assess outcome data relevant to efficacy (attended medical treatment visit, buprenorphine in urine).

4. INVESTIGATORS AND STAFF

4.1. Investigators

4.1.1. Principal Investigator

Karen Derefinko, PhD
University of Tennessee Health Science Center
66 N. Pauline Street, Suite 649
Memphis, TN 38163
901-448-2526
kderefin@uthsc.edu

4.1.2. Co-Investigators

Karen Johnson, MD, MPH - UTHSC, Study Physician, kjohnson@uthsc.edu

Fridtjof Thomas, PhD - UTHSC, Statistician, fthomas4@uthsc.edu

Matt Harris, PhD - UT Knoxville, Economist, mharris@utk.edu

James Murphy, PhD - University of Memphis, Clinical Psychologist, jgmurphy@memphis.edu

Ronald L. Cowan, MD, PhD – UTHSC, Clinical Psychiatrist, rcowan3@uthsc.edu

Marthinus Zeeman, MD - UTHSC, Interim Clinic Director, mzeeman@uthsc.edu

Katie Witkiewitz, PhD (Consultant) - University of New Mexico, Clinical Psychologist,
katiew@unm.edu

4.2. Staff

4.2.1. Project Management

Sarah Hand, MPH
Research Manager
shand@uthsc.edu

Vacant
Research Project Coordinator

4.2.2. Clinical Research Staff

Lakisa Ards, MPH, CHES
Research Study Coordinator I
lards@uthsc.edu

Miesha Sain, BS
Research Coordinator II
msain@uthsc.edu

Kristen Barnett, BA
Research Assistant
Kbarne42@uthsc.edu

4.3. Investigator and Staff Responsibilities

4.3.1. Investigators

Dr. Karen Derefinko will be responsible for the day-to-day supervision of the project and all aspects of the planning, training, recruitment, assessment procedures, and evaluation of the interventions in the proposed study. In collaboration with the research team, Dr. Derefinko will be responsible for decisions about the development of the study protocol, the training needed for the research staff who will be conducting the intervention, and interpretation of the data analysis and manuscript and presentation preparation.

Dr. Zeeman will assist with recruitment from UTHSC Center for Addiction Science and provide the medical care associated with the buprenorphine-naloxone medication.

Dr. Karen Chandler Johnson will serve as the study physician for reporting of Adverse Events associated with the intervention, not the buprenorphine-naloxone medication. Dr.

Johnson will assist with decisions about the development of study protocol, interpretation of the data, and manuscript preparation.

Dr. Fridtjof Thomas will oversee data cleaning, including qualitative data, and conduct all quantitative analyses. He will assist Dr. Derefinko with the rational assignment of participant clauses in qualitative analyses. He will prepare results for publication and assist in manuscript development.

Dr. James Murphy will participate in intervention development and interventionist training. He will also conduct treatment fidelity on an ongoing basis.

Dr. Matt Harris will conduct economic analyses of the intervention costs based upon efficacy.

Dr. Ronald Cowan will assist with the development of recruitment sites and advise on study design.

Dr. Katie Witkiewitz will advise the development of the mindfulness aspect of the intervention.

4.3.2. Project Manager

The Research Manager (Sarah Hand) will be responsible for general oversight of operational activities and supervision of personnel involved in data collection. She will be responsible for initial development of the MOP, development and maintenance of the database, exporting data and preparing for analysis. Ms. Hand will also prepare monthly reports on study progress for the investigative team.

The Research Project Coordinator will be responsible for direct staff supervision (coordinators, interventionists, and research assistants). The Project Coordinator will provide feedback on job performance and will conduct evaluations as per the requirements of UTHSC. The Project Coordinator will also be responsible for assigning additional tasks to staff as necessary to complete study goals.

4.3.3. Study Coordinator

The Lead Study Coordinator (Sain) will be responsible for study management tasks, including updating the Manual of Procedures, maintaining the regulatory binder (electronically), observing and reporting any study procedural issues to the study management, monitoring protocol adherence, ensuring data quality, reporting protocol deviations, completing IRB submissions/updates, developing consent forms, training staff, registering and updating the clinicaltrials.gov record, and relaying specific tasks to study staff members.

4.3.4. Interventionists

The Interventionists (Ards and Sain) will be responsible for participant and clinic relations including recruiting, consenting, and assessing participants. Ards and Sain will conduct BSM and CM intervention and will receive weekly supervision by Drs. Derefinko and Murphy.

4.3.5. Research Assistants

The Research Assistant will participate in recruiting, consenting, retention, blinded follow up assessments, and data abstraction.

4.4 Chain of Command

The Study Coordinator, Interventionists, and Research Assistant will report directly to the Project Coordinator regarding job responsibilities and duties. Should there be a conflict in reporting that requires the Study Coordinator, Interventionists, and Research Assistant to report to someone other than the Project Coordinator, the staff member will report to the Research Manager.

All Clinical Supervision will be provided by designated Investigators (Derefinko and Murphy).

5. TRAINING PLAN

5.1. Pre-Initiation Training

All Clinical Research Staff will be trained in data collection, data entry, database use, informed consent procedures, protection of human subjects, good clinical practice, adverse event reporting, and administrative protocols (e.g., randomization, CAS procedures) by the Project Coordinator.

Interventionists will be trained by Dr. Murphy to deliver the BSM intervention. The Study Coordinator will train the Research Assistant in chart review procedures.

5.2. Ongoing Training

Data will be monitored throughout the study so that any quality assurance issues can be handled in a timely manner. Any issues with data collection, data entry, informed consent, and incentive distribution will be monitored by Ms. Hand and the study coordinator and will be addressed at biweekly staff meetings. A log of data cleaning completions for staff will also be accessible in the study's OneDrive folder.

5.3. Clinical Training

Clinical supervision for Interventionists will be provided by Drs. Derefinko and Murphy. This supervision will cover issues raised by fidelity checks, clinical training maintenance (e.g., practice of motivational interviewing techniques), and general evaluation of participants' progress. This is a good time for Interventionists to bring up clinical issues that have happened during the week, and for problem-solving how to interact with resistance participants.

5.4. Fidelity

All treatment sessions for Project 3 will be audio recorded. Fidelity for content will be conducted on 50% of all sessions (40 of a total 80 intervention sessions recorded) by Dr. Derefinko. Feedback regarding Interventionist performance will be provided by Dr. Derefinko and will be addressed in supervision.

6. RECRUITMENT PLAN

Recruitment will occur through the CAS clinic and the American Recovery Clinic (ARC). Dr. Zeeman and the other physicians at the clinic will be informed of the eligibility criteria so they can note potential participants. At each patient's visit, the physician will tell the new patient they may be eligible to participate in research that will assist them in adhering to buprenorphine treatment. The physician will make sure to explain that this is not required and is different from what they are receiving as standard treatment. If the patient expresses interest, the doctor will bring the patient to a research room where a research staff member will explain the study. The staff member will check for eligibility, and if eligible, consent the participant. Additionally, staff members may approach the physician or clinic staff in regard to determining some eligibilty criteria for the patients after reviewing the clinic's schedule of appointments.

Please see the "Alternative Procedures: COVID" section if in-person recruitment is not possible.

7. ELIGIBILITY CRITERIA

Participants must meet the following eligibility criteria to participate in this study:

- Present for an appointment at CAS or ARC for buprenorphine-naloxone treatment of OUD
- Be eligible for buprenorphine-naloxone treatment (e.g., Suboxone, Bunavail, Zubsolv) as determined by Dr. Zeeman
- At least 18 years of age or older
- Access to a telephone
- Ability to understand consent procedures
- Physician confirmation of a "regular" initiation visit schedule (to ensure completion within pilot study window)

8. PROCEDURES

8.1. Recruitment

Recruitment will occur through the CAS and ARC clinics. Potential participants will be identified from the appointment schedule at the beginning of each day by Dr. Zeeman or the attending physician. At each patient's visit, the physician will tell the patient they may be eligible to participate in research. The physician will make sure to explain that this is not required and is different from what they are receiving as standard treatment. If the patient expresses interest, the doctor will bring the patient to a research room where a research staff member will meet with the participant. The study will be explained to the participant using the consent statement. Additionally, staff members may approach the physician or clinic staff in regard to determining some eligibilty criteria for the patients after reviewing the clinic's schedule of appointments.

8.2. Enrollment

8.2.1. Consent

Project staff will answer any questions about the entire process and an informed consent will be obtained. No study assessment will take place prior to obtaining consent from each subject. Standard language in our consent form assures the participants of the confidential nature of the study and the ability to withdraw from the study at any time. The consent forms will contain HIPAA language. This study will be approved by the UTHSC IRB.

Participants will be given a copy of the consent statement for their records. The consent discussion will be documented on the eligibility page of the FileMaker Database.

Participants will be informed that regardless of their adherence to clinic visits or use of buprenorphine-naloxone (the primary study outcome), they will be eligible to complete assessments at scheduled intervals and will be compensated for these assessments. This will enable the study team to discover whether drop out of treatment leads to relapse to opioids and if treatment is sought elsewhere.

8.2.2. Baseline Visit

After consent, the participant will complete the baseline assessments with the study team member. Dependent upon COVID-19 County and UTHSC requirements for in-person assessments, participants will either fill out paper forms on their own or be interviewed by the staff member. Responses will be recorded in the FileMaker database.

If a participant is unable to complete their baseline assessment on the day of enrollment, that is ok. Assessments may also be completed over the phone. Assessments however, must be finished before Visit 1.

8.2.3. Randomization

Once consent has been signed by the participant and study staff and the baseline assessment is complete, the staff member will randomize the participant. The randomization scheme is posted on the "SMART: Project 3 Regulatory" OneDrive file. Only appropriate staff have editing privileges for this document to avoid tampering. Participants will be immediately informed regarding the treatment arm they have been assigned to.

Participants will also be randomized to a counselor who will work with them throughout their participation in the study.

8.4. Tasks to Complete Prior to the Session

Please remember: Both CM and BSM conditions need to be recorded.

8.5 Session Windows

Following the Baseline Visit, participants will complete 4 sessions in no greater than 30-day increments. These visits will be referred to as Session 1 (S1), Session 2 (S2), Session 3 (S3), Session 4 (S4). The window scheduling guidelines for sessions are as follow:

- S1 opens when their 1st physician return visit is scheduled.
- S1 closes the day before their S2 is scheduled OR at 30 days from S1 window open.
- S2 opens when their 2nd physician return visit is scheduled or the day after S1 window closes (e.g. if S1 is not completed in order to keep under the 30 day maximum).
- S2 closes the day before their S3 is scheduled OR at 30 days from S2 window open.
- S3 opens when their 3rd physician return visit is scheduled or the day after S2 window closes.
- S3 closes the day before their S4 is scheduled OR at 30 days from S3 window open.
- S4 opens when their 4th physician return visit is scheduled or the day after S3 window closes.
- S4 closes 4 weeks from S4 window open (but continue to try to assess).

8.6. Intervention Sessions

Prior to the session, Interventionists will prepare for the brief assessment conducted during each treatment session by finding the participant in the Filemaker database, or if offline, entering the participant information on the top of the assessment materials.

Interventionists will also prepare to administer the appropriate session (1, 2, 3, or 4) (within the appropriate condition).

In addition, Interventionists will prepare the recording device to ensure that the session is recorded. If remote, the interventionist will text or email the participant a Zoom telephone number with a meeting ID for them to call and be placed in a meeting. The interventionist will ensure that Zoom is recording once permission is granted from participant. All sessions will be recorded and uploaded to OneDrive folder (SMART Project 3/Recordings) and labeled with the participant's study ID, session number (1, 2, 3, 4), condition (CM vs. BSM), and staff initials. (e.g. 301 S2 BSM AB)

At each session , the Interventionist will meet with the participant to complete the assessment questionnaires and complete the intervention – either a BSM session or a wheel spin for additional gift cards for CM (if requirements are met).

If the participant drops out of treatment at the Center for Addiction Science, they will no longer receive the CM or BSM. However, all assessments will be conducted regardless of the participant's adherence to medical treatment at the CAS. Upon completion of the assessment, participants will still earn the $50 gift card. This will allow us to understand the reason for the participant's non-adherence to treatment, and to evaluate whether these individuals pursue treatment elsewhere.

The intervention scripts are available in section 13 of the manual of procedures.

8.5.1 CM Intervention Description

Record all interactions with CM participants.

Participants who are assigned to CM will complete their assessments with the Interventionist. After the assessments are complete, the study staff will check the results of the urine screen. In the event that a participant misses their clinic visit, assessments may still be completed at any time during the window. If the participant completes their clinic visit **before the session window closes** they may be contacted to complete a wheel spin, if eligible.

Adherent (buprenorphine present in urine)

If the participant is determined as adherent (i.e., buprenorphine present in urine), they willspin a computer number wheel with varying value gift card amounts ($25-$100) with a bonus $100 gift card given for consecutive adherence (attendance at the clinic and buprenorphine present in urine) across all 4 sessions . The number wheel will consist of 4 $25 gift cards, 3 $50 gift cards, and 3 $100 gift cards.

Non-Adherent (buprenorphine not present in urine)

If the participant is determined as non-adherent (i.e., buprenorphine not present in urine), they will NOT spin the number wheel.

8.5.2. BSM Intervention Description

Record all interactions with BSM participants.

Participants who are assigned to BSM will complete their assessments with the interventionist. After the assessments are complete, the interventionist will engage the participant in the BSM intervention. A SOBER handout will be given to the participant at their baseline visit (*See section 13*). Participants will also receive a Tips for Improving Self-Control handout at session 4.

If a participant misses a session, the interventionist will continue with the next session in numerical order. So, if a participant is on S2 and missed S1, the interventionist will deliver S1 content during session 2.

This intervention consists of 4 sessions:

Session 1

This session will cover reasons for attending treatment, goals, time spent on valued activities, future events, and mindfulness-based coping (SOBER).

Session 2

This session will substance goals check in, substance free activities, and mindfulness-based coping (SOBER).

Session 3

This session will cover goals check in, substance free activities check in, and mindfulness-based coping (SOBER).

Session 4

This session will cover self-control improvement, and review goals, substance free activities, and mindfulness-based coping (SOBER).

In the event that a participant misses their clinic visit, assessments may still be completed at any time during the window. If the participant completes their clinic visit **before the session window closes** they may be contacted to complete a counseling session.

8.6. Distressed Participant Procedures

Detecting severe emotional distress is the responsibility of all SMART staff who interact with participants.

8.6.1. Warning Signs

Warning signs include:

- Talking about/making plans for suicide ("I'm going to end it..")
- Expressing hopelessness about the future (e.g., Things will never get better for me...")
- Displaying severe/overwhelming emotional pain or distress ("I can't take this anymore, I'm at a breaking point!")
- Showing worrisome behavioral cues or marked changes in behavior, particularly in the presence of the warning signs above. Specifically, this includes significant withdrawal from social connections/situations, changes in sleep (increased or decreased), anger or hostility that seems out of character or out of context, recent increased agitation or irritability

People may give direct as well as indirect verbal cues about suicidal thoughts. These typically communicate feelings of being trapped, helpless, and hopeless

SMART staff should use clinical judgment to further assess whether distress indicates lasting and unchanging conditions:

Example of limited distress (time-limited/likely to change):

- Participant: "My husband is driving me crazy! I can't take this anymore!"
- Interventionist: "Sounds like you're experiencing some stress right now."
- Participant: "Yeah, but he's only doing overtime this week. Next week we're back to normal."
- Example of lasting/unchanging distress:
- Participant: "I lost another job, the third one in a row. It never gets better."
- Interventionist: "Sounds like you're experiencing some stress right now."
- Participant: "Yeah, I'm useless, always have been. I'm a burden to my family. At least if I died they could get the insurance money."

8.6.2. Clinic Distress Procedure

If the participant is seen in the clinic, the interventionist will follow UCH's Behavioral Health Emergency-Suicidal Ideation procedure (policy number: BH.001), which requires that the study staff inform the behavioral specialist on staff or clinic doctor (Dr. Zeeman).

8.6.3. Telephone/Zoom Distress Procedure

During phone assessments and psychosocial intervention sessions, the interventionist will follow the procedures below. If the participant is not at the clinic, the following rules will be enacted:

1. Initiate Discussion:
    a. *"I am concerned about you. It sounds like you are experiencing very serious emotional distress right now. Before we continue with the session, I am going to need to ask you some questions to ensure you are doing ok."*
2. Get physical location
    a. *"Just in case we get disconnected, I am going to need you to tell me where you are. Sometimes, when people feel this upset, they need immediate help, and I want to make sure I can provide that for you."*
3. Assess for suicidal ideation/intent/plan:

"Let me ask you some questions about how severe your distress is."

Suicide Behaviors Questionnaire-Revised (fillable for printout)

Osman eta/ (1999) Revised. Permission for use granted by A. Osman, MD

Question	Possible answers	Points	Subtotal
1. Have you ever thought about or attempted to kill yourself?	*Never*	1	_____
	It was just a brief passing thought	2	
	I have had a plan at least once to kill myself but did not try to do it	3	
	I have had a plan at least once to kill myself and really wanted to die	3	
	I have attempted to kill myself, but did not want to die	4	
	I have attempted to kill myself, and really hoped to die	4	
2. How often have you thought about killing yourself in the past year?	*Never*	1	_____
	Rarely (1 time)	2	
	Sometimes (2 times)	3	
	Often (3-4 times)	4	
	Very Often (5 or more times)	5	
3. Have you ever told someone that you were going to commit suicide, or that you might do it?	*No*	1	_____
	Yes, at one time, but did not really want to die	2	
	Yes, at one time, and really wanted to die	2	
	Yes, more than once, but did not want to do it	3	
	Yes, more than once, and really wanted to do it	3	
4. How likely is it that you will attempt suicide someday?	*Never*	0	_____
	No chance at all	1	
	Rather unlikely	2	

	Unlikely	3	
	Likely	4	
	Rather likely	5	
	Very likely	6	
TOTAL FOR ALL ITEMS:			

Scoring:

< 4 = Not reportable	Assessment will be documented.
	"It sounds like you are definitely experiencing some distress, but you have a handle on it at the moment."
	Provide list of resources.
	Document events in file.
4-6 = Mild to Moderate Distress	Assessment will be documented.
	Participant will be provided a listing of community resources and encouraged to seek help.
	"It sounds like you are definitely experiencing some distress. I encourage you to consider reaching out to one of these organizations for help or support."
	Provide list of resources.
	Document events in file.
7 or more points but <u>no immediate plan</u> = Severe Distress and Suicidal Ideations, With No Intent or Plan	Develop an action plan to get help from a mental health professional. The action plan will be documented.
	"You are definitely experiencing distress but it sounds like you are not in immediate danger of self-harm. Is this correct?"
	"I would like to come up with a plan to help you get some support. Is there someone you can talk to about your distress?"
	Provide list of resources.
	Document events in file.
	Follow up with participant in two days to ensure help seeking is occurring.
	Document follow up in file.
	Severe distress incidents will be reported to an on-site Clinical Supervisor (Dr. Marthinus Zeeman).
7 or more points and immediate plan = Severe Distress and Suicidal Ideations With Intent or Plan	Maintain contact with the participant and put the patient in touch directly with emergency services (either by phone if in person or by calling 911, if on telephone). Maintain contact until responsibility is transferred.

	"Because you indicated to me that you intend to harm yourself and that this is likely, I am going to remain with you (on the phone) until help arrives. I am going to call emergency services to come speak with you at the address you provided me at the start of these questions. While I arrange this, I want to keep speaking with you about how you are feeling and what you need to do to feel better."
	If crisis situation (i.e., person is very agitated), may need to text another staff member to call local 911 and provide address This works even if the person is not in Memphis – the police will transfer the information to the local precinct.
	▪ National Suicide Prevention Lifeline: 1 (800) 273-8255 o Hours: 24 hours, 7 days a week o Languages: English, Spanish o Website: www.suicidepreventionlifeline.org)
	Contact Dr. Karen Derefinko to alert her to the situation, during or immediately after.
	All actions should be documented in file.
	Severe distress incidents will be reported to an on-site Clinical Supervisor (Dr. Marthinus Zeeman).

Adult crisis resources in Shelby County:

- National Suicide Prevention Lifeline – 1-800-273-TALK (8255)
- Memphis Police – (901) 545-2677 OR 911
- Mobile Crisis – Adult: (901) 577-9400
- Mobile Crisis – Children and Youth: 1-(866) 791-9226, (901) 252-7734
- Memphis Crisis Center – (901) 274-7477
- Community Behavioral Health – (901) 577-1004, 1-800-538-7540
- Lakeside Hospital – (901) 377-4733, 1-800-323-5253
- MSARC (Memphis Sexual Assault Resource Center) – (901) 272-2020
- St. Francis Hospital Clinical Assessment – (901) 765-1400
- YWCA Abused Women's Services – (901) 725-4277
- **Community Mental Health Centers**
  - Case Management, Inc. (formerly Southwest Mental Health Center)
    14 North Bellevue Boulevard, Memphis, TN 38104
    4041 Knight Arnold Road, Memphis, TN 38118
    (901) 821-5600
  - Alliance Healthcare Services Memphis locations:
    - 3810 Winchester Road or 3628 Summer Avenue: (901) 369-1400
    - 2579 Douglas Avenue: (901) 369-1400
    - 2100 or 2150 Whitney Avenue: (901) 353-5440
    - 951 Court Avenue: (901) 259-8900

8.7. Recording

All sessions (CM and BSM) will be recorded. The staff member will turn on the recording device, then while recording, will inform the participant that the device has started recording and ask permission to continue. At the end of the session, the staff member will inform the participant that the device is being turned off.

Once the participant has left, the recording will be uploaded to a study computer, then uploaded to OneDrive and labeled with the Study ID, session number, group, and the staff member initials. Once the recording is uploaded, it should be deleted from the recording device and the computer (if applicable).

8.8. Tasks to Complete After the Session

8.8.1. Data Checking

Interventionists and the Research Assistant will conduct routine checks of paper forms and the questionnaires in the database following session completion. Checks regarding data fidelity (e.g., values appropriate to the field, such as age = 99) and data completeness (was a question or measure missed) will be completed. If the correct value is unknown by the Interventionist, the participant will be re-contacted to request the correct data value.

The Research Manager will be in charge of data cleaning. All data will be exported every 3 months for review and cleaning.

A data cleaning log for each session is located on OneDrive for staff to log completed data checks.

8.8.2. Gift Card Distribution

All gift cards will be pre-purchased, hard copy gift cards.

Baseline Assessment Incentive: All participants will receive a $50 gift card for enrolling and completing a baseline visit.

Assessment Completion Incentive: After each assessment, participants will receive a $50 gift card to their choice of store (Kroger or Walmart). Research staff will log out the gift card(s), make a photocopy of the gift card(s), and have the participant sign the photocopy to document distribution. Research staff will date the photocopy and file appropriately.

CM Group Rewards: Patients in the CM arm will have the opportunity to spin a computer number wheel if it is determined that buprenorphine is in their urine at the physician visit. If all 4 urine screens across the study duration show buprenorphine in urine, the participant will receive a $100 bonus gift card.

This is allowed by UT policy FI0313.

8.9. Gift cards

8.9.1 Gift card ordering

The Study Coordinator will be responsible for ordering gift cards and maintaining inventory. Gift card orders should be sent to Andrea Briggs via email. Orders typically take 3-6 weeks to receive.

8.9.2. Gift Card Storage

When a gift card order is received, the gift cards are stored in the Pauline 6th floor safe until they can be transported to CAS. The safe at CAS can have a maximum of $3,000 in gift card value at any time. Gift cards and gift card log will be kept in a locked safe in a storage closet in the clinic. The safe should only be opened when a gift card is needed and only 3 staff members are allowed to have the access code to the safe per UT Fiscal Policy.

Gift cards are to be kept in the locked study safe at all times. Gift cards should only be checked out of the safe when they are ready to be disbursed to a participant. The gift card log will be kept in the safe and filled out each time a gift card is moved in or out of the safe. We will also keep a google sheet logging the incentives.

8.9.3. Gift Card Log Example

Card Number	Pin	Amount	LOG IN Initials	LOG IN Date	DISPENSE Date	LOG OUT Initials

8.9.4. Gift Card Receipt

Study ID		[redacted]	
Date:			
The participant and I, the research staff member, checked the balance of the gift card before distribution. We discussed that the SMART Research Study is not responsible for and will not replace lost or stolen gift cards once the gift card has been disbursed.			
Staff Initials:		Gift Card Amount:	
Participant Initials:		Quantity:	

8.10. Option for Scheduling

Since the patient will have scheduled their next physician appointment, we will not schedule their next research appointment (unless we are remote, in which case the session will be yoked to their CAS appointment, to be scheduled immediately following their appointment at the CAS). We will use the medical charts to block off time for the participant's S1 (ex: the participant schedules a 2:00 pm doctor's appointment, their research appointment will be at 2:45 pm). Appointment times are not stringent, so if a participant gets done with their physician visit early and their assigned counselor is free, they can complete their session early.

Note on Assessment for participants who fail to attend treatment:

The study staff will continue to contact the participant to complete their assessments if a participant stops attending CAS. Study staff will inform the participant that they will not be receiving treatment (i.e., CM of BSM intervention). However, they can continue to earn gift cards for completing assessments. Assessments and intervention may occur in two visits if a participant missed their clinic visit, but later rescheduled and completed their clinic visit **before the closing of the session window.** Study staff will also inform the participant that information shared will not be disclosed to clinic staff or doctors.

8.10. Study Contacts

Study Phone: 901-448-3099

Email: smartresearch@uthsc.edu

Website: https://www.getsolidinitiative.org/smart

Facebook: https://www.facebook.com/GetSolidInitiative

8.11. Adverse Events

If patients experience an adverse event during the course of the study, we will conduct an assessment, complete an Adverse Event form, and follow the adverse event reporting system as required by our IRB and NIH regulations. We will assess Adverse Events at each intervention session.

Adverse events are defined as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious adverse events are any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:

(1) results in death;
(2) is life-threatening (places the subject at immediate risk of death from the event as it occurred);
(3) requires inpatient hospitalization or prolongation of existing hospitalization;
(4) results in a persistent or significant disability/incapacity;
(5) results in a congenital anomaly/birth defect; or
(6) any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition

At every session, we will assess both Adverse Events and Serious Adverse Events (AEs and SAEs).

All SAEs related to study participation are to be reported to the Project Manager who will report to the Study Physician (e.g., Dr. Karen Chandler Johnson) within 24 hours of occurrence, and are to be reported to the UTHSC IRB immediately.

UTHSC's IRB operating procedures regarding AE's can be found here: https://www.uthsc.edu/research/compliance/irb/researchers/documents/adverse-event-reporting.pdf

We do not anticipate any study related SAEs (we haven't observed treatment related SAEs in any of our studies) as our study involves an over-the-counter medication and psychosocial intervention.

A copy of the Adverse Events reporting tool is located in the Measures section.

8.12. Participant Retention for Enrolled Participants

If a participant is having difficulty participating in sessions regularly, it is the job of the Interventionist to find out obstacles to treatment and work with the participant to overcome these obstacles.

Once a participant is enrolled, it is the Interventionist's goal is to retain them in the study.

In addition to FileMaker, Interventionists should regularly update the Retention Log in OneDrive with their active participants. Interventionists have the flexibility to provide participants whatever form of treatment is needed to retain them in the study. Before offering participants special arrangements, Interventionists will review these cases with the Study Team.

Procedures are in place to assist you in retaining participants. These include incentives for assessments ($50 gift cards), as well a t-shirt and welcome bag (snacks and cloth face mask) that will be provided at enrollment.

8.12.1. Standard Interventionist Retention Skills

Always take a positive approach with the patient. Always be understanding of their situation.

Acknowledge situation when appropriate, (e.g., condolences for a recent family death; inquiring how they are doing when ill or hospitalized.)

Always document the reason a participant did not participate and any suggested approach for handling the missed session. Also document on the Process Note any participant circumstances that we may want to stay aware of (e.g., death in family, illness).

Standard retention practices include:

- Birthday cards
- Holiday cards
- Reminders pre-session (day before)

8.13. No-Show Protocol

If enrolled participants are not available for a session (despite attending the medical visit), we will attempt to contact non-enrolled participants in a number of ways.

Participants who “no show” for a scheduled session will first be called or texted at 15 minutes past the appointment time. The staff member should contact the participant to check on him/her and attempt to reschedule the appointment (i.e., leaving a message to this effect if the participant does not answer the phone). If the participant is not contacted the day of the appointment, the interventionist should also follow-up with the participant the next day in an attempt to reschedule. Alternate contact info may also be utilized in efforts to reach the participant.

8.13.1. Rescheduling Protocol

Participants will be allowed unlimited occasions of rescheduling a session , as we want to retain all enrolled participants in the study. However, staff (together with the Project Coordinator) should use their judgment about this rule on a case-by-case basis and

always prioritize completing assessments if the participant cannot complete intervention sessions.

8.13.2. “Hard to Reach” Participant Retention

Participants who miss sessions and remain in session window should be subject to intensive retention efforts by Interventionists.

Main strategy: Starting with preferred modality, cycle through different modalities, days of the week, times of day, and different strategies to reach participant.

Modalities: phone, text, email, mail, alternate contact

Phone call strategies:

> Call and leave a voicemail
>
> Call once then follow up with text (ex: Hi _____, I just left you a message trying to reschedule, if you can call me back when you get a chance that would be great!)
>
> Call once, then call again 10-15 minutes later (try leaving a VM the first time, but if they don’t answer the second time don’t leave another message)
>
> Call with google voice number or clinic telephone to catch participant off-guard
>
> Call alternate, ask if they know a good time to call participant or if you can leave a message with them (do not disclose the purpose of the study to alternate)

Alternating times of day within a week

> For those who are early or middle of their window, try one morning call, one afternoon call, and one evening call within the span of a week
>
> Ex: Monday afternoon, Tuesday morning, Thursday evening
>
> Can also send texts or other modalities during this time

E-mail and Mailing strategies:

> For participant who you’ve had a hard time reaching via quicker methods
>
> Examples:
>
> Hope you’re doing well! We’ve had a hard time getting a hold of you by phone so I just wanted to check in. If you could give me a call at 901-448-3099, we’d love to get you scheduled for you next session!

Just wanted to check in on you because I've had a hard time getting a hold of you. The last day for you to do this session is _____. If you can give me a call at 901-448-3099, we can figure out a time that works for us to get this session in!

Facebook Message Strategies:

We will have links stored for participants who message us on Facebook. This will allow us to send a message to those participants from the SMART page.

Use the same type of language used in mailings and/or text messages

Example

Hope you're doing well! We've had a hard time getting a hold of you by phone so I just wanted to check in. You can either message me back on here or give me a call at 901-448-3099.

Just wanted to check in on you because I've had a hard time getting a hold of you. The last day for you to do this session is _____. Would you have some time Tuesday at 9 to do your session?

Also a great tool to get updated contact information if needed

Contact attempts per stage in window:

Early to mid window: contact at least 3 times a week using at least 2 different modalities

Late window (last week): contact daily at different times of the day, leave message with last day to do session so the participant has a deadline.

As a last chance effort the day before a window closes, you could text the participant and offer them a slot the next day. You can tentatively book them on the calendar and even if they don't respond, go ahead and try to call at the suggested time.

Ex: Hi _____, tomorrow's our last day for us to get this session in. Could I call you at 10:00 tomorrow to do that?

Should the window for a session close, retention efforts should be stopped, but resumed just prior to the opening of a new window.

18.13.3. Participant Withdrawal

Some participants may passively drop out of treatment, whether because of scheduling conflicts, life stressors, disappointment with their outcome, or not liking the phone sessions. Some participants will develop conflicts or barriers that keep them from

attending phone sessions on a regular basis and may wish to actively withdraw from the study.

These participants may or may not be aware that there are options to help them stay involved.

For participants who decline all offers of intervention, be sure to leave the door wide open.

If the participant is reached, the Interventionist will attempt to re-engage the participant with any of the following techniques:

Maybe we can change something?

Discuss the barriers with the participant. Help the participant brainstorm solutions to the barriers or any alternative options that will help the participant stay involved.

Offer flexible schedules for participating in phone sessions. Can they participate in just two meetings a month? One meeting a month? Can they take a break for a month or two and then see if they can resume phone sessions? Stick to just email communication for a period of time?

The Project Coordinator may also contact the participant to see if switching counselors would help the participant re-engage.

Document all efforts to keep the participant enrolled in the study on the Contact Notes.

Maybe you will want to start again at the next session ?

Maybe the participant could take a break from the study (become inactive), and possibly resume later if there are later visits that could be completed (ex: a participant cannot complete S1 but they might want to be contacted at S2). Make sure they are aware that you are available to help them with questions or concerns at any time and that we may periodically contact them throughout the remainder of the study. Interventionists should indicate that they would be happy to work with a participant anytime they are ready to focus again on smoking cessation.

Can you still participate in the last follow up?

If the participant does not want to continue participating in phone sessions, emphasize to them the importance of completing the assessments. Ask the participant if he/she is willing to complete these measures. The participant would be considered inactive and would still receive the $50 gift card if the session is completed (S1, S2, S3, or S4). Emphasize that their data is needed for the success of the research, whether or not they have been actively participating or not and whether or not they've quit. In order to answer the research questions, we need to know what worked and what DID NOT work for

participants so we can help others better in the future. Explain that without their data, we will be missing some of the most crucial information we need to collect.

Participants who do not complete the Baseline assessment within the designated window will be administratively withdrawn from the study since they did not complete any treatment.

18.14. Official Withdrawal Procedures

Document all efforts to keep the participant enrolled in the study on the Contact Notes.

If, after all alternative options are explored and exhausted, the participant still chooses to withdraw from the study, document the date of the discussion.

The Study Coordinator will put notification of intent to withdraw in writing in a letter to the participant.

A copy of an official withdrawal letter is provided in Appendix B.

Study Coordinator will then:

Mark as withdrawn on the Regulatory Form.

Report to IRB on annual progress report.

Notify PI by email if there are abnormal circumstances surrounding the withdrawal.

9. Data Safety Monitoring Board

9.1. Members of the DSMB

Chair: Christopher Barrick, PhD, Department of Family Medicine, Jacobs School of Medicine and Biomedical Sciences, State University of New York at Buffalo, Phone: (716) 887-2538, Email: barrick@ria.buffalo.edu

Member: Margaret DeBon, PhD, Executive Director, Baptist Clinical Research Institute, BMHCC Corporate Office, Phone: (901) 226-1673, Email: Margaret.DeBon@BMHCC.org

Member: Todd A DeWees, PhD, Senior Associate Consultant I, Mayo Clinic, Phone: 480-301-9458, E-mail: DeWees.Todd@mayo.edu

Member: Iliyan Ivanov, MD, Associate Professor in Child and Adolescent Psychiatry, Icahn School of Medicine at Mount Sinai, New York, NY, Email: iliyan.ivanov@mssm.edu

Member: R. Kathryn McHugh, PhD, Assistant Professor of Psychology, Department of Psychiatry, Harvard Medical School, Phone: 617.855.3169, Email: kmchugh@mclean.harvard.edu

9.2 Responsibilities of the DSMB

The roster of proposed DSMB members will be submitted to NCCIH prior to initiating recruitment (see DSMB Charter, separate document due to length). Types of credentials that our intended DSMB members will possess are: 1) experience conducting behavioral intervention studies; 2) experience with treating opioid use disorder; and/or 3) biostatistical expertise in intervention studies. As DSMB members, they will review the reports sent by the study statistician (at the frequency outlined above) and will use the checklist attached to this document (Appendix C) to determine whether there is any corrective action, trigger of an ad hoc review, or stopping rule violation that should be communicated to the study investigator, the University of Tennessee Health Science Center IRB and the NCCIH.

10. ALTERNATIVE PROCEDURES: COVID

In the case that study staff are unable to recruit and provide the intervention in-person, the following alternative procedures will take place.

All individuals entering the CAS must abide by the rule of wearing a face mask at all times.
.

Procedures

Recruitment

Study staff will review the clinic schedule the day before and the day of to determine which patients are eligible. Study staff will come into the clinic to discuss the study and recruit eligible patients.

Enrollment

Consent

If the patient agrees to participate, the study staff will consent in person. The study team will take all precautions to protect themselves and the patient (e.g., PPE and practice social distancing).

For participants unable to complete consent in person and who have access to a computer, a DocuSign link will be sent immediately to conduct consent during the call. A blank copy of the consent form will be mailed to the participant

All other consent procedures will be the same as written above.

Randomization

Once the patient consents and completes baseline assessments, randomization procedures will stay the same as written above.

Baseline Assessment

Baseline assessment will take place in-person or over the telephone. Assessment must be completed prior to the participant's first physician return visit. Procedure will stay the same as written above.

Sessions 1-4

Following the Baseline Visit (BV), participants will complete sessions on the same schedule as their appointments at CAS, but windows will not exceed 30-day increments. Sessions and follow-up procedures will stay the same as written above with a few modifications (see below).

CM Session

Study staff will contact participants by phone or text to schedule a time to complete their assessment and CM intervention via Zoom call on the day of the participants' scheduled appointment. The participant will be given a 30-day window (starting with the day of their office visit) to complete the assessment or it must be completed prior to the next scheduled clinic visit for the patient.

If participant attends the physician appointment **and** has buprenorphine in urine:

Once the assessment is complete, the study staff will spin the number wheel while the participant is on the phone ("virtual wheel"). The study staff will inform the participant of the gift card amount earned and will immediately mail the gift card.

Study staff will also take a screenshot of the number wheel results, and text or email the participant the photo. The study staff will upload the photo to FileMaker for future records.

For those who DO NOT have buprenorphine in urine:

Once the assessment is complete, the study staff will inform the participant that they did not have buprenorphine in their urine and are not eligible for the virtual spin.

BSM Session

Study staff will contact participants by phone or text to schedule a time to complete their assessment and intervention via Zoom call. The call will be scheduled and completed within 30-days or the day before their next scheduled office visit. The intervention portion will be audio recorded.

Recording procedures will be the same as written above.

Incentives

Gift Card Distribution Procedures

Procedures will stay the same as written above with slight modifications. Gift cards will be mailed. A google sheet will be used to track the gift cards distributed.

Virtual mailing procedures in section 14.

Gift Card Storage

All procedures will stay the same as written above.

11. PROFESSIONALISM IN THE WORKPLACE

Employees will follow University of Tennessee Policies, some of which are noted in this section.

11.1. Professional Attire

It is important that employees maintain a conservative, neat and clean appearance appropriate for the work environment. Preventive Medicine takes a "business casual" approach which includes suits, dress pants, dresses, and skirts, but may also include collared shirts, golf or "polo" shirts and pressed khaki pants.

Attire that is not appropriate for the workplace includes t-shirts, tight or short pants/skirts, tank tops, halter tops, low-cut blouses or sweaters, or any extreme style or fashion in dress, footwear, accessories, or fragrances. Certain employees may be required to meet special dress, grooming and hygiene standards, such as wearing uniforms or protective clothing, depending on the nature of their job, which will be defined by the department. Some departments adopt casual or dress-down days. In this instance employees are still expected to adhere to the aforementioned appearance but are not permitted to wear ripped, frayed clothing, disheveled clothing, work-out gear, tight clothing, revealing or otherwise workplace-inappropriate clothing is not permitted on any given day.

11.2. Professional Behavior

11.2.1 Respect for Others

People are the University of Tennessee's most important resource for accomplishing its teaching, research, and public service missions. Accordingly, employees are expected to be committed to creating an environment that promotes academic freedom, diversity, fair treatment, and respect for others. Employees are expected to treat one another public in an honest and respectful manner. Specific examples of this behavior include disorderly conduct, including, but not limited to, using discriminatory, abusive, or threatening language; fighting, provoking a fight, or attempting bodily harm or injury to another employee or to any other individual or threatening physical action or injury on university property or during university activities; or other conduct that threatens or endangers the health, safety, or well-being of any person.

11.2.2 Responsible Use of University Resources

Employees must use university property, funds, technology, time, and other resources for legitimate business purposes. Employees must not use university resources for personal gain or to benefit third parties. These could include using university resources for personal needs, family matters, schoolwork, or abusing work time for any personal reasons. This also includes instigating or participating in deliberate low productivity and/or interfering with another employee's work.

11.2.3 Standards of Attendance and Timeliness

SMART Project 3 employees are expected to be on time for work and on time for sessions. Employees should be clocked in and at their desk at their start time at the beginning of the day. Please note: Remote work still requires employee engagement during working hours, as designated.

The university has policies on repeated tardiness and absences. Repeated tardiness is defined as arriving at work past the appointed starting time without supervisory approval. Other absences include the failure of employees to report to their work place at the beginning of the work period, leaving work before the end of the work period, and failure to inform the supervisor when leaving the work area.

All appointments with participants should be started at the exact time scheduled, give or take 1 minute. If a staff member knows they will be more than 15 minutes late for a scheduled appointment, they should ask another staff member to call the participant and inform them that they are running late or to call and reschedule the participant.

12. MEASURES

12.1. Table 1. List of Measures

Measure	Time to Complete (minutes)	Baseline	1,2, 4, and 8 week sessions	8 week blind	Medical Chart at 30 days
Contact Information	1	X			
Referral source (how did they get to the CAS)?	<1	X			
Screening Questionnaire	<1	X			
Exclusion reason (if applicable)	n/a				
Demographics (gender/race/ethnicity/education/zip code/insurance)	3	X			
Opioid Use Disorder (Diagnostic and Statistical Manual of Mental Disorders-5)[93] interview	1	X			
Attended first physician visit	n/a		X		
Attended second physician visit	n/a		X		
Attended third physician visit	n/a		X		
Attended fourth physician visit	n/a		X		
Number of treatment visits attended (allow for drop out, drop back in): CUMULATIVE ADHERENCE	n/a				X
Urine Toxicology (buprenorphine and all other substances)	n/a	X	X		X
Timeline followback on alcohol, substance use, and opioid use	3	X	X		
Delay Discounting[58]	2	X		X	
Opioid Purchase Task[46]	1	X	X		
Engagement in Substance Free Activities[54]	2	X		X	
Time Spent On Activities	2	X			
Opioid Craving Symptoms[95] (Opioid Cravings Scale)	1	X	X		
Buprenorphine-Naloxone dose log (did you miss any days?)	<1		X		
Dosage of Buprenorphine-Naloxone Prescribed (obtained from medical record at each session)	n/a	X	X		X
Treatment Satisfaction	4			X	
Prescription Drug Monitoring data	n/a	X	X		X
PEG for Chronic pain (3 items)	<1	X	X		
EQ5D5L (6 items) Quality of life for cost-effectiveness analyses	3	X		X	
PHQ-2 depression 2 items	<1	X	X		
GAD 2 anxiety 2 items only (also a 7 item version)	<1	X	X		
Treatment history (times in treatment, medication used)	<1	X			
Economy Contribution (3 items)	<1	X	X		
If dropped out: Are you receiving but (or opioid replacement) treatment somewhere else?	<1		X		
Adverse Events	<1		X		
Participant time to complete all measures at sessions:		20.5	11	10	n/a

12.2. Measure Items (NIH REQUIREMENTS HIGHLIGHTED IN YELLOW)

11.2.1. Contact Information

Patient	
Name:	Last, First, MI
Address:	Include Apt # if applicable
Zip Code (enter separately for NIH)	XXXXX
Phone 1 (cell):	(xxx) xxx-xxxx
Phone 2:	(xxx) xxx-xxxx
Email 1:	
Email 2:	
Preferred method of contact?	Phone, text, email
Emergency Contact 1	
Name:	Last, First, MI
Relationship:	(spouse, family, friend)
Address:	Include Apt # if applicable
Phone:	(xxx) xxx-xxxx
Email:	
Emergency Contact 2	
Name:	Last, First, MI
Relationship:	(spouse, family, friend)
Address:	Include Apt # if applicable
Phone:	(xxx) xxx-xxxx
Email:	

12.2.2. Referral source

How did you get referred to the Center for Addiction Science?	open-ended referral to be categorized later

12.2.3. Screening Questionnaire

	Inclusion	
1.	Presenting for their intake visit to the Center for Addiction Science for treatment of opioid use disorder	Yes / No If no: Exclude

2.	Access to a telephone	Yes / No If no: Exclude
3.	Eligible for receipt of buprenorphine-naloxone medication (e.g., Suboxone, Bunavail, Zubsolv)	Yes / No If no: Exclude
4.	Able to understand consent procedures	Yes / No If no: Exclude
	Exclusion	
5.	Have a known contraindication to buprenorphine-naloxone medication treatment for opioid use disorder	Yes / No If **yes**: Exclude

12.2.4. Exclusion reason (if applicable)

Exclusion reason variable to be entered by staff for ease of access for DSMB report:	List number of reason for exclusion from above screener.

12.2.5. Demographics

Date of Birth	xx/xx/xxxx		
Age			
Sex at Birth	Male	Female	
Gender Identity	Male	Female	Other (enter what is said)
Race	White/Caucasian	Black/African American	Multiracial
	Asian	Alaskan Native	Pacific Islander
	Native American	Other (specify)	
Ethnicity	Non-hispanic	Hispanic	
Highest level of education	8th grade or less	9th through 11th grade	12th grade or GED
	Associate's degree	Vocational/trade school	Some college
	Bachelor's degree	Graduate degree	
	Less than $10,000 per year	$10,000 to $19,999 per year	$20,000 to $29,999 per year

Annual household income	$30,000 to $39,999 per year	$40,000 to $49,999 per year	$50,000 to $59,999 per year
	$60,000 to $69,999 per year	$70,000 to $79,999 per year	$80,000 to $89,999 per year
	Over $100,000 per year	Prefer not to answer	
Do you currently have a job?	No	Yes-part time	Yes-full time
Relationship Status	Single	Married	Divorced
	Widowed	Cohabitating	
What insurance do you use when you visit the Center for Addiction Science?	(open-ended write in?)		

12.2.6. Opioid Use Disorder Criteria

Diagnostic and Statistical Manual of Mental Disorders - 5

Check all that apply:

1.	Are you often taking opioids in larger amounts or over a longer period of time than intended?	
2.	Have you tried or been unable to cut down or control your opioid use?	
3.	Have you spent a great deal of time in activities that are necessary to obtain your opioid, use the opioid, or recover from its effects?	
4.	Do you have cravings, or a strong desire to use opioids?	
5.	Is your opioid use resulting in failure to fulfill your role obligations at work, school or home?	
6.	Have you continued to use opioids despite having persistent or recurrent social or interpersonal problems (caused or exacerbated by the effects of opioids)?	
7.	Have you given up or reduced time spent of important social, occupational or recreational activities because of your opioid use?	
8.	Have you used opioids in situations in which it is physically hazardous?	
9.	Have you continued your opioid use despite physical or psychological problems that are caused or made worse by opioids?	
10.	*Tolerance Do you need to use more and more opioids to achieve your high? or Do you get less of an effect from your opioid than you used to?	
11.	*Withdrawal	

	Do you feel withdrawal when you don't take opioids? or Do you take opioids to avoid feeling withdrawal?	
Have Filemaker autoscore:		
Total Number Boxes Checked: _____ Severity designated: Mild: 2-3 symptoms. Moderate: 4-5 symptoms. Severe: 6 or more symptoms		

12.2.7. Adherent for first follow up physician visit

Showed up for Center for Addiction Science appointment at scheduled day/time?	Yes / No
AND	
Had buprenorphine in urine screen (either at the visit or when urine specimen came back from lab)?	Yes / No
If both items answered "Yes" then adherent is affirmed through Filemaker calculation	

12.2.8. Adherent for second physician visit

Showed up for Center for Addiction Science appointment at scheduled day/time?	Yes / No
AND	
Had buprenorphine in urine screen (either at the visit or when urine specimen came back from lab)?	Yes / No
If both items answered "Yes" then adherent is affirmed through Filemaker calculation	

11.2.9. Adherent for third physician visit

Showed up for Center for Addiction Science appointment at scheduled day/time?	Yes / No
AND	
Had buprenorphine in urine screen (either at the visit or when urine specimen came back from lab)?	Yes / No
If both items answered "Yes" then adherent is affirmed through Filemaker calculation	

12.2.10. Adherent for fourth physician visit

Showed up for Center for Addiction Science appointment at scheduled day/time?	Yes / No
AND	
Had buprenorphine in urine screen (either at the visit or when urine specimen came back from lab)?	Yes / No
If both items answered "Yes" then adherent is affirmed through Filemaker calculation	

12.2.11. Cumulative Adherence

Number of treatment visits attended (allow for drop out, drop back in)	Filemaker calculation

11.2.12. Urine Toxicology

Check all that are present in urine collected by Center for Addiction Science		
Buprenorphine	Yes	No
THC	Yes	No
Cocaine	Yes	No
Opiates	Yes	No
Amphetamines	Yes	No
Methamphetamines	Yes	No
Phencyclidine (PCP)	Yes	No
MCMA	Yes	No
Barbiturates	Yes	No
Benzodiazepines	Yes	No
Methadone	Yes	No
Tricyclic antidepressants	Yes	No
Oxycodone	Yes	No
ETC	Yes	No
Fentanyl	Yes	No

12.2.13. Timeline followback

Today's date:							
	(fill in day of the week)	**(fill in day of the week)**	**(fill in day of the week)**	**(fill in day of the week)**	**(fill in day of the week)**	**(fill in day of the week)**	**(fill in day of the week)**
	(example) Monday	**(example) Tuesday**	**(example) Wednesday**	**(example) Thursday**	**(example) Friday**	**(example) Saturday**	**(example) Sunday**
Did you have any illicit substances or	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No

alcohol on ___ day?							
If yes to alcohol: Number of standard drinks on this day	# drinks	# drinks	# drinks	# drinks	# drinks	# drinks	# drinks
Marijuana on this day?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Cocaine on this day?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Crack on this day?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Amphetamine or other stimulant on this day?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Opioid drugs that weren't prescribed to you? (not including fentanyl or methadone)	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Heroin on this day?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Hallucinogens, including MDMA/ecstasy on this day?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Sedatives and hypnotics, excluding Benzodiazepines on this day?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Benzodiazepines on this day?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Inhalants on this day?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Fentanyl on this day?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Methadone on this day?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No

12.2.14. Delay Discounting

In this experiment you will be presented with two amounts of money to choose between. One of the amounts will be available now and the other will be available in the future. Your job is to indicate which option you would prefer by pressing "q" for the left option and "p" for the right option. You should indicate your true preference because at the end of the experiment a random trial will be chosen and you will receive a bonus payment proportional to the option you selected at the time point you chose.	
$54 today	$55 in 117 days
$55 today	$75 in 61 days
$19 today	$25 in 53 days
$31 today	$85 in 7 days
$14 today	$25 in 19 days
$47 today	$50 in 160 days
$15 today	$35 in 13 days
$25 today	$60 in 14 days
$78 today	$80 in 192 days
$40 today	$55 in 62 days
$11 today	$30 in 7 days
$67 today	$75 in 119 days
$34 today	$35 in 186 days
$27 today	$50 in 21 days
$69 today	$85 in 91 days
$49 today	$60 in 89 days
$80 today	$85 in 157 days
$24 today	$35 in 29 days
$33 today	$80 in 14 days
$28 today	$30 in 179 days
$34 today	$50 in 30 days
$25 today	$30 in 80 days
$41 today	$75 in 20 days
$54 today	$60 in 111 days
$54 today	$80 in 30 days
$22 today	$25 in 136 days
$20 today	$55 in 7 days

12.2.15. Opioid Purchase Task

Instructions	
The following questionnaire will ask you how many of your chosen opioids you would purchase depending upon how much they cost. Imagine that you will have to consume all purchases in a single day, you cannot stockpile or get the opioids from another source, and you have no opioids available from previous days.	
How many opioid pills would you purchase if they were:	Number they would purchase:
Free?	
$0.25	
$0.50	
$1	
$1.50	
$2	
$2.50	
$3	
$4	
$5	
$6	
$7	
$8	
$9	
$10	
$15	
$20	

12.2.16. Engagement in Substance Free Activities

Please rate the extent to which the following factors have been helpful in your recovery from opioids either currently or during periods in the past when you stopped using.

Check or mark the box to indicate your answer.

	1 Not at all helpful	**2 Somewhat helpful**	**3 Very helpful**
		√	
1) Change in your social group to avoid drug users			
2) Increasing your social support, making new friends			
3) Developing a new hobby or reinvesting in previous hobbies (e.g., hunting, fishing, gardening)			
4) Exercising			
5) Running			
6) Reading			
7) Participating in yoga, meditation, or other forms of relaxation			
8) Spending more time with your family			
9) Change in your employment situation (working more or changing your job)			
10) Spending time in nature			
11) Addressing relationship or family issues/conflict			
12) Private religious activity (praying, meditating, reading scripture or religious books)			
13) Attending religious services			
14) Finding new ways to manage pain			
15) Taking medication for depression or anxiety			
16) Changing your diet to eat healthier foods			
17) Engaging more with social media (e.g., Facebook)			
18) Engaging less with social media (e.g., Facebook)			
19) Cooking/baking			
20) Changing your living situation/moving			
21) Drinking less alcohol or quitting drinking altogether			
22) Using less marijuana or quitting marijuana use altogether			
23) Quitting smoking			
24) Using more alcohol			
25) Using more marijuana			
26) Smoking more			
27) Engaging in creative activities (music, art, etc.)			
28) Getting involved with a team sport			
29) Getting involved in a community organization			
30) Volunteering			

31) Getting a pet			
32) Participating in a 12-step or other support group			
33) Seeing a professional counselor/therapist			
34) Helping others			
35) Taking a college class or educational/training program			
36) Sexual activity			
37) Eating more			
38) Addressing a health issue			
39) Avoiding high-risk situations for use/relapse			
40) Limiting access to money			
41) Telling your friends about your plan to stop using			
42) A change in your financial situation			
43) Reminding yourself about the risks of using			
44) Increasing your self-confidence/self-esteem			
45) Practicing positive self-talk (e.g., "I'm a good person" or "I can do this without pills")			
46) Managing anger			
47) Other (write in)			

12.2.17. Time Spent on Activities Worksheet (to be uploaded as picture to database).

Instructions:

Please list how many hours EACH WEEK you spend doing each of the activities listed below.

For example, if you spend 2 hours each day playing video games, that would be 14 hours each week for the activity named "Watching TV or surfing the internet."

	How many hours do you spend doing this activity EACH WEEK?
Family	
Work	

Education, hobbies, creative activities	
Exercise, time in nature, or self-care	
Watching TV or surfing the internet	
Religious or spiritual activity, community life	
Using opioids or other drugs/alcohol	
Substance recovery/treatment (includes counseling/medication visits and time in meetings like AA or NA)	
Socializing with people who <u>are</u> supportive of your recovery	
Socializing with people who <u>are not</u> supportive of your recovery	

12.2.18. Opioid Cravings Scale

	0	1	2	3	4	5	6	7	8	9	10
1. How much do you currently crave opiates?	Not at all										Extremely
2. In the past week, please rate how strong your desire to use opiates has been when something in the environment has reminded you of opiates	No desire										Extremely strong
3. Please imagine yourself in the environment in which you previously used opiates. If you were in this environment today and if it were the time of day that you typically used opiates, what is the likelihood that you would use opiates today?	Not at all										I'm sure I would use opiates

12.2.19. Buprenorphine-Naloxone dose log

How many days since your last visit to the Center for Addiction Science?	Enter #
How many days during this period did you skip your buprenorphine dose?	

12.2.20. Dosage of Buprenorphine-Naloxone Prescribed

(obtained from medical record at each session)	
Medication name	
Mg prescribed (buprenorphine)	
MME calculation	

12.2.21. Treatment Satisfaction

	The person who presented the material:					
1.	Was easy to talk to.	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
2.	Was concerned about me.	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
3.	Understands me.	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
4.	Seemed competent and well trained.	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
5.	Seemed well organized.	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
6.	Gave me the opportunity to express my thoughts about treatment.	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
7.	Helped me believe that I can change my opioid use if I want to.	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
8.	Argued with me.	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
9.	Tried to convince me that I needed to change my behavior.	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
10.	Made me feel that it is up to me to make decisions about staying in treatment.	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
11.	Gave me the chance to ask questions.	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
	The next questions are related to your treatment, not your counselor.					
12.	How interesting did you find this treatment?	Totally bad, boring	OK		Excellent, it was great	
13.	How personally relevant did you find this treatment?	Not at all relevant to me	OK		Excellent, it was very relevant to me	
14.	How effective do you think this treatment was in helping you stay in treatment?	Not at all effective	Somewhat effective		Very Effective	

15.	Those who drop out of treatment only: Please indicate how likely you are to restart buprenorphine treatment in the near future	I will not change my smoking	Unsure		I will change my smoking	N/A, already quit
16.	How effective, overall, do you think this program will be in helping people stay in opioid treatment?		1 = Not useful or effective 10 = Highly effective. The best treatment I could imagine.			
17.	What components of the treatment were most effective for you?		(Open ended)			
18.	Can you think of any ways to make this intervention more effective and user-friendly?		(Open ended)			
19.	What initially made you want to enroll in the study?	a.	b. I wanted help staying in treatment c. Gift cards d. One-on-one counseling e. Other (specify)			
20.	What was your motivation to stay in the study and complete your sessions?		(Open ended)			

12.2.22. Prescription Drug Monitoring data

Number of opioid prescriptions found in the prescription drug monitoring database since last visit	#

12.2.23. PEG for Chronic pain (3 items)

	0 No Pain	1	2	3	4	5	6	7	8	9	10 Pain as bad as you can imagine
What number best describes your pain on average in the past week?	0 No Pain	1	2	3	4	5	6	7	8	9	10 Pain as bad as you can imagine
What number best describes how, during the past week, pain has interfered with your enjoyment of life?	0 No Interference with Enjoyment	1	2	3	4	5	6	7	8	9	10 Completely Interfered with Enjoyment
What number best describes how, during the past week, pain has interfered with your general activity?	0 No Interference with Activity	1	2	3	4	5	6	7	8	9	10 Completely Interfered with Activity

12.2.24. EQ 5D 5L

Descriptive System items:					
Instructions: Select the answer that best applies to you					
Answer score:	**1**	**2**	**3**	**4**	**5**
MOBILITY	I have no problems in walking around	I have slight problems in walking around	I have moderate problems in walking around	I have severe problems in walking around	I am unable to walk around
SELF-CARE	I have no problems washing or dressing myself	I have slight problems washing or dressing myself	I have moderate problems washing or dressing myself	I have severe problems washing or dressing myself	I am unable to wash or dress myself
USUAL ACTIVITIES (*e.g. work, study, housework,family or leisure activities*)	I have no problems doing my usual activities	I have slight problems doing my usual activities	I have moderate problems doing my usual activities	I have severe problems doing my usual activities	I am unable to do my usual activities
PAIN / DISCOMFORT	I have no pain or discomfort	I have slight pain or discomfort	I have moderate pain or discomfort	I have severe pain or discomfort	I have extreme pain or discomfort
ANXIETY / DEPRESSION	I am not anxious or depressed	I am slightly anxious or depressed	I am moderately anxious or depressed	I am severely anxious or depressed	I am extremely anxious or depressed

VAS scale item	
Instructions: We would like to know how good or bad your health is today. This scale is numbered from 0 to 100. 100 means the BEST health you can imagine. 0 means the WORST health you can imagine. From 0 to 100, how good is your health today?	
Score (0 to 100):	

12.2.25. PHQ-2 depression 2 items

Instructions: Over the last 2 weeks, how often have you been bothered by the following problems?				
Score:	0	1	2	3
1. Little interest or pleasure in doing things	Not at all	Several days	More than half the days	Nearly every day
2. Feeling down, depressed or hopeless	Not at all	Several days	More than half the days	Nearly every day

12.2.26. GAD 2 anxiety 2 items only (also a 7 item version)

Instructions: Over the last 2 weeks, how often have you been bothered by the following problems?				
Score:	0	1	2	3
1. Feeling nervous, anxious or on edge	Not at all	Several days	More than half the days	Nearly every day
2. Not being able to stop or control worrying	Not at all	Several days	More than half the days	Nearly every day

12.2.27. Treatment history (times in treatment, medication used)

How many times have you been in treatment for opioid use disorder (addiction)?	(fill in number) If "0", end this questionnaire.		
Treatment #1 (most recent)			
How long were you in treatment (months)?	(fill in number of months)		
Was this counseling, medication, or both?	Counseling	Medication	Counseling and Medication
Was it successful (were you able to stop using opioids)?	Yes / No		
Treatment #2			
How long were you in treatment (months)?	(fill in number of months)		
Was this counseling, medication, or both?	Counseling	Medication	Counseling and Medication
Was it successful (were you able to stop using opioids)?	Yes / No		
Treatment #3… etc. up to 5 only			

12.2.28. Economy Contribution Questions

1.	Are you working?	Yes	No
	If yes		
1.a.	How many hours a week?		
1.b.	How much do you make an hour?		
1.c.	How long have you been with your current employer?		
2.	Are you receiving SNAP/TANIF/SSDI/other public assistance?	Yes	No
3.	Have you had any police contact since last session ?	Yes	No

12.2.29. For Participants Who Have Stopped Center for Addiction Science Treatment Only

Are you receiving buprenorphine-naloxone treatment from a different provider at this time?	Yes / No
Are you receiving any treatment for opioid use disorder at this time?	Yes / No

12.2.30. Adverse Events

What was the adverse event? _____

Onset Date: ____ / ____ / ____

End Date: ____ / ____ / ____

Was the participant using the study drug(s) at the time of the event?
- ☐ Yes
- ☐ No

Was the event related to the study intervention or study drug?
- ☐ Unrelated
- ☐ Unlikely
- ☐ Possible
- ☐ Probable
- ☐ Highly Probable

Action Taken:
- ☐ None
- ☐ Study Drug Paused
- ☐ Study Drug Discontinued
- ☐ Study Participation Paused
- ☐ Study Participation Ended

If study participation was stopped, was it stopped due to the AE?
- ☐ Yes
- ☐ No
- ☐ N/A

Was the event expected?

☐ Yes
☐ No

Severity of AE:
☐ Mild
☐ Moderate
☐ Severe

SAE Category:
☐ Not an SAE
☐ Inpatient hospitalization
☐ AE resulted in death
☐ Life threatening
☐ Permanent or severe disability
☐ Congenital anomaly
☐ Treatment to prevent an above serious event

Outcome:
☐ Completely recovered
☐ Recovered with sequalae
☐ Condition improving
☐ Condition present and unchanged
☐ Condition deteriorated
☐ Death due to this AE
☐ Other

_____
_____

Narrative/Comments:

_____
_____
_____
_____
_____

Staff Initials: _____

MD CHECK OFF SECTION

MD Check Off Initials _____

Date: ____ / ____ / ____

☐ Approved
☐ Needs QC

MD Additional Information Needed:

_____
_____
_____
_____

QC Completed By _____
QC Date: ____ / ____ / ____

12. CM INTERVENTION SCRIPT

Hi _____. Nice to see you again. As you may remember, we check on your toxicology results to determine whether you are eligible for the number wheel.

Buprenorphine Present:

I see today you do have medication in your system. Congratulations! You are eligible for the wheel spin. As a reminder, the wheel includes gift cards ranging from $25 to $100. You will spin and land on a random number.

https://pickerwheel.com/

Buprenorphine Not Present:

I see today you do not have medication in your system. I'm sorry, but you will not be eligible for the wheel spin today.

13. BSM INTERVENTION SCRIPT

Psychosocial Intervention Session 1 (40 minutes with assessments):

Session Prep:

a. Ensure participant has received SOBER Handout at baseline
b. Print off blank Goals worksheet for Session 1 to fill out during session
c. Participant should have completed the "Time Spent on Activities Worksheet" at baseline.
    i. *Have a graph of the time spent in each activity prepared and sent to the participant before the session begins*
d. Print off blank Future Event Description worksheet for Session 1 (Goals, Future Event Description) to fill out during session

1. Introduction (2 minutes)
    a. Getting Permission to Record
        i. *Hi _____, is this still a good time for us to do our first session together? Great!*
        ii. *Before we get started today, I wanted to let you know all of our sessions will be recorded for the purpose of the study.*
        iii. *Do I have your permission to record this session? Thank you so much.*
    b. Mandated reporting
        i. *Also, I wanted to let you know that I am a mandated reporter. That means if you let me know about any ongoing abuse, either to yourself or to someone else, or if you inform me of any intentions to harm yourself or someone else, I am obligated by law to report that. If anything like that comes up during any of our sessions, I would let you know ahead of time.*
        ii. *Do you have any questions about that?*

2. Assessment (10 minutes)
    a. Complete session one assessment forms in FileMaker.
    b. *Thank you for taking the time to answer all those questions.*
    c. *Because you finished your assessment, I will mail you that $25 gift card. Do you prefer Kroger or Walmart? Great!*
    d. *Please allow 2-3 business days for it to arrive. If there are any issues, please don't hesitate to reach out!*

3. Build Rapport (1 minutes)
    a. *So I'd like to get to know a little more about who you are. Tell me who are the most important people in your life and one or two things you like to do – just a minute's worth of who you are.*
        i. Wait for participant to tell you about themselves – MAXIMUM 1 minute

4. Orientation to Session (1 minute)
    a. *Thank you for telling me about yourself.*
    b. *Let me tell you about what we will be doing with our time together.*
        i. *My overall goal is to support your treatment at the Center for Addiction Science and help you meet your goals.*
        ii. *During our 4 sessions together, we will discuss your goals and values, identify some drug and alcohol free activities you would like to start doing, and teach you some relaxation skills.*
    c. *Do you have any questions before we start?*

i. Answer questions

5. Goals for Treatment/Motivational Interviewing Discussion (5 minutes)
    a. Have blank "Goals Worksheet" printed out and ready to use
    b. Introduce Purpose
        i. *Now first, I want to talk about your goals, both short and long term. This is to help you start to expand your thinking into the future.*
        ii. *Why did you decide to start treatment that this time?*
            1. Things they want to accomplish as a result of being in treatment
    c. Discuss Goals
        i. *Thank you for sharing that with me.*
        ii. *Now, what are your overall life goals? What would you like to accomplish?*
            1. Listen and reflect.
            2. Summarize the goals they tell you.
            3. Help them to identify at least one goal that might lead to an increase in positive drug-free activities. Many participants will naturally bring up a goal that will serve this purpose (e.g., getting in shape, meeting new people, getting a new job, improving family relationships). If they do not, you can ask them if they can think of a goal that would enrich their life in some way by enhancing their social support, enjoyment, or giving them a sense of accomplishment or purpose?
            4. *OK, great, so you would like to _____ and ____ and _____ .*
    d. Possible activity: Choose Goal and Break Down into Small Steps.
        i. Note: Only ask them to break down a goal into smaller steps if you think that would lead to increases in positive drug-free activities.
        ii. *Now let's choose one of those goals and really think about what it will take to reach it. How about X (goal that can lead to increased drug free activities)*
            1. *Sometimes, breaking a goal down into smaller steps helps you get started on it.*
            2. Write goal on the "Goals" worksheet (see separate page, below).
        iii. *Now let's list some short-term, specific things you need to do that will help you to reach your goal.*
            1. Keep asking open-ended questions to identify 3 very specific behaviors.
    e. Summarize
        i. *OK, so I have that your big goal is to _____, and you will get there by doing ____, _____, and _____. Does that sound right?*
        ii. *Now I would like to ask you, how might relapse impact this goal?*
            1. Let them answer
            2. *I see, so relapse would make it difficult to ____, but if you stay in treatment, this goal might be reachable.*
        iii. *I'm going to text you this worksheet I filled out so you can reflect on these steps we talked about and also fill in the steps for the other two goals you identified*
        iv. Send this list to the participant via text or email (if using social distancing procedures)

6. Time Spent On Activities of Daily Life (5 minutes)
    a. Participant should have completed the "Time Spent on Activities Worksheet" at baseline.

b. Graph participant's time spent in each activity prior to session, and hand it, text it, or email it to the participant. Their answers should be in the baseline assessment in filemaker.
c. Have this graph in front of you for this activity.
d. Introduce Activity
    i. *Let's change gears now and talk about the activities that are important to you in life; your priorities and core goals for yourself.*
        1. *You may remember that when you first came in, we asked you to fill out a questionnaire about how many hours per week you spend doing different things.*
        2. *I took what you wrote, graphed it out, and gave it to you before our session today.*
    ii. *Now, if it's okay with you, I'd like to talk about these activities.*
        1. *One of the reasons we summarize this information is because people rarely think about how they spend their time, even though it says a lot about what they find important.*
    iii. So, looking across this graph at the time you spend doing different things, what stands out to you?
    iv. What are some areas that you might like to change the amount of time you spend on them?
e. FOR THOSE WITHOUT ACCESS TO THE GRAPH
    i. *Since you can't see the graph, let's walk through a few areas.*
    ii. *You stated that you spend ____ hours a week with your family.*
        1. *How do you feel about that when you think about your goals?*
    iii. *You spend _____ hours a week on work.*
        1. *How do you feel about that when you think about your goals?*
    iv. *You spend _____ hours a week on education, hobbies, or creative activities.*
        1. *What kinds of things do you do?*
        2. *How do you feel about the amount of time you spend on this when you think about your goals?*
    v. *You spend _____ hours a week on exercise, time in nature, or self-care.*
        1. *What do you think about your time spent on these activities when you think about your goals?*
    vi. *You spend ____ hours a week watching TV or surfing the internet.*
        1. *What do you think about your time spent on these activities when you think about your goals?*
    vii. *You spend ____ hours a week on religious or spiritual activity, community life.*
        1. *How do you feel about that when you think about your goals?*
    viii. *You spend ____ hours a week using opioids or other drugs/alcohol.*
        1. *How do you feel about that when you think about your goals?*
    ix. *You spend ____ hours a week on substance recovery and treatment.*
        1. *What do you think about your time spent on recovery activities when you think about your goals?*
    x. *You spend _____ hours a week socializing with people who <u>are</u> supportive of your recovery.*
        1. *What do you think about your time spent doing this when you think about your goals?*
    xi. *You spend _____ hours a week socializing with people who <u>are not</u> supportive of your recovery.*
        1. *What do you think about your time spent doing this when you think about your goals?*

f. Summarize:
    1. *So it sounds like you would like to spend more time ____ and also _____ because that fits with your goals of _____ and _____.*
    2. *What would keep you from changing how you spend your time?*

7. Future Events (10 minutes)
    a. Have blank "Future Event Description Worksheet" ready to use
    b. Prepare Think Activity
        i. *Now let's do a short thinking exercise. I am going to ask you to think specifically about positive (nice, happy) future events that could happen if you remain in recovery.*
            1. *If you are comfortable, you may close your eyes for a moment so that you can focus.*
            2. *Visualize your life 3 months into the future.*
        ii. *Think about aspects of your life that matter to you.*
            1. *It could be how you want to grow mentally, spiritually, or physically. Think about how you would want your body and physical fitness to be, or what new skills or hobbies you may want to learn, or what new career building skills you would want to develop, or anything that gives you a sense of meaning, mission, or purpose.*
        iii. *Pick any of these categories that are important in your life and take a minute to visualize and imagine how will feel in your life 3 months from today.*
            1. Wait about 60 seconds to let the person imagine this future event.
    c. Describe Activity
        i. *Now, let's talk about a specific type of positive (nice, happy) experience you are looking forward to having in your life.*
            2. *I want you to be specific about what you will be doing, who you will be with, how you imagine this one experience will feel, and the types of thoughts and emotions you have when this event takes place.*
            3. *Tell me about the future event (or events) you imagined.*
        ii. Write down and summarize for patient.
            1. *So, if you remain in recovery, you are looking forward to _____, with _____, and this will feel _____. Did I get that right?*
            2. *That's really something to look forward to.*

8. Mindfulness-Based Adherence Promotion Intervention (5 minutes)
    a. *The last thing we'll discuss today is something called the SOBER breathing space. We're going to go over this in more detail in the weeks to come, but I want you to have an idea of what it is to help you start working through some of your triggers.*
    b. Explain the Acronym
        i. *SOBER stands for:*
            1. *Stop and see what happens*
            2. *Observe physical sensations and emotion regulation changes in the body*
            3. *Breathe by deliberately bringing attention to the breath*
                a. Describe to the participant how to breathe in through their nose and out through their mouth slowly.
            4. *Expand awareness of the situation*
            5. *Respond mindfully (versus reacting)*

c. Give/Send participant SOBER Handout
    i. *I'm sending you a handout with the SOBER skillset so that you can start using this at home.*
d. Trigger identification
    i. *Is there a trigger that you're worried could come up this coming week?*
        1. i.e., something that reminds them of opioid (or other drug) use.
    ii. *This coming week, if _____ comes up, what would it be like to take a few minutes to SOBER?*

9. Wrap-Up (1 minute)
    a. *We talked about a lot today. I appreciate your openness.*
    b. *To summarize:*
        i. *It seems like you are motivated to spend more time on _____ given how important it is for you.*
        ii. *From all the information we covered today, I'm curious about what stands out most for you?*
            i. Allow participant to answer.
    c. *Do you have any questions for me?*
    d. *Let's schedule our next session together, based around your clinic visit.*
    e. Provide participant with date and time of session.

What to send to participant after Session #1:

1. Completed "Goals Worksheet"
2. Gift Card for completed assessment

Upload into Database after Session #1:

1. Completed "Goals Worksheet"

Goals Worksheet

List participant's goals. If useful, break down goal into smaller steps.

Goal	Short term, specific goals
1.	1.
	2.
	3.
2.	1.
	2.
	3.
3.	1.
	2.
	3.

Following the session, upload this as a picture into the database under session 1 tab.

Time Spent on Activities Worksheet (uploaded at baseline as picture to database)

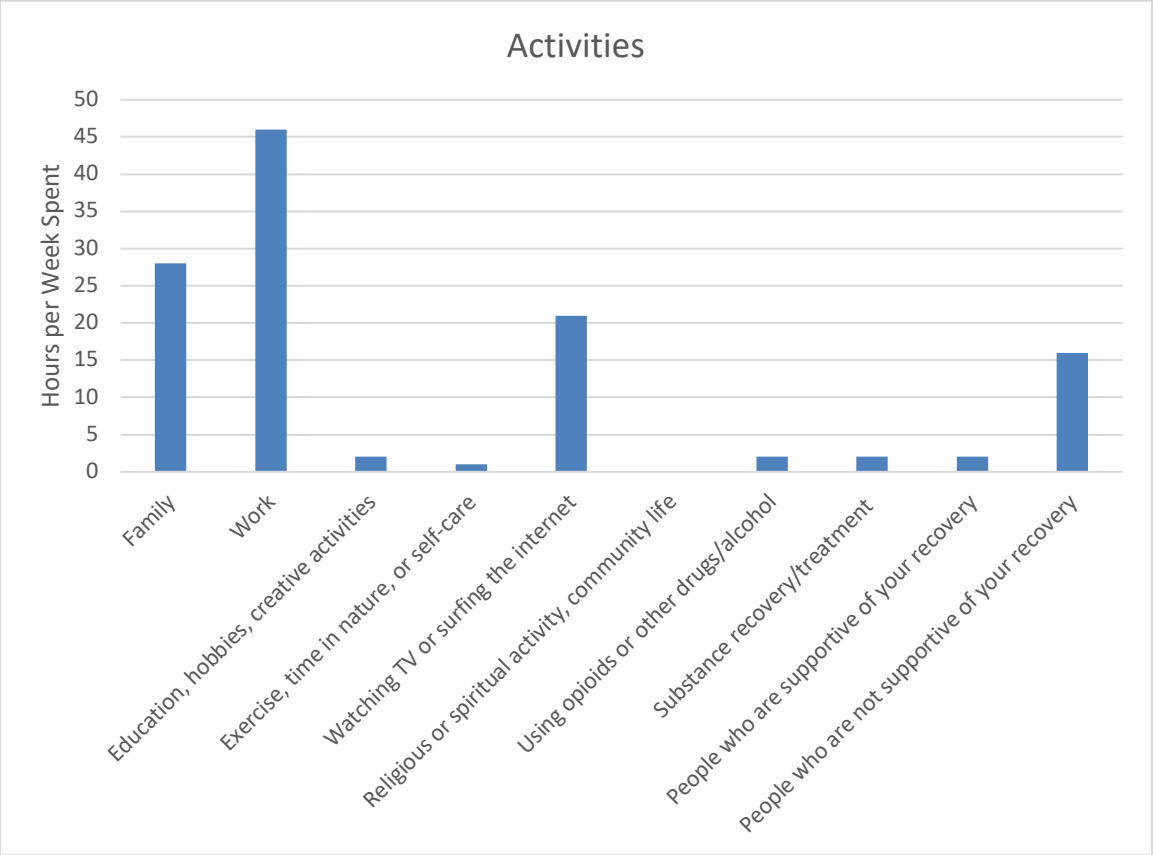
Instructions:

Please list how many hours EACH WEEK you spend doing each of the activities listed below.

For example, if you spend 2 hours each day playing video games, that would be 14 hours each week for the activity named "Watching TV or surfing the internet."

	How many hours do you spend doing this activity EACH WEEK?
Family	
Work	
Education, hobbies, creative activities	
Exercise, time in nature, or self-care	
Watching TV or surfing the internet	
Religious or spiritual activity, community life	
Using opioids or other drugs/alcohol	
Substance recovery/treatment (includes counseling/medication visits and time in meetings like AA or NA)	
Socializing with people who <u>are</u> supportive of your recovery	
Socializing with people who <u>are not</u> supportive of your recovery	

Example Graph of Time Spent on Activities Worksheet



Future Event Description Worksheet

Write event below to summarize for the participant.

Following the session, upload this as a picture into the database under session 1 tab.

SOBER Handout

Handout is to be given to the participant at their baseline visit.

Psychosocial Intervention Session 2 (39 minutes with assessments):

Session Prep:

a. Goals Worksheet from session 1 that you filled out for the participant.
b. Participant's completed Substance Free Activities Worksheet (from Baseline Assessment)
    - Look over participant's preferred substance free activities questionnaire from baseline.
    - Identify activities local to the participant's home or available online that could fulfill these activity needs.
    - **Focus more** on increasing activities that include socializing with people supportive of recovery, exercise/time outdoors, and goal-directed/creative activities.
    - **Focus less** on activities that might jeopardize recovery (time with users, activities that increase stress) or that are recovery neutral (passive leisure activities like watching TV) those should be less of a focus
        - In the case of risky activities, the clinician can ask the client how that activity would relate to their recovery goals – get the participant to make this link.
c. ***during pandemic*** Pleasant Activities handout

1. Introduction (1 minute)
    a. Getting Permission to Record
        i. *Hi _____, how are you today? Is this still a good time for us to do our second session together? Great! And before we get started today, do I have your permission to record this session? Thank you.*

2. Assessment (10 minutes)
    a. Complete session two assessment forms in FileMaker.
    b. *Because you finished your assessment, I will mail you that $25 gift card. Do you prefer Kroger or Walmart? Please allow 2-3 business days for it to arrive. Thanks for getting the assessment completed today.*

3. Continue to Build Rapport (2 minutes)
    a. *Tell me how you've been since the last time we spoke.*
    b. Wait for participant to tell you how they are.

4. Orientation to Session (1 minute)
    a. *Today we are going to build on what we discussed last time by discussing your activities, and revisiting the SOBER breathing exercise.*
    b. *What questions or thoughts do you have about our last session?*
    c. If the participant missed the previous session , take a few moments to inform them of the information they missed.

5. Goal Setting Exercise (5 minutes)
    a. Have completed "Goals Worksheet" available from Session 1
    b. *To start today, I'd like to revisit your goals from session 1.*
    c. Restate Goals
        i. *During session 1, you mentioned that this was your primary goal:*
            1. (read their primary goal from worksheet)

2. *Has this goal changed?*
3. *Have you had the opportunity to work towards this goal in the past week?*
    a. "No" is an acceptable answer.
    b. Normalize that their goal right now may be "survival" and that's ok

d. Benefits and Barriers
    i. *Let's talk more about the goal you identified.*
        1. *What would be the benefits of achieving this goal?*
        2. *What do you think might get in the way?*
    ii. A goal that may seem completely appropriate may have some unforeseen barriers

e. Tracking progress and organizing activities with an app or calendar:
    i. *Finally, I would like to ask you how you keep track of what activities you have planned?*
    ii. *Do you use any sort of calendar?*
        1. *Some people find it helpful to write down activities in your calendar ahead of time.*
            a. *What do you think about this?*
        2. If they are agreeable:
            a. *Do you like a written calendar or use of a device, like a smartphone phone?*
            b. Briefly summarize their thoughts on this (example: ok, so you might consider using the calendar on your phone to keep track of your activities).

6. Substance Free Activity: Identifying Activities (7 minutes)
    a. Have participant's completed Substance Free Activities Worksheet (from Baseline Assessment) available
    b. Orient participant to topic
        i. *Let's move to a new subject now.*
        ii. *Many people who decide to make a change in their drug use find that developing other ways of having a good time, in order to fill the void left by drug or alcohol use, is a crucial part of their recovery.*
    c. Review their answers to the substance free activities worksheet
        i. *When you enrolled in the study, you completed a list of substance free activities that you enjoyed or found important to your recovery*
            1. *These are the activities you ranked the HIGHEST*
                a. *Which of these activities/hobbies do you **enjoy** the most?*
                b. Write down activities participant <u>enjoys</u> the most
            2. *What do you like about _(the activities they mention)_____?*
                a. Talk through a few activities, **focusing on exercise, socializing with non-users, and goal-directed, creative activities.**
            3. *What are some of the reasons you want to focus on ___(the activities they mention)___?*
                a. Talk through each activity they listed (limit this to 5 activities or less)
            4. *What are some of the things that could get in the way of enjoying these activities?*
                a. For people who report few enjoyable activities help them to problem solve how they could access more activities.

7. Increasing Substance Free Activities (7 minutes)
    a. Orient participant to topic
        i. *Now let's talk about taking some steps to increase your drug free activities.*
        ii. *Your preferred activities are ___(list from above)_____ .*
            1. *What are some realistic steps you can start to take to implement this into your life more often?*
            2. *How would _____ activity fit in with your recovery plan?*
    b. Tell them what you found for them
        i. *Great! To help you learn about some of these activities you mentioned last week, I have put together some information on how you can get involved in some of these activities in your community.*
            1. Encourage the participant to ask questions and take a few moments to explain the specific resources you provided (e.g., "You talked a lot about spending time with animals as a helpful tool in your recovery. Did you know that the Humane Society of Memphis is always looking for volunteers or foster homes for animals? Here is their information."
        ii. *What are your thoughts in contacting one or two of these places next week (or doing these activities)?*
            1. Write down plan on the Session 2 Substance Free Activities Plan worksheet.
            2. If the participant does not express any motivation to incorporate substance-free activities into his/her life, the interventionist should focus on fostering ambivalence in the participant about his/her current time allocation. The interventionist should explore with the participant the pros and cons of continuing to allocate his/her time in this manner.
            3. The interventionist could also try to help the participant in considering more long-term goals if they are ambivalent with short-term.
            4. If there are barriers to participating in the substance free activities, the interventionist should help the participant problem solve ways to get involved in said substance-free activities.
    c. Pleasant Activities Worksheet
        i. Give worksheet to participant.
        ii. *Lots of folks are having trouble finding ways to manage their stress during COVID. Here is a handout with a list of relaxing activities people can do at home.*
        iii. *Some of these may work for you, others may not. It is really to help you identify some strategies you can use, even when life isn't normal.*
    d. Wrap Up
        i. *It sounds like you've put a lot of thought into how you would like to use your time. We can continue to talk about this next time.*
        ii. *I am going to send you this worksheet after our session today.*
        iii. Send to participant following session

8. Mindfulness-Based Adherence Promotion Intervention (5 minutes)
    a. *Before we wrap up our time together today, let's talk a little more about the SOBER acronym we discussed last time. How has SOBER been working for you?*
        iv. Remind the participant of the SOBER acronym if needed (Stop, Observe, Breathe, Expand, and Respond).

9. Wrap-Up (1 minute)
    a. *We covered a lot today during our session. Do you have any questions for me?*
    b. *Let's schedule our next session together.*
    c. Provide participant with date and time of session.

What to send to participant after Session #1:

1. Completed "Substance Free Activities Plan Worksheet"
2. Gift Card for completed assessment

Upload into Database after Session #1:

1. Completed "Substance Free Activities Plan Worksheet"

2. Session 2: Substance Free Activities Plan Worksheet

Substance Free Activity	Steps to start this activity

Psychosocial Intervention Session 3 (41 minutes with assessments):

Session Prep:

- Have participant's Substance Free Activities Plan Worksheet available from session 2.

1. Introduction (1 minute)
    a. Getting Permission to Record
    b. *Hi _____. Is this still a good time for us to do our next session together? Do I have your permission to record this session? Thank you!*

2. Assessment (10 minutes)
    a. Complete session three assessment forms in FileMaker.
    b. *Because you finished your assessment, I will mail you that $25 gift card. Do you prefer Kroger or Walmart? Please allow 2-3 business days for it to arrive.*

3. Continue to Build Rapport (2 minutes)
    a. *How have you been doing since we last spoke?*
        a. Wait for participant to answer.

4. Orientation to Session (1 minute)
    a. *Today, we are going to review the opioid-free activities you've been trying, and have a discussion about the deeper meaning of the SOBER breathing exercise.*
    b. *What questions or thoughts do you have about our last session?*
    c. If the participant missed the previous session , take a few moments to inform them of the information they missed.

5. Substance Free Activity Session Review (5 minutes)
    a. *Last time, we talked more about the hobbies/activities you would like to try. What steps were you able to take towards starting the activities you mentioned?*
        i. Allow the participant time to reflect and discuss the resource guide from the last session .
    b. *Since _____ is a really important activity to you, what are some things that you can do to make progress towards this goal?*
        i. Possible questions you might ask:
            1. *What would be the benefits of achieving these goals?*
            2. *What do you think might get in the way?*
            3. *How will you know if your plan is working?*
            4. *How will you know if you are getting off track? What steps would you take to get back on track?*
    c. Summarize the goals/plans to the participant has for implementing substance-free activities.
        i. So you still want to try _____, but it turns out it costs too much to join the gym. So instead, you're thinking about ____. Does that sound right?

6. Mindfulness-Based Adherence Promotion Intervention (20 minutes)
    a. Orientation
        i. *Let's spend a few minutes today talking specifically about the SOBER acronym.*
            1. *S is for Stop and see what happens*

2. *O is for Observe physical sensations and emotion regelation changes in the body*
3. *B is for Breathe by deliberately bringing attention to the breath*
4. *E is for Expand your awareness of the situation*
5. *R is for Respond mindfully*
6. *These last two letters are very important to practice but can sometimes be a little more challenging to understand. Let's talk about it.*

b. Surf the Urge
   i. *Sometimes in the moment urges or moods can feel overwhelming – does that sound familiar? Our natural tendency is to give in to momentary urges and maybe in the past we have used alcohol or drugs to cope with urges, but we do have a choice. We can learn to "surf the urge" of a trigger to ride out cravings, urges, and triggers as they come up.*
   ii. *Let's practice this now.*
   iii. *I want you to imagine a situation that you are currently dealing with, maybe something recent that you found triggering. This doesn't need to be the most difficult situation you can think of, but one that is difficult or challenging for you.*
      1. For those who are currently distressed, no need to elicit a trigger
   iv. *Do you have something in mind?*
   v. *OK, let's walk through the steps.*
      1. ***Stop**: Just take a moment to stop your immediate urge to react.*
      2. **Observe**: *Take a moment to really assess what you're feeling. Notice your emotions. Also, notice how your body feels during this time.*
         a. Also notice any thoughts that are coming up.
      3. ***Breathe**: Take at least three deep and slow breaths to ride the wave of your trigger. Allow yourself to focus on the rhythmic breathing. You don't need to change your breathing, just notice it.*
         a. Take a minute to breathe with the participant in through their nose and out through their mouth slowly.
         b. You might notice your mind wandering. That's ok, just bring it back to the breath.
      4. ***Expand**: Work to expand your awareness of the situation. You already are slowing down your breath, now focus on the breath to allow your body and your mind to soften. We are expanding our awareness back out to the feelings in the body, the sensations of being in the room, and allowing ourselves to be centered and grounded in this moment.*
      5. ***Respond**: Allow yourself to respond mindfully. How can you truly take care of yourself in this situation? What do you really need? Take a moment to choose your response – knowing that you do have a choice.*
         a. People may think of this as "wise mind" – acting with purpose and reason.
         b. Importantly, the person might still choose the same reaction/response – that is okay. Our goal is to just be more present with our response to situations, triggers, urges. Allow the participant some time to process this part of SOBER. Encourage the participant to be empowered to make a choice and to be more present when choosing a response.

7. Wrap-Up (2 minutes)
    a. *We covered a lot today during our session. I did want to remind you that next time is actually going to be our last session together! Do you have any questions for me today?*
    b. *Let's schedule our final session together.*
    c. Provide participant with date and time of session.

Psychosocial Intervention Session 4 (38 minutes with assessments):

1. Introduction (1 minute)
    a. Getting Permission to Record
    b. *Hi _____, how are you today? Is this still a good time for us to do our final session together? Great! And before we get started today, do I have your permission to record this session? Wonderful, thank you!*

2. Assessment (20 minutes)
    a. Complete session four assessment forms in FileMaker.
    b. *Because you finished your assessment, I will mail you that $25 gift card. Do you prefer Kroger or Walmart? Please allow 2-3 business days for it to arrive.*
    c. *Thanks for getting the assessment completed today.*

3. Orientation to Session (1 minute)
    a. *Today, we will discuss improving self-control. We'll also review the opioid-free activities you've been trying, and touch base on how SOBER has been working for you.*
    b. *What questions or thoughts do you have for me before we get started?*
    c. If the participant missed the previous session , take a few moments to inform them of the information they missed.

4. Improving Self-Control (5 minutes)
    a. *I would like to introduce you to an activity we call "improving self-control."*
    b. *You may not know this, but self-control changes for people during the course of recovery.*
    c. *What do you think self-control is?*
        i. Let participant answer.
        ii. *Yes! We also think of it in these ways:*
            1. *The ability to identify your long-term goals and act in a way that is consistent with those goals*
            2. *The ability to wait for a bigger reward to come at a later time.*
            3. *The ability to keep working on a task or goal even if it difficult or results in frustration or set basks*
    d. Improving Self-Control
        i. *What are some ways you think people can improve their self-control?*
            1. *Great ideas! I have some other ideas – do you mind if I share them?*
            2. <u>Identify your short and long term goals</u>
                a. What are your values, what is important to you in life?
                b. Where do you want to be in 2 years? In 10 years?
            3. <u>Write down these goals</u> and consult them regularly as you decide on what you are going to do each day.
            4. <u>Make your goals public</u> (post them on Facebook, tell your friends and family)
                a. <u>GET SOCIAL SUPPORT</u>
            5. <u>Record your progress</u> towards your goals (can do this with pencil and paper, on your phone, or on your computer)

6. Make specific commitments to the things you want to get done (e.g., if you want work out every morning, make a plan to do this with a friend).
7. Use rewards for accomplishing your goals (stickers, money you put away to spend if you accomplish your goal each week, etc.).
8. Remind yourself of the benefits of accomplishing your long term goals (e.g., a promotion, higher salary, nurturing important relationships, being healthy, etc.)
9. Self-control is like a muscle. Self-control gets stronger with practice – its gets easier over time to resist temptation and to stick with your healthy routines and commitments.
    a. Also remember HALT: hungry, angry, lonely, tired. It's hard to have self-control if you are tired, grumpy, hungry, sad, etc. Get good rest, eat well, exercise, take short breaks from challenging activities, and plan fun events to keep your mood good.
10. Identify (and avoid) high risk people and situations that get in the way of your goals
11. *What do you think about these ideas? Would you find any of them useful? Which ones?*

5. Substance Free Activity Check In (5 minutes)
    a. *I know we've talked a lot about some activities/hobbies you've started to work on. How has it been going trying _____?*
        i. Allow the participant a few minutes to discuss the opioid-free activities.
    b. Focus the conversation on problem-solving any barriers that have come up for them with their new activity/hobby.
    c. *I have one more tip to offer you as you continue to fill your time with new opioid free activities. It's always helpful to have a calendar or use your phone to schedule your plans. This will be helpful to increase your awareness of what's on your schedule and the activities you have to look forward to!*
    d. *What other questions do you have about your new opioid-free activities?*

6. Mindfulness-Based Adherence Promotion Check In (5 minutes)
    a. *Tell me a little bit about your experiences in using the SOBER breathing space.*
    b. Take some time to complete one final review of SOBER and problem-solve ways to help the participant use this in daily life.
    c. *SOBER stands for:*
        i. ***Stop*** *and see what happens*
        ii. ***Observe*** *physical sensations and emotion regulation changes in the body*
        iii. ***Breathe*** *by deliberately bringing attention to the breath*
        iv. ***Expand*** *awareness of the situation*
        v. ***Respond*** *mindfully (versus reacting)*
    d. *We've gone over how to use the SOBER breathing space when experiencing cravings, urges, and triggers. How do you think you will continue to use this skill to support your recovery?*

7. Wrap-Up (1 minute)
    a. *We have covered a lot of things during our sessions together over the past few months. What questions do you have for me?*

b. Allow the participant to process any last-minute concerns or questions. Thank the participant for their time in the study.

Participants will also receive a copy of the “Tips for Improving Self Control Handout” located on OneDrive.

14. VIRTUAL MAILING PROCEDURES

Session /Mailing Procedures:

Baseline

- If participant completes the full package in-person, they will receive a $50 gift card before they leave the clinic.

    - Each interventionist is responsible for taking care of their own gift cards and welcome package (T-shirt, copy of consent, SOBER handout [BSM group only], and business card).

        Instructions:
        - **Log gift cards out of the safe.**
        - **Complete the GC sheet and make copy of gift card for study records.**
            - **Ppt. will need to sign off on the sheet. Once completed place in GC binder.**
        - **Present GC to ppt**
        - **Welcome ppt. to the study and hand them their welcome bag.**
        - **Schedule next session (based on their appt. with clinic).**

- If the participant takes the packet home, they will need to return the package back or call to complete the assessment over the phone. Once completed, we will mail them a $50 gift card; if they come back into the clinic, we will give them a gift card in person.

    - Each interventionist is responsible for taking care of their own gift cards and welcome package (T-shirt, copy of consent, SOBER handout [BSM group only], and business card).

        Instructions:
        - **Schedule a time to complete baseline.**
            - **Inform the ppt. that we will not be able to mail GC without completing the pack first.**
        - **Welcome ppt. to the study and hand them their welcome bag.**
            - **T-shirt, copy of consent, SOBER handout [BSM group only], and contact card.**
            - **No GC will be given until pack is completed.**

        Once baseline is completed:
        - **Log gift cards out of the safe.**
        - **Complete the GC sheet and make copy of gift card for study records.**
            - **Once completed place sheet in GC binder (ppt. will not need to sign).**
        - **Mail GC to ppt.**

- **Mail can be dropped off at the UCH lobby or nearest postal office.**
- **Use SMART mailer and envelop.**

Sessions 1-3 (Virtual)

- After the participant completes all the assessments and the intervention, they will receive their GC. Appointments will be scheduled within 30 day windows.

    - **CM Group Instructions:**
        - **Complete assessments**
        - **Inform ppt. of the GC amount they will receive, and to please allow 2-3 business days to arrive.**
            - **$50 for completing assessments.**
            - **Additional GC will depend on the following:**

              Urine toxicology results
              - **If participant is compliant, buprenorphine in their urine, we will spin the virtual wheel for them and inform them of the amount received.**
              - **If participant is not compliant, no buprenorphine in their urine, we will inform them that they will not be able to participate in the number wheel at this time.**

        - **Study team will take a screenshot of the number wheel and will text or email ppt. the results; only when applicable.**

        - **Place ppt. ID and GC amounts in the GC google sheet for future mailing.**
            - **Study staff that is present in the clinic will be responsible for GC mailings for that day.**
            - **If no staff is available that day, please inform the ppt. that they will receive GC in X number of days (based on when staff will be in clinic next).**
        - **Mail GC to ppt.**
            - **Mail can be dropped off at the UCH lobby or nearest postal office.**
            - **Use SMART mailer and envelop.**

    - **BSM Group Instructions:**
        - **Complete assessments and intervention.**
        - **Inform ppt. of the GC amount they will receive ($50), and to please allow 2-3 business days to arrive.**
        - **Place ppt. ID and GC amounts in the GC google sheet for future mailing.**

- **Study staff that is present in the clinic will be responsible for GC mailings for that day.**
- **If no staff is available that day, please inform the ppt. that they will receive GC in X number of days (based on when staff will be in clinic next).**

▪ **Mail GC to ppt.**
- **Mail can be dropped off at the UCH lobby or nearest postal office.**
- **Use SMART mailer and envelop.**

Note: If study team does not have access to postage stamps, Wednesdays and Fridays will be designed gift card mailing days. Study team will alternate days that they deliver gift cards to the UTHSC main campus.

- **Wednesdays**: Red bag will be dropped off at the Pauline bldg.
- **Fridays**: Study team will take the red bag to the mail room in the Madison bldg.

Instructions:

- **Use the GC google sheet to confirm gift cards that need to be mailed.**
- **Log gift cards out of the safe.**
- **Complete the GC sheet and make copy of gift card for study records.**
- **Once completed place sheet in GC binder (ppt. will not need to sign).**
- **Place GC in red bag and take to designed mailing area for that day.**
  - **Use SMART mailer and envelop.**
- **Log mileage from clinic to the main office and submit monthly.**

Session 4 (Virtual): Part 1

- After the participant completes Part 1 of the assessments and the intervention, they will schedule Part 2 of the session .

Instructions:

▪ **Complete Part 1 assessments**
▪ **Complete the intervention**
▪ **Schedule follow-up call with the RA.**
- **RA will be responsible for logging ppt. ID, completion date, and GC amount in the google sheet and notifying team of completion status.**
- **Note: Ppt. will not receive GC unless they complete all parts of the session (Part 1 & 2 Assessments and intervention).**

Session 4 (Virtual): Part 2

To be completed by RA.

- Complete Part 2 assessments and log session info. in the google sheet for future GC mailing.

Instructions:

- **Complete Part 2 assessments**
- **Complete treatment satisfaction survey**
- **Notify team of completion (via email or GroupMe msg.).**
- **Log study ID, date of completion, and GC amount in the google sheet**
- **Mailing will be the same as Sessions 1-3.**

Appendix A. IRB Approval Letter

THE UNIVERSITY OF TENNESSEE
HEALTH SCIENCE CENTER.

Institutional Review Board
910 Madison Avenue, Suite 600
Memphis, TN 38163
Tel: (901) 448-4824

June 30, 2020

Karen J Derefinko, PhD
UTHSC - Preventive Medicine
305 Doctors Office Building
66 North Pauline Street
Memphis, TN 38163-2181

Re: 20-07418-XP UM
Study Title: Pilot Test of Contingency Management and Brief Motivational Interviewing + Substance Free Activity Session Interventions + Mindfulness-Based Adherence Promotion [NIH R61AT010604-01]

Dear Dr. Derefinko:

The Administrative Section of the UTHSC Institutional Review Board (IRB) has received your written acceptance of and/or response dated 06/29/2020 to the provisos outlined in our correspondence of 06/23/2020 concerning the above referenced project. The IRB determined that your application is eligible for **expedited** review under 45 CFR 46.110(b)(1) categories (5)(6) and (7). The IRB has reviewed these materials and determined that they do comply with proper consideration for the rights and welfare of human subjects and the regulatory requirements for the protection of human subjects. Therefore, this letter constitutes full approval by the IRB of your application (version 1.2) as submitted including:

- Main consent form dated 06/23/2020;
- Letter of support dated 06/24/2020;
- SMART Opioid Research Strategy dated 06/25/2020; and
- SMART Project 3 Measures dated 06/26/2020.

All of the above were stamped IRB-approved 06/30/2020. You must use the date-stamped versions of study documents. Date-stamped materials are available in the *Informed Consent* and *Other Project Documents* folders of iMedRIS.

Continuing Review for this study is not required under 45 CFR 46.109(f)(1).

The IRB has determined that the informed consent form, incorporating the authorization of subjects to use their protected health information in research, complies with the federal privacy regulations as specified in 45 CFR 160 and 45 CFR 164.

In addition, the request for waiver of HIPAA authorization in order to identify potential subjects is approved in accord with the criteria and review procedures specified at 45 CFR 164.512(i)(2). The waiver applies to the medical records of adult patients of University Clinical Health Center for Addiction Science.

In the event that subjects are to be recruited using solicitation materials, such as brochures, posters, web-based advertisements, etc., these materials must receive prior approval of the IRB. Any revisions in the approved application must also be submitted to and approved by the IRB prior to implementation. In addition, you are responsible for reporting any unanticipated problems, including reportable adverse events, involving risks to subjects or others in the manner required by the local IRB policy. Lastly, you must request to close your project when you have completed data analysis. All of the above should be submitted to the IRB via the appropriate form in iMedRIS.

Please note that while the UTHSC IRB is still processing IRB submissions during the COVID-19 pandemic, you must follow UTHSC IRB's COVID-19 policy located on our website here: https://uthsc.edu/research/compliance/irb/-covid-19.php . You must review the policy and adhere to it as it relates to any and each of your UTHSC IRB-approved studies.

Sincerely,

Signature applied by Laura Rush on 06/30/2020 01:32:11 PM CDT

Laura Rush, MPH, CIP
Senior Regulatory Specialist
UTHSC IRB

Appendix B. Withdrawal Letter

DATE:

Dear Study Participant:

This is to notify you that as you requested, you have officially withdrawn from the study "*Testing the Effects of Contingency Management and Behavioral Economics on Buprenorphine-Naloxone Treatment Adherence Using a Sequential Multiple Assignment Randomized Trial*" (SMART) Design Internal Review Board Number: 20-07418-XP UM. Please be aware that all data you have provided for this study has been destroyed and is not accessible by anyone.

Please contact the study team if you should have any questions regarding your participation in this study in the future.

Sincerely,

Sarah Hand, MPH, CCRP

Senior Research Project Coordinator
Center for Population Sciences
Department of Preventive Medicine
University of Tennessee Health Science Center
66 North Pauline, Suite 466
Memphis, TN 38163
(901) 448-3174