

Intervention To Increase African-American and Latino Participation in AIDS Clinical Trials: The ACT2 Program

The ACT2 Program is a peer-driven intervention to increase screening for and participation in AIDS clinical trials (ACTs) among adult African Americans/Blacks and Hispanics/Latinos living with HIV/AIDS, populations that are disproportionately affected by HIV and underrepresented in HIV medical studies. The ACT2 Program uses a motivational interviewing approach in small groups of HIV-positive people of color to uncover and explore the potential benefits of being screened for and participating in ACTs, as well as the long-standing barriers to ACT participation experienced by people of color. The intervention addresses common misconceptions about clinical trials, the mistrust and fear of medical research sometimes seen among racial/ethnic minority groups, and the historical and cultural reasons underlying these perceptions. A core value of the intervention is supporting participants' autonomy and decisionmaking without applying pressure or judgment. Participants learn about the direct benefits of participating in screening for ACTs, such as gaining access to new treatments, as well as indirect benefits that can be gained by increasing the representation of racial/ethnic minorities in HIV/AIDS research. Participants also are trained to serve as peer educators in their community and recruit peers to participate in the ACT2 Program. The peer education component is intended to solidify participants' own commitment to being screened for and participating in ACTs, in addition to extending the intervention's reach throughout a community.

The ACT2 Program consists of three phases that are repeated for each wave of recruited participants. All phases are facilitated by master's-level clinicians trained in social work or psychology. In the first phase, participants attend a series of group sessions, totaling 6 hours of meeting time. In the sessions, they learn about the potential benefits and barriers to participating in ACT screening and receive training as peer educators. At least 6-9 "seed" participants, typically recruited from community-based organizations, are required to convene the initial group. Participants receive \$25 for each session they attend. Content of the sessions is as follows:

- In Session 1: Building Knowledge and Developing Motivation, facilitators explain what ACTs are and discuss the problem of underrepresentation of ethnic minorities in these trials. Attitudes toward clinical trials are discussed through a sequence of interactive exercises and discussion.
- In Session 2: Understanding the ACT Screening Process and Determining Personal Readiness for Screening, participants demonstrate knowledge of core concepts from Session 1, including the purposes and types of ACTs, historical and current barriers to getting screened, and the problem of too few people of color in ACTs. Facilitators encourage participants to talk to their doctor about ACTs and involve their family and friends in their decisions about screening and enrollment. The differences between ACT units and other AIDS clinic sites are also discussed.
- In Session 3: Spreading the Word, facilitators build motivation in participants to conduct peer education and to participate in screening for ACTs. Facilitators also teach behavioral skills necessary for successful peer recruitment. Pairs of participants work in dyads to practice specific skills, such as different methods for approaching peers and taking steps to manage confidentiality. At the conclusion of this session, participants receive a wallet card listing 10 core messages to be conveyed (e.g., "AIDS clinical trials study the newest treatments available"; "Screening is discussion to see if an AIDS clinical trial is right for you"; "You don't have to change your current treatment to participate in AIDS clinical trials").

Following the third session, the peer education and recruitment phase begins. Over 4 weeks, participants are encouraged to share and explain the 10 core messages with peers and attempt to recruit three peers to participate in the ACT2 Program. For each referred peer, the participant receives \$25, up to a maximum of \$75 for three referrals. Additional compensation is provided when the referred peers correctly answer questions in a knowledge quiz based on the 10 core messages. Participants can continue in the intervention even if they choose to decline to recruit and educate peers. At the end of the recruitment phase, participants visit an ACT unit and meet individually with the clinical trial staff, with the goal of increasing their comfort level with participating in screening. Participants also finalize their **personal decision about being screened for an open trial or trials.**

The intervention concludes with the patient navigation phase, during which participants receive individualized support to overcome barriers to participation in trials. Over a 3- to 6-month period, facilitators follow up with participants who express interest in participating in screening. This support may include assisting with decisionmaking and logistical challenges (such as finding child care arrangements or transportation) and providing liaison between participants, their primary care provider, and the trial site. Participants who defer or decline to be screened also receive periodic phone calls so that facilitators can offer assistance should the participants change their mind.

The ACT2 Program is based largely on the theory of triadic influence, which emphasizes the importance of multilevel influences on health behavior, and the theory of normative regulation, which describes how norms about health behavior are transmitted through social groups. ACT2 facilitators use motivational interviewing, a goal-directed and client-centered counseling style that elicits behavioral change by helping clients to explore and resolve ambivalence. The intervention can be conducted through community-based organizations, HIV clinics, or clinical trials units.

Descriptive Information

Areas of Interest	Mental health promotion
Outcomes	Review Date: September 2013 1: Rate of screening for HIV/AIDS medical studies 2: Rate of enrollment into HIV/AIDS medical studies
Outcome Categories	No outcome categories are applicable.
Ages	26-55 (Adult) 55+ (Older adult)
Genders	Male Female
Races/Ethnicities	Asian Black or African American Hispanic or Latino Native Hawaiian or other Pacific Islander White Race/ethnicity unspecified
Settings	Outpatient Other community settings
Geographic Locations	Urban
Implementation History	The ACT2 Program was first implemented in 2008 in New York City through a research study conducted in collaboration with two community-based organizations. A total of 540 people participated in the program in 2008-2010.
NIH Funding/CER Studies	Partially/fully funded by National Institutes of Health: Yes Evaluated in comparative effectiveness research studies: Yes
Adaptations	No population- or culture-specific adaptations of the intervention were identified by the developer.
Adverse Effects	No adverse effects, concerns, or unintended consequences were identified by the developer.
IOM Prevention Categories	Selective

Quality of Research

Review Date: September 2013

Documents Reviewed

The documents below were reviewed for Quality of Research. The research point of contact can provide information regarding the studies reviewed and the availability of additional materials, including those from more recent studies that may have been conducted.

Study 1

Gwadz, M., Cleland, C., Belkin, M., Ritchie, A., Leonard, N., Riedel, M., et al. (2013, May 9). ACT2 peer-driven intervention increases enrollment into HIV/AIDS medical studies among African-Americans/Blacks and Latino/Hispanics: A cluster randomized controlled trial. Unpublished manuscript.

[Gwadz, M., Cleland, C. M., Leonard, N. R., Ritchie, A. S., Banfield, A., Riedel, M., 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 and Behavior*, 17\(2\), 801-812. !\[\]\(3211b5d1d968fc1665909b34f9f16010_img.jpg\)](#)

[Gwadz, M. V., Leonard, N. R., Cleland, C. M., Riedel, M., Banfield, A., Mildvan, D., & the ACT2 Project Collaborative Research Team. \(2011\). The effect of peer-driven intervention on rates of screening for AIDS clinical trials among African Americans and Hispanics. *American Journal of Public Health*, 101\(6\), 1096-1102. !\[\]\(6059a5aa8b4ca7bb793408023d6c6e42_img.jpg\)](#)

Supplementary Materials

Gwadz, M. V. (2013, January 23). Memorandum providing additional information in support of the ACT2 intervention's application to NREPP.

Gwadz, M. V. (n. d.). The ACT2 intervention manual. Version 1.0 New York University, College of Nursing.

[Gwadz, M. V., Colon, P., Ritchie, A. S., Leonard, N. R., Cleland, C. M., Riedel, M., et al. \(2010\). Increasing and supporting the participation of persons of color living with HIV/AIDS in AIDS clinical trials. Current HIV/AIDS Reports, 7\(4\), 194-200. !\[\]\(4729e517bc6a7cd81c8025b9646574fb_img.jpg\)](#)

Intervention forms (Brief Liaison Contact and Navigation Action Plan, Screening and Enrollment Report Form, Recruiter and Buy-Back Interview, Session Satisfaction Forms)

[Leonard, N. R., Banfield, A., Riedel, M., Ritchie, A. S., Mildvan, D., Arredondo, G., et al. \(2013\). Description of an efficacious behavioral peer-driven intervention to reduce racial/ethnic disparities in AIDS clinical trials. Health Education Research, 28\(4\), 574-590. !\[\]\(a03a7eb2f4046e1d3c76772003e549ea_img.jpg\)](#)

List of ACT2 Standard Operating Procedures

Quality assurance forms for facilitators and supervisors

Outcomes

Outcome 1: Rate of screening for HIV/AIDS medical studies

Description of Measures	The rate of screening for HIV/AIDS medical studies was assessed by asking participants if they had initiated and completed screening for an open ACT. Trained staff conducted assessments at baseline and at 16 and 52 weeks after baseline using laptop computers. The assessments consisted of a computer-assisted interview conducted by the staff and a computer-assisted, audio-based self-interview. At each follow-up, staff asked participants, "Were you screened for an AIDS clinical trial since your last interview?" Responses were coded by a senior staff member as yes or no. External verification was obtained from one of nine collaborating ACT units in the region that were running therapeutic clinical trials and biomedical observational studies during the study period. Participants were considered to have completed screening if they had reached the point of an eligibility determination.
Key Findings	<p>In a 3-year, cluster randomized controlled trial, HIV-positive African American and Latino adults not currently enrolled in an ACT were recruited from community-based organizations. The initial group of seed participants were randomly assigned in a two-to-one ratio to the intervention or a time- and attention-matched health education comparison condition. Seed participants in both conditions had the opportunity to recruit peers to participate in the study; those in the intervention group were also trained to educate peers on the intervention's core messages. Recruited peers were assigned to the same study condition as the person who recruited them.</p> <p>Across 52 weeks of follow-up, participants in the intervention group were 30 times more likely than those in the comparison group to complete screening. The screening rate among intervention group participants was 49.3%, compared with 3.7% among comparison group participants ($p < .001$). This group difference was associated with a large effect size (odds ratio = 31.8).</p>
Studies Measuring Outcome	Study 1
Study Designs	Experimental
Quality of Research Rating	3.5 (0.0-4.0 scale)

Outcome 2: Rate of enrollment into HIV/AIDS medical studies

Description of Measures	The rate of enrollment into HIV/AIDS medical studies was assessed by asking participants if they had enrolled in an ACT at 16- and 52-week follow-up. Responses were coded by a senior staff member and externally verified by one of nine ACT units in the region that were running open-enrollment therapeutic clinical trials and biomedical observational studies during the study period. If participant self-report and staff coding were not in agreement, staff coding was used as the final measure for analysis. The enrollment rate outcome included only those participants who initiated screening and were found to be eligible for at least one HIV/AIDS medical study; 55.5% (n=195) of participants in the intervention group and only 0.5% (n=1) of participants in the comparison group
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met this criterion.

Key Findings	<p>In a 3-year, cluster randomized controlled trial, HIV-positive African American and Latino adults not currently enrolled in an ACT were recruited from community-based organizations. The initial group of seed participants were randomly assigned in a two-to-one ratio to the intervention or a time- and attention-matched health education comparison condition. Seed participants in both conditions had the opportunity to recruit peers to participate in the study; those in the intervention group were also trained to educate peers on the intervention's core messages. Recruited peers were assigned to the same study condition as the person who recruited them.</p> <p>Across 52 weeks of follow-up, the enrollment rate was high (91.7%) among the 55.5% of intervention group participants who were eligible for at least one HIV/AIDS medical study, while the one comparison group participant who was eligible for at least one HIV/AIDS medical study did not enroll in any study, yielding an enrollment rate of zero ($p < .05$). This group difference was associated with a large effect size (odds ratio = 31.2).</p>
Studies Measuring Outcome	Study 1
Study Designs	Experimental
Quality of Research Rating	3.5 (0.0-4.0 scale)

Study Populations

The following populations were identified in the studies reviewed for Quality of Research.

Study	Age	Gender	Race/Ethnicity
Study 1	26-55 (Adult) 55+ (Older adult)	55.7% Male 44.3% Female	64.4% Black or African American 26.5% Hispanic or Latino 6.7% Race/ethnicity unspecified 1.7% White 0.6% Asian 0.2% Native Hawaiian or other Pacific Islander

Quality of Research Ratings by Criteria (0.0-4.0 scale)

External reviewers independently evaluate the Quality of Research for an intervention's reported results using six criteria:

1. Reliability of measures
2. Validity of measures
3. Intervention fidelity
4. Missing data and attrition
5. Potential confounding variables
6. Appropriateness of analysis

For more information about these criteria and the meaning of the ratings, see [Quality of Research](#).

Outcome	Reliability of Measures	Validity of Measures	Fidelity	Missing Data/Attrition	Confounding Variables	Data Analysis	Overall Rating
1: Rate of screening for HIV/AIDS medical studies	3.3	3.8	3.5	3.8	3.0	4.0	3.5
2: Rate of enrollment into HIV/AIDS medical studies	3.3	3.8	3.5	3.5	3.0	3.8	3.5

Study Strengths

The reliability of the outcome measures was supported by highly structured and well-documented eligibility screening procedures, using standard instruments/scales, for each open HIV/AIDS medical trial that was recruiting locally during the study period. The respondent-driven sampling methodology was well documented and produced a final study sample that was a reliable reflection of the targeted minority populations. The measurement validity of the screening and enrollment outcomes was increased by multilevel verification that

included independent coding by three senior research staff, with high interrater reliability external confirmation by the clinical trials research unit, and monthly cross-checks by the study project director. The intervention is manual-based, and fidelity was strengthened by the use of trained, master's-level clinicians. The clinicians were trained in group skills facilitation, motivational interviewing, and the HIV/AIDS disease process and had an understanding of the types of HIV/AIDS medical trials available, the eligibility screening criteria, enrollment procedures, and ethnic minority underrepresentation. All intervention sessions were videotaped. Facilitators completed written quality assurance forms after each session on what was delivered according to the manual; 10% of sessions were randomly selected and independently reviewed for adherence to the manual. All session reports were reviewed regularly by the clinical supervisor for completeness and corrective feedback as indicated. Fidelity of outcome measurement was well controlled through the use of computer-assisted scripts and electronic entry by laptop computer. Attrition was low at both follow-up points. Although missing data varied across the two outcomes, missing data were not related to the outcomes. Random assignment of seed participants controlled for many potential confounding variables. The statistical modeling of the dataset was consistent with a respondent-driven sampling method prior to randomization. The large sample size increased statistical power to detect between-group differences.

Study Weaknesses

The study did not measure the impact of the larger financial incentive available to intervention group participants (up to \$250) compared with that provided to comparison group participants (up to \$195) to attend sessions, recruit peers, and conduct peer education. The effect of the peer educator/peer recruitment component was confounded by intensive case management provided to participants who expressed interest in being screened for and enrolling in ACTs; this case management included telephone support boosters, appointment reminders, and help with transportation and any other logistical barriers to screening and enrollment. Because so few participants in the comparison condition initiated screening and only one was found eligible for enrollment in an ACT, there was essentially no comparison effect to analyze for the enrollment rate outcome.

Readiness for Dissemination

Review Date: September 2013

Materials Reviewed

The materials below were reviewed for Readiness for Dissemination. The implementation point of contact can provide information regarding implementation of the intervention and the availability of additional, updated, or new materials.

Gwadz, M. V. (n. d.). ACT2 facilitator training manual. New York University, College of Nursing.

Gwadz, M. V. (n. d.). The ACT2 intervention manual. Version 1.0 New York University, College of Nursing.

Other implementation materials:

- Brief Liaison Contact and Navigation Plan
- Locator Form
- Posters
- RDS Recruiter and Buy-Back Interview
- Recruitment Coupons
- Wallet Cards

Quality assurance materials:

- Intervention Participation Log
- Participant Log (Excel spreadsheet)
- Quality Assurance Form for facilitators
- Screening and Enrollment Form

Retention materials:

- Appointment Reminder Card
- Happy Birthday Card
- Happy Fall Card
- Happy Summer Card
- Reminder Business Card
- Reminder E-mail
- Seasons Greeting Card
- Thank You Card

Standard Operating Procedures (SOPs):

- SOP 1: Recruitment
- SOP 2: Obtaining Informed Consent
- SOP 3: Communicating with IRBs
- SOP 4: Source Documentation
- SOP 5: Determining Eligibility
- SOP 6: Participant Accrual

- SOP 7: Participant Retention
- SOP 8: Participant Randomization
- SOP 9: Data Management
- SOP 10: Social Harms
- SOP 11: Support and Referral
- SOP 12: Quality Management
- SOP 13: Training

Readiness for Dissemination Ratings by Criteria (0.0-4.0 scale)

External reviewers independently evaluate the intervention's Readiness for Dissemination using three criteria:

1. Availability of implementation materials
2. Availability of training and support resources
3. Availability of quality assurance procedures

For more information about these criteria and the meaning of the ratings, see [Readiness for Dissemination](#).

Implementation Materials	Training and Support Resources	Quality Assurance Procedures	Overall Rating
3.8	3.8	2.5	3.3

Dissemination Strengths

The intervention manual includes goals, objectives, and thorough instructions for conducting sessions. The developer assists new sites in tailoring the intervention to retain core elements while matching the sites' needs. The training manual includes a description of staffing requirements, techniques and materials for delivering the intervention, and helpful FAQs. Face-to-face and telephone consultation are offered as additional training supports. A feedback form helps sites assess the acceptability of the program from the participants' perspective. Quality assurance tools and processes include fidelity checklists, review of tape-recorded sessions, and telephone consultation.

Dissemination Weaknesses

Facilitators are not required to attend training, which seems inconsistent with the level of cultural competence demanded by the sensitive subject matter. While measures for assessing implementation fidelity are available, no outcome measures are specified. The quality assurance tools are not organized into a cohesive protocol for use outside the research setting.

Costs

The cost information below was provided by the developer. Although this cost information may have been updated by the developer since the time of review, it may not reflect the current costs or availability of items (including newly developed or discontinued items). The implementation point of contact can provide current information and discuss implementation requirements.

Item Description	Cost	Required by Developer
ACT2 Intervention Manual	Free	Yes
ACT2 Training Manual	Free	Yes
ACT2 online video segments (available on DVD by request)	Free	Yes
Posters and handouts	Free	Yes
Pretraining planning meetings by telephone (4-6 hours)	\$100 per hour	No
1 day, on-site training on motivational interviewing	\$1,000 per day, plus travel costs	No
2-day, on-site training for the ACT2 Program	\$1,000 per day, plus travel costs	No
Cofacilitation of client groups (to provide expert modeling and coaching/guidance)	\$1,000 per day, plus travel costs	No
Optional booster training	\$1,000 per day, plus travel	No

	costs	
Review of taped sessions	\$100 per hour	No
Phone and/or email support	\$100 per hour	No
Quality assurance forms	Free	No

Replications

No replications were identified by the developer.

Contact Information

To learn more about implementation or research, contact:

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Consider these [Questions to Ask](#) (PDF, 54KB) as you explore the possible use of this intervention.

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