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Three City Feasibility Study of a Body Empowerment and HIV Prevention Intervention Among Women with Drug Use Histories: Women FIT

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Abstract

Background: New intervention models are needed for HIV prevention among drug-using women.
Methods: The Women Fighting Infection Together (Women FIT) feasibility study enrolled 189 women in three U.S. cities (Providence, New York, Philadelphia) with drug-using histories, who also reported risky sexual behavior. Eligible women had participated previously in a yearlong study of HIV Counseling and Testing (HIV-CT) and limited case management. Two thirds of the sample were black, most were unemployed, and about two thirds reported prior or current crack use. Women were randomized into two groups. In one group, women participated in a manualized, four-session, peer-led, interactive group intervention that stressed body knowledge, woman-initiated HIV/sexually transmitted infection (HIV/STI) prevention, including a focus on women's health (reproductive health screening, sexual violence, self-breast examination, STI signs, symptoms), which aimed to increase comfort with and pride in their bodies. Control group women received HIV-CT enriched by female condom counseling. Outcomes included study retention, session attendance and ratings, changes in knowledge, and use of protection methods.
Results: The study successfully retained 95% of the participants for a 2-month follow-up. Positive assessments from participants and peer leaders exceeded preset thresholds for success. Pre-post changes in body knowledge ($p < 0.0001$) and protection methods knowledge ($p < 0.01$) was greater among the intervention women than the control women.
Conclusions: The body empowerment model deserves further elaboration in interventions focusing on women at high risk of HIV/STI acquisition.

Introduction

The rate of AIDS diagnoses in the United States from 1999 to 2003 for African American women was approximately 25 times the rate for white women and four times the rate for Hispanic women.[1–3] Most cases were attributed to heterosexual transmission (80%) or to injecting drug use (19%).[2] Recent, direct estimates of HIV infections through extended back-calculation indicate that the frequency of annual HIV infection among women continues to rise despite stable rates among men.[1] There remains a critical need to identify and diffuse effective prevention interventions for women. Woman-focused interventions to reduce HIV/sexually transmitted infection (HIV/STI) risk behavior have demonstrated effectiveness for women where drug use was not a criterion for study entry, including adolescent women from ethnic minority communities and women living in low-income housing developments.[4–9] These interventions integrate the concept of personal empowerment for women as a key ingredient in behavior change.

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Of particular interest to the study described in this article is an ongoing empowerment program targeting inner-city women based on collective empowerment principles and prioritizing women's learning and making healthy choices about the body.[10] This program aims to increase the level of resources for women as well as build on their current resource strengths, "particularly their shared strengths as members of dyads, families and social groups."[10(p168)] although not numerous, woman-focused HIV/STI prevention interventions have increasingly demonstrated their relevance for drug users. Wechsberg et al.[11] conducted a randomized trial comparing a woman-focused, mixed individual and group intervention with the National Institute on Drug Abuse (NIDA) standard intervention, which is a Centers for Disease Control and Prevention (CDC)-developed approach comprising standard HIV counseling and testing (HIV-CT), including a woman-focused supplementary discussion for drug users and their sex partners.[11] The authors reported a statistically significant difference in the frequency of unprotected sex at 6 months ($p = 0.03$), favoring the woman-focused intervention. The woman-focused intervention was grounded in empowerment theory and African American feminism and contained psychoeducational information and skills training. A short feasibility study of the culturally adapted woman-focused intervention in South Africa among 93 recent substance users demonstrated changes toward reduced risk over the monthlong follow-up for both standard and woman-focused arms, with a tendency to favor the woman-focused arm for sexual risk reduction outcomes (including any use of male or female condom).[12] Other studies targeting drug-involved women were either not able to demonstrate statistically significant differences between the woman-focused interventions tested (e.g., as against a standard intervention) or were compromised by high losses in retention.[13–16] To the extent that standard or control arms in these trials are enriched in gender-specific content (e.g., female condom), the underlying value of either assigned intervention arm will be difficult to demonstrate using conventional analytical methods.

The Women Fighting Infection Together (Women FIT) study was motivated by the need for novel intervention strategies for female out-of-treatment drug users that nonetheless built on successful themes used in prior interventions among at-risk women. The body empowerment intervention approach tested in this pilot study represents a distinct and complementary approach to empowerment for women. In addition to a framework that examined gender-based power imbalances in heterosexual relationships, a key focus in our study was increasing knowledge about, confidence in, and a sense of ownership of the body, especially the reproductive organs. These desired effects were thought to be mediated through promotion of woman-controlled barrier methods, such as the female condom (in addition to the male condom), and the use of peer counseling and participatory sessions to augment the empowerment process. Group sessions led by near-peers aimed to encourage participation and exchange among the women and to build solidarity among women as a means to confront the collective experience of economic stress and poor health emanating from their low status in a patriarchal society, effects greatly exaggerated in the drug-using culture. Finally, a philosophical framework of risk reduction rather than risk elimination in STI/HIV prevention was considered to be most appropriate for this woman-focused approach, underscoring successes (e.g., achieving greater levels of protection against disease as shown by increasing proportions of protected sex acts and improving negotiation powers) rather than failures (e.g., inability to achieve 100% protected acts).

The body empowerment approach draws heavily from feminist health principles espoused widely in the 1970s in such works as *Our Bodies, Ourselves.*[17] The approach we tested here has evolved through a series of trials on high-risk women in Harlem, NY,[18] among STI clinic attendees in Philadelphia,[9] and among community-based organization members, including African immigrant women in southern France, which proved to be successful and popular.[19] The feminist health model as applied to HIV underscores the need for holistic education about reproductive organs and genitals rather than a narrow focus on HIV. By demystifying the body, women collectively achieve a stronger sense of physical self and experience awe and pride in the functions of the normal female body. The feminist health approach has not, to our knowledge, been tested for efficacy at increasing knowledge or changing behavior, and the population we intervened with could be expected to have little *a priori* exposure to this approach to education and empowerment of women.

The body empowerment approach also draws from Freirian principles for effective community education, underscoring the need for critical consciousness as a precondition for positive behavior change by marginalized social groups (drug-involved women here representing the marginalized).[20] We incorporated numerous elements of Community Empowerment Theory, a model positing that lack of control over destiny reinforced by objective structural constraints promotes susceptibility to ill health for people living in chronically marginalized situations.[21–23] To reverse this cycle, the model thus demands positive inputs, especially skills building. In body empowerment theory, this input is increased access to information, techniques, and technologies to increase a sense of control over the body and keeping it healthy. This, in turn, should increase psychological empowerment.[23] The body empowerment model posits that body information specifically (along with increased sense of ease, ownership, and sense of responsibility to protect the body/self) contributes to a sense of collective identity for women and is moderated by the process of solidarity found in a woman-only group setting. These dynamic effects are theorized to provide an independent pathway to self-esteem, which in turn raises a woman's intention to protect herself from HIV and to self-protective behavior.

This pilot study was undertaken to assess acceptability and feasibility of this multisession, woman-focused intervention model among women at high HIV risk with a recent drug use history. Our intervention made considerable demands on attention spans for this population (sessions of 2.5 hours with one break), and its success was theorized to operate partly through group cohesion. Some of our key questions were: Will women be enthusiastic about participating in the study? Will they find the intervention material relevant to their lives? Will women attend group sessions and actively participate? Will women be able to move beyond the drug culture's deeply negative images of women—breeding mistrust and intense interfemale competition for male partnership and resources—to be able to connect with other women in a

relatively short time frame in order to provide mutual support for prevention behaviors?

Materials and Methods

Recruitment and enrollment

Potential participants were recruited in three sites in the United States: New York, NY, Philadelphia, PA, and Providence, RI. Women were recruited via participant rolls from previously completed studies, then recruited from each site's broader pool of Vaccine Preparedness Study II (VPS-II) participants or, in a minority of cases, those meeting eligibility criteria.[24] The HIV Network for Prevention Trials VPS-II was a prospective cohort study designed to assess HIV-1 seroincidence, risk behaviors, and attitudes toward potential clinical trials of HIV-1 prevention interventions, including vaccines. Participants in VPS-II were enrolled in six metropolitan areas. Eligibility criteria for the study we report on here (Women FIT), included the VPS-II enrollment criteria plus one additional criterion. The VPS-II criteria were (1) being at least18 years of age and HIV negative (confirmed by enzyme-linked immunosorbent assay/Western blot [ELISA-WB]), and (2) at least one of the following: reporting multiple sexual partners, exchange of sex for money or drugs; history of STI diagnosis or crack cocaine use in previous year; having a current male sex partner who was either HIV positive or had a history of drug injection. The additional criterion was (3) reporting at least 30% of all episodes of vaginal or anal intercourse in the last 6 months as unprotected by condoms. All participants provided written informed consent. This study was approved by the University of Pennsylvania Institutional Review Board.

Women who met eligibility criteria were enrolled, administered a risk assessment instrument via Audio Computer-Assisted Self-Interviewing (ACASI), and randomly assigned to one of two conditions, intervention or control, with approximately equal numbers in each condition. Randomization was stratified by study site and blocked within site to ensure balanced assignment within site. Women were recruited and enrolled between January and July 2001. A total of 189 women were enrolled into the study (91 intervention, 98 control).

Study design

We used a prospective design. Study women were enrolled, randomized, and underwent assessment and intervention procedures. They were followed for 5 weeks (control women) or 2 months (intervention women) depending on the study arm. On-site follow-up assessments were administered at the last study visit.

Sample

Across the three study sites, 257 women were screened (66 in NY, 139 in PA, and 52 in RI). Of these, 193 were eligible at screening, and 189 enrolled (59 in NY, 84 in PA, and 46 in RI) and completed study follow-up assessments. The mean age for this cohort was 39 years (standard deviation [SD] = 7, range 21–56). The majority (68%) were African American/black, and 8% reported being Hispanic or Latina. The vast majority were unemployed (76%), with 85% reporting an annual income of <$12,000. In the 6 months before enrollment, approximately half used crack at least twice monthly (and 68% used it at least once), 13% injected heroin, and nearly 20% drank alcohol at least 5 days per week. Thirty percent reported recent attendance at a 12-step drug rehabilitation program. Eighty-three percent of women at baseline reported some use of drugs in the prior 6 months. Table 1 provides additional details about the sample's demographic and drug risk characteristics. No significant site differences were noted.

Table 2 presents selected sexual risk indicators for the entire sample at baseline assessment. No significant differences between the experimental and control groups were found. The vast majority of women reported having a primary partner (88%). Nearly two thirds (62%) of participants reported some male condom use in the prior 6 months, although an average of only 17% of vaginal sex acts with a primary partner were reported as protected. Protection was higher with nonprimary partners of any HIV status, with an average of 36% reported as protected by male or female condoms, although female condom use was very infrequent. No significant site differences were noted.

Experimental procedures

The experimental behavioral intervention consisted of four group sessions delivered weekly for 1 month and included a reunion session 1 month later. Each group session lasted approximately 2½ hours, for a total of approximately 12 hours of contact time. Target group size was 6–10 women; occasionally, groups were held with as few as 4 women, when approved by the Principal Investigator (PI). When <4 women appeared for a session, a minisession of approximately 30 minutes in length was delivered, the content of which was similar to that of the intended intervention session. That session was rescheduled and delivered according to the manual at a later time, usually within 1 week.

Table 1. Baseline Demographics and Risk Behaviors of Sample ($N = 189$)

Variable	n *(%)*[a]
Age, years, mean (range)	39 (21–56)
Race	
Black	129 (68)
White	45 (24)
Other	15 (8)
Hispanic	16 (8)
High school diploma	95 (50)
Unemployed	143 (76)
Monthly income <$6000 annually	101 (53)
Stayed in shelter past year	33 (17)
In jail or prison in past year	53 (28)
Has health insurance	128 (68)
Reports drinking 5–7 days/week, past 6 months	35 (19)
Ever crack use	129 (68)
Ever marijuana use	92 (49)
Reports crack use twice or more per month, past 6 months	99 (52)
Ever injected heroin	24 (13)
Received in past 6 months	
Alcohol/drug detoxification	36 (19)
12-step program	57 (30)

[a]Except for age.

Table 2. Indicators of Sexual Risk at Baseline ($N = 189$)

Variable	n *(%)*
Had STI in past 6 months	21 (11)
Has primary partner in past 6 months	163 (88)
Used male condom in past 6 months	117 (62)
Used female condom in past 6 months	19 (10)
Used spermicides in past 6 months	14 (7)
Used diaphragm/cap in past 6 months	1 (1)
Mean proportion of unprotected vaginal sex acts with primary partner	0.79
Mean proportion of male condom-protected vaginal sex acts with primary partner in past 6 months	0.17
Mean proportion of male condom or female condom-protected vaginal sex acts with primary partner in past 6 months	0.18
Mean proportion of male condom-protected vaginal sex acts with other partner(s) in past 6 months	0.35
Mean proportion of male condom or female condom-protected vaginal sex acts with other partner(s) in past 6 months	0.36
Number of sex partners past 6 months, mean (median)	14 (2)

STI, sexually transmitted infection.

Groups were led by near-peers, women from the community who were specifically trained for this study and who used a standard intervention manual and materials. All sessions employed multiple strategies for conveying information and HIV protective strategies, including videos, charts, brochures, plastic and wooden anatomical models, discussion and brainstorming, problem solving, and role playing. Supplies of male and female condoms and spermicides and referrals for diaphragms and cervical caps were offered at the end of each intervention group session and for all participants at the short-term assessment. The study team attempted where possible to facilitate appointments for diaphragms and cervical caps at local family planning clinics, such as Planned Parenthood. Women were compensated between $20 and $25 for each study visit. Reminder calls and letters were standard procedures to encourage a high level of attendance at study sessions.

We incorporated certain community capacity-building elements into our study. Specifically, we involved community-based organizations (CBOs) in the process of recruitment and conducted a communitywide training day on completion of the study to inform community groups of the key findings as well as detailed information about the educational approach and tools we used in the intervention (e.g., female condom, hierarchical approach to risk reduction counseling). We provided limited technical assistance for organizations seeking to integrate woman-controlled prevention tools into their reproductive health or HIV/AIDS prevention programs. Nevertheless, we did not involve community groups in the formative planning stages of the intervention, nor did we train community group staff in the delivery of the intervention.

Group leader training

Experimental intervention group leaders (i.e., near-peers) underwent a weeklong training before study implementation. Near-peers were defined as women who came from the participant community, who may have been drug users in the past but not at the time of study implementation (a minimum of 3 years of sobriety was required), and who, ideally, had some previous experience discussing sex, sexuality, HIV/STI risk, and other women's health issues in group settings. The training included didactic information on HIV risk knowledge and the theoretical framework for the intervention, as well as a thorough review of intervention content, role playing, and modeling of each intervention session. Standard study-specific materials were employed. After training, each group of leaders completed a set of pilot intervention sessions with women similar to those recruited for the actual study. Study investigators responsible for intervention delivery and the psychological coordinator observed these pilot sessions both in-person and via videotaped sessions and ultimately certified each near-peer group leader before study implementation. Intervention sessions were either observed in-person or videotaped, and feedback and coaching was provided promptly to group leaders. The psychological coordinator, a clinical psychologist, was responsible for regular meetings and debriefing with counseling staff. Each intervention session was facilitated by two group leaders; three group leaders were hired and trained per study site to allow for continuity of group timelines in case of illness or other losses in group leadership.

Description of intervention

Group session 1 sought to increase knowledge of the female reproductive anatomy, knowledge of the risks of HIV infection, and familiarity and comfort level with one's genitals and reproductive anatomy, required for first attempts at various barrier protection methods (such as the female condom). A key aim was to dispel myths about female anatomy that led to fear (e.g., that a tampon could get lost in the vagina). Anatomic models of varied types were used to teach the workings of the normal body (distinctions between vagina, urethra, anus, vaginal lubrication, menstruation, pregnancy), as well as women's greater susceptibility to infection compared with men's, and to demonstrate insertion and removal of protection devices and substances. We sought to engender a sense of alarm and even indignation about women's biologically enhanced risk of HIV, coupled with their frequent economic dependence on men and lack of sufficient resources/strategies for protection, that was behind women's rising AIDS incidence. Our study brochures included the message: Take Control!. Barrier protection methods were introduced and explained in detail and ranked as to their place on a hierarchy of protection. The counseling underscored that male and female condoms are the best methods for HIV and STI

protection and that if a woman was unable to use one of these, she should try to use something to reduce her risk, preferably from the next highest level of protection strategies. The hierarchy was composed of four levels: female and male condoms, diaphragms and cervical caps with spermicide, spermicide alone, withdrawal (coitus interruptus). (This study was completed before data were published indicating possible vaginal epithelial damage with repeated spermicide use.)[25]

Group session 2 sought to contextualize the skills and knowledge from the first session, by elaborating on how HIV/STI protection methods might be used in various scenarios (e.g., with main vs. paying partners, co-occurrent substance use and sex). Role plays were used extensively. Drug-related risk reduction strategies (e.g., needle/syringe cleaning) also were introduced and role played. The notion of a woman's own desires and sexual pleasure and her right to have sex only when wanted were introduced and discussed, based on the personal experiences of group members. Group session 3 focused on women's bodies and health needs, emphasizing group members' own roles as advocates in their own healthcare, including their reproductive health: gynecological health, contraception, dual protection (i.e., contraception and disease protection), STIs, and treatments. Common procedures, such as Pap tests and mammography/breast self-examination, were demonstrated on models and demystified. In addition, group leaders helped women to address their fears and apprehensions about accessing healthcare by discussing strategies for reducing those fears. Group session 4 focused on strategies for reducing or avoiding violence, abuse, and violent sex. Physical self-defense techniques were presented and practiced in the group, and there was a thorough discussion of preparing escape plans in situations of a violent domestic partner. This session, in particular, focused on using community support by maximizing group support. Strategies for staying in touch were brainstormed. The reunion group session occurred 1 month after the fourth session and was tailored to the individual group and its needs, with its main purpose being to provide social support and increase motivation to maintain protective behaviors and seek out community-based support services.

The study sought to preserve the integrity, confidentiality, and trust established at the first intervention session of a particular group of women. Because the development of solidarity among the women was a key issue to the trial's success and central to the theory underlying the trial, a key study implementation rule was that no new member could join a group after its first session. Thus, women assigned to a specific group who did not appear for its first meeting (the first intervention session) were reassigned to a different group of women.

Control condition

The control condition consisted of personalized HIV risk reduction counseling and testing and limited case management, delivered in a one-on-one setting by certified counselors having undergone CDC-based training in HIV-CT. Control women thus continued to receive the counseling and services associated with the VPS-II study that preceded the Women FIT pilot study.[24] Our counseling for the control group was enhanced with the inclusion of female condoms in addition to male condoms as sexual risk reduction methods. HIV-CT includes a two-step HIV testing approach in which clients are physically present at a setting for the HIV test and then return for HIV test results. Each session length is a maximum of 15–20 minutes (including testing and referral). In the first session, a personalized risk assessment encourages clients to identify, understand, and acknowledge high-risk behaviors and circumstances. In the second session, when HIV test results are provided, the counselor discusses the test results, asks the client to describe the risk reduction step attempted (and acknowledges positive steps made), helps the client identify and commit to additional behavioral steps, and provides appropriate referrals.[26]

Assessments

Screening evaluations included a behavioral assessment of sexual and drug-related risk and protective behavior (including use of barrier methods) via ACASI, a health questionnaire via in-person interview including reproductive health history, STI history, healthcare and social services use, anatomy and barrier method knowledge (paper-and-pencil administration), and HIV counseling and testing. We reserved the use of ACASI for the most sensitive behavioral data. Feasibility of ACASI use in this population was also of interest in this study, although not formally considered as an outcome. A final assessment was conducted 1 week after the group session 4 for the experimental group to assess immediate postintervention knowledge gains as well as changes in barrier method use and intervention acceptability. For control participants, follow-up occurred at 60 days postenrollment, when participants were reassessed for anatomy and barrier method knowledge. Control participants were not assessed for barrier method use at follow-up. Also, because of resource constraints, we could not require control participants to return for follow-up at an additional time point before 2 months.

Outcomes and analyses

The primary outcome for this study was feasibility. Feasibility was assessed using five measures, each with an associated success threshold that was preset by the study group in advance of initiating enrollment. These were (1) ability to enroll 180 women within 92 days of start date, (2) ability to retain at least 80% of participants at 2 months, (3) completion rate of at least 65% of all five sessions (intervention plus reunion) by intervention participants (participant-sessions or number of participants$\times$number of sessions), (4) positive intervention acceptability rating of participants by at least 75%, and (5) positive intervention acceptability rating of peer leaders by at least 75%. There were a number of secondary outcomes. The level of participation in group sessions, rated by direct observation by the psychosocial coordinator, ranged from low (1 participant engaged during most of the session) to medium (more than 1 participant but less than half the group) to high (at least half the group engaged during most of the session). In addition, changes were measured in the scores on the anatomy and barrier method knowledge assessment between baseline and month 2 and in intervention participants' use of barrier methods.

Statistical methods

The analysis was designed to describe the baseline demographics and risk behaviors, the protection methods used at

baseline, and the acceptability of the intervention by the intervention arm participants on all screened and enrolled participants. One participant who was randomized was excluded from the analysis when it was determined subsequently that she did not meet the eligibility criteria. For the categorical data, global chi-square tests for independence were calculated between the covariate and the randomization group. Student's t test was calculated to test for average differences between the groups for normally distributed continuous outcomes. For nonnormally distributed data, the Wilcoxon rank-sum statistic was calculated. In cases where the cell counts were inadequate, Fisher's exact test was used. Analysis was conducted using a Sun Microsystems Ultra 5 desktop computer running SAS® version 8. Data from this trial were collected using the DataFax system and converted to SAS data files before analysis.

Results

Primary study outcomes

Table 3 presents the primary study outcomes. Among the 189 randomized participants, 94.7% were retained over the course of the study. Eighty of 91 (88%) intervention participants attended the first session and were allowed to continue with their original group. Eighty-two percent of the expected number of sessions 2–5 were completed. Attendance at sessions 2–5 ranged between 80% and 84%. Seventy percent of all sessions (sessions 1–5) were completed. The majority of both intervention group leaders (86%) and study participants (80%) gave the intervention positive ratings. The mean level of group participation as rated by the site psychosocial coordinator was high (data not shown). No significant site differences were noted in session completion and intervention level ratings.

Intervention acceptability

Participants. Table 4 presents additional participant responses regarding intervention acceptability. The response items were closed-ended, with the category, other, available for responses not captured by precoded responses. Among numerous positive intervention aspects, participants rated "talking in group sessions with other members" and "listening to group leader" as the most valuable for them. Most participants found intervention session length (2.5 hours) to be just right, but substantial numbers found the number of sessions (5) to be insufficient. The nonresponse rate here was higher than for other outcomes (14%); no systematic differences were seen in responders vs. nonresponders. Participants' reasons for not completing all sessions assigned ($n = 34$) did not show pronounced trends. Work obligations, use of drugs, transportation problems, insufficient study compensation, and legal matters (including court date and jail) were all cited by approximately 12%–15%. Children's illness was cited more frequently (35%).

Group leaders. Group leaders reported being either very satisfied (86%) or satisfied (14%) with the training and with supervision (100% very satisfied). Most were either very satisfied (29%) or satisfied (57%) with their delivery of the intervention (14% neutral); they were likewise very satisfied (71%) or satisfied (29%) with participant response. Most found intervention delivery very easy (29%) or easy (42%) (neutral 14% and difficult 14%), and most felt very comfortable (57%) with the intervention content (14% comfortable, 14% neutral, 14% uncomfortable). Suggestions for enhanced intervention content included more drug content (including drug-sex risk) and more information on menopause. A frequent comment was that there was insufficient time to address the multiple questions that arose; counselors reported sometimes feeling rushed in the group sessions. Scheduling groups convenient to working women and post-study termination phone follow-up for maintenance of prevention behaviors were some suggestions on improving study format.

Secondary outcomes

Secondary outcomes are presented in Table 5. Participants in the intervention condition exhibited significantly greater percentage increases in their pre-post anatomy knowledge scores and in their knowledge of protection methods compared with control arm participants.

Use of male and female condoms

Over the course of the study, 65% of intervention participants responding reported using the male condom at least once, and 60% of respondents reported using the female condom at least once. The difference from follow-up to baseline assessments in the median monthly frequency of use of protection among experimental intervention participants was statistically significant for both male condoms (1.13, $p < 0.0001$) and female condoms (0.77, $p < 0.0001$). (Because of nonnormality in these data, the median differences and subsequent nonparametric statistical tests in the rates are reported.) Among women taking the female condom home, substantial numbers tried the device more than once (22%

Table 3. Primary Study Outcomes

Measure	n *(%) (95% CI)*
Participants accrued within 92 days of start date	181 (95.8) (91.8-98.2)
Number of intervention sessions 2–5 completed[a]	262 (81.9) (77.2-85.9)
Number completed of all 5 intervention sessions[b]	319 (70.1) (65.7-74.3)
Frequency of positive assessments from intervention participants ($n = 91$)[b]	73 (80.2) (70.6-87.8)
Frequency of positive assessments from intervention group leaders ($n = 7$)[c]	6 (85.7) (42.1-99.6)

[a]Total expected: 320 (80 participants×4 sessions; 80 participants attended session 1, a prerequisite for attending any of sessions 2–5).
[b]Total expected = 455 (91 intervention participants×5 sessions; 4 intervention plus 1 reunion session).
[c]Positive assessment refers to response indicating very satisfied or satisfied on a 5-point Likert scale.
CI, confidence interval.

Table 4. Intervention Acceptability ($N = 91$)

Measure	*% intervention arm responders*[a]
Study aspect found most valuable	
Listening to group leader	19
Talking in group sessions with other members	41
Watching videos	3
Listening to tapes of women's lives	8
Using plastic/wooden models	3
Doing group activities	9
Getting paid	6
Speaking individually to counselor	3
Getting tested for HIV	5
All other (reading handouts, getting free condoms)	4
Percent feeling that groups helped "very much" or "somewhat" to	
Feel more comfortable about body	99
Reduce risk of infection	100
Feel more connected with other women	94
Talk to partner about protection	96
Get in touch with providers	85
Session length was	
Too long	9
Too short	5
Just right	86
Session number was	
Too many	1
Too few	54
Just right	45

[a]Nonresponse rate to all questions = 14%.

twice, 27% between 3 and 5 times, and 8% between 6 and 15 times).

Qualitative data

Numerous comments recorded during the group sessions attested to the women's favorable attitudes about new protection methods offered.

> I tried a condom for the first time! I swear to God—it felt good! It really did. It was safe sex. I ain't never used safe sex before."

> I have to say that this group really helped me . . . you all saw me the first day, I was sittin' up here sayin' that I would never try that female condom. Now you see me today, I tried it, and I'm going to try it again! I like it!

> If I could just get me one of those caps and some of that gel maybe it wouldn't be so hard. . . .

> I used the diaphragm before, for birth control, that was my choice of method. . . . I didn't realize they were using them for other things now . . . so, that wouldn't be a bad idea to go get a diaphragm anyway, to have in your pocketbook in case you don't have any rubbers or anything. Okay! I think I'm going to go get fitted for one of those. . . .

The women also frequently verbalized the importance of the group support process as well as the nature of the interaction with the peer group leaders.

> I was afraid to go (to the STI clinic), I was afraid of what they might say. But this group and my experiences with it really encouraged me. . . . I finally, finally went. I thought of everyone in the group and the support they gave me, and you ladies, too [gestures to group leaders], and I finally said "this ain't right, I'm tired of douching away this bad smell and it keeps coming back—I'm going to go." And they told me I had a bad infection, I had cervicitis, and I had PID."

> The workers weren't all high and almighty; they laid right down with you. *[Remark made about group leaders during fourth session]*

> I miss being here, I really do. . . . I remember the first time I come in here, telling you anything, get my money. I'd go out and buy me some drugs, I won't lie. But then more and more you come and realize that you're around people that love you, that care about you. People treat you right. It takes you a while to figure out. *[Comment made during reunion session]*

> I never knew I could learn so much from women I just didn't want to be around. . . .

Discussion

We tested the feasibility of a novel approach to HIV/STI risk reduction based largely on women's solidarity and a focus on women's bodies as an independent route to empowerment, self-esteem, and reduction of risk behaviors among a marginalized population. Despite the intensive nature of the intervention tested, all preset study end points for success were exceeded, including enrollment and retention targets,

Table 5. Knowledge Assessment and Condom Use ($N = 189$)

Outcome	*Intervention*	*Control*	p *value*
Mean percent difference (follow-up vs. baseline) in percent of correctly answered questions for body knowledge assessment	19.64	9.51	<0.0001
Mean percent difference (follow-up vs. baseline) in percent of correctly answered questions for prevention methods knowledge assessment	13.81	7.05	0.0136
Median difference (post- vs. pre-intervention) of monthly rate of male condom use (intervention participants only)	1.13	——	0.0007
Median difference (post- vs. pre-intervention) of monthly rate of female condom use (intervention participants only)	0.77	——	<0.0001

group completion rate, and intervention acceptability rating by participants and peer leaders. The participants, women with drug-using histories, generally attended and participated in sessions enthusiastically, feeling that they were neither too long nor too numerous. Many of the women wished for a greater number of sessions.

Intervention participants as compared with control participants demonstrated greater short-term knowledge increases regarding the body and reproductive tract, as well as practical knowledge about the different protection methods offered. As the intervention theory was based on the value of enhancing body knowledge as a key ingredient of the empowerment effect, this result was encouraging. Intervention participants also reported trying the protection methods offered over the 2-month period, including making requests to the study team for clinical referrals to obtain the prescription methods (diaphragm, cervical cap).

Women's narrative comments illustrated the extent to which the intervention was well-liked, practical, and meaningful in the context of their lives. Many of their comments revealed the initiation of an empowerment process, the transformative potential of the intervention experience. In particular, the sense of solidarity achieved in the group interactions and the quality of the peer communications were strongly endorsed by the women.

The present analysis was limited by a number of study design features. Because of resource constraints, this study was designed as a feasibility study; thus, intervention participants could not be followed for longer than 2 months, and follow-up was limited to 5 weeks for control arm participants. Thus, we could not compare 2-month responses across both arms, and we could not assess the lasting nature of the knowledge changes or long-term impact on intervention participants' ability to use protection more frequently.

We pooled data across the three sites for this analysis after investigating site-specific differences. No important differences were found, but this may have been because of insufficient sample size to fully investigate the hypothesis. Our design called for multiple group intervention sessions for intervention participants but only pre-HIV and post-HIV test counseling (two short sessions), administered by trained and certified individuals, for control participants. The intervention participants also received occasional minisessions when attendance was low, which may have added a booster effect to any behavioral change induced by the actual intervention. Neverthess, our aim was to compare standard of care with an enhanced model. This consideration was prioritized over attention control issues. Thus, the actual recommended HIV counseling approach in practice at the time of the study was used as the control condition. In addition, our model specifically theorized that providing information on women's bodies that was not directly related to HIV (e.g., gynecology screening, mammography) provided part of the intervention effect, consistent with feminist health education principles and a more holistic approach to body education. This study design thus does not provide data on the comparison of outcomes among the intervention group as against a control group matched for session number and total duration.

Finally, many study women had participated in VPS-II and may have been either self-selected as ready for change or more amenable to adhering to interventions of any type. Their responses collected at the end of this pilot study might reflect cumulative changes partly induced by prior interventions they underwent. Nevertheless, the principal study aim was to demonstrate the feasibility of this intervention concept among drug-using women at high risk of sexually transmitted HIV/STI who had already undergone regular HIV-CT. These feasibility end points were successfully met. Indeed, it could be argued that the fact that these women were not intervention naïve and had already demonstrated some behavioral change over the course of the VPS-II study rendered them even less likely to demonstrate additional changes.

The results of this woman-focused, body empowerment intervention were incorporated into the design of a 1-year randomized trial (unpublished data). Evidence from the present study supported increasing the number of intervention sessions (i.e., more than 4) both during the initial period and during the follow-up period (i.e., additional reunion sessions) in order to enhance group solidarity and potential intervention effects. Because the intervention theory seeks to integrate community empowerment with feminist health approaches, efforts were made to strengthen collaboration with CBOs from the start, in study design and training, with the eventual goal of establishing new community resources for drug-using women desiring regular access to such a peer-led group process as well as easier access to women-controlled HIV/STI protection methods. Our later trial among active crack users in Philadelphia (for which baseline data are in press[27]; intervention manual available upon request) built on these lessons by training CBO staff to deliver intervention sessions and to moderate postintervention sessions at their community sites.

This short-term feasibility study has demonstrated the relevance and high acceptability of an intervention linking historical themes of the women's health movement with those of empowerment education and community empowerment among one of the hardest to reach groups of women at risk for HIV/STI. The enthusiasm shown by those involved at all levels of the study—participants, peer leaders, staff, and community—testifies strongly to the need to integrate these themes into future approaches targeted to this population and other at-risk populations of women. These data strongly suggest that, especially for at-risk women, the time has come to validate feminist health participatory education approaches alongside other empowerment-based models used for women to reduce the risk of HIV.

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Disclosure Statement

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