Brief Acceptance-Based Retention Intervention for Newly Diagnosed HIV Patients

NCT04201288

Study Protocol – 8/30/21

BRIEF ACCEPTANCE-BASED RETENTION INTERVENTION FOR NEWLY DIAGNOSED HIV PATIENTS

Manual of Procedures (MOP)

INTRODUCTION

The Manual of Operating Procedures (MOP) has been compiled to assist study personnel in conducting the study "Brief Acceptance-Based Retention Intervention for Newly Diagnosed HIV Patients." It documents study flow so that the screening, initial evaluation, enrollment, and follow-up of all study participants are conducted in a standardized manner. It details how data are to be observed, collected, and recorded, and specifies quality control procedures. The MOP defines methods for ensuring confidentiality of participant information.

This MOP serves as a supplement to the protocol and contains study conduct information in the form of administrative or detailed technical information that is not detailed in the protocol or protocol amendment. The MOP must be reviewed carefully in conjunction with the protocol by all study key personnel.

The MOP will be modified accordingly whenever a change in the protocol is approved or a study step has to be refined or re-defined for clarity and safety. The changes are captured by maintaining a version control numerically matching the progressing sequence of dates displayed on the cover page.

MOP CONTENTS AND ORGANIZATION

STUDY PROCEDURES

A. RESPONSIBILITIES

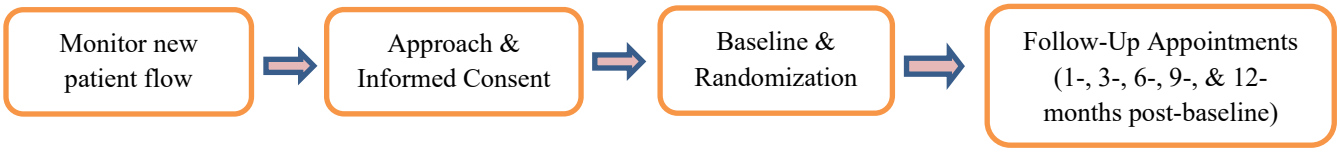
The PI and investigative team are responsible for the implementation of the protocol, including:

- Participating in protocol finalization and preparing study materials
- Assuring that the study is conducted according to the protocol
- Identifying, recruiting, screening and enrolling participants
- Protecting participants' rights
- Obtaining informed consent from each participant
- Collecting study data and following participants through study completion
- Preparing recruitment and enrollment, gender and minority breakdowns, adverse event reports
- Assuring IRB review and approval
- Preparing and sending reports to the Data Safety Monitoring Board (DSMB)
- Preparing and sending annual reports to the funding agency, the National Institutes of Health (NIH)

B. TRAINING PLAN

The Research Assistant and Study Coordinator will be trained on all clinical assessments by the lead investigators. For all measures, the staff in training should familiarize themselves with the measures and complete mock interviews. The PI will lead all trainings on intervention and control condition delivery. Interventionist training will include mock session practice and review of audio recorded sessions.

C. STUDY FLOW



D. SCREENING AND ELIGIBILITY TRACKING

How are potentially eligible individuals identified?

Intake nurses will reach out via email to notify when there is a new patient scheduled. We will find a convenient time during that appointment to approach the patient.

How is the screening conducted?

Study staff will use the screening form to determine eligibility.

How do we know which patients to approach for enrollment?

Staff use the following guidelines to determine whether patients are eligible or ineligible to be approached for study enrollment. The majority of the data to determine eligibility are available in the patient medical record; however, for any additional information not available in the medical record, the staff will need to consult with clinical intake staff.

A patient must meet all of the eligibility criteria listed below before they are approached about enrolling in the Engage study.

Table 1. Eligibility criteria

Inclusion Criteria	Exclusion Criteria
• HIV+ • ≥18 years old • Entering HIV medical care services for the first time (that is, not transferring HIV care from another location) • Able to speak and read English at the level to be able to complete the study procedures • Have telephone access	• Cognitive impairment that would interfere with adequate participation in the project (clinic staff will make this determination)

For each patient screened on that day, the RA will enter the following information into the study Key file:

- ID: A unique screener ID will be generated for all individuals screened
- Date: Date screened

- Name: First *only*
- Telephone number: At least one contact number
- Permission to text appointment reminders: Yes / No
- Permission to leave voicemails for appointment reminders: Yes / No
- Permission to leave messages indicating research affiliation: Yes / No
- Age
- HIV status: Positive / Negative
- Cell phone: Yes / No
- Number of days in past 3 months when individual stopped using their cell phone

E. APPROACHING / ASSESSING PATIENTS

Before approaching the patient

Confirm with intake nurse via email that the RA will approach the new patient at their upcoming intake visit.

When heading to clinic, bring a clipboard with the:

- Screening form
- 2 copies of the consent form
- Release of Information form
- ClinCard FAQs and information documents
- Response cards set
- HIV education slides
- Mental health resources document
- Locator Form.
- Also bring a baseline questionnaire packet in case the patient immediately enrolls and wants to complete the baseline assessment while in clinic.

Remember, slides and consent show content related to the research study. Participants should be warned that these materials might reveal sensitive information. They can decline taking any of them.

Numbering system

Please use the following numbering system for identifying patients (PSID) and enrolling participants (SID): PSIDs=101-n; SIDs=1001-n

PSIDs should be assigned to every patient you identify and try to screen. That means that completed screens will not be continuously numbered – this is ok. The key is to assign a PSID to every new patient in the clinic.

Approaching the Patient

Patients are only approached and assessed during their free time during their clinical intake visit. Most staff are aware of this, but if the staff is not, please remind them that study staff are to only meet with patients during their free time.

Once you have met the patient, introduce yourself and ask if they have a few minutes to talk to you about an ongoing research study at the clinic. If they agree, administer the screener, which includes a brief recruitment script.

Patient consent

If a patient agrees to participate in the study, the staff will guide the patient through the consent form, answer any questions, and ask the patient to sign a copy of the consent form for our records.

After signing the consent form, the patient will need to complete the following:

- Engage Contact Locator Form

After completing these forms, the staff will set up a time to complete the baseline assessment with the patient later that day (if possible) or within 1 week.

Record all patient approaches in the "Key – HIV Engage" tracking file

F. PARTICIPANT PAYMENT (ClinCards)

Participants will be paid $25 for completion of baseline and each follow-up assessment. They will not be paid for completing sessions with study interventionists. ClinCards will be used for all participant remuneration. These are MasterCards that function as reloadable debit cards.

Once the baseline appointment is completed, open up a ClinCard envelope and show the participant the card. Make note of the "Token" number, which is visible through the clear window on the front of the envelope. This links the participant to the specific ClinCard. As ClinCards are distributed, make note of the token number in LSUHSC's tracking log and share the participant ID – token number assignment with PI Moitra. Review the Participant ClinCard Information sheet and the FAQ document with the participant.

Highlight each section of the FAQ sheet, in particular noting:

- The 3-ish business days for payment to load onto the card (at baseline, the ClinCard already has $25)
- How to set up a PIN
- When additional fees could be incurred
- What to do if the card is lost

At follow-up assessments, PI must initiate the upload of additional funds through Brown University. At the conclusion of follow-up assessments, inform the participant that their ClinCard will be loaded with an additional $25 within 2-3 business days. Immediately contact PI at the conclusion of the assessment via email to ask him to initiate the reload process. He will then contact the relevant Brown University staff. Use the following template:

Email to PI as follows:

> Subject Line – Grant: GR5271057
> Hello,
> Please approve my ___ AM/PM interview with Subject ID # XXXX in the amount of $25 for Month, Day, Year on grant #GR5271057

Lost ClinCards

We will give participants the benefit of the doubt if they report losing their ClinCard. If a lost or missing ClinCard is reported, immediately inform PI so that he can cancel the lost card and prevent misuse of funds. A replacement ClinCard will be given one time to participants; if they lose >1 ClinCard, all additional ClinCards will be loaded with a reduced amount to cover the expense of the

replacement card. All replacement ClinCards must be given in-person to the participant.

G. BASELINE ASSESSMENT

The baseline interviews should be completed in a private interview room in the clinic or research offices. All interviews will be audio-recorded.

Baseline Assessment Schedule:

Interviews	Self-Reports (*if possible*)
Sociodemographics	Contemplation Ladder
Thoughts about PrEP	PROMIS Global Health Scale
Alcohol Use Disorders Identification Test (AUDIT-3)	Health Information
Addiction Severity Index Drug Module (ASI)	Well-Being Scale
Patient Health Questionnaire-9 (PHQ-9)	Impulsivity Scale
Disclosure Scale (BHD & SSSES)	Acceptance and Action Questionnaire-II (AAQ-II)
Disclosure List	Multidimensional Scale of Perceived Social Support (MSPSS)
COVID-19 items	Berger HIV Stigma Scale
	Healthcare System Distrust Scale
	Everyday Experience of Discrimination Scale
	Patient Satisfaction Survey

After the interviews are completed, allow the patient to complete the self-report measures independently (if possible). Briefly go over the self-reports with the patient, and ask if they have any questions. **Print all self-reports ONE-SIDED.**

In some cases, participants will consent to be in the study, but will leave the clinic before a baseline appointment can be started and/or completed. If this is the case, arrange a time for them to come complete the baseline appointment within 1 week.

H. POST-BASELINE ASSESSMENT PROCEDURES

After the baseline has been completed, check-in with the PI to verify the patient's eligibility for enrollment and for any questions in assessment/coding that may have arisen. If the PI agrees that the patient is eligible, and no problematic secondary characteristics have been identified that may hinder the patient's participation in the study, the patient is officially enrolled into the study.

Randomization:

Randomization occurs in the REDCap database using information gathered during the baseline interview (participant's depression and substance use scores). See the cover page of the baseline assessment for guidelines. This information can be directly entered into REDCap, which will then generate the allocation.

Follow-Up Assessment Schedule:

Follow-up assessments are conducted at 1-, 3-, 6-, 9-, and 12-months post-baseline. These assessments can be conducted remotely or in-person. All follow-up assessments are audio-recorded.

Measure	*Self-Report*	1-Mo	3-Mo	6-Mo	9-Mo	12-Mo
Sociodemographics II		X	X	X	X	X
Health Questionnaire (PHQ-9)		X	X	X	X	X
Disclosure Scale (BHD & SSSES)		X	X	X	X	X
Disclosure List		X	X	X	X	X
Self-Rating Scale Item (SRSI)	*X*	X	X	X	X	X
Contemplation Ladder	*X*	X				
PROMIS Global Health	*X*	X	X	X		
Health Information	*X*	X	X	X	X	X
Well-Being Scale	*X*	X	X	X	X	X
Acceptance and Action Questionnaire-II (AAQ-II)	*X*	X	X	X	X	X
Multidimensional Scale of Perceived Social Support (MSPSS)	*X*	X	X	X	X	X
Berger HIV Stigma Scale	*X*	X	X	X	X	X
Healthcare System Distrust Scale	*X*	X	X	X	X	X

Everyday Discrimination Scale	*X*	X	X	X	X	X
Visit Specific Satisfaction Questionnaire	*X*	X				
Client Satisfaction Questionnaire-Revised	*X*	X				
End-of-Treatment Questionnaire	*X*	X				

I. REDCap ASSESSMENT DATABASE

This study uses a centralized REDCap database for all data collection and entry.

J. PROCEDURES FOR WITHDRAWAL OF CONSENT

If the participant communicates to research staff that they would like to withdraw their consent to be in the study at any point, the staff must document this in the Engage Tracking Log, and if possible, obtain written documentation from the participant via letter or in-person.

Once the participant has withdrawn consent, the staff no longer has permission to contact the participant regarding the study and will not review any electronic health record information about the individual.

K. PROCEDURE FOR WHEN PATIENT ENDORSES CURRENT SUICIDAL IDEATION/DISTRESS

The PHQ-9 should be administered early in the assessment so that a clinician can promptly respond. If a patient endorses current suicidal ideation at any time during any assessment, and/or as assessed by the PHQ-9 (i.e., score >0 on item #9) or otherwise in conversation, study staff will take the following steps:

- Immediately text a licensed study clinician to notify them that a risk assessment might be needed
- Administer the Modified Scale for Suicidal Ideation (MSSI) at the end of the assessment, unless the participant is in distress and interrupting the appointment is warranted
    - After collecting the MSSI information, explain to the individual that our study values our participants and wants to offer resources or help if needed.

    - Ask who knows about the patient's suicidality (e.g., therapist, case manager). If there are providers who are aware of these issues, ask when the patient will speak to them next.
- Pause the assessment and call the study clinician (outside of the appointment room if conducting the assessment in-person). The clinician will then determine next steps based on the information gathered by the study staff.

If a patient endorses any homicidal ideation (HI) or violent ideation (VI) during the assessment, collect relevant information (frequency of thoughts, intent to act, plan, person/people in question) and report to on-call clinician to determine if patient is at imminent risk of harming others.

If a clinical check-in is completed, the staff will complete a note, to be stored in the research PHI folder, detailing:

- How the event was identified (e.g., follow-up appointment, phone call)
- Pertinent clinical information indicating risk
- Steps taken by the licensed clinical coverage staff to address the risk
- Yes/No contraindications to continuing in the study
- How symptoms will be monitored at the next visit

If a participant is evaluated within the study by a licensed member of the investigative team and it is determined that no additional clinical services are needed, then the note will suffice as a research chart note to be stored with the research study folder. If the participant is seen by a clinic staff right away, document information you gathered at that point, and that they have been transferred to their clinic for further evaluation. This would constitute an adverse event that PI will need to report to the IRB and NIMH. The research chart note for transferred patients will also be stored in the research PHI folder.

L. SAFETY REPORTING

All adverse events related to the participant that come to the staff's knowledge must be communicated to the PI immediately. He will then report to IRB and NIH, as appropriate.