Study Protocol
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Protocol: Motivational Interviewing to Enhance Behavioral Change in Older Adults With Hoarding Disorder

1. Study Personnel

Principal Investigator: Mary E. Dozier, Ph.D.

Co-Investigator: Hilary DeShong, Ph.D.

Biostatistician: Ben Porter, Ph.D.

2. Funding

National Institute of Mental Health R15 award, “Motivational Interviewing to Enhance Behavioral Change in Older Adults with Hoarding Disorder.” Period of support: February 1, 2022 – January 31, 2026. Total award: $427,415. (Dozier: Principal investigator).

3. Specific Aims

Hoarding is one of the few psychological disorders that increases in severity and prevalence in older adulthood (Dozier et al., 2016; Cath et al., 2017; Reynolds et al., 2015); however, interventions specifically for the treatment of hoarding in late life are extremely limited. Hoarding psychopathology results from maladaptive cognitions (e.g., desire to keep items others would discard) and maladaptive behavioral patterns (e.g., avoidance of sorting/discarding items). Extant treatments for hoarding have targeted fear reduction as the mechanism of change, either through cognitive-behavioral therapy focusing on cognitive restructuring (Tolin et al., 2015) or behavior therapy focusing on exposure therapy (Ayers et al., 2018). Older adults have a lackluster response to cognitive restructuring for hoarding (Ayers et al., 2011), and, although exposure therapy increases treatment response (Ayers et al., 2018), both approaches require a lengthy six-month dose. Our preliminary work suggests that fear reduction may not be a universally relevant target mechanism for older adults (Dozier et al., 2020), and that to be responsive to the specific needs of older adults, we need to identify other mechanisms. Motivational interviewing (MI) is a technique that is already typically incorporated into hoarding treatment (e.g., Ayers et al. 2018) and is a proven method to increase motivation for behavioral change (Miller & Rollnick, 2013). However, current practices only include a sprinkling of MI techniques (e.g., goal setting) and there has not yet been systematic investigation of the utility of a more comprehensive implementation of MI for hoarding disorder. Because sorting/discarding is at its core a health behavior that hoarding patients lack the motivation to engage in, MI is likely to decrease hoarding

severity. However, there is a knowledge gap about how behavioral interventions that explicitly target motivation for change will affect treatment efficacy, and dosing, for late life hoarding. Thus, there is a *critical need* to develop and validate geriatric hoarding interventions that target motivation to increase sorting/discarding behavior. If unmet, older adults with hoarding will continue to have treatment options limited in efficacy and lengthy in dose.

Our *long-term goal* is to improve the reach of mental health services by facilitating the implementation of evidence-based treatments for late life hoarding. Our *overall scientific objective* is to determine the initial efficacy of a novel intervention for geriatric hoarding disorder that is designed to explicitly target motivation for behavioral change instead of fear reduction as the mechanism of action. In addition, we aim to provide hands-on research opportunities for undergraduate students and to enhance the research environment at Mississippi State University (MSU). Our *central hypothesis* is that MI combined with sorting practice will reduce hoarding in older adults by directly targeting motivation for behavioral change (i.e., increased sorting/discarding of possessions). Our hypothesis was formulated based on the efficacy of MI to create behavioral change for a variety of health behaviors (Miller & Rose, 2009), including in older adults (Purath et al., 2014). The *rationale* for the proposed project is that identifying modifiable treatment targets other than fear reduction will facilitate the optimization of hoarding outcomes in late life. We propose a clinical trial to test the ability of MI to increase sorting and discarding behaviors in 60 older adults with hoarding disorder using a 16-week randomized controlled trial comparing MI and sorting practice (RECLAIM; Reducing Clutter and Increasing Meaning) with sorting practice (SP) only.

Aim 1. Determine the feasibility of sample recruitment/retention and acceptability of RECLAIM. Based on our previous recruitment rates for a study of late life hoarding in the proposed catchment area (i.e.,13 individuals over three months of active recruitment), we *hypothesize* that 8 older adults will be successfully recruited and treated per four-month wave and will rate RECLAIM as acceptable. Based on prior studies late life hoarding, we further *hypothesize* an attrition rate of <30%.
Aim 2. Establish initial evidence of target engagement. Our *hypothesis* is that level of motivation, assessed through self-report (i.e., participant readiness for change) and behavioral measures (i.e., engagement in sorting/discarding behaviors), will be sensitive to change induced by RECLAIM.
Aim 3 (Exploratory). Identify potential moderators of treatment response. Based on prior research examining the association between psychiatric symptoms, executive functioning, and hoarding (Davidson et al., 2019), we will conduct exploratory analyses of possible moderators for the outcomes in Aim 2.

4. Subject Selection

Sixty older adults with hoarding disorder will be enrolled and randomized to 16 weeks of either individual RECLAIM or individual sorting practice (both administered in the home). The study will use a four-month dose of treatment to be comparable to typical psychotherapy doses.

Inclusion criteria includes being aged 60+, living within the catchment area (60-minute driving radius of Starkville, MS), and having a primary psychiatric diagnosis of hoarding disorder, diagnosed using a semi-structured interview during the baseline assessment.

Exclusion criteria includes major cognitive impairment, active psychosis, drug use, or acute suicidal ideation. Individuals with a history of psychosis or drug use will be included as long as they have had stable symptoms for at least six months. Participants will be excluded if they are currently enrolled in individual psychotherapy or have changed psychotropic medications within the past three months.

5. Recruitment

Study recruitment will take place through a combination of flyering, local media appearances, and referrals from community partners (e.g., Mississippi Regional Housing Authority, Area Agency on Aging, Mississippi State Department of Health). The PI has a current waitlist of local older adults interested in treatment for hoarding disorder within the catchment area (N = 13). Based on prior research of geriatric hoarding (Ayers and Dozier, 2015) and the racial composition of the recruitment area (US Census, 2019), we anticipate that the majority of participants will be female and White, with a substantial minority of participants identifying as Black or African American. The population of the study setting, Starkville, Mississippi, is 57% White and 37% Black or African American. To facilitate recruitment of minority group members, outreach efforts will include a focus on churches with minority congregations.

6. Procedures

Screening. Participants will complete a phone screen to determine if they meet initial study criteria. Hoarding symptoms on the phone screen will be determined using the five-item Hoarding Rating Scale (HRS; Tolin et al., 2010). Individuals who score a total of 10 or higher on the HRS (indicating an average of mild or higher symptoms) and who do not endorse other exclusionary criteria will be scheduled for a baseline assessment in their homes.

All study procedures following the initial phone screen will take place in participants' homes. Older hoarding patients report home visits to be one of the more helpful parts of treatment (Ayers et al., 2012). Conducting assessments in the home will also allow for a more accurate assessment of household clutter and prevent "pre-sorting" of items for the behavioral approach task (i.e., participants will be unable to only "sort" items they have already decided to discard). Finally, this will increase access to participation for rural-dwelling older adults without ready access to transportation.

Independent assessors blind to study condition will complete all assessments with the assistance of undergraduate researchers. Assessors will be graduate students enrolled in the MSU Clinical Psychology Doctoral Program and will receive weekly group supervision from the PI.

Baseline Assessment. After completing the informed consent process, participants will complete a battery of self-report and clinician-administered measures to determine final enrollment status. The assessment will take ~2.5 hours to complete. The measures administered are described below.

Monthly Assessment. Following enrollment, participants will complete monthly assessments in their homes, including measures of target engagement, hoarding severity, and associated constructs (see Table 1). The monthly assessments will take ~1.5 hours to complete.

Randomization. Following completion of the informed consent process and the baseline assessment, final inclusion status will be determined during supervision with the PI. The randomization scheme will be determined by one of the Co-Investigators, Dr. Porter, a priori using Randomization.com. Block randomization will be used to ensure an equal sample size for each treatment condition (Suresh, 2011). Dr. Porter will be the only study personnel to have access to the randomization scheme. Following enrollment, Dr. Porter will notify Dr. Dozier and the assigned clinician of the randomization status.

Compensation. Participants will be provided a $20 Walmart gift card following completion of the baseline assessment and after each monthly assessment (months 1-4), for a total compensation of $100.

Measures

A *demographic questionnaire* administered at baseline only will include questions on psychosocial history (e.g., race, income, employment history, marital status) and information on relevant biological variables (i.e., sex, age, weight, underlying health conditions).

Diagnosis of hoarding disorder will be determined during the baseline assessment using the Structured Interview for Hoarding Disorder (SIHD), a semi-structured interview of DSM-5 diagnostic criteria and specifiers (excessive acquisition and level of insight) for hoarding disorder (Nordsletten et al., 2013). The SIHD has demonstrated excellent inter-rater reliability and discriminant validity (Nordsletten et al., 2013). Consistent with DSM-5 criteria, individuals will be excluded if their hoarding symptoms are better explained by a different psychiatric diagnosis, including OCD or major depressive disorder.

Psychiatric co-morbid diagnoses will be assessed at baseline using the Mini-International Neuropsychiatric Interview Version 7.0 for the DSM-5 (M.I.N.I.), a structured interview that assesses for the major diagnostic categories in the DSM, including possible causes of hoarding symptoms (e.g., Major Depressive Disorder, Obsessive-Compulsive Disorder, Psychosis) (Sheehan et al., 2015).

Construct	Variable	Unit of Analysis	Assessment Schedule

Motivation for Change	Frequency/Duration of Sorting	Behavior	Weekly
	University of Rhode Island Change Assessment Questionnaire	Self-report	Monthly
	Apathy Evaluation Scale	Self-report	Monthly
Feasibility and Acceptability	Attrition	Behavior	N/A
	Treatment Acceptability/Adherence Scale	Self-report	Session 1
Hoarding Severity	Saving Inventory-Revised	Self-report	Monthly
	Clutter Image Rating	Clinician-report	Monthly
	Behavioral Approach Task	Paradigm	Monthly
Suicidal Ideation	Columbia-Suicide Severity Rating Scale	Self-report	Monthly
NIH Toolbox Emotion Battery		Self-report	Monthly
Negative Affect	Anger (Affect; Hostility; Physical Aggression)		
	Fear (Affect; Somatic Arousal)		
	Sadness		
Psychological Well-Being	Positive Affect		
	General Life Satisfaction		
	Meaning and Purpose		
Stress and Self-Efficacy	Perceived Stress		
	Self-Efficacy		
Social Relationships	Emotional Support		
	Instrumental Support		
	Loneliness		
	Friendship		
	Perceived Hostility		
	Perceived Rejection		
PROMIS-57 Profile v2.1		Self-report	Monthly
Daily Function	Physical Function		
	Ability to Participate in Social Roles and Activities		
Psychiatric Symptoms	Anxiety		
	Depression		
Sleep and Fatigue	Fatigue		
	Sleep Disturbance		
Pain	Pain Interference		
	Pain Intensity		
NIH Toolbox Cognition Battery		Paradigm	Baseline
Attention & Executive Functioning	Flanker Inhibitory Control and Attention Test		
	Dimensional Change Card Sort Test		
Episodic Memory	Picture Sequence		
Working Memory	List Sorting		
Language	Picture Vocabulary		
	Oral Reading Recognition		
Processing Speed	Pattern Comparison		

Table 1. Assessment Schedule. Gray cells indicate measures added to enrich dataset for student research.

Motivation for change will be assessed weekly using a behavioral assessment of behavior change (reported frequency and duration of sorting/discarding items) and monthly using a self-report measure, The University of Rhode Island Change Assessment Questionnaire (URICA; McConnaughy et al., 1983). The URICA is a 32-item Likert scale that assesses readiness for change and includes four subscales that individually assess stage of change (Precontemplation, Contemplation, Action, and Maintenance). Previous investigations have found adequate internal reliability for the URICA in treatment-seeking samples (Dozois et al., 2004), including in older hoarding samples specifically (Ayers et al., 2019). In addition to the specific construct of motivation for change, general apathy will be assessed monthly using the self-report version of the Apathy Evaluation Scale (AES-S; Marin, 1991). The AES is an 18-item measure of an individual's deficits in goal-directed thoughts and behavior. The AES was developed to assess apathy in adults aged 55+ and is predictive of motivation for change (Resnick et al., 2012).

Acceptability will be assessed following session one using the Treatment Acceptability/ Adherence Scale (TAAS; Milsevic et al., 2015), a 10-item self-report measure of a patient's perception of the acceptability of a treatment as well as their anticipated adherence to the protocol. A modified version of the TAAS will be administered to community partners. *Feasibility* will be assessed quantitatively as the percentage of participants who complete the intervention and the average number of sessions completed. Clinicians will also complete a worksheet during and after each treatment session of any barriers to treatment engagement encountered by the participant during the week or during the session.

Hoarding severity will be assessed monthly using the Saving Inventory-Revised (SI-R; Frost et al., 2004), the Clutter Image Rating (CIR; Frost et al., 2008), and a behavioral approach task (BAT; Dozier & Ayers, 2017; Dozier et al., 2020). The SI-R is a 23-item measure of the three core hoarding symptoms (urges to save, difficulty discarding, and excessive clutter). The CIR is a three-item pictorial rating scale of clutter level in the bedroom, kitchen, and living room. Assessor ratings of the CIR will be used for the proposed project. The SI-R and the CIR have strong reliability and validity when used in older adult samples (Dozier & Ayers, 2015; Kellman-McFarlane et al., 2019). The BAT involves the participant sorting items in a cluttered part of their home for 15 minutes. The speed of sorting and percentage of items discarded will be used as behavioral indicators of hoarding severity.

Suicidal ideation will be assessed at baseline, monthly, and as needed based on participant disclosure using the Columbia-Suicide Severity Rating Scale (C-SSRS; Posner et al., 2011). The C-SSRS is currently the gold standard in comprehensive suicide risk assessment and has demonstrated high sensitivity and specificity for categorizing suicide risk (Posner et al., 2011). All participants will be provided with the National Suicide Prevention Lifeline, the Crisis Text Line, and the Veterans Crisis Line (if appropriate). Potential participants who report severe and acute suicidal ideation at baseline will be provided with referral information and excluded from the proposed study.

To allow for the inclusion of potential covariates and to enrich the data set available for undergraduate student research, additional measures of cognition, psychiatric severity, and physical functioning will be administered. These measures are all administered using the NIH Toolbox iPad application to allow for Computer Adaptive Testing and automatic scoring of the data. The cognitive battery is estimated to take ~30 minutes to administer and the additional psychiatric and physical functioning self-report batteries together are estimated to take ~40 minutes to administer.

Cognitive functioning will be assessed at baseline using the NIH Toolbox Cognition battery (Weintraub et al., 2014). The NIH Toolbox Cognition battery includes assessments of executive function, attention, episodic memory, language, processing speed, and working memory. In addition to its strong psychometric properties, the NIH Toolbox Cognition battery was chosen to assess cognitive functioning due to its portable nature. The PI piloted administration of the NIH Toolbox Cognition Battery in the homes of older adults with hoarding disorder (N = 7) and found administration of using the iPad to be feasible, with occasional adjustments needed (e.g., standing next to participant when the home did not have room for two people to sit in close proximity).

Psychiatric functioning will be assessed monthly using the NIH Toolbox Emotion Battery (Gershon et al., 2010). The NIH Toolbox Emotion battery contains 17 measures organized across 11 constructs and four domains: psychological well-being (positive affect, general life satisfaction, meaning
and purpose), social relationships (social support, social distress, companionship, positive social development), stress and self-efficacy, and negative affect (fear, sadness, anger).

Additional psychiatric and physical constructs will be assessed monthly using the Patient-Reported Outcomes Measurement Information System (PROMIS)-57 Profile v2.1 (Cella et al., 2010). The PROMIS measures are part of the National Institutes of Health Roadmap initiative and were designed to balance efficiency, flexibility, and precision in the assessment of self-reported constructs. Over 20,000 adults participated in the original validation studies; raw scores are converted to T-scores relative to the general population. The PROMIS-57 Profile v2.1 includes measures of physical function, anxiety, depression, fatigue, sleep disturbance, participation in social roles and activities, pain interference, and pain intensity.

Study Conditions. Both study conditions will be administered by Masters-level clinicians, with the assistance of undergraduate researchers, who will participate in weekly group supervision. *See Study Timeline for details about annual training of study staff.* Participants will receive 16 weekly 1-hour treatment sessions of either RECLAIM or sorting practice in their home. The length of therapy was selected to match the typical dose of psychotherapy intervention and to allow for sufficient dosing to compare conditions. All sessions will be audio-recorded for evaluation of treatment fidelity. Participants will be provided with a binder and monitoring sheets to complete between sessions to monitor sorting practice. Clinicians will complete forms in session to

document participants' sorting efforts over the previous week and any boundaries to sorting/discarding that occurred.

RECLAIM: Reducing Clutter and Increasing Meaning. Traditional cognitive behavioral therapy for hoarding focuses on targeting the maladaptive thoughts (e.g., "It is my responsibility to be family historian" or "I need four sets of wine glasses in case I make friends who drink wine") and exposing patients to the negative emotions that occur when making decisions about discarding (i.e., habituate to and/or learn to tolerate the distress) (Tolin et al., 2015). In contrast, RECLAIM focuses on behavioral change while being agnostic to maladaptive thoughts about objects or negative emotions experienced while sorting. In accordance with the cognitive-behavioral model of hoarding disorder, changing sorting behaviors directly will lead to secondary changes in patients' thoughts about their objects, as well as their level of negative affect and sense of self-efficacy. This will create a reinforcing cycle that leads to normative levels of household clutter, which subsequently results in decreased functional impairment.

To facilitate behavioral change, each of the treatment sessions will involve a combination of sorting practice and MI (Miller & Rollnick, 2013). The rationale behind the sorting practice is *not* for patients to habituate to or learn to tolerate any experienced distress but to develop the skill of sorting and the formation of a daily sorting routine. The MI portion of the initial session will involve an evaluation of client strengths (e.g., care for others, artistic ability) and individual biopsychosocial goals (e.g., improved sleep, host friends and family). The initial and subsequent sessions will include aspects of the four MI processes (Engaging, Focusing, Evoking, and Planning) as needed based on the participant's stage of change. For example, decisional balancing will be used to facilitate individuals' purposeful engagement in the treatment and developing discrepancy will be used to facilitate increased levels of insight of the gap between their stated goals and their behaviors. Personalized feedback will be used to normalize daily sorting/discarding. Clinicians will reinforce participants' sense of responsibility for their actions by collaboratively creating treatment goals and setting session agendas and will foster increased self-efficacy through acknowledgement of current (and increasing) sorting efforts.

Sorting Practice. The selection of sorting practice as the control condition will allow for the initial investigation of target engagement while controlling for the behavioral therapy component of the intervention, as well nonspecific therapeutic factors due to participants having an empathetic clinician visit their home on a weekly basis. Clinicians will encourage participants to sort objects during each session while refraining from use of any specific cognitive or motivational therapeutic techniques. Participants will be asked to record the frequency and duration of any sorting during the previous week.

Treatment Fidelity. Co-Investigator Dr. Nadorff will review 25% of therapy tapes on a monthly basis for each clinician to provide ratings of therapist adherence and competence on a global rating scale of 0-8 (Stanley et al., 2009; Mignogna et al., 2018) and to monitor for treatment diffusion in the sorting practice condition. Any therapist

deficiencies or drift will result in the clinician receiving additional weekly individual supervision from the PI until their ratings have improved.

Role of Undergraduate Researchers in Home Visits. Undergraduate researchers will largely shadow clinicians during home visits and provide logistical assistance (e.g., checking self-report measures for completeness, recording item descriptors during the BAT, holding a trash bag during sorting practice).

Table 2. Project Timeline.

Study Activity	Year 1						Year 2						Year 3					
Hire/train study staff																		
Recruit and enroll participants																		
Deliver treatment (~8 participants/wave)		Wave 1			W2		W3		W4		W5		W6		W7			
Undergraduate Research Symposium																		
Analyze data and prepare annual reports																		

Statistical Analysis Plan

Aim 1. Determine the feasibility of sample recruitment/retention and acceptability of RECLAIM. Feasibility of sample recruitment will be determined based on (1) rates of self-referral and referral from community partners, (2) rates of eligibility among individuals screened for the study, and (3) rates of refusal for study enrollment following baseline assessment. Feasibility of the RECLAIM will be explored qualitatively through an examination of any barriers to engagement reported by clinicians and participants during treatment. Consistent with previous studies of geriatric hoarding, including our own (Ayers, Dozier, et al., 2018), we anticipate low overall attrition rates (i.e., <30%). To further evaluate retention feasibility and intervention acceptability, attrition between RECLAIM and the control condition will be compared quantitatively using χ^2 tests of association and acceptability ratings between the two conditions will be compared using *t*-tests or Wilcoxon-Mann-Whitney tests if data are non-normal.

Aim 2. Establish initial evidence of target engagement. Linear mixed models with random intercepts will be used to evaluate the change in motivation variables over time (i.e., weekly reported frequency/duration of sorting; monthly scores on the URICA and AES). Due to the exploratory nature of the study, separate models will be run for each of the target engagement variables. Time will be centered at four months to evaluate overall treatment effects in the context of the mixed model. These models use full information maximum likelihood estimates which can handle intermittent missingness and attrition.

Aim 3 (Exploratory). Identify potential moderators of treatment response. We will conduct exploratory analyses of possible moderators for the outcomes in Aim 2 using the additional psychiatric and cognitive data collected at baseline.

Consideration of Relevant Biological Variables. The baseline assessment will query participant sex, age, weight, and pre-existing health conditions. Hoarding in late life is associated with being female, obesity, and medical co-morbidities (Ayers & Dozier, 2014; Timpano et al., 2011). Exploratory analyses will be conducted to determine the extent to which these variables moderate the observed outcomes.

Power Analysis and Sample Size Determination. The proposed study is powered based on Aim 2, determining the ability of RECLAIM, compared with sorting practice only, to engage motivation for behavioral change in geriatric hoarding. Our previous investigation comparing six months of behavioral treatment for geriatric hoarding with six months of case management had a found medium effects for post-treatment changes in clutter (d = 0.55; 95% CI: 0.07 – 1.16) and in self-reported hoarding cognitions (d = 0.63; 95% CI: 0.02 – 1.24). Reduced effect size from the shorter timeline of RECLAIM is expected to offset the increase in effect size expected from examining an intervening variable (i.e., motivation) rather than clutter levels. Power was calculated by simulating 10,000 samples with an ICC of 0.2 and a fixed slope of the intervention group of d = 0.15 (4-month difference d = 0.6). With 60 participants, power to detect a significant difference following four months of treatment is 0.81 at an α of 0.05. Using

the same methodology, moderating variables were subsequently examined as standard normal variables (which increases power relative to binary variables) with effect sizes of 0.05, 0.125, and 0.2 (4-month differences d = [0.2, 0.5, 0.8], respectively). Power was low (0.32) to detect small interactions, but high for moderate (0.95) and strong (0.99) interactions.

IRB Approval Number: IRB-21-561

Title of Research Study: Motivational Interviewing to Enhance Behavioral Change in Older Adults with Hoarding Disorder

Study Site: Mississippi State University

Researchers: Dr. Mary E. Dozier, Mississippi State University

Purpose

The purpose of this research is to investigate the efficacy of a behavioral intervention for hoarding disorder (RECLAIM: Reducing Clutter and Increasing Meaning) that uses a combination of motivational interviewing and sorting practice.

Procedures

If you participate in this study, you will be asked to complete a series of assessments in your home, some of which are paper and pencil and some of which are on an iPad. Finally, you will also be asked to complete a sorting task involving items in your home. This initial assessment generally takes around four hours and will most likely be completed across two visits to your home, each taking approximately two hours.

You will then be notified by phone if you qualify for the treatment portion of the study. This will involve sixteen treatment sessions in your home. Sessions will occur once a week for sixteen weeks and last for approximately one hour. During these sessions you will practice sorting and discarding objects with the assistance of a clinician and undergraduate student volunteer. You will then be asked to practice sorting in between sessions and to track your sorting practice.

During and following the treatment phase, you will be asked to completely monthly assessments that will each take approximately two hours.

Risks or Discomforts

As is the case with any research involving disclosure about sensitive information, there are risks to confidentiality in the proposed study. You may feel uncomfortable answering questions and discussing emotional symptoms. You may become more anxious or depressed. You may also experience emotional discomfort when choosing to discard items. The PI may also need to file a report to Adult Protective Services or Child Protective services if she feels that the home environment is unsafe.

Benefits

You will have access to treatment for hoarding disorder. This may result in a decrease in your hoarding symptoms, as well as co-morbid symptoms of anxiety and depression. This may also result in an increase in your quality of life.

Incentive to participate

At the end of your participation today, you will be provided with a $20 Walmart gift card as compensation for your participation in the study. You will also receive a $20 Walmart gift card

after completing each of the monthly assessments (months 1-4), for a total compensation of $100.

Confidentiality

All identifying information about participants, including hard copies (e.g., signed consent forms) and electronic information (e.g., participant contact information) will be kept in separate folders from study data. The master key connecting participant PHI with study data will be kept in a separate folder on the MSU OneDrive.

All study assessments and treatment sessions will be audio-recorded to allow the PI to review clinician adherence and competency. Audio recordings will be stored in a secure folder on the MSU OneDrive.

Please note that these records will be held by a state entity and therefore are subject to disclosure if required by law. Research information may be shared with the MSU Institutional Review Board (IRB) and the Office for Human Research Protections (OHRP) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the National Institutes of Health. The information from the research may be published for scientific purposes; however, your identity will not be given out.

Data from this study will be submitted to the National Institute of Mental Health Database (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many National Institute of Mental Health (NIMH) studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about mental health and substance use more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about mental health and substance use and how to help others who have problems with mental health and substance use. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you know now that you do not want your data in the NDA, you can select that option below. If you decide any time after today that you do not want your data to be added to the NDA, call the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the

study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, this is available on-line at http://nda.nih.gov.

Questions
If you have any questions about this research project or want to provide input, please feel free to contact Dr. Mary E. Dozier at (662) 325-0523.

For questions regarding your rights as a research participant or to request information, please feel free to contact the MSU Human Research Protection Program (HRPP) by e-mail at irb@research.msstate.edu, or visit our participant page on the website at https://www.orc.msstate.edu/human-subjects/participant-information.

To report problems, concerns, or complaints pertaining to your involvement in this research study, you may do so anonymously by contacting the MSU Ethics Line at http://www.msstate.ethicspoint.com/.

Voluntary Participation
Please understand that your **participation is voluntary.** Your **refusal to participate will involve no penalty or loss** of benefits to which you are otherwise entitled. You **may discontinue your participation** at any time without penalty or loss of benefits.

Options for Participation
Please initial your choice for the options below:

___The researchers may contact me again to participate in future research activities.

___The researchers may NOT contact me again regarding future research.

National Institute of Mental Health Database at the National Institutes of Health
Please initial your choice for the options below:

___The researchers may submit my deidentified study data to the National Institute of Mental Health Database.

___The researchers may NOT submit my deidentified study data to the National Institute of Mental Health Database.

Audio Recording
As part of the study, we would like to audio record the home visits. This is for the PI of the study to evaluate the clinicians. The recordings will be kept confidential and deleted following completion of the study.

Please initial your choice for the options below:

___The researchers may audio record me during home visits.

___The researchers may NOT audio record me during home visits.

Please take all the time you need to read through this document and decide whether you would like to participate in this research study.

If you agree to participate in this research study, please sign below. You will be given a copy of this form for your records.

_____	_____
Participant Signature	Date
_____	_____
Investigator Signature	Date

Research Participant Satisfaction Survey

In an effort to ensure ongoing protections of human subjects participating in research, the MSU HRPP would like for research participants to complete this anonymous survey to let us know about your experience. Your opinion is important, and your responses will help us evaluate the process for participation in research studies.
https://forms.office.com/Pages/ResponsePage.aspx?id=sNtR7YavokWcl3P7OTXfF9uShqNaQAdClfXwiCnibYZUOTM4NDUzMDIyUEhTM0NFNEVWNUc3TEw2Vy4u