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Authors

Moitra, Ethan
Chan, Philip A
Molina, Patricia E
et al.

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HIV Engage—a randomized controlled efficacy trial of an acceptance-based behavioral therapy intervention to improve retention in care for HIV treatment naïve patients: study protocol

Ethan Moitra, Ph.D.[1,a], **Philip A. Chan, M.D.**[2,3], **Patricia E. Molina, M.D., Ph.D.**[4], **Frances Ernst, Psy.D.**[5], **Tekeda F. Ferguson, Ph.D.**[4,6], **Matthew J. Mimiaga, Sc.D.**[7,8], **Debra S. Herman, Ph.D.**[1,9], **Michael D. Stein, M.D.**[9,10]

[1]Department of Psychiatry and Human Behavior, Alpert Medical School of Brown University, Providence RI, USA

[2]Department of Medicine, Alpert Medical School of Brown University, Providence RI, USA

[3]Department of Behavioral and Social Sciences, Brown University School of Public Health, Providence RI, USA

[4]Department of Physiology, School of Medicine, Louisiana State University – Health Sciences Center, New Orleans LA, USA

[5]Department of Psychiatry, School of Medicine, Louisiana State University – Health Sciences Center, New Orleans LA, USA

[6]Department of Epidemiology, School of Public Health, Louisiana State University – Health Sciences Center, New Orleans LA, USA

[7]Department of Epidemiology, UCLA Fielding School of Public Health, Los Angeles CA, USA

[8]Department of Psychiatry & Biobehavioral Sciences, UCLA David Geffen School of Medicine, Los Angeles CA, USA

[9]Behavioral Medicine and Addictions Research Unit, Butler Hospital, Providence RI, USA

[10]Department of Health Law, Policy and Management, Boston University School of Public Health, Boston MA, USA

Abstract

[a]Corresponding Author: Ethan Moitra, Ph.D., Brown University, Box G-BH, Providence, RI, 02912, USA, Phone: 401.444.1949 Fax: 401.455.0516, ethan_moitra@brown.edu.

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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Introduction: People with HIV (PWH) who are not consistently retained in medical care, particularly when they are first diagnosed, are at risk for: delayed antiretroviral therapy (ART) initiation, suboptimal ART adherence, unsuppressed viremia, and mortality. Suboptimal retention means effective ART cannot be leveraged to prevent onward HIV transmission. To address this, we developed and previously pilot tested the HIV Engage intervention—a novel behavioral approach to enhance retention in HIV care using acceptance-based behavioral therapy (ABBT)—and established feasibility and acceptability of this approach. In the current study, we investigate the efficacy of ABBT compared to an attention-matched control condition in a full-scale randomized controlled efficacy trial.

Methods: Two hundred seventy HIV care naïve patients from geographically diverse clinics will be recruited and equally randomized to receive (a) the HIV Engage intervention, consisting of two 20–30 minute ABBT sessions delivered in-person or remotely, or (b) an attention-matched HIV education control condition. Primary outcomes are number of HIV care appointments kept and HIV viral load suppression. Secondary outcomes are higher self-reported ART adherence, HIV status disclosure, increased social support, and reductions in perceived HIV stigma. Hypothesized mediators include acceptance of one's HIV diagnosis and willingness to disclose serostatus. We will also assess for epidemiologically-linked moderators of the treatment effect.

Conclusions: ABBT represents a novel, potentially promising approach to enhance retention in ongoing HIV care among treatment naïve PWH. This study will contribute significant actionable data establishing the impact, mediational mechanisms, and effect modifiers of ABBT.

Keywords

HIV; antiretroviral therapy; adherence; care cascade; retention; acceptance; behavioral intervention

1. Introduction

For People with HIV (PWH), the U.S. Department of Health and Human Services (DHHS) recommends a follow-up primary care medical visit at least once every 3–6 months [1] after initiating care. However, drop-out rates following initiation of primary HIV care can be as high as 50% [2], with 31–46% of patients dropping out after the first visit [3]. Unfortunately, up to 50% of the more than one million individuals [4] infected with HIV in the U.S. are not regularly retained in medical care [5, 6]; and, only 45–55% of PWH complete at least one visit every six months [6, 7]. PWH who fail to be retained in medical care, an important step in the HIV care continuum following initial linkage, risk a number of critical consequences to their health and quality of life, and are at increased risk of transmitting HIV [8]. Overall, poorly retained PWH are responsible for more HIV transmissions than the population in care and the undiagnosed population combined [8, 9]. In sum, retention in medical care is essential for PWH's long-term health and well-being, and in reducing future transmissions.

In the past decade, there have been over 20 intervention studies aimed at improving HIV care retention (summarized in [10–12]). According to the U.S. Centers for Disease Control and Prevention, very few of the early interventions increased retention[13] and although results in some more recent studies were promising, many of these interventions focused on retaining patients who showed past engagement in care and they were highly resource

intensive. Previous research [14, 15] showed that Acceptance-based Behavioral Therapy (ABBT) can be a feasible, acceptable, and efficacious behavioral intervention to improve retention for new-to-care PWH in smaller samples of patients. ABBT targets resistance to the HIV diagnosis, which likely puts individuals at risk for emotional distress and behavioral avoidance, including not attending medical appointments. Attempts to avoid distressing experiences (e.g., fearful thoughts of stigmatization) can be broadly defined as "experiential avoidance [16]." By promoting acceptance and reducing experiential avoidance, ABBT aims to reduce psychological distress associated with living with HIV and increase healthy behaviors, such as retention in medical care. Our theoretical framework (see Figure 1) conceptualizes HIV acceptance as the reduction of experiential avoidance, which will, in turn, lead to increased health promoting behaviors, increased willingness to seek social support via informed disclosure of HIV diagnosis, and ultimately, increased willingness to attend medical appointments.

This study is the first to examine ABBT's effects on retention in care among new-to-care PWH in a fully powered, randomized controlled trial (RCT). We hypothesize that compared to an attention-matched control condition (HIV education), ABBT will lead to greater retention in care and greater virologic suppression (primary outcomes). Consistent with HIV care guidelines[1], we define retention dichotomously as attending (or not attending) at minimum three follow-up medical appointments during our 12-month follow-up period. We also hypothesize that compared to HIV education, ABBT will lead to: (a) increased ART adherence; (b) increased disclosure of HIV status, when appropriate; (c) higher perceived social support; and, (d) reduced perceived HIV stigmatization (secondary outcomes).

2. Materials and methods

2.1. Design

In this Phase II RCT, we will recruit 270 PWH who are new to HIV medical care. Participants undergo a baseline assessment to characterize their health, HIV-related indices, and potential barriers to retention. Participants are then randomized to either 2-session ABBT or HIV education. Regardless of treatment or control arm, all participants receive treatment-as-usual (TAU) services at their clinic. These services include referral to psychiatric care, substance misuse counseling, and financial supports (e.g., bus vouchers to ride to the clinic) to facilitate engagement in medical care. Follow-up research study assessments occur at 1-, 3-, 6-, 9-, and 12-months post-baseline.

2.2. Setting

All study recruitment, assessments, and interventions will take place at two diverse HIV medical care clinics. Two study sites enrich the diversity of the sample, as these sites are in geographically distinct areas and serve very different patient populations. Our site in New England serves primarily patients of non-Latinx White backgrounds, with a sizeable proportion of Latinx individuals. Our site in the Southeast primarily treatments African American patients. Also, the use of two sites increases the likelihood that we will meet recruitment goals and will provide a richer insight into future dissemination. In Providence, RI, study activities will take place at the Miriam Hospital, the largest comprehensive HIV

primary and specialty care clinic in the state. We will also conduct this study at University Medical Center in New Orleans, LA, one of the largest HIV clinics in the region. HIV incidence rates in LA are second highest among any state in the U.S. and New Orleans ranks third nationally in HIV prevalence [17].

2.3. Participants and sample size

Using our pilot work and available effect size data, we calculated statistical power needs based on the primary outcome of retention in care. Retention rates in our pilot study (attending at least three follow-up medical appointments during a 9-month follow-up period) were 93.3% and 73.3% in ABBT and TAU, respectfully. This corresponds to a moderately large standardized effect (Cohen's h) of .56 with an implied OR of about 5.07. We recognize that effect size estimates from pilot studies are imprecise and should be used cautiously when planning RCTs. Nevertheless, we believe between group differences of at least 15–20% are realistic and are clinically meaningful. Our proposed sample of 270 will provide power > .9 to detect a difference of 70% vs. 90% and power > .8 to detect smaller differences, such as 75% vs. 90%.

Inclusion criteria are: (a) HIV+; (b) ≥18 years old; (c) entering HIV medical care services for the first time (that is, not transferring HIV care from another location); (d) able to speak and read English at the 7th grade level (measured by the San Diego Quick Assessment of Reading [18]) to be able to complete the study procedures; and, (e) have telephone access. Telephone access is important because participants have the option to complete sessions and follow-up assessments by telephone to reduce the burden of needing to be present at the research office and to reduce potentially confounding our primary outcome of medical appointment attendance by having a reason to attend the clinic space for a non-medical and compensated appointment.

Patients who are cognitively impaired, which will be assessed by the International HIV Dementia Scale [19], are excluded from this study. Clinic staff will administer this scale when clinically appropriate. Active substance use, defined as past month hazardous drinking *or* use of illicit or non-prescribed opioids, cocaine, or methamphetamine, is accounted for in our intervention randomization schedule as it is known to influence clinic retention [20]. But, it will not be an exclusionary criterion.

In our pilot work, which relied on the same recruitment methods and sites [15], 18% of the sample was female. Thus, for this RCT study, we anticipate that approximately forty-nine (18%) study participants will be women. Consistent with ethnicity and race characteristics of our pilot study, we anticipate a diverse sample with high representation of people of color. Based on our pilot data, we expect that overall 6% of the RCT sample will ethnically be Latinx. Racially, we expect a sample that will be 64% African American, 36% White, and <1 % of other racial groups.

2.4. Recruitment

We are recruiting during routine intake appointments for new patients at each of our recruitment sites with the priority of enrolling participants *before* their first appointment with a medical provider. Given the relatively broad inclusion criteria, minimal screening

procedures are needed to support recruitment. Research assistants will regularly monitor new patient flow and approach all new-to-care patients who are deemed potentially eligible by clinical staff (e.g., no dementia concerns). Patients are confirmed as new-to-care by clinical staff and corroborated by the individual.

2.5. Randomization

Stratified permuted block randomization is being used to ensure groups are balanced for: (a) baseline active substance use (alcohol and/or other substances defined as hazardous drinking, measured by the Alcohol Use Disorders Identification Test-C (AUDIT-C; [21]), or past month use of illicit or non-prescribed opioids, cocaine, or methamphetamine, measured by the Addiction Severity Index - Drug Module (ASI; [22])); and, (b) baseline clinically significant depressive symptoms (measured by the Patient Health Questionnaire-9 (PHQ-9; [23]) in which ≥10 indicates moderate+ depression). Substance misuse is a known barrier to care engagement [20] that could potentially confound results, as might depression [24]. Participants will be unblinded to their randomization assignment at the conclusion of the final follow-up assessment.

2.6. Retention plan

Our goal is to achieve low follow-up research assessment attrition rates even if participants decide to drop out of HIV clinical care. Staff call participants to remind them of assessment appointments, which can be conducted by telephone, unless the participant chooses to come to the clinic. Cab rides/bus vouchers are provided for travel to the clinic as needed. Participants provide at least two contact persons we can ask for information about participants' whereabouts should we lose contact. ABBT and HIV education sessions can be delivered by telephone. As in our previous studies, we expect a telemedicine approach to support high retention in study assessments (e.g. [25]).

Participants are reimbursed for their time in assessments *only*: (1) $25 for the baseline assessment; and, (2) $25 at each follow-up. No remuneration is provided for attendance of intervention sessions. Participants' reimbursement can be augmented by prepaid calling cards for telephone minutes if they do not have an unlimited calling plan ($15 for all of the calls as needed; our internal survey showed that <10% will have limited calling plans).

2.7. Interventions

2.7.1. Acceptance-based Behavior Therapy (ABBT)—

ABBT participants will receive the intervention as specified in the manual, added to their receipt of TAU services. Session #1 will occur the same day of the intake clinic appointment or if preferred, within one week of that appointment. Session #2 will be conducted by telephone, if patient privacy can be ensured, within 2–3 weeks of the first session. These two sessions are designed to align with the intake and first medical visit at our sites. See Table 2 for summary of ABBT content.

In the first session, the interventionist will introduce the concept of acceptance and its possible benefits in the context of life values and participant-identified barriers to retention in care. As discussed in our published papers [14, 15], we seek to create a foundation for

HIV acceptance at the first session via experiential exercises, using metaphors developed in the acceptance-based literature [16]. Interventionists use the “Quicksand” metaphor, in which struggling with HIV is compared to struggling with quicksand: it just makes it worse. To elicit life values, interventionists use a “Growing Old” exercise, in which participants are asked to reflect on what they would want their life to stand for, observing their history at an older age. To complement this exercise, we use a “values card” in which participants list their life values on a small index card. We encourage participants to keep these cards easily accessible (e.g., on the refrigerator, in a wallet) as daily reminders about their purpose in life. Interventionists will help participants identify potential challenges to acceptance, including disclosure concerns. Informed decision-making about disclosure will be introduced as a means of identifying disclosure targets. By teaching participants to consider the emotional and physical risks associated with disclosure, they will be better-suited to determine if, how, and when disclosure can occur.

At the second session, which will be delivered via telephone if participants can ensure privacy or in-person if preferred, participants will practice acceptance-based coping skills and a behavioral plan will be developed to targets barriers identified in the first session. To aid participants in assessing the benefits and risks of seeking social support via disclosure, part of our second intervention session (and the first when appropriate) will be used to develop informed decision-making skills about disclosure as described by Kalichman and Nachimson [26]. ABBT is designed to encourage thoughtful and respectful disclosure to all relevant individuals in participants’ lives. However, our priority with disclosure is to facilitate social support, rather than impact transmission risk, meaning that disclosure to sex partners will be considered but not necessarily prioritized. Individuals will be taught and given the opportunity to role play how to make informed disclosure. These discussions will help the participant clarify how best to align their values with decisions on how to manage their HIV. This discussion will highlight how disclosure can support care retention.

2.7.2. HIV education (control)—Because there is no gold standard HIV care retention protocol, and to demonstrate an effect beyond usual care, our control condition will be each clinic’s usual care procedures (TAU) plus HIV education. HIV education will consist of two brief, manualized sessions led by study interventionists, performed at the same times and by the same methods as ABBT. Topics of education include safe sex practices, review of treatment options, and review of HIV-related indices of health. These sessions will be didactic in nature, but designed to provoke conversations with participants about factors associated with living with HIV.

2.8. Study assessment schedule

Follow-up assessments will occur at 1-, 3-, 6-, 9-, and 12-months post-baseline. See Table 1 for summary of study assessments.

2.9. Primary outcomes

Our primary outcomes of interest are: medical care retention and virologic suppression. Retention will be assessed via review of electronic medical records, or as-needed, via self-reported appointment attendance history if participants seek care outside of our study

sites. These data will be available regardless of participants' completion of our follow-up self-report measures unless they are lost to follow-up and we are unaware of where they might be seeking care outside of their primary clinic. We will not review appointment attendance for individuals who withdraw from the study. Virologic suppression (i.e., HIV viral load) data will be obtained via blood draws at the recruitment sites. If a clinic visit recently occurred, viral load data will have already been collected and these data will be pulled from the electronic medical record. If a clinic visit had not recently occurred or phlebotomy was not performed at a clinic visit, a blood draw paid for by the study will be conducted.

2.10. Secondary outcomes

Four secondary outcomes will be assessed by self-report: ART adherence, disclosure of HIV status to participant identified supports such as family or friends, perceived social support, and perceived HIV stigmatization. Standardized measures will be used for all of these variables. We will also assess the raw number of individuals disclosed to at each assessment. To help participants and the research team keep track of disclosures, a running list of individuals disclosed to will be created at baseline and revisited at each assessment.

2.11. Mediators

Proposed mediators of this intervention are increased HIV acceptance (and decreased HIV experiential avoidance) and increased willingness to disclose HIV status. Both variables will be measured by self-report.

2.12. Covariates

Planned baseline covariates include age, gender, race, ethnicity, HIV viral load, and study site. We will also co-vary for cumulative TAU exposure. A 2-tailed probability of Type I error < .05 will be used for all null hypothesis tests. Any variables on which intervention arms vary significantly ($p < .10$) at baseline or which significantly ($p < .10$) predict study attrition will be included as covariates in multivariate models.

2.13. Data collection

Data will be collected via in-person or remotely, depending on participant preference. Electronic data capture technology (REDCap; [27]) will be used for direct data entry during self-report and interviews; clinical data will be collected using abstraction forms and then entered into electronic forms.

2.14. Quality control

2.14.1. Treatment fidelity—Clinical supervision is provided by the study's lead investigator during weekly teleconference sessions throughout the RCT. Interventionists will discuss their caseload, troubleshoot as needed, and otherwise discuss audio recordings of sessions that the investigator listened to prior to the supervision meeting. These audio recordings will be identified by participant ID and will be stored on the study's secure server. At the conclusion of the RCT, two trained postdoctoral students who are not part of the study will rate 50% of the randomly selected ABBT and HIV education sessions.

Fidelity rating training will entail reviewing the intervention manuals with the study investigator, listening to sessions as a group to practice coding, and then independently coding sessions and comparing them to ratings conducted by the investigator to refine coding practices. Once these steps are completed, the two raters will rate a random selection of ABBT and HIV education sessions until adequate reliability is achieved (ICC>.80). Adherence to the treatment manuals will be assessed in a previously developed coding system used in the pilot work. This system focuses on adherence to the intervention manual, allowing raters to note if each topic in the manual was delivered/administered, "yes, no, or partially." A percent adherent statistic is then calculated for each rated session.

2.14.2. Data management—All participants will receive a unique study ID number, including those who are excluded at the time of the baseline interview (e.g., because of cognitive impairment). An electronic tracking database that links participants to their ID numbers will be used; this will be password protected so that only study staff can access it. Interviewer and self-report paper-and-pencil data will be collected in the clinical assessment room at the recruitment site and immediately transferred to the local investigator's office following each appointment. Our recruitment sites requested that this study use paper-and-pencil assessment materials rather than using a computer or tablet in the clinical space for data collection. Paper records will be stored in a locked file cabinet only accessible to study personnel. Informed consent forms will be kept in a separate file cabinet. Data will be double-entered by the research assistants into an interactive online database (REDCap) with extensive checks to ensure the integrity of the data.

2.15. Statistical analyses

2.15.1. Primary outcomes—We will use generalized estimating equation and mixed effects models to test the hypothesis that compared with HIV education, ABBT will increase the likelihood of meeting minimum DHHS recommended HIV care. To test the hypothesis that ABBT will result in improved virologic suppression, relative to HIV education, MANCOVA will be used. A 2-tailed probability of Type I error < .05 will be used for all null hypothesis tests.

2.15.2. Secondary outcomes—We will use latent growth models (LGM) to estimate the effect of intervention on ART adherence, disclosure of HIV status, perceived social support, and HIV stigmatization. Data will be available from baseline, 1-, 3-, 6-, 9-, and 12-month follow-ups. This approach offers the flexibility to accommodate outcomes with a range of exponential family (e.g., normal, binomial, etc.) error distributions and allows a comparison of possible alternative growth processes (linear, quadratic, unconstrained with freely estimated time values) describing change over time. Initially, the Satorra-Bentler Scaled Chi-Square [28] will be used to compare linear change, quadratic change, and models with freely estimated time values. After identifying the best fitting unconditional LGM, conditional LGM models will be estimated in which the intercept and slope growth factors will be regressed on group, age, gender, race/ethnicity, and any baseline measures that significantly ($p < .10$) predict attrition. Significant differences in slope growth factors would be consistent with the hypothesis that the ABBT and HIV education arms experience different patterns of change over time.

2.15.3. Mediator analyses—The hypothesis that the effects of ABBT will be mediated by increased HIV acceptance and increased willingness to disclose HIV status will be tested in a LGM framework [29]. According to Selig and Preacher[30], LGM is well suited to mediation analyses where individual trajectories of change over several assessments are analyzed and where a relatively large amount of intra-individual change would be expected. We will extend the LGMs estimated when testing the effects of ABBT on secondary outcomes. The slope growth factors in the LGM are latent variables that represent change trajectories which can be used to account for differences in more distal outcomes. One distal outcome would be the likelihood of meeting minimum DHHS recommended HIV care over 12 months. Mediation is tested by specifying an indirect effect defined as the product of the effect of intervention on the slope growth factor of the hypothesized mediator (HIV acceptance, increased willingness to disclose) by the effect of the mediator on meeting DHHS recommended HIV care. Bias-corrected bootstrap resampling is generally recommended for testing the statistical significance of indirect effects [31]. Simulation studies have generally shown this to be the most efficient method for testing mediational hypotheses [32, 33]. Lastly, interaction terms will be added one-by-one for the intervention condition and the potential moderators (e.g., substance use at baseline, psychosocial factors). Significant or large interaction terms would suggest that intervention effects differ by subgroups of the moderators.

3. Discussion

Although acceptance-based skills might be well suited to individuals living with chronic illnesses like HIV, little research has examined their application in supporting the HIV care cascade. As reported in our prior work [14], we conducted a small open trial in a sample of nine participants seeking HIV medical care for the first time. Open-ended feedback on the two-session ABBT intervention and assessment materials was wholly positive. Equally important, 75% of those approached agreed to participate, suggesting that recruitment into a research study was possible even during this early phase of care. Quantitative results showed 1-month improvements in participants' psychological acceptance of HIV and perceptions of stigmatization; 50% of participants disclosed to at least one person in their network.

Using what we learned in the open pilot, we conducted a pilot RCT (n=34) [15], comparing ABBT to a TAU control condition. In this study, no serious adverse events occurred and 88% of ABBT participants attended both sessions. One-month exit feedback was generally positive. In a self-report exit measure, participants consistently rated ABBT highly (range of scores is 1–7, with 7 indicating highest agreement): (1) "I plan to continue to use and practice what I learned at these meetings;" mean=6.92 (*SD*=0.29); (2) "Discussion of barriers to attending my medical appointments was useful;" mean=6.75 (*SD*=0.45). Moreover, results from the Client Satisfaction Questionnaire-Revised (CSQ-8-R; [34]), which is an 8-item measure with a score of 32 indicating highest satisfaction, were very high: mean=29.9 (*SD*=2.78).

In terms of ABBT's effects, results were very encouraging in that at most follow-up time-points, ABBT, relative to TAU, had medium to large effects on: experiential avoidance of HIV distress, willingness to disclose HIV status, actual disclosures of serostatus, and social

support. Directionally, results also favored ABBT over TAU with respect to reductions in HIV stigmatization, but the TAU group had significantly higher stigma scores at baseline (standardized difference in baseline means was 0.68), thereby limiting our ability to detect an effect. With respect to our primary outcome, medical care retention, only 6.7% of ABBT participants did not meet the DHHS retention guidelines for medical care over nine months, compared to 26.7% in the TAU condition. Taken together, these preliminary findings lay the groundwork for the present study.

3.1. Strengths

The proposed full-scale RCT represents a substantive departure from the status quo by: (a) using acceptance-based techniques to promote effective longitudinal coping with HIV, which have never been used outside our pilot work; (b) explicitly promoting disclosure as a mechanism of care engagement, which has never been targeted as a retention mechanism for new-to-care patients outside our pilot work; (c) delivering a very brief intervention that is designed for a busy clinical setting, with half of it administered by telephone (if participants can ensure privacy), to facilitate outreach to a broader group of new patients, particularly those who might be at high drop-out risk and reluctant to come to the clinic for any appointment.

3.2. Challenges

Our working hypotheses for primary outcomes are that compared to HIV education, ABBT will lead to greater HIV care retention, defined as meeting DHHS guidelines of having at least three follow-up medical appointments, after the initial medical visit, in the first 12 months of care [1] and greater reduction in viral load. Although our preliminary data support these hypotheses, it is possible that these hypotheses will not bear out. If this is the case, we would turn to other factors that might provide alternative explanations for our findings. A first step would be to examine site-specific factors, including examining efficacy of ABBT at each of the two recruitment sites. We would also compare efficacy of the intervention based on the interventionist and their training level. Another step would be to explore how participant characteristics (e.g., gender, substance use) relate to outcomes; for instance, women might be more reluctant to disclose their HIV status than men. Given our broad eligibility criteria, we do not expect to exclude many new patients at our recruitment sites. However, it is possible that we would not recruit sufficient samples to fully power our examination of ABBT's efficacy. If not, we would consider expanding to another recruitment site. Moreover, it is possible that some eligible participants will decline participation because they are acutely distressed at their first visit. Given the expected drop-out rate of treatment naïve patients, we suggest it is essential to prioritize delivering ABBT early in care, but as previously described, we will allow some flexibility in timing. Lastly, although study funds are available to pay for and process research-related blood draws to assess participants' viral load, it is possible that participants who are poorly retained in care might not agree to this procedure. As such, viral load data might not be available for all participants, particularly those who are not attending medical visits.

Our working hypotheses for secondary outcomes are that ABBT, relative to HIV education, will lead to: (a) increased ART adherence; (b) increased disclosures; (c) increased perceived

social support; and, (d) reduced perceived HIV stigmatization. Although our preliminary data support these hypotheses, it is possible that these hypotheses will not be substantiated. We recognize that the number of individuals to whom a participant might disclose their serostatus is person-specific and that a ceiling on disclosures is possible for many participants, potentially undermining our ability to test our disclosure hypothesis. Also, it should be noted that disclosure can provoke anxiety, shame, fear of stigmatization, fear of abandonment, and, sometimes, fear of violence [35, 36]. For women, accusations of infidelity and the risk of violence are often cited as an acute fear [37]. Violence towards HIV+ females from a partner upon disclosure occurs at similar rates in the U.S. and low-income countries (3–15%; [37, 38]). Thus, it is possible that disclosure differences between intervention groups will not be found. In this situation, we would then examine if ABBT impacted willingness to disclose, regardless of actual disclosures.

Finally, it is possible that the mediational hypotheses will be rejected. If that is the case, we would turn to alternative explanations for ABBT's effects. We would explore other potential mediational pathways, including changes in provider alliance, depressive symptoms, healthcare system distrust, and perceived experiences of discrimination.

3.3. Conclusions

At the conclusion of this efficacy trial, we anticipate demonstrating that ABBT, a simple and easily replicable intervention, can effectively promote retention in medical care for new HIV patients and improve virologic suppression. Our next research steps will be to: (a) further study ABBT implementation and disseminate training materials to promote its integration into usual care at HIV clinics nationwide; (b) test the intervention in non-Western settings (e.g., India, sub-Saharan Africa) to determine if its principles are relevant to other cultures with high incidence of HIV; and, (c) examine if ABBT can be an effective strategy for impacting other facets of the HIV care continuum, such as early linkage to care or as a strategy to re-engage patients who have dropped out of care. Currently, there is no gold standard approach to promoting HIV care retention. Existing psychosocial interventions have had mixed results and those that have shown efficacy are highly specific to certain patients or highly resource intensive. Thus, new intervention directions that have broader applicability by tapping into underlying mechanisms (i.e., acceptance of HIV) relevant to most, if not all, HIV patients warrant further attention.

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Highlights

- Efficacy trial of a novel, acceptance-based intervention for HIV care retention.
- Intervention targets disclosure of HIV status as pathway to acceptance.
- This intervention has the potential to reduce HIV-related stigmatization.

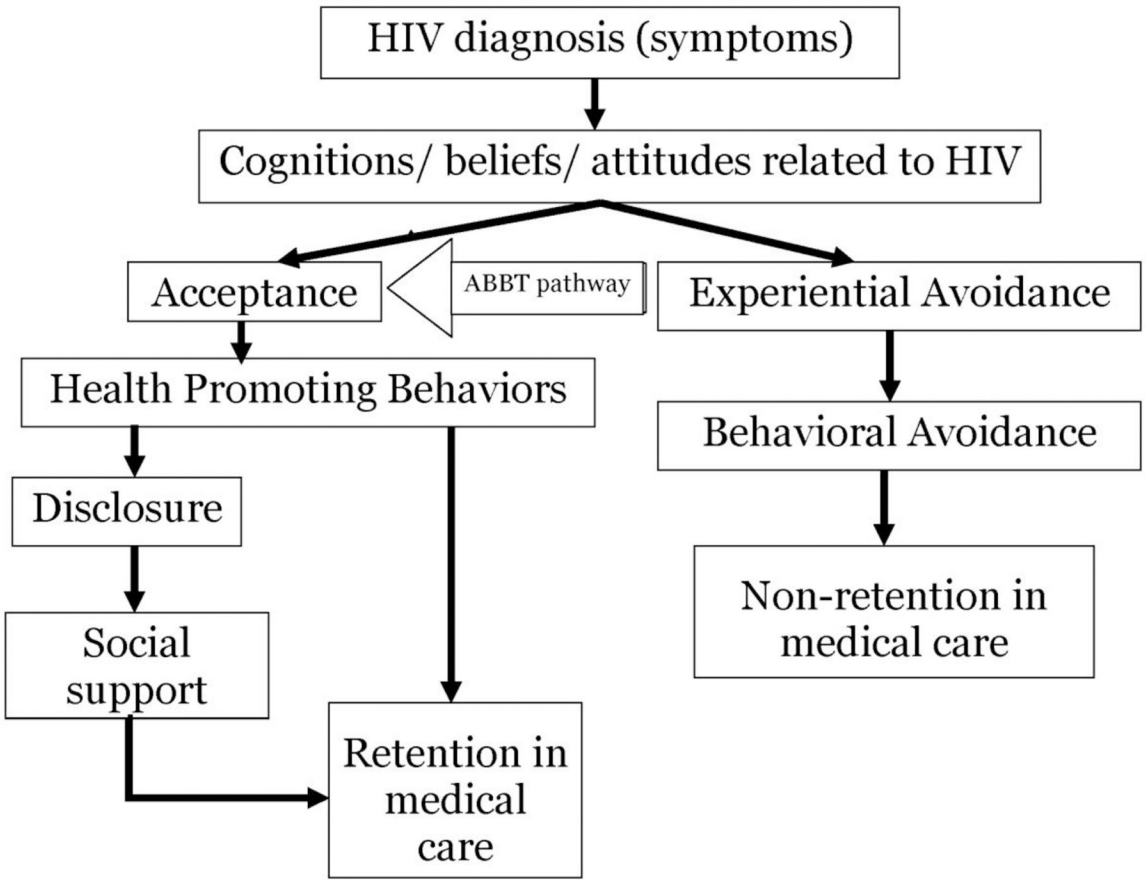

Figure 1.
Acceptance-based model of HIV medical care retention

Table 1.

Measures and assessment schedule

Measure	Baseline	1-, 3-, 6-, 9-& 12-month follow-ups
Demographics	X	
HIV-related data (e.g., diagnosis date)	X	
Substance use		
Alcohol use	X	
Substance use	X	
Retention barriers		
Depression	X	X
Discrimination	X	X
Healthcare system distrust	X	X
Provider alliance		X
Primary outcomes		
Appointment attendance		X
HIV Viral Load	X	X
Secondary outcomes		
Self-reported ART adherence		X
# of disclosures	X	X
Social support	X	X
HIV stigma	X	X
ABBT mechanisms		
Willingness to disclose serostatus	X	X
HIV experiential avoidance	X	X
HIV medical care		
Receipt of TAU services		X
ART initiation and medication(s)		X
ABBT acceptability		
Satisfaction		1-month
ABBT participant exit interviews		1-month

Table 2.

Acceptance-based Behavioral Therapy (ABBT) intervention.

Session	Topic	Content
1	Introduction and assessment of experiences since HIV diagnosis	Reaction to HIV diagnosis? Physical symptoms? Coping skills/strategies? Mental or physical comorbidities? Quality of social support?
	Review benefits of HIV care and disclosure (psychoeducation)	Reasons for regular HIV care Benefits of disclosure Assess risk of drop-out Discuss why patients drop-out
	Creative hopelessness, cognitive defusion, acceptance	Quicksand metaphor
	Values	Growing old exercise Values card
2	Barriers to engaging in HIV care	Assess motivation to engage in care
	Review highlights of session 1	Potential barriers to engaging in care? Reaction to discussion of values? Reaction to quicksand metaphor?
	Setting goals related to disclosures and values	Who will you tell? How will you tell? Setting the stage for disclosure Practicing disclosure