

# Eliminating Racial/Ethnic Disparities in AIDS Clinical Trials in the United States: A Qualitative Exploration of an Efficacious Social/Behavioral Intervention

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## Abstract

**Background:** African American/Black and Hispanic persons living with HIV (AABH-PLWH) are under-represented in AIDS clinical trials (ACTs) in the United States. Barriers AABH-PLWH experience to ACTs are multi-faceted, including distrust of medical research, low levels of knowledge, unsupportive social norms, lack of referral, and challenges navigating ACT systems. In past research we found a multi-component peer-driven intervention was efficacious in boosting rates of screening for/enrollment into ACTs. The present qualitative study seeks to understand AABH-PLWH's perspectives on which specific intervention features or components had utility. Interventions features explored included structural elements (e.g., small group sessions, individual sessions on the ACT research unit); approaches (e.g., Motivational Interviewing); and specific components (e.g., small-group discussion of historical and cultural factors reducing participation among AABH-PLWH).

**Methods:** A total of 37 AABH-PLWH (mean age 50.6 years, SD=7.5 years; 48.6% female; 62.2% African American/Black, 27.0% Hispanic) were purposively selected from a larger study for in-depth interviews, which were audio-recorded, transcribed verbatim, and analyzed using systematic content analysis.

**Results:** We found the intervention improved knowledge and positive attitudes toward ACTs, and triggered social-level facilitators such as altruism and more positive social norms. Discussions of cultural/historical barriers to ACTs associated with race/ethnicity had utility. Holding a session on the ACT research unit reduced fear and increased motivation. Results highlighted the value of Motivational Interviewing, and several components were perceived as less useful (e.g., involving social network members in ACT decisions).

**Conclusion:** Findings can inform future intervention designs to address racial/ethnic disparities in ACTs and have implications for trials of other conditions where racial/ethnic disparities persist.

**Keywords:** Qualitative; Health disparities; AIDS clinical trials; Medical distrust; Race, African American; Hispanic; HIV

## Introduction

Clinical trials are central to the development of new treatments for HIV/AIDS [1,2]. Yet for decades in the United States, African American/Black and Hispanic persons living with HIV, referred to here as "AABH-PLWH," have been substantially under-represented in AIDS clinical trials (ACTs) compared to their White peers [3-6]. This under-representation of AABH-PLWH is a concern on several levels. First, it may reduce the generalizability of research findings to the groups most affected by HIV. Further, it denies AABH-PLWH equitable access to chances to contribute to and potentially benefit from participation in biomedical research [3,7,8]. Recently we demonstrated that a culturally appropriate, multi-component social/behavioral intervention called the ACT2 Project resulted in substantially higher rates of screening for and enrollment into ACTs compared to a control intervention comprised of health education and treatment as usual [9-11]. We found participants in the intervention arm were 30 times more likely to be screened for ACTs than controls (49.3% vs. 3.7%;  $p < 0.001$ ). Half (55.5%) of those screened were found eligible for ACTs, primarily observational studies, and 9 out of 10 found eligible enrolled (91.7%), compared to no enrollments among controls. The present qualitative study now seeks to advance our understanding of how barriers to ACT screening and enrollment can be ameliorated by exploring aspects of the ACT2 Project intervention, from the perspectives of AABH-PLWH participants themselves. Acronyms used in the present study are presented in Table 1.

AABH-PLWH faces complex barriers to accessing ACTs. The present study's approach to understanding such barriers, and addressing them in the ACT2 Project social/behavioral intervention, was grounded in the Theory of Triadic Influence (TTI) [12]. The TTI is a social-cognitive

AABH-PLWH	African American/Black and Hispanic persons living with HIV
ACT	AIDS clinical trials
CTRU	Clinical Trials Research Unit
HIV	Human Immunodeficiency Virus
MI	Motivational Interviewing
RDS	Respondent-Driven Sampling
TTI	Theory of Triadic Influence

Table 1: Acronyms used.

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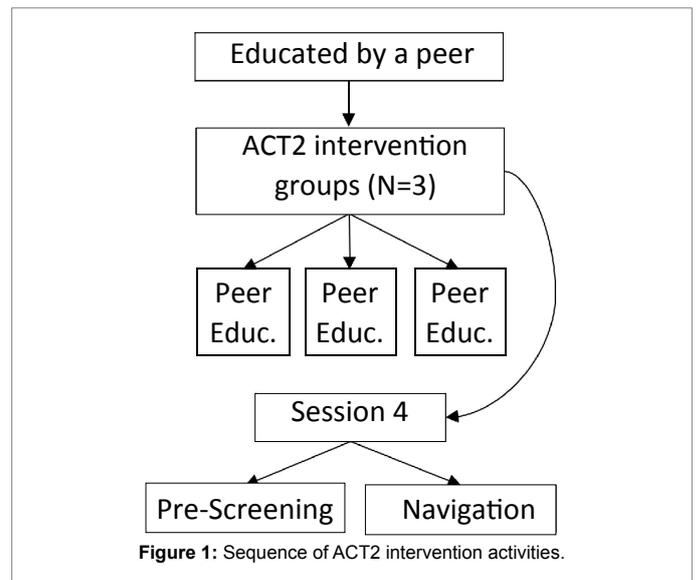
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theory that emphasizes three streams of influence on health outcomes: the individual/attitudinal, social, and structural. At the individual/attitudinal level of influence, the literature indicates barriers to ACTs among AABH-PLWH include insufficient knowledge of and low self-efficacy to manage ACT participation [6]. Substance use problems are another potential impediment. In fact, health care providers are understandably hesitant to refer individuals with substance use to ACTs, but there is great variability in PLWH's substance use patterns and many who use alcohol and drugs can adhere well to trial protocols [13]. Moreover, fear and distrust of trials are potent barriers [14], based on individual experiences of inequity in society at large, as well as maltreatment in medical establishments. Another barrier to ACTs is an awareness of adverse historical events in medical research involving populations of color – the Tuskegee Syphilis Study being the most well-known example of such abuses [15-19]. Further, the impact of collective memories regarding prior maltreatment of African American/Black and Hispanic populations in research resonates at the social level of influence by fostering social norms that discourage participation in biomedical research [20,21]. At the same time, AABH-PLWH report high levels of willingness to explore ACTs when invited to do so [7,11].

At the structural level of influence, AABH-PLWH are much less likely to be recruited for or referred to ACTs compared to their White peers [9], including by HIV/AIDS primary care providers, who are typically the main source of such referrals [3,22,23]. The physical location of clinical trials research units (CTRUs), commonly situated in neighborhoods that are distant from patients and located in unfamiliar formal hospital settings, can also serve as an impediment [4]. Further, the CTRU setting itself may be experienced as difficult to navigate [4,24]. Theoretically, these multi-level factors work together to reduce access to ACTs, as well as motivation to seek out or participate in ACTs when asked, among AABH-PLWH. In the next section we describe the efficacious ACT2 Project intervention designed to ameliorate these specific barriers to ACTs.

PLWH enter ACTs through a screening process to determine eligibility, comprised generally of a medical interview followed by medical testing as appropriate. Due to strict inclusion and exclusion criteria, only a minority of those screened will be found eligible for studies [25]. The main goals of the ACT2 Project intervention were to increase rates of screening for ACTs, in the context of these low eligibility rates, and enrollment into ACTs among those found eligible was examined as a secondary outcome. This primary focus on screening was based on the view that screening is a minimal-risk exchange that may yield indirect benefits to those who participate, such as enhanced knowledge and reduced fear and distrust of ACTs, as well as providing direct access to ACTs either at the time of screening, and/or in the future. Thus improving access to screening for ACTs among AABH-PLWH can play a crucial role in reducing racial/ethnic disparities in ACTs.

The ACT2 program was a peer-driven intervention [26] made up of the following main segments (Figure 1): 1) Participants first received education from a trained peer on 10 culturally appropriate “core messages” about ACTs, which addressed primary barriers to ACTs for this population (Table 2). These core messages were designed to begin a process among those receiving education of considering screening for an ACT, and also to influence the peer educators’ own motivation to screen for ACTs. This was followed by 2) 5.5 h of structured facilitated activities conducted in three small group sessions; 3) the opportunity to educate three of the participant’s own peers on the 10 core messages; 4) a single, brief individual session (30 min) located on the actual



**Figure 1:** Sequence of ACT2 intervention activities.

1. AIDS clinical trials study the newest treatments available.
2. Screening is just a discussion to see if an AIDS clinical trial is right for you.
3. Screening does not mean joining a trial.
4. AIDS clinical trials can treat other health problems such as Hepatitis C virus.
5. People who use drugs or alcohol can participate in AIDS clinical trials.
6. Even if you never took anti-HIV medications, AIDS clinical trials can still help you.
7. People who feel good still get screened for AIDS clinical trials.
8. You don't have to change your current treatment to participate in AIDS clinical trials.
9. Every year thousands of women and people of color join clinical trials.
10. More women and people of color are needed in AIDS clinical trials.

**Table 2:** Core intervention messages.

CTRU in a hospital setting where screening took place and, 5) for those interested in screening for ACTs, easy access to screening, and navigation services through the screening process. (Navigation is a low-threshold and individualized approach to addressing structural and personal barriers that arise in accessing HIV services [27].) Themes related to the 10 core messages were incorporated into the group and individual sessions, so these topics were repeated and expanded upon throughout the intervention. The intervention used Motivational Interviewing (MI), a goal-oriented, client-centered counseling style, as its main counseling approach. MI is designed to elicit behavior change by helping participants explore and resolve ambivalence [28]. Importantly, the MI approach elicits personal decision-making, with an emphasis on supporting autonomy, by not imposing goals or applying pressure or judgment.

Holding an intervention session at the CTRU site was a strategy to help participants overcome structural barriers to ACTs, such as difficulty locating or logistically negotiating the CTRU appointment processes, and to reduce fear of the CRTU setting. Participants received modest compensation for engagement in study activities (~\$25/session). As we describe in more detail elsewhere [29], the ACT2 Project intervention was innovative in directly introducing and fostering exploration of the specific reasons why AABH-PLWH are under-represented in ACTs. In short video components and facilitated exercises, participants were encouraged to discuss the complex historical, cultural, structural, and social factors that underlie the under-representation of AABH-PLWH in ACTs. These included historical factors such as the Tuskegee Syphilis Study, and present day experiences of discrimination and structural

racism [18], alongside rates of over-representation of people of color in the HIV epidemic in comparison to their proportions in the underlying general population [30] and their under-representation in ACTs. (The intervention curriculum is available from the second author.)

The aims of the present study were to explore participants' experiences in the social/behavioral intervention, to further elucidate impediments to ACTs for AABH-PLWH and how they can be overcome, including understanding whether initiating discussions of barriers associated with race/ethnicity and their historical and cultural underpinnings had positive or counter-productive effects, from the perspectives of AABH-PLWH.

## Methods

### Sample selection for the present study

Participants for the present qualitative study were drawn from a larger study of 540 adult PLWH, primarily from African American/Black and Hispanic backgrounds. The study recruited participants through respondent-driven sampling (RDS) [31] in New York City between June 2008 and April 2010. Participants who were found eligible were enrolled into a two-arm cluster randomized controlled trial (N=351 in an intervention arm, N=189 control arm) [11]. The qualitative study was designed to better understand participants' perceptions of the intervention components, thus the sample for the present study was drawn solely from the participants in the larger study's intervention arm. We sought to include participants representing the full range of ACT screening experiences, by including those who either did or did not agree to screen for ACT eligibility, those who were or were not found to be eligible, those who did or did not enroll in an ACT, as well as those who had not completed the screening/enrollment process at the time of the qualitative interviews. Participants were selected at random from computer-generated lists of those who either declined or attended screening using a random number generator prepared by the principal statistician. All participants randomly selected for inclusion in the present study agreed to participate in qualitative interviews. From among those in the intervention arm (N=351), there were four sampling categories. First we sampled a set of participants who declined screening (Category 1; 9 out of 153 participants who were not screened). Next from among those who attended screening (total N=198 had been screened), we enrolled those who completed screening but were not found eligible (Category 2; N=7); who completed screening, were found eligible, and who enrolled (Category 3; N=11); and who had not completed screening at the time of their qualitative interviews (Category 4; N=10) for a total of 37 participants. Procedures were approved by the Institutional Reviews Boards at New York University and the collaborating CTRU, and participants provided signed informed consent for activities.

### Procedure

Semi-structured face-to-face interviews were conducted at a study field site by one of three Master's level researchers trained in qualitative research methods. Interviews lasted 45–90 min and were audio-recorded and transcribed verbatim. The interviews followed a guide that explored barriers to ACTs and perspectives on aspects of the intervention. Specific questions and probes were linked to the theoretical model and to the primary areas hypothesized to be targets for behavior change (e.g., knowledge of ACTs, fear, distrust, willingness to participate in ACTs, self-efficacy, social norms, altruism, perceptions of CTRU staff, peer interactions, social support for participating in ACTs, and structural barriers to accessing the CTRU). Other questions

focused on the intervention's key characteristics (small group size, individual sessions, receiving or conducting peer education, direct introduction in the intervention curriculum of barriers associated with race/ethnicity, locations of meetings, navigation, the MI approach, and compensation). Participants received \$25 and fare for round-trip local public transportation for the qualitative interview. We conducted interviews until saturation of responses on core research questions was reached. Saturation was assessed by the senior research team while interviews were being conducted.

### Data analysis

We took a systematic content analysis approach to uncover both explicit and latent themes [32]. The three researchers who conducted the qualitative interviews also coded the transcribed interviews using ATLAS.ti [33]. First, we began with a "start list" of codes based on the study's theoretical model (e.g., fear, distrust, and motivation) and the intervention's key characteristics (e.g., small groups, peer education, and race/ethnicity). Then we randomly selected two transcripts from any of the four sampling categories described above, which the three researchers coded separately using this initial code universe. Codes were applied to sections of text that represented a discrete idea or phenomenon or that were meaningful with regards to the research questions, including emergent codes [34]. In order to evaluate and maintain inter-coder reliability, the coders met and compared each of their separately coded transcripts for discrepancies and similarities in coded blocks of text. Differences in coding were discussed until unanimous agreement was reached, and thus the meaning of codes was refined, along with the code list, as newly emergent codes were added. Once consensus was reached among the three analysts on a consolidated and final list of relevant codes, the main analyst re-visited interview transcripts coded at the beginning of the analysis to incorporate the final list of codes, and then coded the remaining transcripts. Then, when coding was complete, the larger multi-disciplinary analytic team (data analysts and senior research staff) shifted to an iterative analysis process, comprised of regular meetings to discuss codes, relationships among codes and their explicit and underlying, latent meanings, which are presented below as themes. In addition to the rigorous data collection and analysis procedures described above, methodological rigor of the qualitative data analysis was maintained through an audit trail of process and analytic memos, periodic debriefing with the research team, including experts in HIV care continuum issues [35].

## Results

### Description of the sample

As shown in Table 3, about half the sample was female (48.6%). Most were African American/Black (62.2%), 27% were Latino/Hispanic and 11% were White or bi- or multi-racial. Participants were 50.6 years of age, on average (SD=7.5 years). Approximately a quarter (24.3%) identified as lesbian, gay or bisexual. Approximately two-thirds (64.9%) had children, and almost a third (37.8%) were currently with a serious romantic partner. Almost all had medical insurance (91.9%). A minority (16.2%) was employed. With respect to health, most (65.8%) were on antiretroviral therapy, had an undetectable viral load level (75.0%) and were diagnosed with HIV 10 or more years prior (82.9%). Less than a third (27.0%) used drugs weekly or more, and alcohol (8.1%) and drug (8.1%) use problems in the recent period were uncommon. A total of 32.4% had injected drugs in the past and almost a third (29.7%) had been infected with the hepatitis C virus (HCV).

	Mean (SD) or %
<b>Sociodemographic characteristics</b>	
Female	48.6
Age in years (Mean, SD)	50.6 (7.5)
Aged 18-40 years	5.4
Aged 41-50 years	46.0
Aged ≥ 51 years	48.6
African American/Black	62.2
Hispanic/Latino	27.0
White/bi- or multi-racial	10.8
Non-heterosexual identity	24.3
Any biological or adopted children	64.9
Serious romantic partner or spouse	37.8
Medicaid recipient	91.9
Held a job past 3 months	16.2
<b>Health characteristics</b>	
Currently taking antiretroviral therapy	67.6
Undetectable viral load	75.0
HIV diagnosis ≥ 10 years	82.9
Drug use at least weekly in past 3 months	27.0
Alcohol problem in past 3 months	8.1
Drug problem in past 3 months	8.1
Ever injected drugs	32.4
Ever had Hepatitis C virus (HCV)	29.7

**Table 3:** Participant characteristics (N=37).

## Overview of results

Study findings illuminated the main barriers that AABH-PLWH experience to ACTs and the specific intervention components that contributed to their greater interest in and/or access to ACT screening. In keeping with ACT2 Project intervention as a multi-component program addressing complex topics, a substantial number of themes were found. First, participants reported meaningful improvements in knowledge of, and more positive feelings and attitudes toward, ACTs. Second, the introduction by the study of the potential role of race/ethnicity in HIV and ACT disparities was found useful. Third, changes in social-level factors such as altruism and perceived social norms were described as enhancing interest in ACTs. Fourth, introducing participants to the CTRU setting by holding a session on the unit reduced fear and increased motivation to screen. Last, as we describe below, several components were perceived as less salient. Throughout these themes, the utility of the MI approach as an important contributing factor to intervention efficacy was highlighted. We describe these findings in detail below.

## Changes in knowledge of, and feelings and attitudes toward, ACTs

We found that knowledge of, emotions regarding, and attitudes toward ACTs were closely entwined, whereby changes in knowledge of ACTs affected emotions and attitudes and vice versa. The fear of loss of autonomy if one became involved in ACT screening was a nearly universal theme. Specifically, participants commonly expressed fear of being used as a “guinea pig” in medical research; that is, fear of having something done to them without consent. Participants reported two aspects of the intervention served to reduce fears of ACTs. First, from the 10 core messages, those emphasizing personal choice during the screening process resonated strongly with participants (e.g., messages 2 and 3). Further, interactive exercises delivered during group sessions to address gaps in knowledge of the ACT screening process were useful, including that these exercises similarly highlighted material relevant to

the themes of participants’ autonomy and choice in the ACT screening process. Further, the repetition of core messages used in peer education in the context of the group intervention had utility. We found prior to the intervention, participants commonly believed that taking part in an ACT screening session would automatically result in their being enrolled into the clinical trial (possibly even against their will). This in many cases contributed to fear or avoidance of ACT screening due to concerns about a loss of autonomy. Thus we found that participants’ improved understanding of the steps involved in enrollment into ACTs (i.e., screening, determination of eligibility, enrollment), and the fact that their autonomy and choices would be respected throughout, served to allay concerns and increase motivation to explore ACT screening, as one participant noted:

*I learned that [laughs]...just because you go and get (screened), that it doesn't mean that you're in (a trial)...I figured that once you go there and you start talkin' to them, then it was like a binding contract...(I learned) I had more of a choice. [Male, 52 years old]*

Further, the MI approach used in the ACT2 Project intervention played a role in promoting this sense among participants that their autonomy and choices would be respected. Participants reported project staff did not apply pressure on them to decide one way or another about ACT screening during the intervention, consistent with the MI approach. Participants reported this lack of pressure or judgment promoted an open exploration of both the potential benefits and drawbacks of ACT screening. This, in turn, increased their feelings of trust in the ACT2 Project intervention and project staff, and the CTRU itself, as the following excerpt highlights.

*Then the (ACT2) staff, everybody I worked with was really good. There wasn't not one person that...I felt like was deceiving me or wasn't giving it to me straight...That's a big deal...Like all the staff, like they'll tell you point blank, this might be for you, it might not be for you, but you need to find out if it's for you, you know. If it's not for you, you know, no problem. [Female, 49 years old]*

We found that prompting participants to uncover and explore the range of beliefs regarding ACTs was a critical aspect of the intervention. Encouraging exploration of their feelings and attitudes toward ACTs, many of which were contradictory, was also critical. As one participant noted, “we got into the good, the bad, and the ugly,” regarding factors underlying under-representation in ACTs, as well as their potential benefits.

## Introducing the potential role race/ethnicity in ACT disparities

We found the components designed to foster discussion of the potential role of race/ethnicity in ACT disparities were a potent aspect of the intervention, although some found it uncomfortable, or even painful, to unpack. In particular, the component directly addressing the history of scientific ethical violations against African American/Black and Hispanic populations, such as those in the Tuskegee Syphilis Study, had particular resonance among participants. We found these intervention elements designed to uncover and unpack barriers to ACTs specific to AABH-PLWH reverberated powerfully with participants’ own personal life experiences in a variety of other settings. For example, these intervention elements typically resonated with participants’ own personal understandings of racism and other forms of inequality, with unequal access to health care cited as one example. Moreover, feelings of distrust of medical research, medical settings, medications, and the government were pervasive. We found a frank discussion among

participants of the role of race/ethnicity in ACT under-representation, including structural barriers such as poor access, served a number of important functions. It served to validate the “elephant in the room;” namely, the fact that AABH-PLWH have serious and legitimate reasons to avoid or otherwise evidence under-representation in ACTs. This, in turn, served as another means of building trust between participants and the research study, and also the CTRU. Typically, participants were hesitant to discuss fears, distrust, and “counter-narratives” (a less stigmatizing term for conspiracy theories) in the intervention sessions, but were eager to explore them when encouraged to do so by the intervention curriculum. Importantly, the intervention staff did not seek to dispel counter-narratives, but allowed the small group of participants to work through them and reach their own conclusions.

The following excerpt articulates this theme. (This participant’s personal perspective on the Tuskegee Syphilis Study differs from the historical record, but represents a view that was fairly common among participants.) Further, this quote highlights the important role of social norms regarding medical research and ACTs:

*From my experience and, you know, looking at the percentage wise that, that there’s not a lot, a lot of Blacks, people of color, joining the (studies). It’s because what happened in the past, you know, in the 1940s when they did that (study) with the syphilis they gave men. I mean, most of my friends who are Black and of color they always bring this up. Oh, the government is not to be trusted and this is why we don’t do (studies) and that’s how come the numbers are lacking. Because the government is not to be trusted. I mean, that’s their opinion, you know. So (my friends) try to brainwash me with it. [Male, 47 years old]*

While not seeking to discount the reasons why AABH-PLWH might avoid or distrust trials, the ACT2 Project intervention did include components to review the current state of participants’ rights of consent or refusal, and both voluntariness and protections of confidentiality in contemporary medical research. The curriculum noted that as a result of these protections, ethical violations are now quite rare in contemporary America compared to the past. Participants reported these intervention elements directly addressed a number of concerns that interfered with their interest in ACTs, another example of how closely linked knowledge, attitudes, and feelings about ACTs can be. As one participant said:

*You know bein’ Black...from going back to the days of the Tuskegee, you know we had those fears about that. Maybe subconsciously ya know? So when you hear about trials, that always pops up in my mind...Yeah, (the intervention helped) takin’ the fear out, ya know, taking apprehension out of participatin’ in ‘em you know. The (CTRU) had confidentiality forms and things and all that. They made sure we signed those ...and they told us that there’s a law you know (to protect confidentiality). Yeah, the confidentiality thing, I didn’t know about those you know. [Male, 60 years old]*

### **Changes in altruism and perceived social norms (Social-Level factors)**

Intervention components triggered a sense of altruism among participants, namely, a desire to aid their larger communities by participating in ACT screening. This desire boosted motivation to screen for ACTs and to participate in studies once found eligible. We found the ACT2 Project intervention component that directly addressed past research abuses directed against people of color, combined with a discussion of rates of their under-representation in ACTs as described above, fostered a belief that engagement in ACT

screening was a means of helping their communities; namely, “those (living with HIV) who came after them.” Some viewed participation in ACT screening as a potential means of promoting change in the current ACT system. The fact that participants experienced the intervention in conjunction with other PLWH contributed to this emergent desire to contribute to one’s community. We found group participants together developed a shared understanding of the extent to which people of color are over-represented in the HIV epidemic, as well as their rates of under-representation in ACTs [30]. Understanding the extent of such disparities was a powerful motivator of action, as one participant described:

*(I learned) there wasn’t too many women and minorities going through process of trials and stuff so there was no real information on what effects the virus has on minorities...(The ACT2 intervention) played a part in just clearing the air...‘Cause when I found out it was like [the facilitator] had said it was more than 70% of (women infected with HIV were) minorities...I’m like, oh my God, how do we stop this? [Female, 55 years old]*

We found that group sessions raised awareness of and addressed social norms regarding ACTs. Addressing these specific norms was not built into the ACT2 curriculum, but instead emerged from it. The most common social norms included a belief that participation in medical research is generally viewed unfavorably in African American/Black and Hispanic communities, that people of color are not wanted in medical research, and that African Americans/Blacks and Hispanics are typically treated as “guinea pigs” in medical research. We found these social norms emerged, and then were challenged and re-shaped, during the small group component of the intervention. These findings, therefore, provide support for the small group intervention modality, as well as these specific intervention elements.

### **Introducing participants to the CTRU setting**

We found the intervention components intended to help participants overcome structural barriers to ACTs did not resonate as strongly as others, with one exception: the brief intervention session held on the CTRU where screenings took place. This component was designed a means of helping participants locate and increase their comfort with the CTRU, and was experienced as a useful element. Participants reported being pleasantly surprised that the CTRU looked like a “regular” medical office, in contrast to their concerns that such a setting would be foreboding and intimidating. Participants were pleased to find CTRU staff to be pleasant and supportive. As one participant reported, she was relieved that CTRU staff did not “snatch (her) up and inject (her) with something,” reflecting a common fear of coercion or loss of autonomy. Another participant described her brief individual intervention session held on the CTRU:

*I went to see (the facilitator) for the last (intervention) session. And so what happened is when I was there, there’s a receptionist there, I can’t remember her name, she’s very nice, Black girl, she’s so sweet. She said, “You know...there’s a study going on where we pay ten dollars. The only thing it involves is drawing blood. And we use it for future DNA” or something like that. “And it’s only ten dollars.” And so I said, no problem, that’s okay. She said I seemed like a good candidate for it. She said we need one hundred vials and she mentioned that they were only up to like 19 or something like that at the time. So then when the nurse was taking out the blood, we just talked and this and that. And she said “you seemed like a good person to be involved with studies and all that. If something comes up can I call you?” [Male, 57 years old]*

Thus the quote above highlights an additional benefit of engagement

with a CTRU, namely, access to trials in the future, and an on-going relationship between the patient and CTRU.

### Components found less salient

A number of other intervention components were less salient for participants. These included exercises designed to encourage and train participants to enlist the support of health care providers and other social network members in ACT decisions. Results indicated participants were focused on their personal decisions regarding ACT screening, a low-risk activity, but did not feel the need to involve others. Moreover, as noted above, the intervention included navigation through the screening process to resolve structural and practical barriers to screening. We did not find that participants generally made direct reference to the navigation component, although they generally engaged in that component. Thus the component may have actually been useful to them, but not necessarily apparent. Last, peer education experiences were highly variable, with some participants doing little or no peer education, and others doing extensive education. In many cases peers were effective and credible teachers about ACTs, and the peer education encounter encouraged both the educator and the peer to explore the idea of ACTs, which they may not have done otherwise.

### Discussion

The low rates of enrollment of people of color in medical research are a national problem that affects clinical trials of the vast majority of diseases and conditions, including the very large number of cancer clinical trials [36]. The ACT2 Project intervention was the first social/behavioral intervention shown to increase rates of screening for and enrollment into ACTs among AABH-PLWH [11,13,29]. This paper advances what is known regarding how barriers to ACTs can be addressed for AABH-PLWH by uncovering and exploring which specific intervention components had the greatest potency, and how they operated, from the perspective of AABH-PLWH.

Ambivalence about participation in ACTs was common, where both fear of and willingness to explore ACTs was experienced simultaneously, alongside distrust of ACTs and the CTRU, and a desire to engage in ACTs as a means of helping others. In this context, the MI approach functioned as it was designed to in theory: it facilitated participants' abilities to recognize these contradictions and ambivalent feelings, and to express a range of positive, negative, and neutral opinions about ACTs. We found that uncovering and accepting these contradictions was a critical aspect of building high-quality, durable, intrinsic motivation to screen for ACTs among participants. The present study findings suggest this intrinsic motivation was critical to the intervention's effects. In fact, there is a growing awareness of the importance of self-determination, an accepted theoretical underpinning of MI, and intrinsic motivation in social/behavioral interventions [37].

Moreover, the "no pressure, no judgment" ethos of the intervention allowed participants with no intention of screening for ACTs to remain as valuable and respected members of the intervention groups. The MI approach appeared to foster participants' trust in the research project and CTRU system – a change in attitude that was profound for many and which boosted motivation to screen for ACTs. Past research has found MI to be effective with a range of racial/ethnic groups, but more effective with African American/Black populations than Whites [38]. This, combined with study participants' comfort with and perceptions of the utility of MI, suggests that MI may be an important component of the intervention examined in the present study. In fact, MI may be important for behavior change interventions for racial/ethnic minority

populations more generally, particularly when health care decisions trigger fear and distrust. Similarly, Cuffee et al. found that distrust is a powerful barrier to health care among persons not living with HIV and highlighted the importance of patient, physician and system approaches to increase "earned" trust [39]. Earned trust may, in turn, enhance existing interventions for promoting medication adherence.

The intervention component prompting a discussion of barriers to ACTs specific to AABH-PLWH, with an emphasis on the historical, cultural, and social causes of these barriers, had great meaning and potency. This is consistent with the literature in that we found participants were aware of historical ethical violations and abuses in research, but this awareness did not necessarily eradicate motivation to screen for ACTs [40]. We found participants valued the intervention component that directly addressed these past abuses, and that these elements resonated with their own personal understandings of racism and other forms of structural inequality. Indeed, medical distrust may stem in part from historical events, represented by the infamous Tuskegee Syphilis Study, but, perhaps more importantly, may be reinforced by present-day health system issues and discriminatory events [41]. Participants reported the approach taken in the intervention to directly acknowledge these historical ethical violations and individual perceptions of contemporary inequality served to reduce fear, built trust, and to allow individuals to overcome ambivalence, which thereby increased their interest in exploring ACT screening. These findings are consistent with approaches such as the anti-racist stance [42] and projects grounded in Critical Race Theory [43] that call for direct examination of the multi-level barriers to health related to racial/ethnic minority status.

A number of studies have described aspects of the CTRU setting that impede access to ACTs for racial/ethnic minority populations [44,45]. Some have highlighted the need for patient-friendly clinical trials systems to reduce pre-existing fear of ACTs and CTRUs, in order to help patients navigate clinical trials systems. Others emphasize the need for extra time and support to assist some patients to understand and feel comfortable with CTRUs and their procedures, including consent and confidentiality forms [7,36,46]. We found explanations of confidentiality protections provided in the intervention were experienced as important and reassuring. Perlman and colleagues (2014) found similar results in a study of African American/Black and Hispanic drug users and their perspectives on consent for genetic testing. Participants were highly uncomfortable with genetic testing when they felt pressured to do so, but expressed feeling much more comfortable with testing when rationales and confidentiality protections were explained [47]. Similarly, in the present study, participants benefited from reassurance that their autonomy to choose or decline ACT participation would be respected.

We found participants did not express a need for the navigation component nor did they articulate that it was valuable to them, yet they generally actively participated in it. However, participants reported the intervention session that helped them physically locate the CTRU was particularly helpful. Behavioral economic theory suggests having a mental image of the steps involved in taking an action can facilitate taking that action [48]. Thus this particular intervention component may have fostered this type of cognitive process, and played a role in boosting motivation to screen for ACTs.

### Limitations

One general limitation of this study is its purposive sampling method, which may limit its generalizability to the population of

AABH-PLWH as a whole. Yet purposive, rather than a random sampling method, is consistent with the goals of qualitative research, which aims for depth rather than breadth. Further, the sample selected included few younger PLWH, and only a small proportion not currently on antiretroviral therapy, gaps that future studies on this topic can address.

## Implications

The present study used qualitative interviews to better understand participants' attitudes toward and perceptions of a multicomponent social/behavioral intervention. Qualitative data such as individual interviews or focus groups can contribute important insights into how multicomponent interventions are experienced by participants and can help inform both intervention design and intervention modification or re-design [49]. Further, the present study highlights the important role that culturally appropriate social/behavioral interventions can play in boosting participation of AABH-PLWH in ACTs, although busy CTRUs will likely need additional partnerships and funding streams to implement such an intervention. Further, interventions targeting CTRUs and health care providers directly are needed. Although HIV is unique in some respects because it is more highly stigmatized than other health concerns [50], study findings likely have implications for other disease conditions where under-representation of African American/Black and Hispanic populations persists.

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## References

1. National Institute of Allergy and Infectious Diseases (2008) HIV infection in minority populations.
2. The AIDS Clinical Trials Group (2016) Our mission.
3. Gifford AL, Cunningham WE, Heslin KC, Andersen RM, Nakazono T, et al. (2002) Participation in research and access to experimental treatments by HIV-infected patients. *N Engl J Med* 346: 1373-1382.
4. Sullivan PS, McNaghten AD, Begley E, Hutchinson A, Cargill VA (2007) Enrollment of racial/ethnic minorities and women with HIV in clinical research studies of HIV medicines. *J Natl Med Assoc* 99: 242-250.
5. DeFreitas D (2010) Race and HIV clinical trial participation. *J Natl Med Assoc* 102: 493-499.
6. Castillo-Mancilla JR, Cohn SE, Krishnan S, Cespedes M, Floris-Moore M, et al. (2014) Minorities remain underrepresented in HIV/AIDS research despite access to clinical trials. *HIV Clin Trials* 15: 14-26.
7. Gwadz MV, Cylar K, Leonard NR, Riedel M, Herzog N, et al. (2010) An exploratory behavioral intervention trial to improve rates of screening for AIDS clinical trials among racial/ethnic minority and female persons living with HIV/AIDS. *AIDS Behav* 14: 639-648.
8. Menezes P, Eron JJ, Jr., Leone PA, Adimora AA, Wohl DA, (2011) Recruitment of HIV/AIDS treatment-naive patients to clinical trials in the highly active antiretroviral therapy era: Influence of gender, sexual orientation and race. *HIV Med* 12: 183-191.
9. Gwadz M, Cleland CM, Belkin M, Ritchie A, Leonard N, et al. (2014) ACT2 peer-driven intervention increases enrollment into HIV/AIDS medical studies among African Americans/Blacks and Hispanics: A cluster randomized controlled trial. *AIDS Behav* 18: 2409-2422.
10. Gwadz MV, Cleland CM, Leonard NR, Ritchie AS, Banfield A, et al. (2013) Predictors of screening for AIDS clinical trials among African-Americans and Latino/Hispanics enrolled in an efficacious peer-driven intervention: Uncovering socio-demographic, health and substance use-related factors that promote or impede screening. *AIDS Behav* 17: 801-812.
11. Gwadz MV, Leonard NR, Cleland CM, Riedel M, Banfield A, et al. (2011) The effect of peer-driven intervention on rates of screening for AIDS clinical trials among African Americans and Hispanics. *Am J Public Health* 101: 1096-1102.
12. Flay BR, Snyder F, Petraitis J (2009) The theory of triadic influence. *Emerging theories in health promotion practice and research*. Jossey-Bass, New York, pp: 451-510.
13. Gwadz MV, Colon P, Ritchie AS, Leonard NR, Cleland CM, et al. (2010) Increasing and supporting the participation of persons of color living with HIV/AIDS in AIDS clinical trials. *Curr HIV/AIDS Rep* 7: 194-200.
14. Mills E, Cooper C, Guyatt G, Gilchrist A, Rachlis B, et al. (2004) Barriers to participating in an HIV vaccine trial: A systematic review. *AIDS* 18: 2235-2242.
15. Freimuth VS, Quinn SC, Thomas SB, Cole G, Zook E, et al. (2001) African Americans' views on research and the Tuskegee Syphilis Study. *Soc Sci Med* 52: 797-808.
16. Gwadz MV, Leonard NR, Nakagawa A, Cylar K, Finkelstein M, et al. (2006) Gender differences in attitudes toward AIDS clinical trials among urban HIV-infected individuals from racial and ethnic minority backgrounds. *AIDS Care* 18: 786-794.
17. Wynia MK, Gamble VN (2006) Mistrust among minorities and the trustworthiness of medicine. *PLoS Med* 3: e244.
18. George S, Duran N, Norris K (2014) A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans and Pacific Islanders. *Am J Public Health* 104: e16-e31.
19. Shavers VL, Lynch CF, Burmeister LF (2000) Knowledge of the Tuskegee study and its impact on the willingness to participate in medical research studies. *J Natl Med Assoc* 92: 563-572.
20. Priddy FH, Cheng AC, Salazar LF, Frew PM (2006) Racial and ethnic differences in knowledge and willingness to participate in HIV vaccine trials in an urban population in the South-eastern US. *Int J STD AIDS* 17: 99-102.
21. Slomka J, Ratliff EA, McCurdy SA, Timpson S, Williams ML (2008) Decisions to participate in research: views of underserved minority drug users with or at risk for HIV. *AIDS Care* 20: 1224-1232.
22. Cargill VA, Stone VE (2005) HIV/AIDS: A minority health issue. *Med Clin North Am* 89: 895-912.
23. Stone VE, Mauch MY, Steger KA (1998) Provider attitudes regarding participation of women and persons of color in AIDS clinical trials. *J Acquir Immune Defic Syndr Hum Retrovirol* 19: 245-253.
24. el-Sadr W, Capps L (1992) The challenge of minority recruitment in clinical trials for AIDS. *JAMA* 267: 954-957.
25. Gandhi M, Ameli N, Bacchetti P, Sharp GB, French AL, et al. (2005) Eligibility criteria for HIV clinical trials and generalizability of results: The gap between published reports and study protocols. *AIDS* 19: 1885-1896.
26. Broadhead RS, Heckathorn DD, Altice FL, van Hulst Y, Carbone M, et al. (2002) Increasing drug users' adherence to HIV treatment: Results of a peer-driven intervention feasibility study. *Soc Sci Med* 55: 235-246.
27. Freeman HP (2006) Patient navigation: A community based strategy to reduce cancer disparities. *J Urban Health* 83: 139-141.
28. Miller WR, Rollnick S (2012) *Motivational interviewing: Helping people change* (3rd Ed) Guilford Press, New York, NY.
29. Leonard NR, Banfield A, Riedel M, Ritchie AS, Mildvan D, et al. (2013) Description of an efficacious behavioral peer-driven intervention to reduce racial/ethnic disparities in AIDS clinical trials. *Health Educ Res* 28: 574-590.
30. Centers for Disease Control and Prevention (2015) HIV Surveillance report, p: 26.
31. Heckathorn DD (1997) Respondent-driven sampling: A new approach to the study of hidden populations. *Soc Probl* 44: 174-199.
32. Schreiber G, Schwarz M, Modre-Osprian R, Kastner P, Scherr D (2013) Design and evaluation of a multimodal mHealth based medication management system for patient self-administration. *Conf Proc IEEE Eng Med Biol Soc* 2013: 7270-7273.
33. Muhr T, ATLAS ti (1997) *Scientific software development*; Berlin.
34. Bernard HR, Ryan G (1998) *Text analysis: Qualitative and quantitative methods*. Handbook of Methods in Cultural Anthropology. AltaMira Press, Walnut Creek, CA 595-646.
35. Lincoln YS, Guba EG (1985) *Naturalistic Inquiry*. Sage Publications Newbury Park, CA.

36. Rivers D, August EM, Sehovic I, Green BL, Quinn GP (2013) A systematic review of the factors influencing African Americans' participation in cancer clinical trials. *Contemp Clin Trials* 35: 13-32.
37. Patrick H, Williams GC (2012) Self-determination theory: Its application to health behavior and complementarity with motivational interviewing. *Int J Behav Nutr Phys Act* 9: 18.
38. Hettema J, Steele J, Miller WR (2005) Motivational interviewing. *Annu Rev Clin Psychol* 1: 91-111.
39. Cuffee YL, Hargraves JL, Rosal M, Briesacher BA, Schoenthaler A, et al. (2013) Reported racial discrimination, trust in physicians and medication adherence among inner-city African Americans with hypertension. *Am J Public Health* 103: e55-e62.
40. Floyd T, Patel S, Weiss E, Zaid-Muhammad S, Lounsbury D (2010) Beliefs about participating in research among a sample of minority persons living with HIV/AIDS in New York City. *AIDS Patient Care STDS* 24: 373-380.
41. Scharff DP, Mathews KJ, Jackson P, Hoffsuemmer J, Martin E, et al. (2010) More than Tuskegee: Understanding mistrust about research participation. *J Health Care Poor Underserved* 21: 879-897.
42. Smedley BD (2012) The lived experience of race and its health consequences. *Am J Public Health* 102: 933-935.
43. Ford CL, Airhihenbuwa CO (2010) Critical race theory, race equity and public health: Toward antiracism praxis. *Am J Public Health* 100: S30-S35.
44. Andersen JW, Fass R, van der Horst C (2007) Factors associated with early study discontinuation in AACTG studies, DACS 200. *Contemp Clin Trials* 28: 583-592.
45. Baquet CR, Henderson K, Commiskey P, Morrow JN (2008) Clinical trials: The art of enrollment. *Semin Oncol Nurs* 24: 262-269.
46. Swanson GM, Ward AJ (1995) Recruiting minorities into clinical trials: Toward a participant-friendly system. *J Natl Cancer Inst* 87: 1747-1759.
47. Perlman DC, Gelpi-Acosta C, Friedman SR, Jordan AE, Hagan H (2015) Perceptions of genetic testing and genomic medicine among drug users. *Int J Drug Policy* 26: 100-106.
48. Kahneman D (2011) *Thinking, Fast and Slow* (1st ed) Farrar, Straus and Giroux, New York, NY.
49. Krueger RA, Casey MA (2014) *Focus groups: A practical guide for applied research* (5th ed). Sage Publications, Thousand Oaks, CA.
50. Earnshaw VA, Smith LR, Cunningham CO, Copenhaver MM (2013) Intersectionality of internalized HIV stigma and internalized substance use stigma: Implications for depressive symptoms. *J Health Psychol* 20: 1083-1089.