Study Protocol

Targeting HIV Retention and Improved Viral load through Engagement

Short Title: THRIVE

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Overview

Objective: To conduct a pilot randomized clinical trial (RCT) of the THRIVE intervention (N=35) compared to treatment as usual (TAU; N=35) to 1) to evaluate feasibility and acceptability for a full-scale RCT; and 2) examine trends in outcomes of interest (VL improvement and retention in care) for the definitive RCT.

Study Design: The study is a two-arm, randomized, controlled pilot trial. Participants will be randomly assigned to one of two groups: 1) The THRIVE intervention; or 2) Treatment as Usual (TAU). Primary and secondary outcomes will be measured at 3 months and 6 months post-discharge.

Scientific Rationale

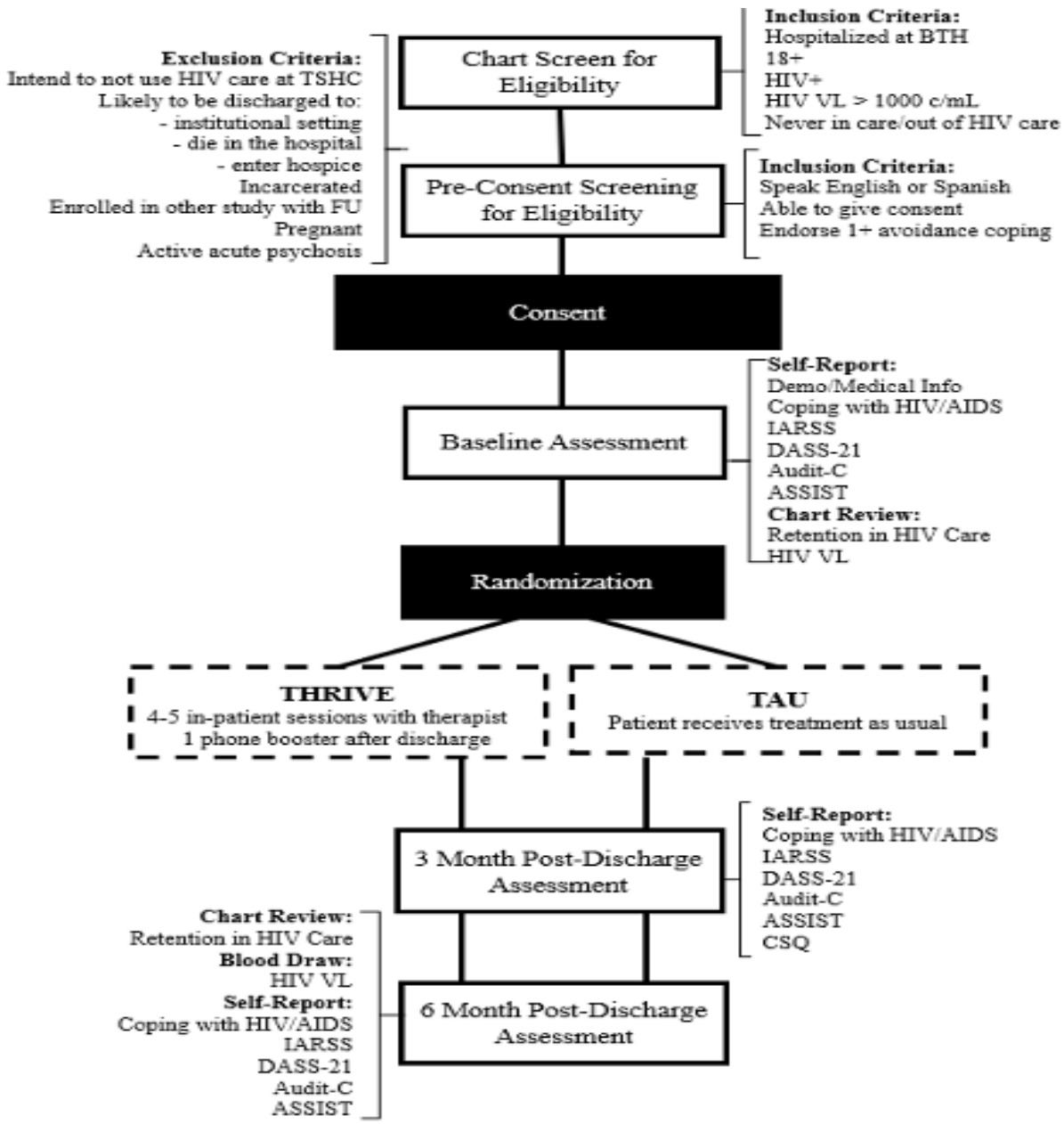
Antiretroviral therapy (ART) has transformed HIV infection into a treatable, chronic condition. However, about 40% of people diagnosed with HIV infection are not regularly engaged in HIV primary care in the US. Hospitalization presents a rare opportunity to find out-of-care people with HIV (PWH) since it remains relatively common in PWH, especially in persons with uncontrolled or advanced HIV infection and in the US South. Unfortunately, few interventions effectively retain PWH in HIV care. How to better retain out-of-care PWH with unsuppressed HIV RNA viral load (VL) remains one of the most important questions in HIV care and solutions are critical to end the HIV epidemic.

Avoidance coping is a maladaptive coping strategy whereby people avoid uncomfortable internal states and situations that trigger such states. Avoidance coping, which may arise from stigma, distrust, low self-efficacy and other factors, is predictive of poor clinical outcomes in PWH. In fact, among PWH, avoidance coping is common and predicts poor re-engagement in care after hospitalization. Thus, a psychotherapeutic intervention that targets maladaptive avoidant coping strategies, which are barriers to care, could improve clinical outcomes for a targeted population.

Acceptance and Commitment Therapy (ACT) is a behavioral intervention that targets avoidance and has the capacity to address psychosocial and behavior-related issues that PWH experience. The ACT framework posits that avoidance, particularly avoidance of uncomfortable internal states and situations that trigger such states, influences multiple types of difficulties. ACT helps patients to overcome avoidance by promoting acceptance-based coping and engagement in valued life activities. ACT has one of the strongest bases of empirical support among specific therapies with demonstrated efficacy or effectiveness across an array of conditions, including anxiety, depression, and importantly, dealing with chronic disease. ACT also holds promise for non-diagnostic phenomena such as stigma and ACT is feasible and acceptable among outpatient PWH. Innovative brief ACT interventions appear to be feasible, acceptable, and at least preliminarily, have efficacy. Thus, ACT content and delivery processes have been meaningfully adapted to the specific needs of different populations, but they have not been adapted for out-of-care PWH.

We propose to pilot test an ACT intervention for out-of-care PWH who present with avoidant coping. 'Targeting HIV Retention and Improved Viral load through Engagement' (THRIVE) will aim to help out-of-care PWH overcome the cycle of avoidance coping which can keep PWH out of care and exacerbate/maintain stigma and comorbid mental health difficulties that are common in PWH. Delivering THRIVE in the hospital will increase behavioral therapy initiation and completion, the lack of which is often the greatest obstacle to effective delivery of mental health services for PWH.

Study Flow Diagram



Inclusion and Exclusion Criteria

The target study population is people with HIV who are out-of-care.

Inclusion Criteria

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

- Hospitalized at Ben Taub Hospital (BTH), Houston, Texas
- At least 18 years of age

- Able to speak English or Spanish
- HIV infection, confirmed by medical record review
- Able to provide informed consent and participate in the study (patients who are temporarily unable to participate will be followed and approached for enrollment if and when they are cognitively and physically capable of consenting and participating)
- HIV VL>1000 c/mL
- Never in care or currently out of HIV care for HIV, defined as not meeting the 'visit constancy' measure (completed HIV primary care visit in a Houston area clinic in each of the three 4-month intervals preceding admission); or 2 or more "no shows" to HIV primary care visits in a Houston area clinic in the last year. All persons with VL>1000 c/mL would be expected to be seen 3 times in a given year, and "no shows" to clinic visits have been independently predictive of increased morbidity and mortality, especially in Black PWH.
- Endorse one of the two avoidance coping statements with the highest factor loadings on the Avoidant Coping Subscale from the Coping with HIV/AIDS scale.

Exclusion Criteria

All candidates meeting any of the exclusion criteria will be excluded from study participation.

Exclusion criteria are:

- Intending to use a source of HIV primary care other than Thomas Street Health Center (TSHC) after discharge, because their outcomes cannot be evaluated (>70% of PWH hospitalized at BTH intend to use TSHC after discharge)
- In the opinion of the primary medical team caring for the patient, likely to be discharged to an institutional setting, die in the hospital or enter hospice
- Incarcerated or expected to be discharged to prison or jail
- Enrolled in another research study with prospective follow-up
- Pregnant, since pregnant women receive additional efforts to be linked and retained in care
- Admitted with acute psychosis which would preclude informed consent or meaningful participation with the intervention.

Sample Size

Since hypothesis testing is not recommended for pilot studies, no formal hypothesis testing on the efficacy of the intervention will be performed in this pilot trial for the primary and secondary outcomes. However, estimates of the difference or the relative ratio between arms, with 95% confidence intervals, will be obtained that will provide information on the direction and possible range of the intervention effect which may be used as a basis to support a larger RCT. We will compare the ACT group to the TAU group on retention in care and undetectable VL 6 months after hospital discharge with descriptive statistics calculated for these primary outcomes. Assuming a composite outcome (retention in care and VL improvement) of between 30% and 65%, a sample size of N=35/group will allow us to estimate the outcome rate for each group to within 15 to 17 percentage points (95% CI). Estimates of the difference between treatment arms will also be assessed for exploratory outcomes, including mental health, stigma, and coping. Likewise, descriptive statistics will be computed for the demographic, clinical, and baseline variables to describe the characteristics of the pilot study sample population. These analyses

will also help validate our methods and data gathering techniques. These descriptive analyses will also be performed for the sub-populations that we anticipate will have more difficulty relinking to outpatient HIV care (e.g., substance abuse).

Study Timeline

Timeline	Yr 1				Yr 2			
Recruit 70 pts (10/m): follow for 6m	X	X	X	X	X			
Review EMR, analyze data, finalize protocols, publish					X	X		

We anticipate enrolling 8-10 persons per month and should complete enrollment in < 9 months. We will need 6 months to follow the last participants. We will also need time for data analysis and final protocol revisions. The pilot study will be completed within 18 months.

Recruitment, Consent, and Enrollment

Screening

With an IRB-approved waiver to review records, the research coordinator will use an EMR-based application that identifies all patients currently hospitalized at BTH who have HIV listed as a diagnosis in their "problem list" or have a positive HIV test result. The coordinator will maintain regular contact with the HIV Service Linkage Worker (SLW) at the hospital, who sees all patients with HIV in the hospital. The coordinator will then perform a brief chart review of patients to preliminary assess inclusion/exclusion criteria. If the patient appears eligible for enrollment, a member of the care team will ask the patient if he/she is interested in learning about a research project. Care providers who have legitimate access to a patient's HIV status for patient-care purposes include physicians, nursing staff, social workers, and case managers.

If the patient declines screening or is ineligible by chart review or in-person screening, the coordinator will record the patient's age, race, and sex, and, temporarily, his or her medical record number to ensure that we do not inadvertently approach the patient again during that hospital stay.

Consent

If the patient appears eligible for enrollment, a member of the care team will ask the patient if he/she is interested in learning about a research project. Care providers who have legitimate access to a patient's HIV status for patient-care purposes include physicians, nursing staff, social workers, and case managers. Care providers at BTH will be informed of the study and encouraged to obtain the permission of their patients for identification for recruitment. Care providers will be encouraged to remind patients that any participation in research is voluntary. The research staff will not be informing patients of their HIV diagnosis. If the patient is interested in learning more about the study, the care provider will introduce the research coordinator to the patient. The coordinator will describe the study in detail and initiate the screening and informed consent process.

If the patient is willing to participate, all sections of the informed consent document and the HIPAA authorization form will be reviewed with the patient, including sections on risks and benefits and

voluntary nature of the study. The research coordinator will be prepared to answer any questions. Potential participants will be told that their decision to participate in the study or not will not affect the clinical care he/she receives. If the patient is still interested, they will be asked to provide consent. In addition, the patient will sign a HIPPA authorization form.

Randomization

This study will randomize at the participant level. Randomization will occur following enrollment in the study. The study statistician will generate the randomization sequence to ensure adequate distribution of the two interventions over the study period. The randomization sequence will be maintained by the statistician in a password protected file.

Blinding

Neither participants nor study personnel are blinded in this study.

Study Intervention

A therapist trained in Acceptance and Commitment Therapy (ACT) will provide the ACT based intervention individually at the bedside as 4 individual, 30-40 minute sessions. If study participants complete the THRIVE intervention sessions, he or she will have opportunities to 1) reflect on personal values and personal barriers that could prevent them from living out those values on a day-to-day basis, 2) receive education specific to HIV and managing HIV, 3) HIV stigma, and 4) coping skills. Subjects will be asked to document a goal that will be reviewed at the booster session.

A research team member will work with each participant prior to discharge to schedule the booster session and follow-up assessments. Prior to the participant's first scheduled outpatient follow-up visit with TSHC, the therapist will call participants to check on them and conduct an individualized phone booster session. This phone call will last 20-40 minutes. Participants will receive a reminder call/message approximately 1 day before the session.

Therapist Training

A master-level therapist will be trained over a 2-day period on the entire protocol and intervention manual. Training methods will include didactics on the ACT model, demonstration of each of the ACT processes through examples, and role-playing each of the ACT sessions. In the final training step, the therapist will conduct the intervention with a standardized patient learning case, using professional actors as standardized patients. Each session will be monitored live via video and video-recorded. Fidelity and competence will be assessed by three raters and immediate feedback will be provided. The therapist will be certified to work with patients when his/her adherence and competence ratings are 6 or higher (`good' on a 0-8 scale).

Therapist Fidelity

Sessions with participants will be audio-recorded by a digital recorder or by Zoom. The recordings will be used for therapist's evaluation and training. Fidelity and competence will be assessed by the investigators on 10% of intervention sessions for each therapist. We will modify the therapist training and provide additional training as needed based on the evaluation of the recordings. Participants will be

informed during the consent process that the sessions will be audio-recorded to evaluate the therapists. If a participant declines the audio recording of the session, their eligibility to participate will not be affected.

Intervention Sessions

Participants are provided a handbook that includes the key concepts, exercises and homework for each session.

THRIVE Sessions Description

Session	Session Name	Description	Exercises	Homework
1	Find Direction	• Introduce study • Establish and clarify values • Discuss internal barriers to engaging in values-based action	• Your Life Now • 80-year-old birthday • "What if I asked you to run into a fire?"	The Bull's Eye
2	Doing What Matters	• Provide HIV education • Introduce willingness and "how to face the difficult"	• 5-senses mindfulness exercise • Care of HIV blocks • BOLD technique	Willingness and Action Plan
3	Stuff That Gets in the Way	• Review HIV stigma and education • Introduce and explore self-compassion • Review previous modules and foster committed action • Discuss automaticity of thoughts/feelings and how to move from autopilot to conscious choice	• A Compassionate Hand mindfulness exercise	BOLD: A Way to Get off Autopilot
4	Do It Anyway	• Acceptance • Teach defusion skills • Share goals and principles of ACT • Conclusion	• Drop Anchor mindfulness exercise • "I can't walk" or "I can't raise my hand" exercise • "But" versus "And" • Be Like the Sky	N/A

MODULE 1: Introduce Study and ACT Matrix

• Establish rapport between interventionist and patient, introduce study, introduce Acceptance and Commitment Therapy (ACT), and establish patient's values (i.e. who or what is important to them). Values will be the motivation for changing behaviors. Discuss negative experiences patient is avoiding and what behaviors s/he uses to avoid (e.g. drug use, denial). Avoidance strategies will be specifically targeted throughout the intervention to increase likelihood of remaining in care.

• Establish the difference between internal experiences (thoughts and feelings) and external experiences (objectively observed through 5-senses). Highlight the difference in moving away from

negative experiences (avoidance) versus moving towards values (value-driven behavior). Use examples about HIV care [not talking about status due to shame (avoidance) versus taking HRT medication (health value-driven behavior)].

• Discuss the short-and long-term effects of avoidance. Specifically, we will go over examples of how avoidance reduces immediate contact with distressing experiences and thus provides short-term relief (e.g., drinking alcohol to reduce anxiety). In the long term, however, avoidance leads to greater dysfunction (e.g. dependence on alcohol) and increased distress. Elicit examples of patient's own avoidant coping.

MODULE 2: Review ACT Matrix, Discuss HIV Stigma & Education about HIV Care

• Review ACT Matrix from previous session.

• Discuss HIV stigma using the matrix framework (internal/external and avoidance/value-driven behavior) – how does stigma act as a barrier and create avoidance? What value-driven behavior can patients engage in even when HIV stigma is high? Patients will also be encouraged to examine the costs or non-workability of stigmatization on their life (e.g. avoidance of medical care, sense of isolation).

• Encourage willingness to confront uncomfortable stimuli, especially those connected to HIV care.

• Teach alternative skills to avoidance-based coping, including acceptance and defusion, that will help a patient cope with difficult emotions and thoughts that may interfere with living a values-driven life.

• Teach BOLD technique for perspective taking: Breath to take a minute to slow down; Observe what you are feeling; Listen to your values; Decide how to react.

• The interventionist will provide brief education on the beneficial impact of medical care, substance use care, and mental health care on overall health, and will inform participants about the comprehensive medical and social services available at TSHC (including services they may not be aware of, such as care for general medical issues, mental health issues, substance use issues, diabetes and hypertension, case management, physical therapy, hepatitis C treatment, gynecology, and others) to address health needs related to comorbidities.

MODULE 3: Review Matrix, HIV Stigma & Education, Discuss Acceptance & Defusion

• Review ACT Matrix and HIV education from previous sessions. Review avoidance-based coping versus willingness to confront uncomfortable stimuli. Review acceptance and defusion techniques.

• In order to increase a sense of acceptance toward themselves, participants will be asked to think about how they would treat someone else they know and love with HIV, to notice the differences between their reactions to their own struggles (e.g., self-stigma) and to those of others, and to examine which is more adaptive.

• Teach "Urge Surfing" by (1) acknowledging the urge/craving, (2) observe the urge and accompanying sensations, (3) rather than avoid the sensations; sit with them, (4) notice fluctuations in the urge, (5) connect to values.

• Practice mindfulness exercise to connect to present moment. Connection to present moment through their body/5 senses may be difficult for PWH as they may experience their body negatively (fused with thoughts of self-stigma).

MODULE 4: Committed Action & Wrap up

• Review material and skills learned throughout the intervention.

• Consider values from first session and what action can be taken in the service of them now (and as discharged from the hospital).

• Teach SMART goals (specific, meaningful, achievable, realistic, time-limited) to assist patient in making a concrete plan to incorporate value-driven behavior and decrease avoidant coping in their life.

PHONE BOOSTER

• Discuss any difficulties patient has had connecting with care. Use ACT skills and matrix framework to conceptualize any barriers.

• Review ACT Matrix and key points from intervention.

Post-Intervention Evaluations

Evaluation Overview

Participants will receive the THRIVE intervention or treatment as usual. Treatment is assigned by random allocation. Participants will receive the intervention during their hospital stay. For evaluation purposes, enrolled patients will provide baseline demographic, clinical, and behavioral data. The information will be self-report or gathered through medical record review. Follow-up assessments will occur 3- and 6-months post-discharge. Assessments will include coping skills, stigma, depression, anxiety, stress, substance use, and client satisfaction. Medical record data will include HIV laboratory testing results and medications as well as data on kept and missed HIV primary care appointments. The medical record review will include retrospective data and data for the year after enrollment. The baseline survey contains 85 items and should take 30 minutes, while the 3- and 6-month follow-up surveys contains 70 and 60 items, respectively.

To avoid bias, the 3- and 6-month assessments will take place in the field, e.g., at the patient's residence, at a Harris Health facility other than the HIV clinic, or at other mutually agreed upon and safe places. They will not be allowed to occur at TSHC. Any self-reported use of health resources external to Harris Health System will be verified by medical record review.

All patients have a VL done as standard of care in the hospital. We will obtain 6-month VL by study phlebotomy in the field (not at the clinic, to avoid biasing participants to return to the clinic to obtain the compensation for the assessment visit) and review the EMR for additional VLs to minimize missing data. About 10 mL of blood will be drawn per participant at the 6-month evaluation. All VL assays will be conducted by the BTH laboratory, a fully certified clinical laboratory that performs all HIV-related

laboratory studies for TSHC and BTH.

Participants will provide detailed contact information and permissions at enrollment (e.g., what numbers are OK for text messages and voice messages, whether contacts are aware of the participant's HIV status, etc.). All contact with the participants' associates and family will not reveal that the participant has HIV or is involved in research. Contact information will be updated at all follow-up interviews.

Participants will also complete a brief phone call with the research coordinator to verify and update contact information at 2, 8 and 18 weeks after hospital discharge. These calls are to promote retention in assessment visits. Participants will be given a card with the study's telephone number (no information traceable to HIV will be included). Phone interviews will be used for follow-up assessments as a last resort.

The 2-week call will also include the CSQ and satisfaction self-report assessments for participants in the THRIVE arm.

3-month Follow-up Self-Report

At 3 months, the survey will include: Coping; IARSS; DASS-21; AUDIT-C; ASSIST.

6-month Follow-up Self-Report

At 6 months, the survey will include: Coping; IARSS; DASS-21; AUDIT-C; ASSIST; Chart Review; and HIV VL.

6-month Chart Review

The Harris Health EMR, an Epic product, is accessible via Citrix on any computer. Researchers can review the entire EMR from their research offices, including discharge summaries, inpatient and outpatient notes, laboratory results, all appointment schedules, and prescriptions. Epic data include appointment, laboratory, and ART data on all patients seen at BTH, TSHC or one of its satellite HIV clinics from 2002 to present. Appointment data include all visits at TSHC, including HIV primary care, mental health, and chemical dependency counselor visits. Clinic visit data include whether the visit was kept, missed, cancelled, or rescheduled. Dates of hospitalization at BTH are included. Completed and missed visit data will be abstracted from Epic. The Centralized Patient Care Data Management System (CPCDMS) is a regional database in which clients must be registered to receive medical and case management services funded by the 6-county Ryan White Part A funds. CPCDMS will indicate if participants have transferred care from TSHC to other Ryan White-funded providers, substantially reducing the chance of misclassifying patients regarding care re-engagement.

6-month Viral Load

All patients have a VL done as standard of care in the hospital. We will obtain 6-month VL by study phlebotomy in the field (not at the clinic, to avoid biasing participants) if none are available in the EMR, and review the EMR for additional VLs to minimize missing data. All VL assays will be conducted by the BTH laboratory, a fully certified clinical laboratory that performs all HIV-related laboratory studies for TSHC and BTH.

Data Collection and Quality Assurance

REDCap

All data collection forms will be available through a REDCap (Research Electronic Data Capture) database and patients can directly enter data into these forms. They will enter data into a central database through a study computer. This will eliminate error in data entry, and reduce time necessary for data entry, cleaning and analysis. Range checks will be programmed into the data entry system when the nature of the data allows so that it will not permit invalid values to be entered into the database.

When a data collection session is completed, the research coordination will review electronic forms for completeness and validity. The research coordinator will resolve all queries and will enter an override for all values that have been confirmed as being accurate. Reports will also be run periodically to confirm or correct questionable values. All changes will be tracked through the REDCap audit trail. Assessments completed on paper will be entered into REDCap by the research coordinator.

The data entered into the REDCap database is stored on servers at Baylor College of Medicine and is backed-up on a regular basis.

Strategies for minimizing missing data

1. Reviewing all surveys for completeness before finalizing.
2. Reviewing all electronic medical records for internal and external records.
3. Requesting medical records for participants who report use of external facilities.

Protocol Deviations

Protocol deviations will be recorded as they are known to happen on a hard-copy form and then entered in the study's Tracking Database to compile an electronic log for reporting purposes. Quarterly hard- copy-to-electronic-copy audits of Protocol Deviation forms and audits of consent forms will be performed.

Monitoring

Data will be routinely monitored at the time of data collection. REDCap will be used to collect data and the researchers will be prompted at the end of each session to check missing entries. Regular team meetings will be held where researchers can report ongoing data collection concerns to ensure proper adherence to the protocols and high-quality data collection. Audio files will be stored on a secure BCM server. Only the participants' ID will be used to identify the participants. Coordinators will ensure the data is de-identified.

Summary of Measures at Each Evaluation

Type of Measure	Measures	Baseline Visit	THRIVE: In-hospital sessions (4hrs.)	THRIVE: Phone booster session (.5 hrs.)	Post-discharge 2 wk.	3 mo.	6 mo.
Characterize Sample. Possible Covariates	Demographic/ Medical Information	X					
	Coping Skills	X				X	X
Primary Outcomes	Retention in HIV Care	X					X
	HIV VL	X					X
Exploratory: Stigma & Mental Health	Stigma	X				X	X
	Depression, Anxiety, and Stress	X				X	X
	Substance Use	X				X	X
Treatment Satisfaction	Client Satisfaction				X		

Data Collection Instruments

Demographics/Medical Information

Description: Demographic information will be collected via a questionnaire including age, sex, race, ethnicity, marital status, education, household income, and when participant was first told they were HIV positive.

Coping with HIV/AIDS

Description: Coping with HIV/AIDS scale is a 16-item scale that measures avoidance coping, positive coping, and seeking social support in patients with HIV (Fleishman and Fogel, 1994). The measure asks questions focuses on positive coping (items a-e), avoidance coping (items f-n), and seeking social support (items o-p). Items include, “Since your HIV diagnosis, did you... try to learn more about HIV or aids” or “tell yourself to accept it.” Items are rated on a 3-point scale (from 1= never to 3= often or a lot of the time. The measure has been well validated and widely used including internationally.

IARSS

Description: Stigma will be measured with **I**nternalized AIDS-Related Stigma Scale (IARSS) (Kalichman, et al., 2009), a 6-item measure that has been validated in US and international populations. (Kalichman et al., 2009; Tsai et al., 2013). It focuses on internalized stigma, e.g., “I hide my HIV status from others” and “Being HIV positive makes me feel dirty,” which is the focus of our treatment model. Responses are “agree” and “disagree” and the score is a count of the affirmative responses (range 0-6). The scale is used in the US national Medical Monitoring Project (Baugher et al., 2017) and many other studies, allowing direct comparison to national and international populations.

Depression Anxiety and Stress Scale (DASS-21)

Description: The DASS is a self-report scale to measure the negative emotional states of depression, anxiety and stress. It contains 21 items, 7 items per subscale (depression, anxiety and stress) (Lovibond & Lovibond, 1995). Participants are asked to rate the extent to which they have experienced each state over the past week with a 4-point scale (from 0 = did not apply to me at all to 3 = applied to me very much). Scores are summed per subscale and then multiplied by 2 for possible scores on each subscale ranging from 0 to 42 (Lovibond & Lovibond, 1995). Higher scores indicate more severe symptoms of depression, anxiety and stress. Internal consistency of the DASS-21 subscales in a non-psychiatric sample were high (0.88 for Depression, 0.83 for Anxiety, and 0.85 for Stress) (Osman et al., 2012). Depression, Anxiety and Stress subscales also showed adequate convergent validity (r = 0.55, 0.44, and 0.61, respectively) with Affective Distress subscale of the Multidimensional Pain Inventory and adequate discriminant validity (r = -0.67, -0.50, and -0.63, respectively) with Mental Health subscale of the SF-36 in elderly patients with persistent pain (Wood et al., 2010).

AUDIT-C

Description: The AUDIT-C is a self-report scale to measure problematic alcohol use in both men and women (Bush et al., 1998). It contains 3 items that focuses on alcohol use, e.g., "How many drinks did you have on a typical day when you were drinking in the past year?" The Audit-C is scored on a scale of 0-12, with each question having five answer choices (each scored from 0 to 4 points). In men, a score if 4 or more is considered "positive," or optimal for identifying hazardous drinking or active alcohol use disorders. In women, a score of 3 or more is considered "positive." Psychometric properties for identifying patients with heavy/hazardous drinking and/or active-DSM alcohol abuse or dependence were high (men=.86; women=.66), and for identifying patients with active alcohol abuse or dependence (men=.90; Women=.80) (Bradley et al., 2003).

ASSIST

Description: The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) was developed for the World Health Organization (WHO) by an international group of substance abuse researchers to detect psychoactive substance use and related problems (Group WAW, 2002). The ASSIST is short screener that includes eight questions.

Client Satisfaction Questionnaire

The Client Satisfaction Questionnaire (CSQ) (Larsen et al., 1979), is an 8-item, empirically derived, self-report measure is widely used to assess patient satisfaction with services. The instrument was designed to assess satisfaction with a specific service, rather than health care in general (Atkisson et al., 1999) and thus is appropriate for measuring participants' satisfaction with THRIVE. The CSQ's psychometric properties are strong, and it has been widely used in adults and adolescents with HIV, including persons with substance use and mental health problems (Fals-Stewart, 2010; Hosek, 2011). In addition, we will include a single-item measure of overall satisfaction with the intervention and a single-item measure of likelihood of recommending the intervention to others.

Chart Review

The Harris Health EMR, an Epic product, is accessible via Citrix on any computer. Researchers can review the entire EMR from their research offices, including discharge summaries, inpatient and outpatient notes, laboratory results, all appointment schedules, and prescriptions. Epic data include appointment,

laboratory, and ART data on all patients seen at BTH, TSHC or one of its satellite HIV clinics from 2002 to present. Appointment data include all visits at TSHC, including HIV primary care, mental health, and chemical dependency counselor visits. Clinic visit data include whether the visit was kept, missed, cancelled, or rescheduled. Dates of hospitalization at BTH are included. Completed and missed visit data will be abstracted from Epic. The Centralized Patient Care Data Management System (CPCDMS) is a regional database in which clients must be registered in order to receive medical and case management services funded by the 6-county Ryan White Part A funds. CPCDMS will indicate if participants have transferred care from TSHC to other Ryan White-funded providers, substantially reducing the chance of misclassifying patients regarding care re-engagement.

Blood Draw

All patients have a VL done as standard of care in the hospital. Then at 6-month, a VL by study phlebotomy in the field (not at the clinic, to avoid biasing participants) will be conducted if there is not one in the EMR, and a review the EMR for additional VLs to minimize missing data. All VL assays will be conducted by the BTH laboratory, a fully certified clinical laboratory that performs all HIV-related laboratory studies for TSHC and BTH.

Data Analysis Plan

Analysis Methods

A randomized clinical trial (RCT) pilot of the refined THRIVE intervention (N=35) will be compared to treatment as usual (TAU; N=35). An N=70 is sufficient to establish feasibility and acceptability of a treatment procedure. Feasibility and acceptability are the primary aims of the randomized controlled trial.

The primary goal is to demonstrate the feasibility and acceptability of the THRIVE intervention. Findings from this pilot study will provide useful data that will serve as a basis for enrollment time estimates, attrition estimates, and outcome estimates to support a definitive RCT designed to investigate the efficacy of the THRIVE intervention compared to TAU on retention and VL in hospitalized, out-of-care PWH. The data will also inform sample size and power calculations. We will generate summary statistics of the feasibility and acceptability data. Our pre-defined outcomes (i.e., "benchmarks of success") are: at least 8 participants per month recruited on average (10 per month is the goal); <20% refusal rate among eligible persons; at least 80% receive the outpatient booster phone call; at least 80% of participants alive at 6 months have appointment and 6-month VL data (needed to construct the primary outcome for the definitive full-scale trial); at least 90% of persons who initiate an assessment survey complete it; and at least 80% of the participants in the THRIVE arm rate the intervention positively on the client satisfaction questionnaire.

Suicide Risk Management

If at any time during the assessments, intervention or booster session a participant indicates suicidal ideation, a research team member will inform the crisis team and/or Dr. Giordano of the crisis who will assess the participant at the time of the research visit. If the patient does not have a plan or intent, they

will be provided with resources appropriate for the clinical setting (Ben Taub Hospital or Thomas Street Health Center). If they do have a plan or intent, they will be handled by emergency clinical services.

Participant Rights & Confidentiality

Institutional Review Board (IRB) Review

The study protocol and the informed consent document and any subsequent modifications will be reviewed and approved by the IRB at Baylor College of Medicine.

Informed Consent

Informed consent will be obtained from each participant. The consent form describes the purpose of the study, the procedures to be followed, and the risks and benefits of participation. The study will be conducted during the COVID-19 pandemic and, to reduce the risk to participants and personnel posed by fomites, verbal consent to participate will be obtained.

Participant Confidentiality

The consenting process will include all required elements (e.g., nature of the intervention, risks, confidentiality) and patients will be given the opportunity to ask questions. Study personnel will give participants more time if there are any uncertainties or discomforts on the part of the participant or family member. The participant will be reminded that consent can be revoked at any time over the course of the study.

Data collection as part of the study will be kept confidential in accordance with state and federal laws. Participants will be further assured of their right not to answer particular questions.

Data collected from patients/participants is in the form of medical record abstraction and self-report through questionnaire completion. All data forms, audio-tapes and questionnaires will be coded and stored separately from identifying information. Hardcopy data will be kept in a locked filing cabinet in the research office. Electronic data will be kept on a secure server in which only team members will have access.

All participants will be assigned a research number (or study identification number). A master list of all participants and their corresponding number will be in a study folder on the BCM server. The list will be maintained on a computer that requires an access code. All data entered in the computer will be entered by participant's study identification number. The data will be encrypted and password protected. Only the PI and research coordinators will have access to the file linking participant study ID and participant identifiers. Data shared with the data manager and statistician will be coded data.

Study Discontinuation

The study may be discontinued at any time by BCM, the IRB, NIH or other government agencies as part of their duties to ensure that research participants are protected.

Compensation

Participants in Aim2 will receive up to $125 over the course of their participation in the study according to the following schedule:

Completion of baseline assessment: $20

Completion of 3-month assessment: $30
Completion of 6-month assessment: $40
Blood draw at 6-month: $20
Verify contact information at two weeks: $5
Verify contact information at eight weeks: $5
Verify contact information at eighteen weeks: $5

Payment Processing

A ClinCard will be used for study payments. Participants will complete and sign an authorization form. Study compensation will be loaded to the same card as the participants completes assessments. Payments will be loaded onto the ClinCard within 2 to 3 days of visit completion. The research coordinator will provide a handout to the participants about the ClinCard. An email address and/or cell phone number will be collected in the event the participant wants email or text notification when payments are loaded to the ClinCard. Baylor College of Medicine (BCM) and Greenphire (the ClinCard Company) have entered into an agreement that requires Greenphire to protect personal information.

Verbal Informed Consent Script

Some people with HIV have a hard time staying in medical care. A Baylor College of Medicine (BCM) research team is doing a research project to see whether talking with a counselor about HIV can help improve your health and quality of life. The name of the study is THRIVE. As a participant, you are a volunteer. You might work with a counselor. Whether you work with the counselor or not will be decided at random, like by the flip of a coin. If you work with the counselor, you will spend about 3-4 hours (over several sessions) with the counselor at the hospital before discharge and will also talk to the counselor by phone once a couple weeks after discharge. You will complete surveys while in the hospital and then 3 months after discharge. Coded survey responses will be shared with the study team at BCM, University of Iowa, Brown University, and the University of Texas Health Science Center. You will also complete another visit 6 months after discharge, and a blood sample will be obtained to measure HIV viral load. The 6-month blood draw will measure your HIV RNA copies or viral load. The results will be recorded in your medical record. The research coordinator can give you the results of your viral load, at your request. The 3 and 6- month visit, will be at any safe location, but won't be at the hospital or the clinic. The researchers will also call you three times after discharge, to make sure we stay in touch. Surveys and interviews will either be completed in person, by phone or Zoom video conference. The visits will take up to 1 hour to complete.

Researchers will also review your medical records from the past and up to 12 months from now. This will include medical records from all the Harris Health System facilities you used and were scheduled to have used. The medical record reviews will gather information on your HIV disease and any other diseases you have, which might include hepatitis, sexually transmitted diseases, psychiatric diseases, and problems with the use of illegal substances and alcohol. The medical record review will also gather laboratory and other test results, information about your visits to health care providers, your prescribed treatments, your use of prescribed treatments and other health care resources, and how well those treatments are working for you. Coded data from the medical record and surveys will be sent securely to a study investigator at the University of Iowa for analysis.

The risks of participating in the study include anxiety from thinking about HIV and loss of confidentiality. If you express suicidal thoughts, we will discuss how you are feeling and refer you to services if needed. The researchers have strict measures to protect confidentiality and the risk to you is low. By participating in the research, you may learn some skills to better care for your health, but it is possible that you will not benefit from participating in the research. Participation in the study is completely voluntary, and if you decide to not participate in the research the care you receive will not be affected.

You will receive compensation on a pre-paid card after each survey. You will receive $20 after completing the baseline survey in the hospital, $30 after completing the 3-month survey, and $40 after completing the 6-month survey. You will receive $20 for completing the 6-month blood draw. You will receive $5 for completing a phone call to verify and update your contact information at weeks 2, 8, and 18 after discharge. The call at 2 weeks after discharge will also include a brief survey of 10 questions. The maximum total compensation is $125. A ClinCard will be used for study payments. Payments will be loaded onto the ClinCard within 2 to 3 days of visit completion. The research study team will provide you with a handout about the ClinCard. Your email address and/or cell phone number will be collected in the event you want email or text notification when payments are loaded to your ClinCard. Baylor College of Medicine (BCM) and Greenphire (the ClinCard Company) have entered into an agreement that requires Greenphire to protect your personal information. BCM will replace your ClinCard free of charge if your first card is lost or stolen. After that, there is a $7 ClinCard replacement fee. This replacement fee will be charged to the balance on your ClinCard at the time of replacement. Your ClinCard has an expiration date. If your ClinCard expires while you are participating in this study, BCM will provide you with a new ClinCard at no cost to you. For a period of three months following your final study visit, you may request replacement of an expired ClinCard at no cost to you.

Payments for research participation are considered taxable income per Internal Revenue Service (IRS) regulations. If the total amount of payment received by you, your parent, guardian or Legally Authorized Representative (LAR) reaches or exceeds $600 in a calendar year, BCM will send an IRS Form 1099 to that person for tax purposes. In order to issue the IRS Form 1099, BCM will collect your first and last name, social security number, date of birth and home address. The name you provide should match the social security number. Please note study payments are considered income and may or may not affect government or public assistance benefit programs you or your parent, guardian or LAR may be participating in, such as SSI (Supplemental Security Income) or TANF (Temporary Assistance for Needy Families).

Can you summarize the study?

What are your questions or concerns?

Do you give consent for study participation?

If you have questions, contact the Baylor College of Medicine study coordinators at (XXX) XXX-XXXX.

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