Reducing Stigma towards Opioid Use Disorder on Interpersonal and Intrapersonal Levels

Manual of Procedures: Intrapersonal Arm

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PREFACE

The purpose of this document is to provide a Manual of Operating Procedures (MOP) for the SMART Supplement Project 5a — Intrapersonal Stigma Reduction. 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.

OVERVIEW

Objectives

The goal of this project is to develop and evaluate the efficacy of a stigma reduction intervention that functions at the Intrapersonal (individual) level. Our intervention will address this cost/benefit evaluation among individuals known to face intersecting stigma of alcohol or substance use disorder and African American race, with treatment elements chosen explicitly to increase the value of treatment using salient forms of reward, and to ease perceived costs through explicit services in an effort to encourage the occurrence of the first treatment visit.

Design and Outcomes

This project consists of a pre-post survey, separated by a two-week interval. All elements of our individual intervention are based in Behavioral Economics theory, with the intention of increasing benefits and reducing costs to facilitate individual decision making and reduce subsequent experienced, anticipated, and associative stigma for the individual seeking treatment.

The primary outcome for Project A is reduction in stigma at two weeks post intervention. This will be assessed by using the Substance Use Stigma Mechanisms Scale.

Secondary outcomes include Addiction Treatment visit attendance (e.g., did they attend the visit that was scheduled?) and Feedback and Satisfaction with treatment.

Duration

Participants will be enrolled at baseline (week 0) and will have one follow-up assessment to be completed two weeks after enrollment.

Sample Size and Population

Approximately 50 participants will be recruited from the Frayser community of Memphis, at the recruitment site of Legacy of Legends (or associated venue, as dictated by Legacy events). Participants must identify as having a substance use problem and must not currently be in treatment. All participants must be over age 18, able to understand consent procedures, reside in the Frayser community, identify as African American or mixed race, and have access to a telephone for retention/follow up.

IRB

Project number: 20-07852-XP

The University of Tennessee Health Science Center IRB (FWA00002301) is the reviewing IRB for this study. Initial approval was received on 02/05/2020.

Award Information

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

Award number: 3R61AT010604-01S1

Grant Title: Behavioral Economics based stigma reduction intervention for low income, African American individuals with Opioid Use Disorder. (3R61AT010604-01S1).

Grant Years:

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TRAINING PLAN

Pre-Initiation Training

The Research Coordinator will be trained in data collection, data entry, adverse event collection, incentive distribution, and informed consent procedures by the Project Manager (Hand). Dr. Derefinko will train the coordinator on intervention delivery and fidelity.

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 will be addressed at biweekly staff meetings. Issues regarding study fidelity will be addressed by Dr. Derefinko as needed.

ELIGIBILITY CRITERIA

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

- Age 18 or older
- Able to understand consent procedures
- Identify as African American or mixed race,
- Access to telephone for retention/follow up
- Self-identified alcohol or substance use disorder (SUD) related issues, and
- Not currently in treatment for SUD.

PROCEDURES

Cascade of Events

Baseline

- Engage with potential participants to provide information about participation.
- If interested, complete screening for eligibility/exclusionary criteria.
- Complete informed consent.
- After participants have signed the informed consent form, we will collect the remaining baseline data and deliver the intervention.
    - Administer assessments which include contact information, demographics, and SU-SMS (stigma scale)
    - Deliver intervention
    - Offer to help schedule appointment at CAS (or other clinic)

    - Set appointment date/time for 2-week follow-up visit or call.
- Provide a $20 Kroger gift card as compensation for enrollment.
    - Kroger gift cards will be given via a hard copy gift card following the incentive procedures**.**
- If the participant schedules a visit and needs transportation support, schedule a Lyft ride
- Provide participant your contact information to ensure that the Lyft ride can be changed as needed (Lyft is scheduled only through us, not the participant).

Follow-Up Visit

- At two weeks post baseline:
- Complete follow-up assessments including SU-SMS, attendance at physician visit, and treatment feedback & satisfaction
- Provide the $20 Kroger gift card upon completion of visit
    - Kroger gift cards will be given via a hard copy gift card following the incentive procedures.

Recruitment

Potential participants who are being referred for potential substance use disorder treatment will be recruited by the Research Coordinator I and Pastor Caswell through Frayser community events, Impact Ministries events, and Legacy of Legends CDC events.

Recruitment Script

This is a general script, but can be changed as needed for each situation.

"Hi, ____! My name is ____ and I am part of the research staff with the Department of Preventive Medicine at the University of Tennessee Health Science Center. You're here today because you agreed to speak with us about your feelings about drug and alcohol use, and you're open to hearing about treatment options. We're doing a research study where we ask people questions, have a discussion, and then ask a few more questions.

If you think you might be interested in being in this study, I can ask you a few questions to see if you're eligible, then we can go through a consent form with you to help you decide if you'd like to participate. Are you interested in seeing if you're eligible?

If a person does not wish to participate, we can still provide a handout or information about how to get treatment.

Consent

The consent of the adult subject will be obtained at the first study visit at baseline after assessing for eligibility but before any identifying data collection begins.

Inviting the subject to read and sign the consent form is not sufficient for securing informed consent. Study staff will go through the consent form with the participant, reviewing all elements of informed consent as stated in 21 CFR 50 § B and will answer all questions regarding the study.

A copy of the informed consent will be given to the subject and the original(s) will be placed in the subjects' research record. An entry documenting informed consent must also be made in the subjects' research record to confirm that informed consent was obtained prior to any study-related procedures and that the subject received a signed copy. The objection of any subject in word or action to the performance of study procedures will be sufficient for their withdrawal or exclusion from the study. Study procedures will not continue until a signed consent form is received.

Electronic Consent

This project received approval for alteration of consent through the UTHSC IRB. In circumstances where a participant is unable to consent in person due to COVID restrictions, the participant may be consented using DocuSign.

All standard procedures for consent must be followed including the participant being able to view the document while staff reviews with them, having sufficient time to review the document and ask questions, etc.

Intervention

The Intrapersonal Stigma Reduction Intervention will address the stigma of addiction, education about addiction, life goals, deciding whether to disclose addiction, and links to services. These modules are covered in an effort to encourage the occurrence of the first treatment visit at the Center for Addiction Science. See Appendix A for the full intervention script.

Data Collection

Whether in-person or on the phone, research staff will read aloud the items from each measure for the participant to answer. The staff member will record the responses on the paper forms and will later enter the data electronically.

Incentives

Gift Card Distribution

Participants will receive $20 upon completion of each visit (baseline and follow-up) in the form of a Kroger gift card. The gift cards will be photocopied or scanned onto the gift card receipt. The staff member will take the receipt, gift cards, and a computer back into the room with the participant and check the gift card balance on the Kroger website before distributing. Once the balance is verified, the staff member will fill out the receipt in front of the participant. Both the

research staff and the participant will sign the receipt verifying the information to be true. We will provide a copy of the receipt to the participant.

Gift Card Storage

Since this project is remote and we will not have ready access to a safe, a minimal number of gift cards should be checked out each week and stored in the locked briefcase with other study documents. Gift cards should only be checked out of the safe when they are ready to be disbursed to a participant. The remaining gift cards will be kept in the safe on the 6th floor of the Pauline Building. 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.

Adverse Events

Adverse events (AE's) are defined as any unfavorable medical occurrence in a human subject, including any abnormal sign, 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 (SAE's) are any adverse event temporally associated with the

subject's participation in research that meets any of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- Requires inpatient hospitalization or prolongation of existing hospitalization;
- Results in a persistent or significant disability/incapacity;
- Results in a congenital anomaly
- 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

If a participant experiences any 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.

All SAE's that are potentially related to the study are to be reported to the Project Coordinator (Sarah Hand) within one working day. The Project Coordinator will review and escalate to the PI via email within 48 hours of initial documentation.

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

Retention

It is the job of the research staff to retain all participants in the study in an attempt to have all participants complete their follow up visit. Staff will use various retention efforts to remain in contact with the participants after enrollment. Staff will also send participants an appointment reminder via text the day before their follow up visit (or via phone if preferred by participant).

Participants will have an additional 2 weeks to make up their missed appointment in order to provide us with the data and so they may receive their compensation. The following retention efforts should be made:

1. Calling the participant to check in and/or offer another date to reschedule.
2. Texting the participant to offer another date.
3. Emailing the participant.
4. Mailing a letter to the most recent address on file.

The research staff will cycle through these retention efforts during the 2 weeks to ensure they are doing their due diligence to contact the participant. The visit can be completed over-the-phone or in-person.

MEASURES

Assessment Schedule

Measure	Baseline	Follow-Up
Contact Information	X	
Demographics	X	
Substance Use Stigma Mechanisms Scale (SU-SMS)	X	X
Agreement to set up intake visit at Center for Addiction Science (or other treatment facility)	X	
Attendance at intake visit at Center for Addiction Science (or other treatment facility)		X

Feedback & Treatment Satisfaction		X

CONTACT INFORMATION	
First:	
Middle:	
Last:	

Street:	
Apt/Suite:	
City/State/Zip:	

Email:	

Primary Phone:		
Can we leave a voicemail?	Yes	No
Can we send a text?	Yes	No
Secondary Phone:		
Can we leave a voicemail?	Yes	No
Can we send a text?	Yes	No

DEMOGRAPHICS			
Date of Birth:			
Gender:	Male	Female	Transgender
Sex at birth:	Male	Female	
Race (circle all that apply):	African American or Black	White	Alaskan Native
	Pacific Islander	Native American	Other: _____
Are you of Spanish, Hispanic, or Latino origin?	Yes	No	

Current Marital Status:	Married or living as married	Widowed	Divorced
	Separated	Single, never married	

Current Household Income per year:	Less than $10,000	$10,000-19,999	$20,000-29,999	$30,000-39,999
	$40,000-49,999	$50,000-59,999	$60,000-69,999	$70,000-79,999
	$80,000-89,999	$90,000-99,999	Over $100,000	Unsure

Highest level of schooling completed:	8th grade or less	9th-11th grade	12th grade or GED	Associate's degree
	Vocational or Trade School	Some college	Bachelor's degree	Graduate degree

SU-SMS

How often have people treated you this way in the past because of your alcohol and/or drug use history? Please circle your response.

		Never	Not often	Somewhat often	Often	Very Often
1.	Family members have thought that I cannot be trusted.	1	2	3	4	5
2.	Family members have looked down on me.	1	2	3	4	5
3.	Family members have treated me differently.	1	2	3	4	5
4.	Healthcare workers have not listened to my concerns.	1	2	3	4	5
5.	Healthcare workers have thought that I'm pill shopping, or trying to con them into giving me prescription medications to get high or sell.	1	2	3	4	5
6.	Healthcare workers have given me poor care.	1	2	3	4	5

How likely is it that people will treat you in the following ways in the future because of your alcohol and/or drug use history?

		Very unlikely	Unlikely	Neither unlikely nor likely	Likely	Very likely

1.	Family members will think that I cannot be trusted.	1	2	3	4	5
2.	Family members will look down on me.	1	2	3	4	5
3.	Family members will treat me differently.	1	2	3	4	5
4.	Healthcare workers will not listen to my concerns.	1	2	3	4	5
5.	Healthcare workers will think that I'm pill shopping, or trying to con them into giving me prescription medications to get high or sell.	1	2	3	4	5
6.	Healthcare workers will give me poor care.	1	2	3	4	5

How do you feel about your alcohol and/or drug use history?

		Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly agree
1.	Having used alcohol and/or drugs makes me feel like I'm a bad person.	1	2	3	4	5
2.	I feel I'm not as good as others because I used alcohol and/or drugs.	1	2	3	4	5
3.	I feel ashamed of having used alcohol and/or drugs.	1	2	3	4	5

4.	I think less of myself because I used alcohol and/or drugs.	1	2	3	4	5
5.	Having used alcohol and/or drugs makes me feel unclean.	1	2	3	4	5
6.	Having used alcohol and/or drugs is disgusting to me.	1	2	3	4	5

TREATMENT INITIATION		
Did you go to any facility for substance use treatment since we last spoke?	Yes	No
If yes, where did you get treatment?		

FEEDBACK & TREATMENT SATISFACTION				
1.	How interesting did you find this study?	Totally bad, boring	OK	Excellent, it was great
2.	What made you want to enroll in this study? (select all that apply)	I wanted help getting treatment	Gift cards	Other _____
3.	How personally relevant did you find this study?	Not at all relevant	Somewhat relevant	Very relevant
4.	How effective do you think this study was in helping you start treatment?	Not at all effective	Somewhat effective	Very Effective
5.	For those who haven't sought treatment: How likely you are to seek treatment in the near future?	Unlikely	Unsure	Likely
6.	How effective, overall, do you think this program will be in helping substance users seek treatment?	1 = Not useful or effective 10 = Highly effective. The best treatment I could imagine.		

7.	What was the most effective part of this study for you?	(Open ended)
8.	Can you think of any ways to make this study more effective and user-friendly?	(Open ended)

OTHER DOCUMENTATION

Gift Card Log – Example

Kroger $20 Gift Cards

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

Gift Card Receipt

Study ID _____

The participant and I, the research staff member, checked the balance of the gift card before distribution. We discussed that the Research Study is not responsible for and will not replace lost or stolen gift cards once the gift card has been disbursed.

Date	____ /____/____		
Staff Initials	_____	**GC Amount**	$ _____
Participant Initials	_____	**Quantity**	_____