STUDY PROTOCOL

Title: Open Trial of a Behavioral Activation Telepsychology Intervention for People Who Inject Drugs

Sponsor: University of North Carolina at Chapel Hill

Document Date: February 28, 2023

NCT number: NCT04943432

University of North Carolina at Chapel Hill
Chapel Hill, NC
USA

Catherine Paquette, PI
email: cpaq@live.unc.edu

Table of Contents

PROTOCOL SYNOPSIS

Study Title	Behavioral Activation for Substance Use Among People Who Inject Drugs
Funder	National Institute on Drug Abuse
Study Rationale	People who inject drugs (PWID) experience severe substance-related harms and yet have low rates of engagement in substance use disorder treatment. Low-barrier and telepsychology interventions represent promising strategies for engaging PWID in treatment, but few studies have tested the feasibility of these approaches among non-treatment-seeking PWID. A behavioral activation (BA) treatment for substance use was adapted through a harm reduction lens to assist PWID in working toward healthy and meaningful lives and achieving personal goals.
Study Objective(s)	Aim A.1. To examine the feasibility and acceptability of administering a behavioral activation treatment for substance use (The Life Enhancement Treatment for Substance Use – LETS ACT) among non-treatment-seeking PWID. Aim A.2. To revise the LETS ACT manual through an iterative development and piloting process. Aim A.3. To test the efficacy of the revised LETS ACT treatment for PWID from baseline (BL) to a 1 month follow-up (FU1).
Test Article(s)	8 sessions of adapted Behavioral Activation for Substance Use
Study Design	Pilot open trial
Subject Population key criteria for Inclusion and Exclusion:	Inclusion Criteria: (1) at least 18 years of age, (2) report regular recent injection drug use, defined as injecting illicit drugs on at least one day in the last week and for a minimum of at least two months, (3) has regular (i.e., at least twice weekly) access to an electronic device (e.g., mobile phone, tablet, computer) that can make phone and/or video calls and has an internet browser with a reliable internet connection, (4) able to identify at least one goal or area for change to address in treatment. Exclusion Criteria: (1) attending or on a wait list to receive psychosocial substance use treatment, (2) impairment due to active psychosis, (3) unable to read at a minimum of a 5th grade reading level, (4) or are unable to give informed, voluntary, written consent to participate.
Number Of Subjects	Up to 33 (proposed)
Study Duration	Contact with participants in Phase I will include a baseline assessment (2 hours), eight treatment sessions (8 hours), four brief weekly online questionnaires (30 minutes), and a post-treatment assessment (1.5 hours). Participants in Phase II will have contacts identical to Phase I with the addition of a 1-month follow-up assessment (1.5 hours).

Study Phases Screening Study Treatment Follow-Up	(1) Screening: screening for eligibility and obtaining consent. (2) Pretreatment assessment (3) Intervention: Behavioral activation (4) Posttreatment assessment (5) 1-month posttreatment follow-up assessment
Efficacy Evaluations	Behavioral Activation for Depression Scale (BADS) Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES) Short Inventory of Problems – Alcohol and Drugs (SIP)
Statistical And Analytic Plan	Repeated measures t-tests on outcome variables comparing within-subject change from pre → posttreatment, and pretreatment → follow-up.
DATA AND SAFETY MONITORING PLAN	Oversight of all study and treatment procedures by the PI and faculty sponsor, Dr. Daughters.

BACKGROUND AND RATIONALE

People who inject drugs (PWID) experience severe addiction-related harms and yet have low rates of engagement in substance use treatment. A number of individual and structural barriers have been shown to prevent PWID from entering treatment. These include barriers related to treatment accessibility [1, 2] as well as lack of readiness for cessation of drug use [3], and related lack of readiness for treatment [2]. Low-threshold treatment approaches reduce barriers associated with traditional substance use treatment, including the expectation of complete abstinence from drug use, and aim to make treatment more accessible in order to engage active users [4]. Although low-threshold HIV risk reduction interventions have demonstrated effectiveness in reducing risk behavior among PWID [5, 6], there has been very little research evaluating low-threshold psychosocial treatments that target the mechanisms driving problematic drug use.

Lack of environmental reward, defined as both the quantity and quality of environmental positive reinforcement, is one mechanism thought to drive problematic substance use that is a promising target for psychosocial treatment with PWID. Drug addiction is associated with reward deficits and a loss of drug-free positive reinforcement, resulting in decreased engagement in naturally rewarding (i.e., drug-free) activities [7]. This phenomenon is similar to behavioral patterns seen in depression; indeed, PWID (as well as other active drug users) have high rates of depression [8], which is associated with poorer outcomes in substance use treatment [9]. Helping active drug users engage in naturally rewarding activities may be one way to improve engagement in treatment and treatment effectiveness. By increasing sources of reinforcement through naturally rewarding activities, this approach may make the process of recovery more appealing to individuals who are not yet committed to abstinence. Behavioral Activation (BA) is an established empirically supported treatment for depression [10, 11] and more recently demonstrated effectiveness as a treatment for substance use disorders [12, 13]. BA may be a particularly effective treatment for non-treatment-seeking PWID because it targets environmental reward deficits. In this way, BA aims to bolster motivation for recovery by increasing engagement in value-based substance-free activities. Given the high rates of comorbid depression and substance use disorders among PWID, BA's effectiveness for both disorders is a clear benefit for this population. Furthermore, BA has been hypothesized to be a more accessible treatment than cognitive-behavioral approaches for substance users like PWID who have, on average, impaired cognitive abilities [14, 15]. Lastly, BA is a treatment that has high potential for cost-effective dissemination through support workers without formal training in psychotherapy [16], making it a practical approach for reaching underserved substance users.

Low-threshold behavioral treatment for PWID could be a useful tool to reduce drug-related problems and health risk behavior in this population. If effective, this treatment approach could be implemented in community-based settings where PWID already access services, such as syringe exchange programs (SEPs). This would fill an important gap in services for high-risk substance users. PWID are a particularly appropriate target population for this type of treatment due to the severe harms associated with injection and the growing infrastructure of SEPs across the U.S. that could administer treatment using nonspecialized support staff. Thus, we aim to assess the feasibility, acceptability, and preliminary efficacy of a pilot BA treatment for non-treatment-seeking PWID. This study would be the first to examine the use of this treatment in a sample of out-of-treatment substance users.

References

1. Appel, P.W., A.A. Ellison, H.K. Jansky, and R. Oldak, *Barriers to Enrollment in Drug Abuse Treatment and Suggestions for Reducing Them: Opinions of Drug Injecting Street Outreach Clients and Other System Stakeholders.* American Journal of Drug & Alcohol Abuse, 2004. **30**(1): p. 129-153.
2. Pollini, R.A., L. McCall, S.H. Mehta, D. Vlahov, and S.A. Strathdee, *Non-fatal overdose and subsequent drug treatment among injection drug users.* Drug and Alcohol Dependence, 2006. **83**(2): p. 104-110.
3. Neff, J.A. and W.A. Zule, *Predictive validity of a measure of treatment readiness for out-of-treatment drug users: enhancing prediction beyond demographic and drug history variables.* Am J Drug Alcohol Abuse, 2002. **28**(1): p. 147-69.
4. Mofizul Islam, M., L. Topp, K.M. Conigrave, and C.A. Day, *Defining a service for people who use drugs as 'low-threshold': What should be the criteria?* International Journal of Drug Policy, 2013. **24**(3): p. 220-222.
5. Copenhaver, M.M., B.T. Johnson, I.C. Lee, J.J. Harman, and M.P. Carey, *Behavioral HIV risk reduction among people who inject drugs: meta-analytic evidence of efficacy.* J Subst Abuse Treat, 2006. **31**(2): p. 163-71.
6. Gilchrist, G., D. Swan, K. Widyaratna, J.E. Marquez-Arrico, E. Hughes, N.D. Mdege, M. Martyn-St James, and J. Tirado-Munoz, *A systematic review and meta-analysis of psychosocial interventions to reduce drug and sexual blood borne virus risk behaviours among people who inject drugs.* AIDS and Behavior, 2017. **21**(7): p. 1791-1811.
7. Murphy, J.G., C.J. Correia, and N.P. Barnett, *Behavioral economic approaches to reduce college student drinking.* Addict Behav, 2007. **32**(11): p. 2573-85.
8. Brienza, R.S., M.D. Stein, M. Chen, A. Gogineni, M. Sobota, J. Maksad, P. Hu, and J. Clarke, *Depression among needle exchange program and methadone maintenance clients.* J Subst Abuse Treat, 2000. **18**(4): p. 331-7.
9. Rounsaville, B.J., M.M. Weissman, K. Crits-Christoph, C. Wilber, and H. Kleber, *Diagnosis and symptoms of depression in opiate addicts. Course and relationship to treatment outcome.* Arch Gen Psychiatry, 1982. **39**(2): p. 151-6.
10. Mazzucchelli, T., R. Kane, and C. Rees, *Behavioral Activation Treatments for Depression in Adults: A Meta-analysis and Review.* Clinical Psychology: Science and Practice, 2009. **16**(4): p. 383-411.
11. Soucy Chartier, I. and M.D. Provencher, *Behavioural activation for depression: efficacy, effectiveness and dissemination.* J Affect Disord, 2013. **145**(3): p. 292-9.
12. Daughters, S.B., J.F. Magidson, D. Anand, C.J. Seitz-Brown, Y. Chen, and S. Baker, *The effect of a behavioral activation treatment for substance use on post-treatment abstinence: a randomized controlled trial.* Addiction, 2018. **113**(3): p. 535-544.
13. Magidson, J.F., S.M. Gorka, L. MacPherson, D.R. Hopko, C. Blanco, C.W. Lejuez, and S.B. Daughters, *Examining the effect of the Life Enhancement Treatment for Substance Use (LETS ACT) on residential substance abuse treatment retention.* Addictive Behaviors, 2011. **36**(6): p. 615-623.
14. Harrell, P.T., B.E.E. Mancha, S.S. Martins, P.M. Mauro, J.H. Kuo, M. Scherer, K.I. Bolla, and W.W. Latimer, *Cognitive performance profiles by latent classes of drug use.* The American Journal on Addictions, 2014. **23**(5): p. 431-439.
15. Anand, P., S.A. Springer, M.M. Copenhaver, and F.L. Altice, *Neurocognitive Impairment and HIV Risk Factors: A Reciprocal Relationship.* AIDS and behavior, 2010. **14**(6): p. 1213-1226.
16. Ekers, D., C. Godfrey, S. Gilbody, S. Parrott, D.A. Richards, D. Hammond, and A. Hayes, *Cost utility of behavioural activation delivered by the non-specialist.* The British Journal of Psychiatry, 2011. **199**(6): p. 510-511.

1 STUDY OBJECTIVES

Aim A.1. To examine the feasibility and acceptability of administering a behavioral activation treatment for substance use (The Life Enhancement Treatment for Substance Use – LETS ACT) among non-treatment-seeking PWID.
Aim A.2. To revise the LETS ACT manual through an iterative development and piloting process.
Aim A.3. To test the efficacy of the revised LETS ACT treatment for PWID from baseline (BL) to a 1 month follow-up (FU1).

1 INVESTIGATIONAL PLAN

1.1 Study Design Overview

The current study will extend ongoing research of a behavioral activation (BA) treatment for substance use in an intensive outpatient substance use treatment center (i.e., the parent study) by offering the BA treatment as a low-threshold intervention to non-treatment-seeking PWID. This study will be implemented in two phases. Phase I will address Aims 1 and 2 by adapting the LETS ACT treatment manual and testing the feasibility of the treatment through an iterative piloting process with a small sample of PWID. Phase II will address Aim 3 by testing the initial efficacy of the treatment through a pilot open trial. During Phase I, treatment will be delivered in two waves, making adjustments to the treatment manual as needed after the first wave. Phase I will be used to establish the treatment feasibility and to inform any major modifications to the treatment manual, which will occur prior to Phase II. Participants will be people who inject drugs (PWID) recruited from various community sites. Assessments will include a baseline assessment, post-treatment assessment, and a one-month follow-up assessment (Phase II only) to evaluate treatment outcomes.

1.2 Study Duration, Enrollment and Number of Subjects

Proposed recruitment: Up to 33 subjects

Study Duration: Contact with participants in Phase I will include a baseline assessment (2 hours), eight treatment sessions (8 hours), four brief weekly online questionnaires (30 minutes), and a post-treatment assessment (1.5 hours). Participants in Phase II will have contacts identical to Phase I with the addition of a 1-month follow-up assessment (1.5 hours).

1.3 Study Population

Participants will be people who inject drugs (PWID) recruited from various community sites. **Inclusion Criteria**: (1) at least 18 years of age, (2) report regular recent injection drug use, defined as injecting illicit drugs on at least one day in the last week and for a minimum of at least two months, (3) has regular (i.e., at least twice weekly) access to an electronic device (e.g., mobile phone, tablet, computer) that can make phone and/or video calls and has an internet browser with a reliable internet connection, (4) able to identify at least one goal or area for change to address in treatment. **Exclusion Criteria**: (1) attending or on a wait list to receive psychosocial substance use treatment, (2) impairment due to active psychosis, (3) unable to read at a minimum of a 5th grade reading level, (4) or are unable to give informed, voluntary, written consent to participate.

2 STUDY PROCEDURES

Training and Planning Stage

During the initial training and planning stage, Ms. Paquette will adapt the LETS ACT treatment manual and materials (e.g., treatment booklet) in order to tailor them for non-treatment-seeking PWID. Dr. Daughters will provide consultation throughout this process and will approve the final LETS ACT treatment manual before recruitment for the current study commences.

Screening

Participants will be recruited on a rolling basis through community sites such as the SEPs, clinics, and community organizations. Study flyers will be distributed with basic study details and a web URL for a brief online pre-eligibility survey; participants will fill out the survey and then will be contacted by study staff for a full screen. The pre-eligibility survey will be available online via Qualtrics and will include questions about access to the internet & electronic devices, as well as contact information for the participant and consent to be contacted by study personnel. Individuals will be told that their potential participation would be kept confidential and would not affect the services they receive from the SEP or other recruitment sites. If initial eligibility criteria are met, study staff will contact participants to make arrangements for a screening assessment conducted over secure video conferencing (e.g., HIPAA-secure Zoom) or phone call. Participants will be screened using the Word Reading subtest of the Wide Range Achievement Test (WRAT), which they will view online via Qualtrics during the screening assessment, and a screening questionnaire. Trained research assistants will administer these screening tools following a protocol script (available in the attached Appendix). Administration of the WRAT and screening questionnaire should take no longer than 20 minutes. Eligible participants will provide informed consent online via Qualtrics and complete a baseline assessment (BLA).

BLA Procedure

Participants will be asked to provide detailed information relating to mental/physical health, past and current substance use behaviors, and HIV risk behaviors. Information will be collected primarily through computer-based self-report measures, although some data will be collected through an interview with a trained researcher. The interview will be audio recorded to ensure accuracy. Based on the length of self-report measures and interview questions, the BLA will take 1 to 2 hours to complete.

After the BLA, all participants will receive a behavioral activation treatment called LETS ACT. The treatment will be administered by Ms. Paquette (Phases I and II) and two additional graduate-level therapists (Phase II) under the supervision of Dr. Daughters. In order to assess therapist adherence with treatment protocol, all treatment sessions will be audiotaped and a selection will be rated using checklists.

In order to maintain the validity of the assessment data, participants will be given 2 weeks after their BLA to schedule and attend their first therapy appointment. If the first appointment does not occur within that time frame (e.g., because the participant cannot be reached after their BLA), they will be given the option to 1) be re-assessed (i.e., complete BLA measures again) without additional compensation after which they can start the treatment sessions, or 2) complete their PT within the normal time frame after their BLA without participating in the treatment (participants can also withdraw from the study at any time).

Intervention

The LETS ACT treatment will consist of eight one-hour sessions delivered twice weekly over four weeks. Treatment will be provided remotely via secure video conferencing or by telephone. The key components of the treatment are described below. Earlier sessions introduce the treatment rationale by focusing on

examples relevant to the participant. The majority of sessions focus on modifying behavior during treatment. In later sessions, there is a gradual move toward post-treatment planning.

Each session begins with a discussion of the Treatment Rationale, with a specific emphasis on the cycle of depression/negative mood, substance use, and the effects of negative mood on self-care behaviors. Participants learn that LETS ACT is based on the belief that best way to improve mood and make long-term life changes is by systematically increasing one's activity level and/or by changing the activities in which they currently are engaged. When an individual becomes more active and is regularly engaging in activities that generate a sense of pleasure and/or accomplishment, they are more likely to increase exposure to positive/enjoyable situations and experiences, and less likely to feel sad/angry/down/depressed and have a desire to use substances and engage in other risk behavior. Following the treatment rationale, emphasis shifts to identifying values and goals within up to 11 life areas (e.g., family relationships, employment, physical health). Patients complete the Life Areas and Values Assessment with the therapist, answering questions such as "What areas of my life are important to me?" and "What is important to me in this life area?" Patients are then asked to generate a list of specific and measurable Activities that in line with the Life Areas and Values Assessment. Emphasis is given on the importance of balancing mastery and pleasure activities. Information derived from the Life Areas and Values Assessment and identification of rewarding activities is then used make daily plans. The therapist assists the clients in planning activities during the session, troubleshooting, and referencing the treatment rationale to help patients identify their cycle of negative mood and behavior.

Post-Treatment Assessment Procedure

After their eighth and final treatment session, all participants will complete a post-treatment (PT) assessment similar in length and content to their BLA: information relating to mental/physical health, past and current substance use behaviors, and HIV risk behaviors. Information will be collected primarily through computer-based self-report measures, although some data will be collected through an interview with a trained researcher. Based on the length of measures, the PT will take up to 1.5 hours to complete. Upon completion of the PT, participants are given the opportunity to ask any questions. Those in Phase II will also schedule their 1-month follow-up appointment.

Follow-up Procedure

Participants in Phase II will complete a follow-up appointment 1 month after their final therapy session. The follow-up assessment similar in length and content to that of the BLA and PT; the follow-up assessment is expected to take approximately 1.5 hours to complete, and will be completed online (Qualtrics) and via secure video conferencing or phone call. If any participants miss their PT but are able to attend FU1, key measures from PT (including the post-treatment feedback interview, Client Satisfaction Questionnaire) will be included in the FU1 assessment in order to gather as much data as possible about the feasibility and acceptability of the intervention.

3 STUDY EVALUATIONS AND MEASUREMENTS

Eligibility screening. Participants will be screened for eligibility criteria using a questionnaire with questions about current drug use/injection, treatment involvement, and active psychosis, as well as via an informed consent questionnaire. Additionally, participants will be screened for reading level using the Wide Range Achievement Test (WRAT).

Demographic information and treatment history. Demographic information and treatment history will be collected using questionnaires developed for the study. This will include age, race/ethnicity, employment, income, housing, education, current and past involvement in any substance use treatment, type and dates of treatment, and reasons for discharge/withdrawal.

Substance use, related problems, and readiness to change. Lifetime and recent (past 3 months) substance use will be assessed using the World Health Organization's Alcohol, Smoking and Substance Involvement Screening Test (ASSIST; WHO ASSIST Working Group, 2002). We will add a question about the frequency of injection for each illicit drug used in the past 3 months. The Timeline Follow-Back (TLFB) (Sobell, Maisto, Sobell, & Cooper, 1979) will be used to gather more detailed information about past month substance use. The TLFB uses a calendar format and semi-structured interview style to collect information about the type and amount of substance used during a specific time period. We will assess past month substance-related problems using the Short Inventory of Problems – Revised (SIP-R) (Kiluk, Dreifuss, Weiss, Morgenstern, & Carroll, 2013). The SIP-R is a 17-item scale that asks about the frequency of problems in a range of life areas (e.g., physical health, relationships, money) during the specified time period. Readiness to change will be assessed using The Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES) (Miller & Tonigan, 1996). The SOCRATES is a 19-item scale based on the transtheoretical model of behavior change. It includes three subscales: Recognition, Ambivalence, and Taking Steps.

Psychological symptoms. Depressive symptoms will be assessed with the PHQ-9 Depression (Kroenke, Spitzer, and Williams 2001), and anxiety symptoms will be assessed using the GAD-7 Anxiety (Spitzer et al., 2006); both are well-validated self-report symptom measures.

Behavioral activation and environmental reward. Behavioral Activation will be assessed using the Behavioral Activation for Depression Scale (BADS) (Kanter, Mulick, Busch, Berlin, & Martell, 2006). The BADS is a 25-item self-report questionnaire which assesses engagement in a range of activities using four subscales: Activation, Avoidance/Rumination, Work/School Impairment, and Social Impairment. Environmental reward will be measured with the The Environmental Reward Observation Scale (EROS), a 10-item validated measure (Armento 2006).

HIV risk behaviors. The HIV Risk Behavior Scale (HRBS) (Darke, Hall, Heather, Ward, & Wodak, 1991) assesses past-month sexual and drug-related risk behaviors.

Treatment acceptability and engagement. Treatment engagement will be assessed by calculating the percent of treatment sessions attended and homework completion (i.e., self-reported engagement in homework). Treatment acceptability will be assessing using a measure of client satisfaction as well as a measure of therapeutic alliance. Satisfaction with treatment will be assessed using the 8-item Client Satisfaction Questionnaire (CSQ-8) (Larsen, Attkisson, Hargreaves, & Nguyen, 1979) and semi-structured qualitative interviews. The CSQ-8 is a brief self-administered rating scale that assesses satisfaction with treatment. Qualitative interview topics will include treatment satisfaction; likes and dislikes related to treatment; suggestions for improvement; perceived impact of treatment; comparison to past treatment experiences; and opportunity for open-ended feedback. Qualitative interviews will be transcribed verbatim. Therapeutic alliance will be assessed at PT using the Working Alliance Inventory – Short Form, Revised (WAI-SR) (Hatcher & Gillaspy, 2006). The WAI-SR assesses agreement between the patient and therapist on the goals of the treatment the strategies for achieving these goals, as well as their bond.

STATISTICAL CONSIDERATIONS

3.1 Statistical Methods

After both study phases, we will calculate summary statistics for session attendance, homework completion, attrition, therapist fidelity, working alliance (WAI-SR) and client satisfaction (CSQ-8). For **Aims 1 and 2,** data analysis will focus on treatment engagement, acceptability, and participant feedback. Qualitative interviews will be transcribed verbatim and verified for accuracy by a second reviewer. The PI will read all interview transcripts and create summaries (e.g., bulleted lists of participant suggestions), as well as identifying themes in the areas of interest. This analysis will inform final revisions to the treatment manual. For **Aim 3,** we will use statistical methods to evaluate preliminary treatment outcomes by comparing within-subject changes across time points. We will examine statistically significant change by running repeated measures t-tests on our outcome variables comparing within-subject change from pre → posttreatment, and pretreatment → follow-up. Given the small sample size, results are considered preliminary and are interpreted with caution.

3.2 Sample Size and Power

Our small target sample size was determined based on feasibility, given the study's exploratory nature. Thus, all results will be considered preliminary and will be interpreted with caution.

3.3 Interim Analysis/Study Termination

This study may be prematurely terminated if, in the opinion of the investigator or Dr. Daughters, there is sufficient reasonable cause. Circumstances that may warrant termination include, but are not limited to, an event during which a participant experiences an SAE during an assessment or treatment session. In case of an SAE, a temporary hold will be placed over the study and further investigation will be pursued. Based on investigational findings, the study may be stopped prematurely or may be continued with further safety measures in place. The individual will be referred for further medical/psychological services as needed. The IRB will be informed promptly and provided the reason(s) for the termination or suspension by the sponsor or by the investigator/institution, as specified by the applicable regulatory requirement(s).

7. SAFETY MANAGEMENT

We will safeguard against and regularly monitor for unanticipated problems by ensuring appropriate oversight of all study and treatment procedures by the PI and Dr. Daughters. The PI will be available to address adverse events throughout the duration of the study, and Dr. Daughters will be readily available for consultation as needed. Adverse events (AEs), serious adverse events (SAEs), and unanticipated problems (UPs) will be monitored throughout the duration of the study and will be compiled in a file by the research staff. All AEs, SAEs and UPs will be reported immediately to Dr. Daughters. Any incidents that involve a breach of Dr. Daughters' data and safety monitoring plan or serious accident/injury will be reported to the IRB chair at UNC-CH, as well as to the NIDA PO. Dr. Daughters and Ms. Paquette will monitor the filed record of adverse effects with the research team at a weekly study meeting. At this weekly study meeting, the researchers and Dr. Daughters will discuss ongoing and appropriate oversight of all safety monitoring procedures.

8. DATA COLLECTION AND MANAGEMENT

All of the information obtained from participants is entirely for research purposes and deidentified using ID numbers. Information is kept in password-protected files on a secure UNC server with limited access to only research staff. Consent and contact forms are separated from research data and kept in separate password-protected files. All computerized data collection methods will use a secured, encrypted web survey, and only ID numbers will be linked to study data. Data will be stored on a secured network at UNC with access to password protected files granted only to research staff.

No information apart from the brief pre-screening form will be collected until the individual agrees to participate in the study and has provided informed consent and passed the informed consent quiz (see attachment). Aside from the pre-screening form, consent form, and contact form (all collected online via secure Qualtrics), the participant's name will not appear anywhere on other collected information and will instead be marked with a participant number that will be listed on all data forms; only research staff will have access to a database that links participant numbers and names.

With regard to information confidentiality of the digital treatment homework and self-report questionnaires, Qualtrics will be the distribution platform. Qualtrics is an online software survey program affiliated with UNC used to design and administer our self-report measurements. With the implementation of Qualtrics, all collected data will be automatically encrypted and uploaded to the online Qualtrics database, which can only be accessed by the investigators of the study. Interview questionnaires will also be entered into Qualtrics by the interviewer, and will only be accessible to the research staff. Data will be coded with study ID numbers that can only be matched to a participant's name via a database stored in a separate, secure location on the server, only accessible to the researcher staff using a password.

We will safeguard against breaches of confidentiality by refraining from collecting personal identifying information and instead coding participant data by assigned ID numbers. Study participant information linking these ID numbers to specific individuals will be kept in a password-protected document on a secure UNC server accessible only to research staff.

9. RECRUITMENT STRATEGY

Participants will be recruited on a rolling basis through community sites such as the SEPs, clinics, and community organizations. Study flyers will be distributed with basic study details and a web URL for a brief online pre-eligibility survey; participants will fill out the survey and then will be contacted by study staff for a full screen. The pre-eligibility survey will be available online via Qualtrics and will include questions about access to the internet & electronic devices, as well as contact information for the participant and consent to be contacted by study personnel. Individuals will be told that their potential participation would be kept confidential and would not affect the services they receive from the SEP or other recruitment sites.

10. CONSENT PROCESS

The informed consent process will begin with a detailed description of the purpose and procedure of the study emphasizing our policy regarding privacy and confidentiality and an opportunity of the individual to ask any questions or voice any concerns. Individuals who agree to participate in the study and provide informed consent will receive a subject number that will be listed on all data forms. Before entering the study, each participant must fill out and pass an "informed consent quiz" with 100% accuracy. This 10-item True/False questionnaire includes statements about the study to measure their comprehension of the consent form.

Example questions include, “For this study, you will be asked to complete more than one assessment”, and “You can withdraw from the study at any time.” Following this quiz, participants will be asked to sign an electronic informed consent in Qualtrics by typing their name into a text box. All research assistants will be trained to follow a provided script for the consent process based on the experimental condition.