



# Development of a Telephone-Delivered Acceptance and Commitment Therapy Intervention for People Living with HIV who are Hazardous Drinkers

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## Abstract

Alcohol use among people living with HIV (PWH) has been increasingly recognized as an important component of HIV care. Transdiagnostic treatments, such as Acceptance and Commitment Therapy (ACT), that target core processes common to multiple mental health and substance-related problems, may be ideal in HIV treatment settings where psychological and behavioral health comorbidities are high. In advance of a randomized clinical trial (RCT), the overall objective of this study was to systematically adapt an ACT-based intervention originally developed for smoking cessation, into an ACT intervention for PWH who drink at hazardous levels. Consistent with the ADAPT-ITT model, the adaptation progressed systematically in several phases, which included structured team meetings, three focus group discussions with PWH ( $N=13$ ), and in-depth interviews with HIV providers ( $N=10$ ), and development of standardized operating procedures for interventionist training, supervision, and eventual RCT implementation. The procedures described here offer a template for transparent reporting on early phase behavioral RCTs.

**Keywords** HIV · Alcohol · ACT · Treatment

## Introduction

The routine assessment and treatment of alcohol use among people living with HIV (PWH) has been increasingly recognized as an important component of HIV care. Sixty

seven percent of PWH report using alcohol in the previous year, [1] 27–40% report drinking at hazardous levels (i.e., typically a score of  $\geq 8$  on the Alcohol Use Disorders Identification Test [AUDIT]), [1, 2] and ~30% meet criteria for alcohol use disorder [3]. Compared to those who abstain or drink relatively less, PWH who are hazardous drinkers experience a significant increase in risk for: mortality, [4] lack of viral suppression, [5, 6] less utilization of antiretroviral therapy (ART), [6, 7] and sub-optimal adherence to ART [8]. Hazardous alcohol consumption is thus a critical factor in HIV treatment that significantly contributes to poorer HIV treatment-related outcomes, and consequently increased risk for onward transmission [9]

## Alcohol Interventions for PWH

There is a growing literature on randomized clinical trials (RCTs) of alcohol interventions for PWH, with several systematic reviews and meta-analyses published in the past ~10 years [10–14]. The results of these trials have been mixed, with few showing clinically and statistically

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significant effects on quantity and/or frequency of alcohol use maintained over time. For example, the most recent review published in 2019 included 21 RCTs, [14] the majority of which used motivational interviewing, brief behavioral intervention, Cognitive Behavioral Therapy (CBT), or a combination of these approaches. Efficacy was inconsistent across studies; while some isolated studies, especially motivational interviewing and CBT, showed significant effects on quantity and frequency of alcohol use, overall the magnitude of the effects were generally small, and effects, when present, were often not maintained over time. A 2017 meta-analysis of 21 RCTs had similar findings, revealing that while there was an overall, small effect for quantity of alcohol use (*weighted mean effect size* = 0.11) and heavy drinking (*weighted mean effect size* = 0.24), there were no significant differences between intervention and control groups on frequency of alcohol consumption [13]. Consistent with these mixed results, Madhombiro et al. (2019) recommended a shift in the literature towards “transdiagnostic interventions that target alcohol use, adherence, and [other] mental disorders” (p. 13) [14]. Indeed, the high levels of alcohol use observed among PWH tend to occur in conjunction with a high prevalence of other mental disorders. Prior year prevalence of any mood/anxiety disorder among PWH is as high as 67% [15, 16] and several studies have also indicated high levels of dual diagnosis, ranging from approximately 10% up to 63% of PWH meeting criteria for both a substance use disorder and another psychiatric disorder [16].

### Acceptance and Commitment Therapy (ACT) for PWH who are Hazardous Drinkers

Transdiagnostic treatments, such as Acceptance and Commitment Therapy (ACT), target core processes and maintaining mechanisms common to multiple mental health and substance-related problems, which may be ideal in treatment settings with high psychological and behavioral health comorbidities [17]. The goal of ACT in particular is to alter the *function*, rather than *content*, of difficult thoughts and feelings by enhancing mindfulness skills, clarifying core values, and increasing commitment to values-guided behavioral action plans [18, 19]. ACT interventions target experiential avoidance—i.e., repeated attempts to eliminate or avoid unwanted thoughts, emotions, memories and/or urges—a process that is theorized to underlie multiple forms of maladaptive behavior, including substance use [20, 21]. The alternative to experiential avoidance is *acceptance*—the active process of fully experiencing emotions, thoughts, memories and/or urges while still behaving effectively [21]. Mindfulness skills are used to increase acceptance of aversive internal experiences in the pursuit of valued outcomes [20, 21]. These skills culminate in the ability to accept

uncomfortable private experiences as “transient psychological events,” resulting in broad psychological symptom reduction [20].

There is a rapidly growing literature in support of transdiagnostic treatments, [19] including ACT. For example, a recent review of the meta-analytic evidence on ACT identified 20 meta-analyses that were based on 133 studies and 12,477 participants [22]. Results showed that ACT was efficacious across a broad range of intervention targets, including depression, [23–30] anxiety, [24–26, 28–32] chronic pain, [27, 29, 33] substance use, [34–36] eating disorders [37], psychosis, [38] stress, [26, 30] somatic complaints, [34] physical conditions, [23] and transdiagnostic combinations of conditions [23, 31, 33, 39] with small to medium controlled effect sizes. Three meta-analyses also identified 17 unique RCTs that found ACT to be efficacious for smoking and other drug use [34–36] with preliminary evidence of efficacy for treatment of co-occurring substance use and affective disorders [18, 41–45].

ACT has recently been identified as a promising treatment for AUD, although the literature is still in its infancy. Based on a recently published review, [46] and our own assessment of the literature, only three studies have assessed ACT as a treatment for alcohol use [44, 47, 48] (two others examined ACT as a treatment for AUD and comorbid depression and/or distress, but did not measure the effect of the treatment on alcohol consumption) [45, 49]. While none of these studies were randomized trials, all provided preliminary evidence to suggest that ACT is a promising intervention for alcohol use and comorbid stress, anxiety, and/or trauma. Thekiso et al. (2015) conducted a pilot study of a group-based ACT intervention designed to enhance treatment as usual (TAU) for inpatients with AUD and either depression or bipolar disorder [37]. The ACT group received 4 weeks of daily (5 sessions/week) group ACT-based therapy, while TAU received 4 weeks of standard integrated inpatient treatment [37]. Patients in the ACT group reported a significantly higher cumulative abstinence duration (i.e., percentage of total number of days abstinent from alcohol during the past 90 days) at 6-months post intervention, as well as significantly lower symptoms of anxiety and depression. Harvey et al. (2017) compared the effects of a group-based ACT intervention on anger, stress, and alcohol-related difficulties for military personnel to a waitlist control group [38]. Patients in the intervention group received one week of daily (5 sessions in total) group ACT-based therapy. Relative to the waitlist control group, patients in the ACT group reported significantly reduced alcohol consumption (i.e., AUDIT-C total score), anger, perceived stress, and anxiety at 1-month post-treatment. Finally, Meyer et al. (2018) conducted an uncontrolled pilot study of an individual-based ACT intervention for outpatient veterans with co-occurring post-traumatic stress disorder (PTSD) and AUD [39].

Treatment consisted of 12-weekly individual outpatient sessions of ACT [39]. At 3-months post intervention, patients reported significant reductions in past 30-day total drinks and heavy drinking days, as well as significant reductions in depressive symptoms. One other study investigated the effects of a brief (3, 11–13 min phone calls) acceptance-based coping skills training on alcohol-related outcomes among individuals dually diagnosed with PTSD and AUD [50]. Participants were randomized to either acceptance skills, cognitive restructuring skills, or an attention-matched control, and results indicated that both coping skills significantly reduced drinking compared to a control condition, but did not differ from one another on drinking frequency at 5 week follow-up. While the literature on ACT as a treatment for alcohol use is promising, none of these studies were conducted with PWH and none formally examined efficacy with a full-scale RCT.

The literature on ACT for other substance use is more well-developed, especially in the area of smoking cessation [51]. The brief format, innovative telephone, web-based, and smartphone-based platforms, and high comorbid psychiatric and medical conditions of the populations included in these studies provide a useful template for the development of ACT interventions for PWH who drink at hazardous levels [41]. More specifically, Bricker and colleagues recently completed a pilot RCT of a brief, 5-session, telephone-delivered ACT intervention for smoking cessation (The TALK Intervention), and compared it to standard CBT (matched for length and intensity) [41]. In this trial, quit rates at 6 months post randomization for participants who screened positive for depressive symptoms at baseline were 33% in the ACT condition compared to 13% in the CBT condition (OR = 1.2; 95% CI = 1.0–1.6); and were even higher among participants scoring low on acceptance of cravings at baseline (37% vs 10%; OR = 5.3; 95% CI: 1.3–22). The availability of ACT in this brief, manualized, telephone-delivered format makes it an ideal framework from which to adapt a treatment capable of addressing the multiple needs of PWH who are hazardous drinkers.

## Purpose of the Present Study

The overall objective of this study was to systematically adapt Bricker et al.’s TALK intervention [40] for PWH who drink at hazardous levels— hereafter, referred to as the ACCEPT intervention— in advance of a pilot, and eventual full-scale, RCT. The Centers for Disease Control and Prevention (CDC) defines intervention adaptation as: “the process of modifying key characteristics of an intervention, recommended activities and delivery methods, without competing with or contradicting the core elements, theory, and internal logic of the intervention thought most likely to produce the

intervention’s main effects” [52]. While it has become more common in the behavioral HIV intervention and substance use treatment literature to describe pilot RCTs and other preliminary studies in advance of full-scale efficacy trials, what is less common is a comprehensive description of the process by which a treatment is developed and/or adapted. In an effort to increase transparency and rigor in the behavioral RCT literature, several models (e.g., the ORBIT model [53], the Stage Model [54], the ADAPT-ITT model [55]) have been developed to guide early phase studies, which include intervention development and adaptation. The ADAPT-ITT [55] model is particularly relevant to our study, as it was specifically designed to provide a theoretical framework for systematically adapting evidence-based HIV interventions [55]. Consistent with the ADAPT-ITT [55] model, the formative work for the ACCEPT intervention progressed systematically in several phases, which included structured team meetings, focus group discussions (FGDs) with PWH who drink at hazardous levels, in-depth interviews with HIV clinic providers, and development of standardized operating procedures for interventionist training, supervision, and RCT implementation. Our goal in describing this process is to offer a model for other behavioral interventions to replicate in the reporting on early phase studies.

## Methods and Results

### Overview of Study Phases

The adaptation of Bricker et al.’s TALK intervention [41] into the ACCEPT intervention, occurred in several phases guided by the ADAPT-ITT model (see Table 1) [55]. We describe next the process by which we chose the TALK intervention (Steps 1–2), determined what in the TALK intervention needed to be adapted and how (Step 3), documented changes to the TALK intervention manual and produced a draft of what would become the manual for the ACCEPT intervention (Step 4), involved key stakeholders to solicit feedback on the first draft of the ACCEPT intervention manual (Step 5), integrated suggestions from key stakeholders into a final ACCEPT intervention manual (Step 6), trained interventionists on the ACCEPT manual (Step 7), and developed and implemented procedures for a pilot RCT to test the feasibility and acceptability of the ACCEPT intervention (Step 8). We emphasize Steps 3–8 in this manuscript, as the formative work in Steps 1–2 has been previously described and published [56]. Our multidisciplinary team included two licensed clinical psychologists specializing in alcohol interventions and behavioral aspects of HIV treatment and prevention (SWK, SAM), one licensed clinical psychologist specializing in smoking cessation and ACT (JB), an epidemiologist specializing in alcohol and

**Table 1** ADAPT-ITT model [55] adaptation process

Adaptation phase	Task	Methods
1. Assessment	Who is the new target pop. and why is it at risk?	Reviewed literature on alcohol use and other mental health needs among PWH Conducted qualitative interviews on acceptability of ACT among PWH
2. Decision	What EBI is to be adapted?	Reviewed literature and identified brief, telephone-delivered ACT for smoking cessation as intervention to adapt
3. Administration	What in the original EBI needs to be adapted and how?	Identify what elements of intervention need to be adapted by examining the ACT for smoking cessation manual
4. Production	How to produce and document adaptation to EBI?	Consult study team to solicit feedback on first round for changes and document agreed upon changes Generate final draft of adapted intervention manual, maintaining fidelity to core elements and underlying theory of original EBI
5. Topic experts	Who can help adapt the EBI?	Conduct qualitative interviews & focus group discussions with PWH who are hazardous drinkers, and HIV care providers, to gather input on draft of adapted intervention manual
6. Integration	What is going to be included in the adapted EBI to pilot?	Analyze qualitative data Integrate feedback and modify intervention manual content Generate final adapted intervention manual
7. Training	Who needs to be trained and how?	Establish procedures for/conduct ACT interventionist trainings Finalize procedures for (1) supervision format, frequency, & intensity, (2) fidelity monitoring and analysis, (3) trainings for all laboratory-based tasks
8. Testing	Did adaptation work?	Conduct pilot feasibility and acceptability RCT

ACT acceptance and commitment therapy, EBI evidence-based intervention, PWH people living with HIV, RCT randomized clinical trial

HIV (JAH), an infectious disease physician specializing in HIV treatment (EAR), a peer advocate and person living with HIV (JW), and four clinical psychology PhD students specializing in HIV, alcohol, and condom use behavior (MF, JF, AS, DM).

### Steps 1 and 2: How the TALK intervention was chosen for adaptation

As described in the introduction, the research team systematically reviewed the literature on transdiagnostic treatments for people in medical settings who use alcohol and other substances and have a high prevalence of psychological and behavioral comorbidities. The large literature supporting ACT's efficacy contributed to it emerging as the core intervention of choice. Additionally, a brief, telephone delivered version of ACT had previously shown preliminary efficacy

for smoking cessation [41], which seemed ideal for adaptation to an HIV treatment setting. Finally, ACT's focus on value-driven behavioral action plans, and tools for managing automatic behaviors, particularly substance use, that result from an inability to cope effectively with negative emotion, mapped onto mechanisms (e.g., avoidant coping, substance use to cope) for poor HIV treatment related outcomes identified in the literature [57–59]. Indeed, ACT is designed to build skills that increase capacity for *acceptance* of difficult thoughts and feelings, rather than *avoidance*.

Prior to officially moving forward with adaptation of the TALK intervention, we published preliminary data on the feasibility and acceptability of ACT as a treatment for PWH who are hazardous drinkers [56]. Briefly, 25 PWH participated in individual interviews designed to expose participants to the ACT model via three experiential exercises that represented the central principles of ACT (i.e., contacting

the present moment, acceptance, and values-clarification). After each activity, participants were probed for their reactions and feedback. Overall, the qualitative interviews indicated that the activities were highly acceptable and feasible to PWH who are hazardous drinkers. As one participant explained: *“Well I think that in this case it could be very helpful. Because people that you know that have HIV go through many different traumas you know it’s hard to... it was very difficult for me to accept or whatever. And then you think you’re gonna die or whatever... So these kind of activities could help people deviate from those thoughts and help them you know nurture themselves, help them see the great in them, you know not just the negative. And again acceptance and self-love that we all need, but especially with HIV positive people”* (p. 9) [56].

### Step 3: Determining What in the Talk Intervention Needed to be Adapted and how

The Co-PIs (SWK and SAM) led the team of graduate students in an initial session-by-session adaptation of the TALK manual, spending approximately 1–2 h per session suggesting changes to the intervention content to be more consistent with targeting alcohol use among PWH. Adaptation of each session was followed by a broader team meeting with the co-investigators to discuss the proposed changes, solicit feedback, and integrate additional suggestions from the team (see Step 4). The primary changes at this stage were related to: (1) shifting from an abstinence-based approach to a harm reduction approach, and assuming variability in motivation to change, rather than a desire to initiate a quit attempt [60]. Consistent with this shift, the manual was modified to include a committed action plan at the end of each session that was tailored to the participant’s readiness for change. For example, the plan could focus on “thinking about changing alcohol use” or could include a specific drinking goal related to quantity and/or frequency (e.g., reducing the number of drinking days and/or number of drinks per drinking day). (2) In the sections designed to increase awareness of substance use behavior and motivation for change, we modified language describing “triggers” for smoking to focus on the “ABCs”—antecedents, behaviors, and consequences—of drinking behavior. We also replaced the word “trigger” with “internal/external events that tend to precede heavier drinking.” Our decision to eliminate the use of the word “trigger” was based on the immediacy the term conveys, which, in our opinion was more consistent with smoking events, and less consistent with drinking events (3) Referencing resources and guidelines published by the CDC and National Institute on Alcohol Abuse and Alcoholism (NIAAA), we added an educational section on alcohol (e.g., definition of a standard drink, at-risk vs lower-risk drinking), HIV (e.g., definition of undetectable viral load, description

of CD4 cells), and the association between alcohol and HIV (e.g., alcohol-associated non-adherence to ART), (4) Consistent with the behavioral alcohol intervention literature, we also added an expanded educational section to the final call that described the natural course of behavior change (i.e., not linear, characterized by steps forward and back). We emphasized this in the final intervention session in order to prepare the participant for inevitable setbacks as they continued to try and maintain changes to their alcohol use [61]. (5) Finally, we created a table for the interventionists that organized each session to include a check-in from the prior week, a review of self-monitoring data, a metaphor designed to introduce an ACT concept (e.g., values, defusion), and an experiential exercise to introduce a new ACT skill. We also added psychoeducation about each new ACT concept as well as a harm-reduction based action plan to set a SMART goal related to alcohol use and the practice of ACT skills. Once the first round of modifications was complete, the revised treatment manual—hereafter referred to as the ACCEPT manual—was ready for distribution to the study team, and the study progressed to Step 4.

### Step 4: Producing and Documenting Changes to the ACCEPT-Version #1 (ACCEPTv1) Intervention Manual

SWK and SAM led the team in a session-by-session review of the new ACCEPTv1 intervention manual to solicit feedback on the first round of modifications. The full study team received each session of the ACCEPTv1 manual with modifications to the TALK intervention summarized in a written summary of the major changes described above. Team members submitted written feedback via email, which was supplemented with verbal discussion at team meetings (conducted via Zoom). This process was repeated until all five sessions of the ACCEPTv1 manual developed in Step 3 were reviewed by all members of the study team. The feedback was collated, and several additional substantive changes were incorporated: (1) In response to feedback that the first session was potentially too long and dense, given that we had added education on alcohol and HIV, the intervention was expanded to six sessions, splitting session one into two separate phone calls; (2) the educational component of session one was modified to include information about contemporary public health messaging related to HIV treatment and transmission (i.e., Undetectable = Untransmissible; Treatment as Prevention); (3) the language in the ACCEPTv1 treatment manual and workbook was modified to ensure it was at an 8<sup>th</sup> grade reading level in order to accommodate literacy concerns. (4) an expanded educational section on creative hopelessness, and how it relates to alcohol use, was added to reinforce understanding of alcohol use as a strategy for engaging in experiential avoidance; (5) the phrase “uncomfortable thoughts, feelings, and situations that you

tend to have before you drink heavily” replaced “internal/external events” as an alternative to the word “triggers.” A new intervention manual (ACCEPTv2) was drafted based on all the suggestions/changes from the study team and the adaptation process moved on to Step 5.

### Step 5: Soliciting Feedback on the ACCEPTv2 Manual From Key Stakeholders

A semi-structured interview guide was used to demonstrate core concepts from the adapted ACCEPTv2 manual and assess receptivity, suggestions for improvement, and relevance to PWH who are hazardous drinkers. We conducted three focus group discussions (FGDs) with PWH ( $N=13$ ) and 10 in-depth interviews (IDIs) with HIV treatment providers ( $N=10$ ). The average age of the PWH who participated in the FGDs was 50.5 years ( $SD=12.3$ , range: 33–68), and all reported hazardous alcohol use on the AUDIT-C (score  $\geq 4$  for men or  $\geq 3$  for women) [62]. Three participants identified as cis-gender women and 10 identified as cis-gender men; approximately half (53.8%) of the FGD participants identified as homosexual/gay/queer, 23.0% identified as heterosexual/straight, and 15.4% identified as bisexual. The majority (77%) of the participants identified as Black and the average number of years living with HIV was 18.8 years ( $SD=11.77$ ). One third (30.7%) of participants reported an income of less than \$10,000/year, 30.7% reported an income between \$10,000–\$19,999/year, and 23.0% of participants reported an income between \$20,000–\$29,999/year. The average education level across participants was a high school graduate or GED (53.8%). Of the 10 HIV clinic providers, 70% were White, 80% were women, and the mean age was 40.2 ( $SD=15.6$ , range: 24–55). Providers represented a variety of professional backgrounds including registered nurses, nurse practitioners, psychotherapists, and peer support leaders. Providers had an average of 6.4 years (range: 2–12) of experience working with PWH.

### Procedures

The FGDs and IDIs were conducted in a clinical research space adjacent to (0.25 miles) the local infectious disease clinic from which participants were recruited. The clinic provides outpatient and inpatient medical care for PWH from the 15-county Central New York area with an active outpatient census of approximately 1200 PWH. While located in a mid-size city, the geographic area served by the clinic includes urban, suburban, and rural populations. For this study, PWH were either recruited in-person or via a database of people who had formally participated in our studies and indicated an interest in additional research opportunities. For those recruited in-person, a graduate student research assistant assigned to recruit at the HIV clinic that day would

enter the exam room before or after the patient’s visit with their provider, explain the purpose of the study, and, if appropriate, collect the participant’s contact information. Formal screening was done via phone and again once the participant presented to the lab for the FGD. Providers were recruited from word-of-mouth (e.g., a provider who participated would suggest another) and via direct contact from the graduate research assistant. For those recruited from previous studies, the database included men who have sex with men (MSM) living with HIV who reported regular alcohol consumption. Former participants were contacted via telephone and informed about the opportunity to participate in a new study, and if interest was communicated, a formal screening was conducted. For participants who were eligible and scheduled to attend a FGD, informed consent and permission to audio record was obtained immediately upon arrival at our lab. Subsequently, two graduate students (MF & JF) in a clinical psychology PhD program conducted role-plays of intervention content to demonstrate core concepts and exercises included in the ACCEPTv2 manual. Specifically, the interventionists demonstrated: (1) the overall goal of the ACCEPT study by asking participants to imagine the program as a car journey, with the participant in the driver seat, the interventionist in the passenger seat, and the participant’s baggage (i.e., all the reasons that lead people to drink) in the trunk (*Car Journey metaphor*); (2) the section of the manual that provided education about alcohol use (e.g., what are safe drinking limits, what is a standard drink), HIV (e.g., what is viral load), and the relationship between them (e.g., how does alcohol use impact ART adherence); (3) the section of the manual describing values and committed action in which participants are asked to create a fantasy of their ideal 80<sup>th</sup> birthday celebration and imagine someone they care about making a brief speech about what the participant stood for in life, and (4) acceptance, by asking participants to imagine being stuck in quicksand and, instead of trying to get out, dropping the struggle, laying back, and allowing their body to naturally come to the surface (*Quicksand metaphor*). After each section, participants were asked to provide feedback via structured open-ended questions such as: “What did you think about the Car Journey story as an explanation for the overall goal of the program?”; “What do you think about the alcohol/HIV education section? What could we do to make it easier to understand?”; “What are your thoughts about using the Quicksand metaphor to demonstrate ‘dropping the struggle’?”; “What is your overall opinion about this intervention? How would the skills taught in this session be applicable to the lives of PWH who consume alcohol?” We also probed for information regarding issues that were raised during Step 3 related to the use of approachable language (e.g., the appropriateness of the term “antecedents”, referring to the treatment as an “intervention”) and reactions to study branding (e.g., logo for the study).

## Qualitative Data Management and Analysis

All de-identified audio files were uploaded to a secure, password-protected server immediately after IDI or FGD completion and subsequently deleted from the recording device. All FGDs and IDIs were transcribed by a professional transcriptionist, double checked for accuracy, and subsequently uploaded into Dedoose—a secure, cloud-based qualitative data analysis software program (<https://www.dedoose.com/>). Thematic analysis was used to analyze the qualitative data [63]. SWK and two graduate students (MF and JF) independently read all of the transcripts and met weekly to discuss emerging themes. At the descriptive level, analyses involved identifying and summarizing preliminary themes related to acceptability, relevance, and improvement of the adapted intervention. We developed a list of preliminary thematic content codes and child codes, agreed on definitions for each, and coded one transcript in Dedoose with the preliminary code book. We met again as a team to compare coding, resolve discrepancies, and refine definitions of parent and child codes. Consensus in coding was built when two of the three coders were in 100% agreement, and any discrepancy among coders was resolved with discussion. Once we achieved consensus in coding, the final codebook was uploaded to Dedoose, all transcripts were double coded, and the coding team continued to meet weekly for ongoing discussion. Illustrative quotes were chosen for overall representativeness of the central and/or sub-themes.

## Results

Results of the qualitative data analysis from the PWH who participated in the FGDs, and the providers who participated in the IDIs, are presented in Table 2. The FGDs lasted approximately 120 min each, and the IDIs ranged from 45 to 70 min. Findings from the three FGDs and ten IDIs were organized into three major themes within each of the assessed intervention exercises: (1) general satisfaction, (2) areas of concern, and (3) suggestions for improvement.

1. *General Satisfaction:* Overall, HIV patients and providers reported high satisfaction with the content and skills depicted in the ACT exercises. Participants expressed an interest in the utility of the program for this patient population and reported that the acceptance and values-clarification exercises (i.e., 80<sup>th</sup> birthday exercise, Quicksand metaphor) in particular were highly promising, could be valuable for PWH who are hazardous drinkers, and were feasible to implement. A majority of participants emphasized the universality of the core premises of ACT, while noting that PWH may uniquely benefit from the acceptance skills demonstrated in ACT, especially with regard to managing co-morbid health

conditions. Although most HIV patients and providers endorsed high satisfaction with the intervention content, some minor areas of concern about intervention content, format, and modality were identified.

2. *Areas of Concern:* HIV patients and providers expressed concerns regarding the length of the first session and lack of rapport-building. More specifically, they noted that the telephone-based modality may lead participants to become disengaged more quickly than an in-person intervention. HIV patients also noted that the language used to describe key concepts, such as “antecedents,” was not appropriate for the target demographic, and HIV providers reported that the intervention workbook was not written at an appropriate literacy level for this patient population.
3. *Suggestions for Improvement:* With respect to suggestions for improvement, it was recommended by patients and providers that we incorporate greater rapport-building and more frequent in-session “check-ins” to increase participant engagement and better sustain attention via the telephone. Another suggestion was to substitute academic jargon (e.g., “antecedents”) with more colloquial terms (e.g., “any thoughts, feelings or situations”). Participants also recommended that intervention exercises be better tailored to PWH. For example, some HIV patients noted that it may be challenging for PWH to fantasize about an 80<sup>th</sup> birthday due to their HIV status and other health-related comorbidities. Given the prevalence of mental and physical comorbidities among PWH, both HIV patients and providers suggested including more general health-related education, such as information about self-care, medication adherence, STI prevention, and interactive toxicity beliefs. To ensure comprehension of the educational content, participants recommended utilizing a teach-back method where the person receiving the intervention would summarize the educational content and explain it to the interventionist as if the roles were reversed.

In summary, HIV patients and providers viewed the intervention as having the potential to positively impact the lives of PWH; however, several recommendations were provided regarding how best to adapt the intervention for PWH.

## Step 6: Integrating Feedback From HIV Patients and Providers

SWK and SAM presented the results of the coding analysis to the research team via email and scheduled one-on-one meetings as-needed to discuss and distill the results into a list of recommended changes to the adapted intervention manual. A comprehensive review of the changes made to the

**Table 2** Summary of qualitative feedback and associated changes to the ACCEPT intervention manual

Sub-theme	Feedback	Illustrative Quote	Changes
<b>I. General suggestions for improvement</b>			
Length of first session	<ul style="list-style-type: none"> <li>Both FGD participants and providers expressed concern with the length of the first session and recommended shortening the session</li> </ul>	<p>P: “I’m not clear as to whether – this was one phone conversation.”</p> <p>I: “This was one phone call yeah. So what do you all think about that?”</p> <p>P: “That’s too long.” [PWH/FGD participant]</p> <p>“This reminded me of going to a doctor’s appointment where you get about 2 min of hi, how you are doing and then we are in the meat and potatoes man. We got meat and potatoes for 20 min and then I’m out of here. That’s what it reminded me of.” [PWH/FGD participant]</p> <p>“Keep engaging them. I think it’s one of the things I did like on this last one you asked her a question.” [PWH/FGD participant]</p> <p>“More check-ins.” [PWH/FGD participant]</p>	<ul style="list-style-type: none"> <li>A sixth intervention session was added so that all intervention sessions stayed between 30–45 min</li> <li>The educational section was shortened, the 80<sup>th</sup> birthday exercise was moved to the 2<sup>nd</sup> session, and the Quicksand exercise was moved to the 3<sup>rd</sup> session</li> <li>Additional rapport-building was added to the beginning of the first session; participants are asked to briefly share about themselves</li> </ul>
Rapport-building	<ul style="list-style-type: none"> <li>FGD participants expressed concern with the lack of rapport-building incorporated in the first phone call</li> </ul>	<p>“Check-ins”</p> <p>FGD participants suggested including more regular check-ins, particularly in the educational section, to ensure comprehension</p>	<ul style="list-style-type: none"> <li>To assess for understanding and sustained attention, we incorporated additional “check-ins” into the intervention that vary from inquiring about reactions to an activity to asking for specific examples from the participant’s own life or asking the participant to explain educational content in their own words</li> </ul>
Health literacy	<ul style="list-style-type: none"> <li>Providers expressed concern regarding participants’ literacy levels and ability to comprehend the educational content</li> </ul>	<p>“I don’t know if you guys will require your participants to have a particular literacy level, but I do have some patients who can’t read at all.” [Provider/IDI participant]</p>	<ul style="list-style-type: none"> <li>We added an inclusion criterion related to literacy (8<sup>th</sup> grade level) using the Rapid Estimate of Adult Literacy in Medicine, Revised (REALM-R)</li> <li>All content of the workbook was reviewed to ensure an eighth-grade literacy level</li> </ul>
Managing comorbidities	<ul style="list-style-type: none"> <li>FGD participants and providers expressed concerns regarding the management of participants’ mental health comorbidities</li> <li>FGD participants suggested including more educational content on managing other physical health comorbidities (e.g., diabetes)</li> </ul>	<p>“I find that many of our patients have serious mental health problems caused either by having the diagnosis of HIV or because of trauma that they’ve had.” [Provider/IDI participant]</p>	<ul style="list-style-type: none"> <li>Alternative metaphors/exercises were added throughout the manual in the event that a participant finds an activity too triggering</li> <li>A brief education section on how mindfulness-based skills can be applied to physical health comorbidities (e.g., diabetes) was added</li> </ul>
Tailoring	<ul style="list-style-type: none"> <li>FGD participants and providers emphasized the importance of tailoring the intervention to participants</li> </ul>	<p>“Just be willing to adapt, adapt, adapt.” [Provider/IDI participant]</p>	<ul style="list-style-type: none"> <li>Alternative metaphors/exercises were added throughout the manual</li> <li>Interventionists were trained on how to tailor the intervention to participants using basic MI skills (e.g., summarizing, active listening)</li> </ul>
“Intervention”	<ul style="list-style-type: none"> <li>Some FGD participants and providers expressed concern with the term “intervention,” stating that it may be too stigmatizing</li> </ul>	<p>“I mean you draw pictures of three family members showing up at your door to do the intervention because you have this deep problem that everyone can see but you.” [PWH/FGD participant]</p>	<ul style="list-style-type: none"> <li>The term “intervention” was replaced with the phrase “our time together” to emphasize the framing of the intervention as a journey</li> </ul>
<b>II. Car journey metaphor</b>			
Overall impression	<ul style="list-style-type: none"> <li>The car journey was generally well-liked and perceived as an accurate metaphor for the goal of the intervention</li> </ul>	<p>“I like the analogy or the comparison to the car. It’s pretty clear, you know what the intention is from that.” [PWH/FGD participant]</p>	<ul style="list-style-type: none"> <li>No changes were made</li> </ul>

**Table 2** (continued)

Sub-theme	Feedback	Illustrative Quote	Changes
III. Education section			
Sustaining attention	<ul style="list-style-type: none"> <li>Both providers and FGD participants expressed concern that participants would have difficulty sustaining attention throughout the entire first session, including during the educational content</li> </ul>	<p>“Because a lot of people, at least a lot of the patients that I know, will tune out after—after reading a few sentences.” [Provider/IDI Participant]</p>	<ul style="list-style-type: none"> <li>We reduced the length of the first call by including a sixth session</li> <li>We changed the format of the education section to be more conversational by asking about participants’ knowledge of a topic prior to providing an explanation or definition</li> </ul>
Additional education	<ul style="list-style-type: none"> <li>FGD participants and providers requested several additional educational components, including but not limited to: more education on STIs, self-care, medication adherence, and interactive toxicity beliefs</li> </ul>	<p>“And teaching over and over and over is something we always do especially about HIV, and you know, the goal is to take your medication every day. Don’t miss any doses. The importance of the possibility they can develop a resistance to the ER if they do miss doses, the importance of regular pharmacy refills, we don’t want any interruption in treatment.” [Provider/IDI participant]</p>	<ul style="list-style-type: none"> <li>We formatted the educational content as bullet points and interventionists were trained to use a teach-back method to facilitate comprehension</li> <li>To prevent substantially increasing the length of the education section, or extending beyond the scope of this intervention, we added the following:             <ul style="list-style-type: none"> <li>Brief education on other STIs and how mindfulness-based skills can be useful for other areas of one’s life (e.g., managing stress)</li> <li>A footnote containing references regarding interactive toxicity beliefs was added to the treatment manual</li> </ul> </li> </ul>
Standard drink explanation	<ul style="list-style-type: none"> <li>FGD participants requested more concrete examples during the explanation of a standard drink</li> </ul>	<p>“I would like to see the alcohol ounces be more relatable.” [PWH/FGD participant]</p>	<ul style="list-style-type: none"> <li>Interventionists now use a handout that provides concrete comparisons of a standard drink to commonly consumed containers of alcohol (e.g., red solo cup, bottle of wine)</li> </ul>
IV. 80 <sup>th</sup> birthday exercise			
80 is too old	<ul style="list-style-type: none"> <li>Several FGD participants and providers noted that it may be challenging for participants to fantasize about their 80<sup>th</sup> birthday given their HIV status and other health-related comorbidities</li> </ul>	<p>“Yeah, I’m thinking 80 years old might as well be a kingdom. It’s not even a fantasy of mine.” [PWH/FGD participant]</p> <p>“80 is a milestone within itself.” [PWH/FGD participant]</p>	<ul style="list-style-type: none"> <li>We slightly modified the exercise by asking participants to think about any celebration of their life, such as an 80<sup>th</sup> birthday party or retirement party</li> </ul>
Too personal too soon	<ul style="list-style-type: none"> <li>Some FGD participants expressed concern that the 80<sup>th</sup> birthday exercise was too personal for the first phone session</li> </ul>	<p>“Yes, it’s too much. Picture like this, your first call is you’re dealing with an infant. You’re trying to shove a hamburger down his throat. Just feed him liquids right now. So they could absorb the meat when it gets to the meat time. [PWH/FGD participant]</p>	<ul style="list-style-type: none"> <li>We moved this exercise to the second phone session to allow for more rapport-building prior to introduction of the activity</li> </ul>

Table 2 (continued)

Sub-theme	Feedback	Illustrative Quote	Changes
V. ABCs/Self-Monitoring			
“Antecedent”	<ul style="list-style-type: none"> <li>• A majority of FGD participants and providers disliked the term “antecedent” as it was considered too academic and not commonly known to this population</li> </ul>	<p>“Well, I don’t like the word antecedent, even though I know what it means but I don’t think that’s a common word for most people. So I just don’t like it.” [PWH/FGD participant]</p>	<ul style="list-style-type: none"> <li>• We replaced the term “antecedent” with “Any thought, feeling, or situation that occurs before your drink.”</li> <li>• This modification allowed us to maintain the acronym ABCs while providing a clearer description of the self-monitoring activity</li> </ul>
Self-monitoring phone app	<ul style="list-style-type: none"> <li>• Both FGD participants and providers expressed interest in the use of a phone-based app as an option for collecting self-monitoring data</li> </ul>	<p>“I think some people would have an easier time doing it on their phone or computer.” [PWH/FGD participant]</p> <p>“You can put an app in there and would be better or at the bar. I can whip my phone out.” [PWH/FGD participant]</p>	<ul style="list-style-type: none"> <li>• We tested an app in which participants could input what happens before, during, and after they drink, however further development of the app was considered beyond the scope of the developmental grant</li> </ul>
VI. Quicksand metaphor			
Overall impression	<ul style="list-style-type: none"> <li>• This metaphor was generally well-received by both FGD participants and providers</li> </ul>	<p>“I think it’s good. People understand it. It’s very relatable. Some people they feel like their life they’ll even say it’s like quicksand. Things just start happening and I try to fight it, and it gets worse. So, I think it will be very relatable to people.” [Provider/IDI participant]</p>	<ul style="list-style-type: none"> <li>• We did not make any changes to the exercise except moving it to the third session to reduce the length of the first session</li> </ul>

FGD focus group discussion, IDI in depth interview, PWH person with HIV

intervention manual is outlined in Table 2. Briefly, (1) the educational section was shortened, the 80th birthday exercise was moved to the 2nd session, the Quicksand metaphor was moved to the 3rd session, and “check-ins” to assess for understanding and sustained attention were incorporated throughout the intervention; (2) additional rapport-building was added to the beginning of the first session by asking participants to briefly share about themselves; (3) an inclusion criterion related to literacy level (8th grade level) was added, and all workbook content was reviewed to align with an 8th grade literacy level; (4) several terms (i.e., antecedent) were replaced with more colloquial language (i.e., any thought, feeling, or situation); (5) alternative metaphors and exercises were added throughout the manual in the event that a participant finds an activity emotionally overwhelming or unrelatable; (6) brief education about how mindfulness-based skills can be applied to other areas of one’s life (e.g., physical comorbidities) was added; and (7) interventionists were trained on how to tailor the intervention to participants using basic MI skills (e.g., summarizing, reflections). SWK incorporated these changes into a final adapted intervention manual, distributed it to the team, and the adaptation process moved on to Step 7. A session-by-session overview of the final manual is presented in Table 3.

#### Step 7: Protocol for Training Accept Interventionists

We adopted a “train-the-trainer” approach, which has been recognized as a useful method of disseminating and implementing evidence-based psychological treatments—allowing the trainer to develop supervisory skills that permit ongoing use of the intervention in new contexts [41] SWK participated in a two-day training with JB and two clinical psychologists trained in ACT. SWK read “The Happiness Trap” [64] and “ACT Made Simple” [65] prior to the in-person training, in addition to familiarizing herself with the TALK intervention manual. At the training, SWK participated in a series of role-plays such that she took turns acting as both the participant *and* the interventionist for each of the 5-sessions of the TALK intervention. After each role-play, which were observed by JB and the two ACT-trained psychologists, SWK was given feedback and encouraged to share her own observations. Once SWK had successfully role-played all sessions, as both an interventionist and a participant, at a level of competency deemed satisfactory by JB and his team, she was considered trained and subsequently became the primary ACT trainer and supervisor for the ACCEPT interventionists. ACCEPT interventionists are all Masters-level PhD students in a clinical psychology program. To be trained for ACCEPT, each interventionist has to participate in a multi-day workshop modeled after SWK’s training with JB. Interventionists are required to read the “The Happiness Trap” and “ACT Made Simple”, in addition

to the ACCEPT intervention manual. Subsequently, the interventionists are required to role-play each session of the ACCEPT intervention with SWK, once as a mock participant, and once as an interventionist. The entire training, not including the readings, takes approximately six hours. Once trained, ACCEPT interventionists are required to participate in one hour per week of group supervision, led by SWK and SAM, for the duration of their tenure on the ACCEPT trial. In group supervision, audio of the intervention sessions is reviewed and discussed, as well as any practical issues in the delivery of the ACCEPT manual.

#### Step 8: Development of Standardized Operating Procedures for a Feasibility and Acceptability RCT of Accept

The final step of the adaptation process was to develop detailed standardized operating procedures (SOPs) for a pilot RCT designed to determine the feasibility and acceptability of the ACCEPT intervention ahead of a full-scale RCT. SOPs covered all relevant aspects of the execution of the RCT including (but not limited to): recruitment, screening, consent, scheduling, collection of self-report and biospecimen data, interventionist training and supervision, retention, and adverse events. SOPs were developed through an iterative process that involved multiple weekly team meetings, with input from RAs, project coordinators, and faculty Co-Investigators. Co-PIs SWK and SAM provided detailed feedback on the initial drafts of each SOP until a final laboratory manual was developed to train all study staff. The final manual is 74 pages, and includes 34 distinct SOPs, and 32 appendices. All study staff are required to read the entire lab manual as part of training, and to collect data from 1–2 mock research participants prior to the official onset of data collection. The manual is reviewed annually by the Co-PIs and the study staff to ensure accuracy and fidelity to procedures. Interim concerns are discussed during weekly lab meetings with the research team, with changes made on an as-needed basis. The lab manual will serve as the basis for the implementation of the pilot and eventual full-scale RCT.

## Discussion

We successfully adapted a telephone-delivered ACT-based treatment for PWH who are hazardous drinkers. Using the ADAPT-ITT model, we implemented the adaptation process in several structured phases that included multidisciplinary team meetings, feedback from key stakeholders, and iterative changes responsive to both. As a result, we have a standard treatment manual that will ultimately be used in a full-scale RCT designed to test the efficacy of the adapted ACT intervention. We also formalized procedures for training

**Table 3** Session-by-session overview of final ACCEPT intervention

Intro	Metaphor ( <i>Alternative</i> )	Education	Skill	Action plan	Closing
Session #1: Intro, Alcohol & HIV Ed, Self-monitoring	Car journey ( <i>The sailing boat</i> )	Alcohol & HIV education	Self-monitoring	<ul style="list-style-type: none"> <li>Self-monitor over next week</li> </ul>	<ul style="list-style-type: none"> <li>Summary, preview call #2</li> <li>Confirm time/date of next call</li> <li>Thank person</li> </ul>
Session #2: Values	Celebration of Life ( <i>Writing your autobiography</i> )	Values vs Goals	Take 3 Breaths	<ul style="list-style-type: none"> <li>Self-monitor over next week</li> <li>Practice 3 breaths</li> <li>Review values</li> </ul>	<ul style="list-style-type: none"> <li>Summary, preview call #3</li> <li>Confirm time/date of next call</li> <li>Thank person</li> </ul>
Session #3: Acceptance	Quicksand ( <i>Crying baby on a plane</i> )	What is creative hopelessness?	Pause-Allow-Take a step forward (PAT)	<ul style="list-style-type: none"> <li>Self-monitor over next week</li> <li>Practice PAT</li> </ul>	<ul style="list-style-type: none"> <li>Summary, preview call #4</li> <li>Confirm time/date of next call</li> <li>Thank person</li> </ul>
Session #4: Defusion	Thoughts like radio playing in background ( <i>Master Storyteller</i> )	Concept of unhooking	Thoughts on a moving stream	<ul style="list-style-type: none"> <li>Self-monitor over next week</li> </ul>	<ul style="list-style-type: none"> <li>Summary, preview call #5</li> <li>Confirm time/date of next call</li> <li>Thank person</li> </ul>
Session #5: Self-compassion	Puppy ( <i>Child</i> )	Importance of self-care	I'm having the thought that List of things to comfort/care for self	<ul style="list-style-type: none"> <li>Practice thoughts on a stream and/or I'm having the thought that</li> <li>Self-monitor over next week</li> </ul>	<ul style="list-style-type: none"> <li>Summary, preview call #6</li> <li>Remind person the next is the final call</li> <li>Confirm time/date of next call</li> <li>Thank person</li> </ul>
Session #6: Acceptance, values, Wrap-up	Quicksand Thoughts like the weather Values as compass	Variable course of behavior change	Name favorite tools from the program to keep practicing	<ul style="list-style-type: none"> <li>Practice self-care</li> <li>Final action plan</li> </ul>	<ul style="list-style-type: none"> <li>Confirm time/date of next call</li> <li>Thank person</li> <li>Wrap-up</li> <li>Mutual goodbyes/thank yous/sharing impressions</li> <li>Remind of next study visit</li> </ul>

and supervision of interventionists, and protocols for RCT implementation. The results described in this manuscript provide a template for early phase behavioral RCTs and illustrate a way to increase transparency in reporting on the adaptation and efficacy testing of behavioral treatments for PWH.

There have been several efforts to increase transparency and rigor in reporting on the development and implementation of psychological and behavioral RCTs [66, 67]. Consistent with this movement, models such as ORBIT Model for Behavioral Treatments [53] and the Stage Model of Behavioral Therapies Research [68–70] have been developed to standardize and operationalize the behavioral treatment development process, from early phase developmental studies (Phases I–II) to efficacy (Phase III) and effectiveness (Phase IV) RCTs. These models suggest that early phase studies include: the specification of a hypothesized pathway by which an intervention could solve a clinical problem, the adaptation or development of an intervention and an associated training manual, the determination of mode and frequency of intervention delivery, development of a training and supervision program for study clinicians, development and piloting of standardized operating procedures for the efficacy trial, and eventual demonstration of feasibility and acceptability. We used the ADAPT-ITT model to further standardize and guide the intervention adaptation process and development of the adapted intervention manual. Implementing the suggestions of these models, and reporting on this process in peer-reviewed publications, is consistent with the movement to increase reproducibility in NIH-funded clinical research [71], and adds to the growing literature on the development of alcohol interventions for PWH.

## Strengths and Limitations

The ACCEPT intervention, and the process by which it was developed, has several strengths. First, our decision to adapt an existing intervention, rather than develop one from the ground up, allowed us to leverage Bricker et al.'s innovative work on a novel treatment with high potential to reduce alcohol use among PWH. Doing so accelerated the process by which we could move through the phases described in the ORBIT and Stage Models of Behavioral Therapies Research. Second, the telephone-delivered format of the TALK intervention provided evidence that the intervention could be successfully delivered via telephone. The ACCEPT intervention could therefore be developed as a telehealth intervention, increasing the likelihood that, if efficacious, it can be feasibly integrated into HIV care settings. The COVID-19 pandemic has significantly increased the use of telemedicine in health care, expanding the provision of psychological services to those who would otherwise

be unable to access them [72]. Telehealth-delivered mental and behavioral health care may be a particularly novel and useful tool for PWH given that HIV clinics often serve large geographic areas with highly diverse patient populations who have a wide range of psychosocial barriers to accessing care [73, 74]. Third, while the ACCEPT intervention was designed to target alcohol use, the skills and mechanisms by which it is hypothesized to do so underlie a wide range of psychological and behavioral health concerns. ACCEPT thus has the potential to be flexibly applied to patient populations, such as PWH, who present with diverse psychosocial and mental health needs.

We also acknowledge some limitations. First, the patients and providers included in Step 5 were from a single HIV clinic in a medium-sized city in Central New York. While valuable, the feedback provided about the ACCEPT intervention is restricted to a small sample from a relatively small HIV clinic in the Northeastern United States, that was composed predominately of Black, cis-gendered men. While we do not expect issues with generalizability in the skills, metaphors, and activities included in the intervention, it is possible that regional variability in contextual factors such as HIV-related stigma and access to HIV-related services could affect participant's willingness and/or ability to engage with intervention content. It is also possible that transgender individuals living with HIV, and cis-gender women living with HIV, may have reactions to intervention content that were not represented in our formative work. Regarding this limitation, the feasibility/acceptability RCT recruited participants from the entire U.S., and as part of this trial we are soliciting additional feedback about intervention content. We will thus be able to review and integrate feedback from a larger and more diverse group of PWH prior to implementation of the full-scale efficacy trial. Second, given the time constraints associated with the IDIs and FGDs, we were only able to role-play a proportion of the experiential exercises and metaphors from the ACCEPT manual. We were thus unable to solicit feedback on the entire manual. Future studies using the ADAPT-ITT model could hold a series of FGDs, each of which is designed to solicit feedback on a different section of the treatment manual, thereby ensuring that feedback is received on the entire intervention. We will also be able to partially address this limitation via the pilot RCT in which intervention participants who have received all six sessions will be asked to comment on their overall experience of the intervention.

## Conclusion

ACT is a novel and promising transdiagnostic treatment for alcohol use. Using the ADAPT-ITT model, an existing brief, telephone-delivered, ACT intervention developed for

smoking cessation was successfully adapted for PWH who drink at hazardous levels. An ongoing pilot RCT will formally determine feasibility and acceptability of the ACCEPT intervention, and a planned Phase III RCT will determine the relative efficacy of ACCEPT compared to an existing brief alcohol intervention already shown to be efficacious for PWH [75]. The procedures described here are an example of how to apply the models that have been developed to increase transparency, rigor, and reproducibility in behavioral RCT research.

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## Declarations

**Conflict of interest** The authors declare they have no conflicts of interest.

**Informed Consent** Informed consent was obtained from all individual participants included in the study.

## References

- Crane HM, McCaul ME, Chander G, et al. Prevalence and factors associated with hazardous alcohol use among persons living with HIV across the US in the current era of antiretroviral treatment. *AIDS Behav.* 2017;21(7):1914–25. <https://doi.org/10.1007/s10461-017-1740-7>.
- Ferguson TF, Theall KP, Brashear M, et al. Comprehensive assessment of alcohol consumption in people living with HIV (PLWH): the new orleans alcohol use in HIV study. *Alcohol Clin Exp Res.* 2020;44(6):1261–72. <https://doi.org/10.1111/acer.14336>.
- Duko B, Ayalew M, Ayano G. The prevalence of alcohol use disorders among people living with HIV/AIDS: a systematic review and meta-analysis. *Subst Abuse Treat Prev Policy.* 2019;14(1):52. <https://doi.org/10.1186/s13011-019-0240-3>.
- Justice AC, McGinnis KA, Tate JP, et al. Risk of mortality and physiologic injury evident with lower alcohol exposure among HIV infected compared with uninfected men. *Drug Alcohol Depend.* 2016;161:95–103. <https://doi.org/10.1016/j.drugalcdep.2016.01.017>.
- Cook RL, Zhou Z, Kelso-Chichetto NE, et al. Alcohol consumption patterns and HIV viral suppression among persons receiving HIV care in Florida: an observational study. *Addict Sci Clin Pract.* 2017. <https://doi.org/10.1186/s13722-017-0090-0>.
- Williams EC, McGinnis KA, Edelman EJ, et al. Level of alcohol use associated with HIV care continuum targets in a National US Sample of Persons Living with HIV Receiving Healthcare. *AIDS Behav.* 2019;23(1):140–51.
- Cook RL, Sereika SM, Hunt SC, Woodward WC, Erlen JA, Conigliaro J. Problem drinking and medication adherence among persons with HIV infection. *J Gen Intern Med.* 2001;16(2):83–8. <https://doi.org/10.1111/j.1525-1497.2001.00122.x>.
- Woolf-King SE, Sheinfl AZ, Ramos J, et al. A conceptual model of alcohol use and adherence to antiretroviral therapy: systematic review and theoretical implications for mechanisms of action. *Health Psychol Rev.* 2020. <https://doi.org/10.1080/17437199.2020.1806722>.
- Rehm J, Probst C, Shield KD, Shuper PA. Does alcohol use have a causal effect on HIV incidence and disease progression? A review of the literature and a modeling strategy for quantifying the effect. *Popul Health Metr.* 2017;15(1):4. <https://doi.org/10.1186/s12963-017-0121-9>.
- Samet JH, Walley AY. Interventions targeting HIV-infected risky drinkers: drops in the bottle. *Alcohol Res Health J Natl Inst Alcohol Abuse Alcohol.* 2010;33(3):267–79.
- Wang N, Sun X, Yin L, et al. Meta-analysis of interventions for reducing number of sexual partners and drug and alcohol abuse among people living with HIV/AIDS. *J AIDS Clin Res.* 2013. <https://doi.org/10.4172/2155-6113.1000213>.
- Brown JL, DeMartini KS, Sales JM, Swartzendruber AL, DiClemente RJ. Interventions to reduce alcohol use AMONG HIV-infected individuals: a review and critique of the literature. *Curr HIV/AIDS Rep.* 2013. <https://doi.org/10.1007/s11904-013-0174-8>.
- Scott-Sheldon LAJ, Carey KB, Johnson BT, Carey MP. Behavioral interventions targeting alcohol use among people living with HIV/AIDS: a systematic review and meta-analysis. *AIDS Behav.* 2017. <https://doi.org/10.1007/s10461-017-1886-3>.
- Madhombiro M, Musekiwa A, January J, Chingono A, Abas M, Seedat S. Psychological interventions for alcohol use disorders in people living with HIV/AIDS: a systematic review. *Syst Rev.* 2019;8(1):244. <https://doi.org/10.1186/s13643-019-1176-4>.
- Chaudhury S, Bakhla AK, Saini R. Prevalence, impact, and management of depression and anxiety in patients with HIV: a review. *Neurobehav HIV Med.* 2016;7:15–30. <https://doi.org/10.2147/NBHIV.S68956>.
- Cook JA, Burke-Miller JK, Steigman PJ, et al. Prevalence, comorbidity, and correlates of psychiatric and substance use disorders and associations with HIV risk behaviors in a multisite cohort of women living with HIV. *AIDS Behav.* 2018;22(10):3141–54. <https://doi.org/10.1007/s10461-018-2051-3>.
- Dindo L, Van Liew JR, Arch JJ. Acceptance and commitment therapy: a transdiagnostic behavioral intervention for mental health and medical conditions. *Neurother J Am Soc Exp Neurother.* 2017;14(3):546–53. <https://doi.org/10.1007/s13311-017-0521-3>.
- Vujanovic AA, Meyer TD, Heads AM, Stotts AL, Villarreal YR, Schmitz JM. Cognitive-behavioral therapies for depression and substance use disorders: an overview of traditional, third-wave, and transdiagnostic approaches. *Am J Drug Alcohol Abuse.* 2017;43(4):402–15. <https://doi.org/10.1080/00952990.2016.1199697>.
- Kahl KG, Winter L, Schweiger U. The third wave of cognitive behavioural therapies: what is new and what is effective? *Curr Opin Psychiatry.* 2012;25(6):522–8. <https://doi.org/10.1097/YCO.0b013e328358e531>.
- Harris R. Embracing your demons: an overview of acceptance and commitment therapy. *Psychother Aust.* 2006;12(4):70.
- Blackledge JT, Hayes SC. Emotion regulation in acceptance and commitment therapy. *J Clin Psychol.* 2001;57(2):243–55. <https://doi.org/10.1080/08931160108839222>.

- [doi.org/10.1002/1097-4679\(200102\)57:2%3c243::aid-jclp9%3e3.0.co;2-x](https://doi.org/10.1002/1097-4679(200102)57:2%3c243::aid-jclp9%3e3.0.co;2-x).
22. Gloster AT, Walder N, Levin ME, Twohig MP, Karekla M. The empirical status of acceptance and commitment therapy: a review of meta-analyses. *J Context Behav Sci.* 2020;18:181–92. <https://doi.org/10.1016/j.jcbs.2020.09.009>.
  23. Powers MB, Vörding MBZVS, Emmelkamp PMG. Acceptance and commitment therapy: a meta-analytic review. *Psychother Psychosom.* 2009;78(2):73–80.
  24. Hacker T, Stone P, MacBeth A. Acceptance and commitment therapy – Do we know enough? Cumulative and sequential meta-analyses of randomized controlled trials. *J Affect Disord.* 2016;190:551–65. <https://doi.org/10.1016/j.jad.2015.10.053>.
  25. Brown M, Glendenning AC, Hoon AE, John A. Effectiveness of web-delivered acceptance and commitment therapy in relation to mental health and well-being: a systematic review and meta-analysis. *J Med Internet Res.* 2016;18(8):e6200. <https://doi.org/10.2196/jmir.6200>.
  26. Spijkerman MPJ, Pots WTM, Bohlmeijer ET. Effectiveness of online mindfulness-based interventions in improving mental health: a review and meta-analysis of randomised controlled trials. *Clin Psychol Rev.* 2016;45:102–14. <https://doi.org/10.1016/j.cpr.2016.03.009>.
  27. Veehof MM, Trompetter HR, Bohlmeijer ET, Schreurs KMG. Acceptance- and mindfulness-based interventions for the treatment of chronic pain: a meta-analytic review. *Cogn Behav Ther.* 2016;45(1):5–31. <https://doi.org/10.1080/16506073.2015.1098724>.
  28. French K, Golijani-Moghaddam N, Schröder T. What is the evidence for the efficacy of self-help acceptance and commitment therapy? A systematic review and meta-analysis. *J Context Behav Sci.* 2017;6(4):360–74. <https://doi.org/10.1016/j.jcbs.2017.08.002>.
  29. Hughes LS, Clark J, Colclough JA, Dale E, McMillan D. Acceptance and commitment therapy (ACT) for chronic pain: a systematic review and meta-analyses. *Clin J Pain.* 2017;33(6):552–68. <https://doi.org/10.1097/AJP.0000000000000425>.
  30. Reeve A, Tickle A, Moghaddam N. Are acceptance and commitment therapy-based interventions effective for reducing burn-out in direct-care staff? A systematic review and meta-analysis. *Ment Health Rev J.* 2018;23(3):131–55. <https://doi.org/10.1108/MHRJ-11-2017-0052>.
  31. Ruiz FJ. Acceptance and commitment therapy versus traditional cognitive behavioral therapy: a systematic review and meta-analysis of current empirical evidence. *Int J Psychol Psychol Ther.* 2012;12(3):333–57.
  32. Bluett EJ, Homan KJ, Morrison KL, Levin ME, Twohig MP. Acceptance and commitment therapy for anxiety and OCD spectrum disorders: an empirical review. *J Anxiety Disord.* 2014;28(6):612–24. <https://doi.org/10.1016/j.janxdis.2014.06.008>.
  33. Veehof MM, Oskam MJ, Schreurs KMG, Bohlmeijer ET. Acceptance-based interventions for the treatment of chronic pain: a systematic review and meta-analysis. *Pain.* 2011;152(3):533–42. <https://doi.org/10.1016/j.pain.2010.11.002>.
  34. Tjak AJGL, Davis ML, Morina N, Powers MB, Smits JAJ, Emmelkamp PMG. A meta-analysis of the efficacy of acceptance and commitment therapy for clinically relevant mental and physical health problems. *Psychother Psychosom.* 2015;84(1):30–6.
  35. Lee EB, An W, Levin ME, Twohig MP. An initial meta-analysis of acceptance and commitment therapy for treating substance use disorders. *Drug Alcohol Depend.* 2015;155:1–7. <https://doi.org/10.1016/j.drugalcdep.2015.08.004>.
  36. Ii T, Sato H, Watanabe N, et al. Psychological flexibility-based interventions versus first-line psychosocial interventions for substance use disorders: Systematic review and meta-analyses of randomized controlled trials. *J Context Behav Sci.* 2019;13:109–20. <https://doi.org/10.1016/j.jcbs.2019.07.003>.
  37. Linardon J, Gleeson J, Yap K, Murphy K, Brennan L. Meta-analysis of the effects of third-wave behavioural interventions on disordered eating and body image concerns: implications for eating disorder prevention. *Cogn Behav Ther.* 2019;48(1):15–38. <https://doi.org/10.1080/16506073.2018.1517389>.
  38. Tonarelli S, Pasillas R. Acceptance and Commitment Therapy Compared to Treatment as Usual in Psychosis: A Systematic Review and Meta-Analysis. *J Psychiatry.* 2016;19. doi:<https://doi.org/10.4172/2378-5756.1000366>
  39. Ost LG. The efficacy of acceptance and commitment therapy: an updated systematic review and meta-analysis. *Behav Res Ther.* 2014;61:105–21. <https://doi.org/10.1016/j.brat.2014.07.018>.
  40. Bricker JB, Watson NL, Mull KE, Sullivan BM, Heffner JL. Efficacy of smartphone applications for smoking cessation: a randomized clinical trial. *JAMA Intern Med.* 2020;180(11):1472–80. <https://doi.org/10.1001/jamainternmed.2020.4055>.
  41. Bricker JB, Bush T, Zbikowski SM, Mercer LD, Heffner JL. Randomized trial of telephone-delivered acceptance and commitment therapy versus cognitive behavioral therapy for smoking cessation: a pilot study. *Nicotine Tob Res Off J Soc Res Nicotine Tob.* 2014;16(11):1446–54. <https://doi.org/10.1093/ntr/ntu102>.
  42. Bricker J, Wyszynski C, Comstock B, Heffner JL. Pilot randomized controlled trial of web-based acceptance and commitment therapy for smoking cessation. *Nicotine Tob Res Off J Soc Res Nicotine Tob.* 2013;15(10):1756–64. <https://doi.org/10.1093/ntr/ntt056>.
  43. Jones HA, Heffner JL, Mercer L, Wyszynski CM, Vilardaga R, Bricker JB. Web-based acceptance and commitment therapy smoking cessation treatment for smokers with depressive symptoms. *J Dual Diagn.* 2015;11(1):56–62. <https://doi.org/10.1080/15504263.2014.992588>.
  44. Thekiso TB, Murphy P, Milnes J, Lambe K, Curtin A, Farren CK. Acceptance and commitment therapy in the treatment of alcohol use disorder and comorbid affective disorder: a pilot matched control trial. *Behav Ther.* 2015;46(6):717–28. <https://doi.org/10.1016/j.beth.2015.05.005>.
  45. Petersen CL, Zettle RD. Treating inpatients with comorbid depression and alcohol use disorders: a comparison of acceptance and commitment therapy versus treatment as usual. *Psychol Rec.* 2009;59(4):521–36. <https://doi.org/10.1007/BF03395679>.
  46. Byrne SP, Haber P, Baillie A, Costa DSJ, Fogliati V, Morley K. Systematic reviews of mindfulness and acceptance and commitment therapy for alcohol use disorder: should we be using third wave therapies? *Alcohol Alcohol.* 2019;54(2):159–66. <https://doi.org/10.1093/alcac/agy089>.
  47. Harvey ST, Henricksen A, Bimler D, Dickson D. Addressing anger, stress, and alcohol-related difficulties in the military: an ACT intervention. *Mil Psychol.* 2017;29(5):464–76. <https://doi.org/10.1037/mil0000173>.
  48. Meyer EC, Walser R, Hermann B, et al. Acceptance and commitment therapy for co-occurring posttraumatic stress disorder and alcohol use disorders in veterans: pilot treatment outcomes. *J Trauma Stress.* 2018;31(5):781–9. <https://doi.org/10.1002/jts.22322>.
  49. George B, Guzman RGD. Effectiveness of acceptance and commitment therapy based intervention program (ACTP) on perceived stress and emotion regulation among alcoholics in Kerala, India. Published online. 2015. <https://doi.org/10.15614/IJPP/2015/V611/88437>.
  50. Stappenbeck CA, Luterek JA, Kaysen D, Rosenthal CF, Gurrad B, Simpson TL. A controlled examination of two coping skills for daily alcohol use and PTSD symptom severity among dually diagnosed individuals. *Behav Res Ther.* 2015;66:8–17. <https://doi.org/10.1016/j.brat.2014.12.013>.

51. McCallion EA, Zvolensky MJ. Acceptance and commitment therapy (ACT) for smoking cessation: a synthesis. *Curr Opin Psychol*. 2015;2:47–51. <https://doi.org/10.1016/j.copsyc.2015.02.005>.
52. McKleroy VS, Galbraith JS, Cummings B, et al. Adapting evidence-based behavioral interventions for new settings and target populations. *AIDS Educ Prev Off Publ Int Soc AIDS Educ*. 2006. <https://doi.org/10.1521/aeap.2006.18.supp.59>.
53. Czajkowski SM, Powell LH, Adler N, et al. From ideas to efficacy: the orbit model for developing behavioral treatments for chronic diseases. *Health Psychol Off J Div Health Psychol Am Psychol Assoc*. 2015;34(10):971–82. <https://doi.org/10.1037/hea0000161>.
54. Onken LS, Carroll KM, Shoham V, Cuthbert BN, Riddle M. Reenvisioning clinical science: unifying the discipline to improve the public health. *Clin Psychol Sci J Assoc Psychol Sci*. 2014;2(1):22–34. <https://doi.org/10.1177/2167702613497932>.
55. Wingood GM, DiClemente RJ. The ADAPT-ITT model: a novel method of adapting evidence-based HIV Interventions. *J Acquir Immune Defic Syndr*. 1999;2008(47 Suppl 1):S40-46. <https://doi.org/10.1097/QAI.0b013e3181605df1>.
56. Woolf-King SE, Sheinfl AZ, Babowich JD, Siedle-Khan B, Loitsch A, Maisto SA. Acceptance and commitment therapy (ACT) for HIV-infected hazardous drinkers: a qualitative study of acceptability. *Alcohol Treat Q*. 2019;37(3):342–58. <https://doi.org/10.1080/07347324.2018.1539630>.
57. Gonzalez A, Mimiaga MJ, Israel J, Andres Bedoya C, Safren SA. Substance use predictors of poor medication adherence: the role of substance use coping among HIV-infected patients in opioid dependence treatment. *AIDS Behav*. 2013;17(1):168–73. <https://doi.org/10.1007/s10461-012-0319-6>.
58. Batchelder AW, Foley JD, Wirtz MR, Mayer K, O’Cleirigh C. Substance use stigma, avoidance coping, and missed hiv appointments among MSM who use substances. *AIDS Behav*. 2021;25(5):1454–63. <https://doi.org/10.1007/s10461-020-02982-3>.
59. White JM, Gordon JR, Mimiaga MJ. The role of substance use and mental health problems in medication adherence among HIV-infected MSM. *LGBT Health*. 2014;1(4):319–22. <https://doi.org/10.1089/lgbt.2014.0020>.
60. Marlatt GA, Witkiewitz K. Update on harm-reduction policy and intervention research. *Annu Rev Clin Psychol*. 2010;6:591–606. <https://doi.org/10.1146/annurev.clinpsy.121208.131438>.
61. Miller WR, Rollnick S. *Motivational Interviewing: Helping People Change*. 3rd ed. New York: The Guilford Press; 2012.
62. Strauss SM, Rindskopf DM. Screening patients in busy hospital-based HIV care centers for hazardous and harmful drinking patterns: the identification of an optimal screening tool. *J Int Assoc Physicians AIDS Care Chic Ill*. 2009;8(6):347–53.
63. Braun V, Clarke V, Hayfield N, Terry G. Thematic Analysis. In: Liamputtong P, editor. *Handbook of Research Methods in Health Social Sciences*. New York: Springer; 2019. p. 843–60.
64. Harris R. *The Happiness Trap: How to Stop Struggling and Start Living: A Guide to ACT*. US: Shambhala Publications; 2008.
65. Harris R, Hayes S. *ACT Made Simple: An Easy-To-Read Primer on Acceptance and Commitment Therapy*. 1st ed. US: New Harbinger Publications; 2009.
66. Montgomery P, Grant S, Mayo-Wilson E, et al. Reporting randomised trials of social and psychological interventions: the CONSORT-SPI 2018 extension. *Trials*. 2018;19(1):407. <https://doi.org/10.1186/s13063-018-2733-1>.
67. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ*. 2014;348:g1687. <https://doi.org/10.1136/bmj.g1687>.
68. Rounsaville B, Carroll K, Onken L. A stage model of behavioral therapies research: getting started and moving on from stage I. *Clin Psychol Sci Pract*. 2001;8:133–42. <https://doi.org/10.1093/clipsy.8.2.133>.
69. Carroll KM, Rounsaville BJ. A vision of the next generation of behavioral therapies research in the addictions. *Addict Abingdon Engl*. 2007;102(6):850–69. <https://doi.org/10.1111/j.1360-0443.2007.01798.x>.
70. Onken LS, Blaine JD, Battjes RJ. Behavioral therapy research: A conceptualization of a process. In: *Innovative Approaches for Difficult-to-Treat Populations*. American Psychiatric Association; 1997: 477–485
71. Collins FS, Tabak LA. Policy: NIH plans to enhance reproducibility. *Nature*. 2014;505(7485):612–3. <https://doi.org/10.1038/505612a>.
72. Inchausti F, Macbeth A, Hasson-Ohayon I, Dimaggio G. Telepsychotherapy in the Age of COVID-19: a commentary. *J Psychother Integr*. 2020. <https://doi.org/10.1037/int0000222>.
73. Yehia BR, Stewart L, Momplaisir F, et al. Barriers and facilitators to patient retention in HIV care. *BMC Infect Dis*. 2015;15(1):246. <https://doi.org/10.1186/s12879-015-0990-0>.
74. Dombrowski JC, Simoni JM, Katz DA, Golden MR. Barriers to HIV care and treatment among participants in a public health HIV care relinkage program. *AIDS Patient Care STDs*. 2015;29(5):279–87. <https://doi.org/10.1089/apc.2014.0346>.
75. Chander G, Hutton HE, Lau B, Xu X, McCaul ME. Brief Intervention Decreases drinking frequency in hiv-infected, heavy drinking women: results of a randomized controlled trial. *J Acquir Immune Defic Syndr*. 2015;70(2):137–45.

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