

Description of an efficacious behavioral peer-driven intervention to reduce racial/ethnic disparities in AIDS clinical trials

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Abstract

AIDS clinical trials (ACTs) are critical to the development of new treatments for HIV infection. However, people of color living with HIV/AIDS are involved in ACTs at disproportionately low rates, with African-Americans experiencing the greatest under-representation. In this article, we describe the core elements and key characteristics of a highly efficacious multi-component peer-driven intervention (PDI) designed to increase rates of screening for and enrollment into ACTs among African-American and Latino/Hispanic individuals, by addressing the main complex, multi-level barriers they experience to ACTs. We discuss the process of developing the intervention, the theoretical models guiding its delivery format and content, and provide an overview of the intervention's components. We then use brief case studies to illustrate a number of key issues that may arise during intervention implementation. Finally, we describe lessons learned and provide recommendations for the PDI's uptake in clinical and clinical trials settings.

Introduction

AIDS clinical trials (ACTs) are research studies designed to evaluate promising therapies to fight HIV infection, prevent and treat the opportunistic

infections and cancers associated with HIV/AIDS, treat the complications of antiretroviral therapy and reconstitute HIV-damaged immune systems [1]. As such, ACTs are critical to the development of new medication and treatment regimens for HIV infection. However, persons of color living with HIV are involved in ACTs at disproportionately low rates, with African-Americans experiencing the greatest under-representation [2, 3]. This disproportionality is of great concern because it may limit the generalizability of research findings, including the populations most adversely affected by HIV [4, 5]. Furthermore, the under-representation of populations of color denies these groups the opportunity to contribute to medical research and impedes their access to the high level of care made available through ACTs, as well as potential new treatments and prophylaxes [6–10].

Barriers to ACTs for PLHA of color

People living with HIV/AIDS (PLHA) of color face complex and multi-level barriers to accessing ACTs [9, 10]. These barriers include poor knowledge of ACTs, and substantial fear and distrust of trials [11, 12]. Particularly in African-American communities, conspiracy theories about the cause of AIDS and skepticism about HIV treatments are persistent, and these beliefs appear to perpetuate social norms that discourage participation in medical research

[13, 14]. At the same time, evidence is growing that PLHA of color report great willingness to explore ACTs [8–10]. Yet PLHA of color are less likely to be referred to ACTs by their health care providers compared with Whites [15]. Finally, structural factors, such as clinical trial settings and systems that are difficult to navigate, also appear to impede access to ACTs for PLHA of color [6, 16].

The ACT2 project

In recent research, we developed and evaluated the efficacy of a targeted peer-driven intervention (PDI) to reduce barriers to ACTs for PLHA of color, called the ‘ACT2 Project’. The ACT2 study used a peer-referral recruitment method called respondent-driven sampling [17], where peers recruit peers for the study. We found that the ACT2 intervention was highly efficacious in increasing rates of screening for ACTs among African-American/Black and Latino/Hispanic persons living with HIV/AIDS [8], with 56% in the intervention (198/351) and <5% in the control arm (7/189) initiating screening for ACTs [odds ratio (OR) = 33.65, $P < 0.0001$]. Among those screened in the intervention arm, almost all (87.4%; 173/198) completed screening and about half of these were found eligible for ACTs or other biomedical studies (55.5%; 96/173). Moreover, almost all of those found eligible enrolled in studies and trials (91.7%; 88/96). Because <5% of those in the control arm were screened for ACTs, very few enrolled in studies, and the difference in enrollment rates between intervention and control arms was substantial (OR = 6.49, $P < 0.0001$) [8, 18]. We also found that, as anticipated, eligibility rates were much higher for observational than therapeutic studies [McNemar’s chi-squared ($df = 1$) = 75.2, $P < 0.001$] [19]. The main aim of this article is to describe the core elements and key characteristics of the highly efficacious ACT2 PDI and to provide case vignettes to illustrate key clinical issues that arise in the implementation of the intervention program. The intervention curriculum is available from the last author.

Intervention development

We conducted a 2-year pilot study to examine barriers to ACTs and explore intervention strategies to increase access to ACTs [10, 11]. Upon completion of the pilot study, we established a multidisciplinary intervention working group (IWG) to evaluate its successes and failures and how to improve upon the original intervention. The IWG used the Intervention Mapping approach [20] to refine the intervention concept. Intervention Mapping included a review of quantitative and qualitative data from the pilot study and the larger empirical literature, a discussion of salient theoretical approaches and intervention modalities and feedback elicited from a Community Advisory Board (CAB).

Intervention modality

In response to the multi-level individual/attitudinal, social and structural barriers to ACTs identified in the pilot study and described above, we selected the PDI method as the basis of the intervention, called ‘ACT2’ [21, 22]. PDI is an intervention methodology that incorporates social–cognitive strategies and adds a potent peer education and recruitment strategy intended to alter social norms that impede behavior change—in this case, screening for ACTs. In PDI, participants engage in intervention activities such as small group sessions and then are trained to educate their peers on a set of core intervention messages. These peers in turn have the opportunity to enroll in the study and recruit and educate their own peers. Furthermore, PDIs are specifically targeted to the barriers that the population of interest experiences to the target health behavior and as such are considered a culturally appropriate intervention modality.

PDI’s potency comes from the fact that it taps into six critical elements of behavior change: knowledge, skill building, motivation, peer influence, social norms and repetition [23–25]. Furthermore, PDI capitalizes on social influence processes that exist among social networks. When individuals appeal to peers in their network to act in a certain way, their ‘own’ commitment to the desired health behavior is strengthened as educating or urging peers is a public

affirmation of the desired health behavior. Indeed, messages delivered by peers can be potent because peers have more credibility than professionals [26]. Moreover, peer education involves repetition of the intervention's core messages and is intended to result in greater internalization of the messages. Finally, when used with PLHA, PDI capitalizes on the personal and community-minded transformative changes that often occur among HIV-infected individuals [27–30].

Furthermore, we have found among health care providers and the general public an assumption that PLHA of color do not participate in ACTs at high rates because they are unwilling to participate or unable to adhere to trials [4, 31, 32]. Yet as we have discussed above, structural, organizational and social barriers are major causes of disparities in ACTs. By explicitly addressing social and structural barriers to ACTs, the ACT2 intervention shifts the 'blame' for the problem of under-representation away from individual PLHA of color to also include the supra-individual factors that impede their participation.

Theoretical models

The intervention's overarching theoretical frame is the Theory of Triadic Influence (TTI) [33], which emphasizes three 'streams of influence' on health behavior—individual/attitudinal, social and structural. As a social-cognitive theory, the TTI describes the interplay between the environment and individual knowledge, attitudes and behavioral

factors. The intervention's mechanisms of action were grounded in the Theory of Normative Regulation [17], which posits that the behaviors of individuals are amplified through their social groups, as well as motivational interviewing, an approach for enhancing intrinsic motivation to change by exploring and resolving ambivalence [34].

Guided by this integrated theoretical model, the ACT2 intervention directly targeted the following factors for change, which taken together were hypothesized to increase motivation and ability to screen for and enroll into ACTs. The ACT2 intervention was designed to: increase self-efficacy to manage screening; increase knowledge of ACTs and the enrollment process; expose a range of both positive and negative attitudes toward ACTs including distrust, fear, willingness and altruism, framed as ambivalence about ACTs; improve behavioral skills to manage ACT screening (e.g. communicating with health care providers); change perceived social norms regarding ACTs; trigger communication with health care providers about ACT screening and reduce structural barriers to the clinical trials site and the process of screening and enrollment.

Development of the ACT2 core intervention messages

As noted above, PDIs include core messages that form the basis of peer education. The core messages for the ACT2 PDI were designed to be simple but to target the specific barriers to ACTs experienced by PLHA of color (found below in Table I and described in more detail in Appendix A). In addition

Table I. ACT2 core intervention messages

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

to being used by participants to educate peers, the messages were also integrated into and repeated throughout the intervention sessions. Indeed, because we found in our preliminary studies that PLHA of color find the topic of ACTs to be confusing, complex and emotionally laden, the intervention intentionally includes a substantial amount of repetition of its core messages and themes.

Training and experience of facilitators

The intervention was facilitated by master's level clinicians with expertise in the following areas: the basics of HIV/AIDS; the basics of ACTs, including types of trials typically offered and the process of screening and enrollment; group facilitation skills; motivational interviewing and the topic of structural racism and its relationship to access to ACTs.

Fidelity to the intervention manual

The intervention is manual-based and the project used a rigorous quality assurance protocol. Intervention sessions were tape recorded. Facilitators completed quality assurance forms after every session. These forms were reviewed by the clinical supervisor for completeness of session delivery and issues that facilitators wished to discuss in supervision. Approximately 10% of session recordings were subject to quality assurance ratings for fidelity to the intervention and adherence to the protocol, with such information fed back to the facilitator. Facilitators participated in weekly staff meetings and monthly clinical supervision meetings.

Overview of the ACT2 intervention

The ACT2 intervention consists of 6 hours of structured group and individual sessions, plus peer education experiences. The ACT2 intervention is focused on facilitating the decision about whether to be screened for ACTs. Most PLHA screened for ACTs will not be found eligible for a study, because of strict inclusion and exclusion criteria [35]. Yet being screened for ACTs has a number of benefits to PLHA regardless of whether they are found eligible, primary among them is the provision of access to the

Peer-driven intervention

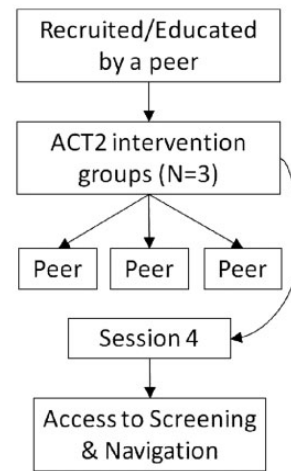


Fig. 1. Sequence of ACT2 intervention activities.

ACT system going forward. The sequence of activities in the ACT2 intervention is outlined in Fig. 1, with a detailed description of the program provided in Appendix B. In this section, we describe each activity in the order in which it occurs.

Education by a peer

As noted above, in the ACT2 model, participants recruit their peers for participation in the intervention. Thus, with the exception of a set of 'initial seeds' recruited from community-based organizations who initiate the peer recruitment chains, potential participants are educated by their peers on the core messages at the time they are recruited for the ACT2 project. This is intended, at minimum, to pique the potential participant's interest in and enhance his/her motivation to explore the topic of ACTs.

Group sessions

Participants then engage in three small group sessions with six to nine other participants. The sessions, described in detail below, are made up of interactive exercises and video presentations and include pre-printed posters and handouts. As such, the intervention is not didactic, but instead is designed to facilitate the exploration of the salient issues from

the perspective of the group members. The limit on the number of participants in each group to <10 is intended to allow participants time to discuss and process the intervention material, which is typically unfamiliar and can be emotionally laden. Participants are trained during the group session on how to educate peers. Participants in the ACT2 study received an incentive of \$25 for each intervention session attended.

Peer education

Participants are offered the chance to independently educate up to three of their peers on the core intervention messages and recruit them for participation in the intervention at the same time. The educator receives compensation for each peer recruited (\$15) as well as compensation based on the peers' performance on a 10-item true-false quiz of the core messages (\$1 for each correct item). This is a strategy in the PDI approach intended to boost motivation to conduct the peer education. We found that 65% of participants educated/recruited an average of approximately two peers each. Participants could decline to educate/recruit peers and continue in the study [8].

Individual intervention session to address structural and personal barriers

Session 4 is an individual session lasting 30 min that is held on the ACT unit (ACTU) where future screening visits would take place. The intent of this short session is to encourage participants to locate and explore the clinical trial setting, and therefore increase their level of comfort with the clinical trial setting. As such, Session 4 is intended to reduce structural barriers to screening, namely, those associated with its physical location, as well as to solidify an individual's commitment to screening. Participants received a \$25 incentive for this session.

Access to screening and navigation to reduce structural barriers to screening

Navigation is an efficacious intervention approach first designed to reduce disparities in cancer care for low-income women of color [36, 37]. Navigation

focuses on identifying and overcoming individual and structural barriers that individuals encounter at various steps during the course of accessing services [38]. Importantly, navigation is individualized based on participant need. It is a strength-based approach and includes the motivational interviewing approach [34] to assist participants in accessing needed services [36, 38–40].

During the intervention sessions participants are informed that they will be provided with access to screening at the ACTU after Session 4, although they will need to initiate the contact and will not be compensated for the screening visits. Thus, we consider the provision of 'access' to screening one structural component of the intervention. Participants interested in screening then receive 1–10 short navigation phone contacts from staff to resolve barriers to screening and enrollment, such as transportation or obtaining necessary health records, although most individuals required only one to three contacts to complete screening.

Description of the ACT2 intervention components

In the next section we describe the intervention sessions in detail and provide case studies (using pseudonyms) to highlight key clinical issues that arise in implementation.

Session 1: building knowledge and developing motivation

The primary goals of this 2-hour small group session are to enhance knowledge of ACTs and the problem of under-representation, uncover attitudes toward ACTs (both positive and negative), articulate and challenge negative peer norms regarding ACTs—all of which in turn builds motivation to screen for ACTs. The sequence of interactive exercises for this session is described below in the order in which they are conducted.

- (1) Engagement and introduction: Introductions among group members and review the structure and purposes of the ACT2 intervention.

- (2) Brief description of ACTs: Increase awareness of ACTs to provide a context for the session.
- (3) Disproportionality in ACTs: Review the extent of under-representation of PLHA of color in ACTs and explore the reasons that this is a problem at individual level (e.g. PLHA of color do not have access to the potential benefits) and scientific level (e.g. research findings may not generalize to those most affected by the disease).
- (4) Multi-level barriers to ACTs for people of color and protections: Explore the current and historical barriers between medical research and communities of color, including examples of past abuses of communities of color by medical research such as the Tuskegee syphilis study [41]. Assist participants in connecting this history to persistent fears of trials and a general lack of trust in medical research. Review the Belmont Principles [42] and the rights of individuals participating in research.
- (5) Understanding ACTs: Review in detail the 10 core messages through a lively, interactive exercise where participants break into two teams and engage in a game show-like contest to answer questions about ACTs as a means of increasing knowledge of ACTs.
- (6) Contextualizing and normalizing ACTs as part of positive health behavior for PLHA: Participants identify their own positive health behaviors (e.g. spirituality, social services, alternative therapies) and place them in the context of systems of care for PLHA, which include ACTs. This is intended to contextualize and normalize ACTs for PLHA.
- (7) Understanding screening for ACTs: Clearly define the purposes of ACT 'screening', separate from enrollment and place ACT screening in a larger context of other health screenings (e.g. blood pressure) to help normalize screening and reduce fear.
- (8) Preliminary decision about whether to be screened for ACTs: Engage in a group decisional balance exercise where

participants list the pros and cons of screening for an ACT to reduce ambivalence about and build motivation for screening.

Understanding under-representation

Many of the exercises in this session are designed to 'unpack' the complex topic of under-representation in ACTs, including the structural, social and individual factors driving this problem, and the resultant feelings and beliefs among PLHA of color. For example, in Exercises 4 and 5, we describe the extent to which PLHA from African-American and Latino backgrounds are under-represented in ACTs graphically using simple charts. Furthermore, this set of exercises is intended to increase awareness about the ACT system from which PLHA of color have generally been excluded, and to increase awareness of the implications of under-representation at the community, research and individual levels. Consistent with the motivational interviewing approach, these exercises are designed to raise participants' concern about this structural disproportionality. At the same time, the facilitator sets the tone for the intervention by noting that PLHA of color are wanted and needed in ACTs. Indeed, this set of exercises typically elicits great curiosity and some willingness to explore ACTs as well as deep-seated feelings of fear and distrust of medical research. This pattern of conflicting feelings and attitudes is considered 'ambivalence' in the language of motivational interviewing and is a desired state for this type of behavior change intervention.

Past abuses in medical research

One of the most important aspects of the intervention is the exploration by group members of the various factors that lead to under-representation of people of color in medical research. Indeed, mistrust of medical research resulting from past abuses of communities of color was consistently named by group members as a primary barrier to their participation in trials. Although group members raised numerous examples of these abuses, such as sterilization campaigns aimed at people of color [43], the

Tuskegee syphilis study was the event most commonly cited. Thus, one goal of Session 1 is to explore the topic of past abuses in medical research and provide a forum for participants to discuss the Tuskegee study and other abuses and their impact on communities of color. We found it critical to provide a sufficient amount of time for participants to express their fears and anger about past research abuses, a discussion rarely encouraged in clinical settings in part because clinicians may not feel they have the skills to facilitate such a discussion. Importantly, the session also reviews federal research protections that were developed as a result of these past abuses. Consistent with motivational interviewing, facilitators strove to listen actively but in a non-defensive manner during these discussions and also monitor the level of distress in a clinically appropriate way.

Increasing knowledge of ACTs

Participants' knowledge of ACTs tended to be poor. In order to provide information about ACTs in a clear and engaging manner, we developed a video for use in Exercise 6 that depicts an informal discussion between PLHA of color who have participated in ACTs and those who are interested but hesitant to be screened. The 'actors' in the video were members of the study's CAB who discussed their personal feelings about ACTs. The actors discuss questions and fears about trials and issues of trust, and those who have participated in trials provide realistic, helpful information, challenging the norm that PLHA of color do not participate in trials. The following vignette highlights the importance of understanding the diversity of types of ACTs and is one component of building motivation to screen for ACTs.

Sharon indicated that the prospect of entering a clinical trial made her nervous. She was a long-term survivor of HIV/AIDS with a complicated health history. However, Sharon had mixed feelings about her current antiretroviral medication regimen. On the one hand, it was "saving her life," but on the other hand, she suffered from lipodystrophy and neuropathy,

which she attributed to the regimen. During Session 1, she stated that she was not interested in screening because she did not want to change her medication regimen. During the session, however, she learned that some ACTs evaluate treatments for conditions such as lipodystrophy and do not necessarily require a change to one's antiretroviral regimen. Sharon decided to be screened, with the intention of entering a lipodystrophy trial if found eligible. She also planned to bring information about ACTs to a support group for HIV-infected women that she attended.

Disentangling screening and enrollment

In Exercise 7, the facilitator uses a flow chart to illustrate the difference between screening and enrollment, namely, screening is a low-risk activity with few potential drawbacks and a number of potential benefits. For example, in addition to being the key gateway to ACTs, 'screening' can result in improved knowledge of HIV and ACTs, reduced fear of ACTs and provide access to the ACT system. Conversely, 'enrollment' in an ACT entails a higher level of risk, with more serious potential risks and benefits.

Preliminary decisions about screening

In Exercise 8, we conduct a decisional balance exercise, intended to help participants resolve ambivalence about being screened by eliciting the pros and cons of both being screened (i.e. changing) and not being screened (i.e. staying the same) [44]. The following case vignette highlights the utility of the Decisional Balance exercise.

Malik had been infected with HIV for over 20 years. He was very wary of trials, saying he knew people who had participated and later died because, "they let the doctors experiment on them without knowing what the doctors were really doing." He feared that, "the researchers will lock you up [during screening] and start experimenting on you like a guinea pig." He also believed that you could not stop

participating in a trial once you enrolled. During Session 1, Malik found that many of his personal concerns about trials were raised by the group, and then discussed in an open and accepting manner. He also learned more about his rights as a potential participant in ACTs. At the end of Session 1, Malik could not think of any “cons” for getting screened as he completed the Decisional Balance and stated to the group, “Screening can’t hurt you, it can only help you. You will definitely learn something by getting screened.”

Session 2: understanding the ACT screening process

The primary aims of this 2-hour group session are to further enhance knowledge of the screening process, uncover and address complex attitudes toward screening and build behavioral skills to manage screening, thereby building motivation to screen. The sequence of exercises is

- (1) Welcome and review Session 1: Demonstrate knowledge of the core concepts from Session 1 including the purposes and types of ACTs, historical and current barriers to getting screened and the problem of disproportionality of people of color in ACTs.
- (2) The screening process: Describe and depict the ACT screening process using video and discussion. The core intervention messages are highlighted: screening is a low-risk activity and does not imply a commitment to join a trial and is a way to gain access to ACTs and to learn about ACTs and possibly about one’s own medical situation, from a top-notch medical team.
- (3) Involving family and friends in screening and enrollment decisions: Elicit the support of participants’ family and friends for getting screened is useful, as family and friends are likely to have similar levels of knowledge of and hold mixed attitudes toward ACTs. Using a social-network mapping exercise, participants identify family and friends who

they might engage in their decision-making process for ACT screening and participate in a role play to practice involving social network members.

- (4) Talking to your doctor about screening and enrollment: Understand the role of the primary health care provider in ACTs and improve skills to talk to primary care providers about ACT screening or enrollment. Provide a ‘Dear Doctor’ letter to explain the ACT2 Project to the provider and trigger a discussion of ACTs.
- (5) Expectations of screening and the ACTUs: The clinic sites serving PLHA of color typically have different practices than ACT sites, for example, clinic appointments are often double-booked and patients experience long waits. In order to boost participant efficacy and skills to manage these differences, facilitators review these differing expectations to assist participants and ACTU staff to establish a good relationship.
- (6) Personal readiness for screening: Determine personal readiness for screening using a 0–10 scale.

Increasing comfort with the screening process

In order to increase participants’ understanding of and comfort with the screening process and their self-efficacy for managing the screening process, and reduce their fears of screening, a second video is shown which depicts a female PLHA of color going through the screening process. In the video, a research nurse conducts a health history interview to determine if the ‘patient’ is potentially eligible for a trial. Throughout the interview, the patient is invited to ask questions about the unit, the available trials and about her health in general. The research nurse emphasizes the fact that the eligibility rates are typically very low and informs the patient that although she is not eligible at this time, the ACTU will contact her if a trial begins that fits her medical profile.

When Silva came into the first group session she stated, “I am going to tell you like I told

my friend who gave me the (recruitment) coupon to come here, I will sit through your group, but I'm not doing no clinical trial. I finally got my doctor to understand me and my medications and as far as I'm concerned, if it ain't broke, don't fix it." Silva was told her frankness was appreciated and that she was welcome in the groups. She asked many questions and told the group she was very skeptical that screening was as simple as answering and asking questions. After viewing the video depicting the screening process however, she gave herself a 10 on a ten-point "readiness to screen scale." She soon attended a screening appointment, was found eligible, and enrolled in and completed a trial.

Relationship between PLHA and their health care providers

Health care providers are often hesitant to refer PLHA of color to ACT screening or to engage in a discussion about ACTs, in part because of the short duration of the typical health care encounter and the complexity of barriers to ACTs [4, 15]. At the same time, patients may be hesitant to ask providers about ACTs. However, we agree that it is not generally feasible for providers to successfully address patients' complex barriers to ACTs within the context of the typical brief health encounter. Therefore to involve providers in the discussion of ACTs, the intervention provides a 'Dear Doctor' letter explaining the ACT2 Program and the participants' interest in screening, which participants can provide to providers if they so choose to initiate a discussion of ACTs, as the following case vignette highlights.

Kasper reported that 25 years ago his partner participated in a clinical trial and suffered so many side effects from the medications that he had to stop the trial. Unfortunately his partner died soon after, and since then Kasper has been afraid of trials. Kasper said that he came to the ACT2 groups because he heard he could receive compensation for his time and also learn something, but that he would

not consider anything without talking to his trusted, longtime doctor. Kasper felt that the "Dear Doctor" letter might be useful to explain the ACT2 project better than he could. He indicated that if his doctor approved of his being screened, then he would be screened. In his later individual session Kasper reported that his doctor thought that screening would be a good opportunity for him to learn more about clinical trials, and so Kasper scheduled an appointment to be screened.

Session 3: spreading the word

Session 3 is a one and half-hour small group session with the primary aims of enhancing knowledge of the peer recruitment and education process, building motivation to conduct peer education and participate in screening and increasing behavioral skills to recruit and educate peers, thereby increasing motivation to screen for ACTs. The specific exercises are

- (1) Introductions and brief review of previous sessions: A brief repetition of core intervention content is designed to increase comfort with and mastery of the material. Group members are encouraged to ask questions about the material presented in the previous sessions.
- (2) Review of information about ACTs: A lively, interactive exercise is used to solidify knowledge of the core messages about ACTs and increase self-efficacy for educating peers on these messages.
- (3) Introduction to peer education and recruitment: The context and rationale for peer education is discussed in an effort to build motivation for educating and recruiting up to three peers to the project.
- (4) Steps for peer education/recruitment: The peer education experience is modeled, including who to approach, how and when to approach them and how to manage confidentiality. Participants are given a 'wallet card' containing the 10 core messages and an outline of steps of peer recruitment.

- (5) Practice peer education/recruitment: Participants practice peer education in dyads to increase skills for educating and recruiting peers.

Participants are then provided with coded recruitment coupons to give to peers, which will be used to link the peers to the participant. Peers then contact the study independently, participate in a brief interview to determine eligibility and take a simple true/false quiz on the 10 core messages. As noted above, the education of peers is another means of reinforcing the core intervention messages and theoretically serves to boost the recruiter's motivation to be screened [8], as the next case vignette highlights.

Bishop told the group that in the past he was very skeptical about clinical trials and vowed never to participate in one, stating that he would rather "die than be a lab rat." However, Bishop had been recruited into the ACT2 Project by a peer who he very much respected. Bishop shared with the group that the peer who had educated him on the core messages took the time to answer many of Bishop's questions and did an excellent job. As a result of the peer education experience, Bishop had decided to participate in the ACT2 Project, and also said he was much more open to the idea of learning more about clinical trials than he had ever been in the past, even before attending the first group. In fact, he told the group that he was hopeful that he could do as good a job conducting peer education as the person who educated him. Although Bishop had not yet decided whether or not to be screened, he did intend to bring the information about ACTs to his peers.

Peer education period (4 weeks)

Participants leave Session 3 with the skills and tools needed to recruit and educate up to three of their peers and are provided with telephone support throughout the process as needed. During the study, potential negative effects of peer recruitment

were systematically monitored in qualitative and quantitative research but none was identified.

Session 4: individual session, readiness for screening

The brief individual session is designed to increase participants' level of comfort with the ACTU, practice locating the ACTU as a means of overcoming structural barriers and finalize personal decisions regarding screening. The session lasts 30 min and takes place at the ACTU. The exercises for this session are

- (1) Introduction and tour of ACT site: Conducting this session at the clinical trial site is intended to help participants locate the unit and increase their level of comfort with the site and ACT personnel.
- (2) Review efforts at peer recruitment, including attempts made, outcomes and the positive and negative aspects of recruiting and educating peers.
- (3) Assess level of readiness for getting screened and discuss any barriers the participant anticipates to getting screened. Help the participant brainstorm potential solutions and selecting the best one(s) (e.g. childcare).
- (4) Assist participant to commit to getting screened or 'leave the door open' if participant declines: Participants are provided with the phone number for making a screening appointment. Participants who decline are asked if they can be contacted.
- (5) Review session and acknowledge achievements: Facilitators inform all participants that they will stay in touch and are given a 'graduation' certificate.

Consistent with motivational interviewing, the facilitator explores the participant's individual level of readiness and personal barriers to screening rather than trying to 'convince' the participant to be screened. During the individual session, participants are reminded that unlike the ACT2 Project sessions, there is no financial compensation for screening. Thus, the screening experience is congruent with

‘real-world’ practices where patients are referred to screening but must take the initiative to attend.

Toni started the individual session by saying, “Oh my gosh! It was so hard finding this place but I’m glad I made it – show me this place, I’ve been dying to see it.” She was surprised that the unit looked more like a welcoming clinical setting rather than having “hospital beds and beeping machines and doctors and nurses running back and forth.” She continued, “When I first came to the groups I didn’t think I would be interested in a clinical trial because I always thought of it as being in scary Intensive Care Unit. After learning more about it, I was open to screening.”

Navigation (1–10 brief phone calls)

Facilitators stay in contact with PLHA who express some interest in ACT screening to assist them with overcoming barriers that arise during the screening process such as transportation, screening appointment schedule or childcare. Facilitators also act as a liaison between participants, their primary care provider and the clinical trial sites. For participants who decide to be screened, facilitators provide support and information throughout the process. For participants who are found eligible for a trial, facilitators assist with enrollment decision-making and problem-solving barriers to participation. The facilitators also stayed in sporadic contact with those who had deferred or declined to be screened. In fact, some participants decided to be screened several months after their participation in the intervention.

Discussion

The ACT2 intervention is the first social/behavioral intervention shown to be highly efficacious at increasing rates of screening for and enrollment into ACTs among African-American and Latino/Hispanic PLHA [8, 18, 19]. This article describes the core elements and key characteristics of the ACT2 PDI. In this section, we summarize a number of the program’s salient components and

aspects of its delivery essential to its successful implementation.

The elicitation and exploration of the social and structural barriers to ACTs associated with being African-American or Latino in the United States was a key feature of the ACT2 intervention. Acknowledging and providing a safe forum for a discussion of the long history of exclusion and mistreatment of people of color by medical research appeared to enhance the credibility of the facilitators and the potency of the intervention. Moreover, these discussions appeared to promote trust and an increased openness to engaging in screening. However, as this discussion of historical barriers and structural racism is often emotionally laden for participants and facilitators, we found that it was vital for facilitators be trained and supervised to manage heightened emotions that typically arise in such discussions.

The motivational interviewing approach, which seeks to elicit and resolve ambivalence about health behavior change, appeared to be another important aspect of the ACT2 intervention. We believe this is because the approach ‘fit’ well with this particular health disparity. Participants in the ACT2 study reported being ‘leery’ of the topic of ACTs and sensitive to being pressured or coerced. Motivational interviewing was useful in this respect, because facilitators are trained to ‘roll with resistance’ from participants regarding ACTs. The ACT2 intervention has a stance; namely, that all PLHA should have access to ACTs, whether or not they wish to make use of that access. However, it does not assume that screening is the right decision for any individual participant, and thus allows for the range of decisions regarding ACT screening in a way that is comfortable for participants and facilitators.

The aspects of the intervention that seek to reduce structural barriers to screening were also critical to the success of the ACT2 intervention. PLHA of color may be highly motivated to access clinical trials, but may still have difficulties accessing and managing the system. Furthermore, the screening and enrollment process can unfold over a number of months, creating junctures where PLHA can be

lost to the clinical trials system. We found that providing PLHA with support through the screening process, particularly with respect to interfacing with their primary care providers and ACTU staff, and addressing transportation issues, ensured that all ACT2 participants who initiated screening completed the process. Thus, locating Session 4 on the ACT unit and providing the brief phone contacts through the screening process were vital elements of the ACT2 intervention that should be maintained in any future implementation of the program.

Limitations

Similar to other sampling methods, respondent-driven sampling, together with PDI, may introduce selection bias. In our previous report on the efficacy of the ACT2 intervention [45], when we compared intervention and control arm participants on socio-demographic and health characteristics at baseline, we found no differences with two exceptions. First, participants assigned to the intervention arm were more likely to be African-American and less likely to be Hispanic. This difference was the result of a slight imbalance in race/ethnicity among initial seed participants, a stronger preference for in-group recruitment among African-Americans, and more successful recruitment by African-Americans in that study arm. Second, those in the intervention arm were more likely to have been screened for an ACT in the past because more initial seeds in the intervention arm (28%) had prior screening than did initial seeds in the control arm (12%), and initial seeds with prior screening initiated more productive recruitment chains. We controlled for the effect of these two between-group differences in the analysis of intervention effects.

Selection bias may affect external validity as well, that is how representative the sample was of the target population of adult PLHA of color in New York City. On the whole, the sample was vulnerable in a number of respects. More than 80% of the participants in both arms had not received a school degree higher than a high school diploma or GED. Most (94%) qualified for Medicaid benefits were not

employed in the 3-month period before baseline (87%) and had been homeless or in a shelter during their lifetime (72%). While it is difficult to assess with precision how well the sample represents all PLHA of color, we believe it is reasonable to expect the intervention to work well in other contexts where similarly vulnerable PLHA of color are found.

Implications

Clinical trial sites, community-based organizations and HIV clinics have the potential to greatly reduce racial/ethnic disparities in ACTs by offering all patients regular and repeated access to ACT screening, regardless of their potential eligibility or perceived interest [46], and implementing multi-level interventions such as the ACT2 PDI can build patients' motivation and capabilities to screen for and join ACTs.

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Conflict of interest statement

None declared.

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Appendix A. Intervention core messages and detailed explanation

ACTs study the newest treatments available.	By enrolling in an ACT, you may be provided with treatments that are not available elsewhere. Although some of the treatments are new, they may not be better than existing treatments. That is the reason they are being examined in a clinical trial. This message is intended to reduce anxiety or fear about the aims of the ACT2 study and increase motivation to participate.
Screening is a discussion to see if an ACT is right for you.	The aim of the ACT2 study is to increase rates of screening, a low-risk activity that is nonetheless very infrequent among PLHA of color. Indeed, screening is a determination of whether there are ACTs that match a person's current health status that begins with a medical interview.
Screening does not mean joining a trial.	PLHA typically conflate screening for ACTs and enrollment. However, participating in screening does not mean one is committed to enrolling in an ACT. Separating screening from enrollment is an important aspect of the ACT2 intervention.
ACTs can treat other health problems such as Hepatitis C.	Many PLHA are doing well on their medication regimens and do not wish to add a medication or change medication. However, PLHA typically assume that all ACTs involve ART. Yet some ACTs address complications of HIV/AIDS, such as wasting, lypodystrophy or 'Buffalo Hump', Hepatitis C, high cholesterol, neuropathy, etc. Thus it may be worthwhile for PLHA to explore ACTs, even if they do not wish to change their ART regimen.
People who use drugs or alcohol can participate in ACTs.	PLHA of color often assume they will be ineligible for trials because of past or current substance use, even if that substance use is infrequent. Although very heavy users may be excluded from trials, the use of drugs and/or alcohol does not automatically disqualify one from enrolling in ACTs.
Even if you never took anti-HIV medications, ACTs can still help you.	ACTs may be appropriate for you even if you have never been on anti-retroviral therapy (ARV or HAART).
People who feel good still get screened for ACTs.	Some ACTs are appropriate even if one does not feel sick or if one is satisfied with his/her antiretroviral regimen.
You don't have to change your current treatment to participate in ACTs.	You do not always have to stop taking your other antiretroviral medications to join ACTs.
Every year thousands of women and people of color join clinical trials.	Every year thousands of women and people of color join clinical trials.
More women and people of color are needed in ACTs.	More women and people of color are needed in ACTs, for numerous reasons.

Appendix B. Description of the multi-component ACT2 intervention. (Activities are presented in the order they are conducted.)

Peer education. Main intervention targets: motivation to join the ACT2 project and explore the topic of ACTs, change perceived peer norms about ACTs.

Participant is introduced to the ACT2 project and educated by a peer at the time of recruitment on the 10 core messages (5–60 min, conducted independently without staff supervision in the community).

Session 1 (2-hour small group session, including video components that depict peers)

Main intervention targets: increase motivation to screen by increasing awareness, knowledge, and uncovering ambivalent attitudes about ACTs, and challenge negative peer norms regarding ACTs.

- Understand 10 core messages about ACTs (e.g. screening is a discussion to see if an ACT is right for you; screening is not a commitment to join an ACT; people who feel healthy still get screened for ACTs; you don't have to change your current treatment to participate in an ACT; even if you never took HAART ACTs can still be appropriate for you; more women and people of color are wanted and needed in ACTs).
- Understand types and purposes of ACTs including potential benefits of ACTs.
- Understand why people of color and women are needed in ACTs.
- Understand patterns of racial/ethnic and gender disproportionality in ACTs.
- Uncover historical and cultural reasons for under-representation in ACTs.

- Identify and discuss fears of, and individual, social and structural barriers to, ACTs.
- Identify and discuss research protections instituted in response to past mistreatment of people of color and women in research.
- Contextualize and normalize ACTs as one of many resources for PLHA.
- Separate the decision to screen for ACTs from the decision to enroll in ACTs.
- Using decisional balancing, evaluate personal readiness to screen for ACTs.

Session 2 (2-hour group session, including video components that depict peers)

Main intervention targets: increase motivation to screen, increase self efficacy to manage screening, and challenge negative peer norms regarding ACTs.

- Review 10 core intervention messages regarding ACTs.
- Understand and increase comfort with the ACT screening process.
- Increase skills for engaging social network members in ACT decisions.
- Increase skills and resources for involving the primary health care provider in ACTs screening decisions.
- Understand how clinical trials units may differ from typical clinic settings and how to successfully manage these disparate settings.
- Using decisional balancing, re-evaluate personal readiness to screen for ACTs.

Session 3 (1.5 hour group session)

Main intervention targets: increase motivation to screen and to conduct peer education, increase self efficacy and skills to manage screening and peer education.

- Review the 10 core intervention messages that will form the basis of peer education.

- Understand the role and importance of educating peers about ACTs.
- Learn the peer recruitment and education process through modeling.
- Practice the peer recruitment and education process.

**Peer education experiences (up to three peers, if participant so decides).
Main intervention targets:**

For peer educator: repeats and reinforces 10 core intervention messages and solidifies commitment to getting screened.

For potential participants (as noted above): provides introduction to core messages and begins to build motivation to get involved in the project and explore ACTs; challenges peer norms that PLHA of color are not involved in ACTs.

Session 4 (30 min individual session on the clinical trials unit where screening would take place). Main intervention target: reduce structural barriers to screening.

- Review peer education experiences (if any).

- Increase familiarity with the location where screening takes place.
- Increase familiarity and comfort with the clinical trials unit team
- Assess level of readiness for screening and finalize personal screening decision.
- Provide participant with screening contact information if appropriate.
- Close session and acknowledge accomplishments during intervention.

**Navigation (1–10 brief phone contacts).
Main intervention target: structural and personal barriers to screening and enrollment.**

- Staff initiates contact with participant to identify and resolve potential barriers to screening (e.g. transportation, directions, childcare issues).
- Provide reminders of appointment times.
- Coordinate communication between primary care provider and clinical trials unit.
- Provide support and information through the screening and enrollment process.