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Reducing Human Immunodeficiency Virus and Sexually Transmitted Infections Risk in African American Women with At-Risk Male Partners: A Randomized Trial

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Abstract

Introduction: We examined the efficacy of the Females of African American Legacy Empowering Self (FemAALES) intervention in a cohort of 203 publicly insured Black women in Los Angeles.
Materials and Methods: Women who reported recent sex with a male partner who was at increased risk for infection by human immunodeficiency virus (HIV) and sexually transmitted infections (STI) were randomized to the six-session FemAALES intervention or to a single client-centered family planning and STI/HIV counseling session. Participants were followed at 3 and 9 months post-intervention. To investigate between-group behavioral changes in condomless sex in the prior 90 days and other HIV/STI risks, we used generalized estimating equations that accounted for repeated observations in individuals.
Results: Most participants (mean age 34 ± 11 standard deviation) were low-income and unemployed, despite three-quarters having completed high school or the equivalent. The most common HIV/STI risk factors among recent male partners were incarceration (58.8%) and concurrent sex with other women (72.2%). At 3 months, the FemAALEs group showed a larger increase in the odds of asking their partner to test (adjusted odds ratio = 2.14; 95% confidence interval [CI], 1.02–4.47; $p = 0.0431$) and in sexual health self-efficacy scores (adj$\beta = 1.82$; 95% CI, 0.02–3.62; $p = 0.0471$) compared to the control group, although these changes did not hold at 9 months. Both groups showed statistically significant declines in the frequency of several sexual risk factors between baseline and 9 months.
Conclusion: Although we did not find evidence that the FemAALES intervention was more efficacious than the less-intensive control condition in reducing sexual risk behaviors, the overall declines in risk behaviors we observed warrant further research.
ClinicalTrials.gov (Identifier: NCT02189876)

Keywords: HIV, sexually transmitted infections, race, health disparities, intervention, behavioral health

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Introduction

Black/African American people experience the heaviest burden of human immunodeficiency virus and sexually transmitted infections (HIV/STIs) compared to other racial/ethnic groups in the United States. In 2019, Black women still accounted for 54% of new HIV cases among women in the United States, despite a 27% decline in their HIV rates between 2010 and 2017.[1] In addition, Black women had reported rates of chlamydia and gonorrhea that were, respectively, 5.2 and 6.8 times the rates among White women.[2]

African Americans often come of age, partner, and develop sexual behaviors and patterns of health care seeking in segregated contexts characterized by limited educational and employment opportunities, inadequate access to quality health care, and overpolicing, along with rigid and sometimes bi/homophobic norms related to masculinity.[3–8] These contexts contribute to low male-to-female sex ratios[9–11] and relatively high levels of poverty.[4,10–13] Research has shown that specific sexual network patterns[4] affecting Black women's sexual health emerge in these contexts. These include an increased probability of engaging in heterosexual relationships with unhealthy power dynamics, or with men who have concurrent partners.[9,14–16]

Black women are more likely than women of other races to partner with men of the same race and to be in sexual network clusters characterized by a central male partner who has multiple, often monogamous partners.[4] Black/African American men have higher rates of HIV/STIs than other race/gender groups.[2] Given that heterosexual contact is the primary mode of HIV transmission for women of all races/ethnicities,[1] these patterns increase risk for Black women.[16,17]

The disproportionately high rates of incarceration experienced by Black men have been associated with HIV risk, substance use, restricted opportunities, and relationship disruption.[15,18–20] Research shows that, relative to adolescent Black women with male partners without a recent incarceration history, those with male partners who were recently released from incarceration were more likely to be diagnosed with an STI[20] or engage in sex while they or their partners were intoxicated.[15] Rates of sexual risk behaviors in a nationally representative sample of men were higher among those who used illegal substances than among those who did not, regardless of incarceration status.[21]

Finally, HIV risk is increased among men who have sex with both men and women (MSMW) compared with those who only have sex with women.[1,17,22] Disclosure of same-sex relationships or sexual identities is lower among Black MSMW than among other-race MSMW[17,23] decreasing the likelihood that their partners will take action to reduce their HIV risk.[17,23,24] We can infer from these and other studies that Black women whose sexual partners are MSMW have been incarcerated or who use specific substances are at increased risk for HIV and STIs.

Although several HIV/STI prevention interventions have targeted women's sexual behaviors that increase risk (*e.g.*, substance misuse and sex with multiple partners),[25–33] and many have been culturally tailored for African American and Black women,[34–36] most do not address the complicated nexus of contextual- and partner-level risk in which many Black women find themselves.[12,37] This highlights a need for tailored HIV/STI prevention interventions that address individual- and partner-level risk factors while taking into consideration sociocultural contexts. This study assessed the efficacy of one such intervention, known as *Females of African American Legacy Empowering Self (FemAALES)*. FemAALES was grounded in the Theory of Reasoned Action and Planned Behavior (TRA/TPB),[38,39] Critical Thinking and Cultural Affirmation (CTCA),[40] Social Cognitive Theory (SCT),[41,42] and Empowerment Theory[43] and adapted for women from the demonstrated-effective Men of African American Legacy Empowering Self or MAALES intervention.[44,45]

We conducted a randomized parallel-group trial to determine the impact of the FemAALES intervention on STI/HIV risk factors and outcomes among African American women with at-risk male partners in Los Angeles County. In this, FemAALES is unique, because HIV preventions for Black women have typically not considered partner-level factors nor focused on subgroups of women at increased risk for HIV.[46] The most recent systematic review on HIV interventions for Black women by Sophus and Mitchell[46] indicates that, ''Among all interventions, only 6 focused on women identified as an 'at risk' sub-group for HIV….'' One of these interventions was for adolescents, one for sex workers, one for women living with HIV, and one for women who had experienced intimate partner violence. This leaves just two previously tested, published interventions focused on women similar to those we studied and none that recruited women based on their partners' risk factors.

We hypothesized that, compared to the control condition (a client-centered counseling intervention), the FemAALES intervention would reduce numbers of sex partners, episodes of condomless vaginal and anal intercourse, and incidence of gonorrhea and chlamydia, and that it would increase self-efficacy related to sexual health negotiation and partner testing for HIV/STIs. We used the incidence of gonorrhea and chlamydia as proxy measures for HIV risk. Although the power to measure differences in incidence of STIs over a short timeframe is also limited, the risk of STI infection is generally much higher than the risk of HIV infection. The presence of these and other STIs may increase a person's risk of acquiring HIV.[47]

Materials and Methods

Participants

Participants were recruited from the community through a range of street/event venues and community partner sites between July 2013 and March 2017, including family planning centers, community clinics, health festivals, and shopping centers. Individuals were eligible if they identified as female, Black/African American, were at least 18 years old, spoke English, were uninsured or insured through public insurance, had not participated in any HIV prevention research study or multi-session program in the past 12-months, and reported unprotected vaginal or anal sex in the prior 3 months with a potentially at-risk man. The latter was defined as someone for whom the participant (1) did not know their sexual history, (2) knew or suspected had had sex with a man, (3) knew or suspected had had sex with a transgender woman, (4) knew or suspected was an injection drug user, (5) knew or suspected was a crack cocaine or

methamphetamine user, (6) knew had been incarcerated for at least 6 months, or (7) knew had concurrent sex with other women.

All participants provided written informed consent. This study was approved by the Charles R. Drew University Institutional Review Board.

Surveys

Participants completed a survey at baseline, usually on the same day as screening. The median length of time between screening and the baseline survey was 5 days, although the maximum length of time was 64 days in one case. Participants were asked to complete follow-up surveys 3 and 9 months after their scheduled interventions concluded. The first baseline survey was completed September 2013, and the final 9-month follow-up was completed in April 2018. Surveys were completed using audio-computer-assisted self-interview software (Questionnaire Development System™) in a private location at a partner organization or at the participant's home. In a small number of instances (2%), the participants completed a follow-up interview *via* phone.

An interviewer asked the initial survey questions, which consisted of questions on sociodemographics, and participants' Internet usage and methods of access in the last 90 days. Participants then answered a set of questions designed to allow them to practice operating the software before completing the remainder of the survey by themselves. During the self-administered portion, participants could listen to the questions and responses over headphones and/or read them on the screen. Participants were asked all survey questions directly in the case of phone interviews.

The survey included questions about sexual partners the participant had had in the previous 3 months, with detailed questions about the two most recent partners. Partner characteristics assessed included HIV status and history of long-term incarceration (at least 6 months), history of sex with cisgender men or transgender women, or with other cisgender women concurrently with the participant, and use of injection drugs, crack cocaine, and methamphetamine. These substances were selected because of the extensive literature showing positive associations with HIV risk, either through needle use or sexual behaviors, such as exchange sex.[48–53] A partner riskiness score, equal to the number of positive responses, was then calculated for each partner. Finally, we asked whether the participant had discussed their partners' HIV status or asked them to obtain HIV testing. For this analysis, we focused on the most recent partner.

We measured several outcomes related to sexual risk in the prior 3 months, including the number of male sex partners, episodes of vaginal and anal sex, and times that a condom had been used during those encounters. Because the distribution of these variables was bimodal, we determined whether condoms were used during at least 80% of the encounters, based on the total and condom-protected sexual encounters of each type. We evaluated *condom self-efficacy* by asking participants to rank their agreement with a set of 11 statements relating to confidence in using condoms (*e.g.*, ''I can use a condom with a new male partner without breaking the mood'') modified from the National Institutes of Health multisite condom use self-efficacy scale.[54] Responses were scored on a 5-point Likert scale ranging from 1 = ''Not at all sure I can do'' to 5 = ''Completely sure I can do'' and summed for a total score. The scale had a Cronbach's alpha of 0.91 in our sample. Participants were also asked if they had a condom with them, and the interviewer visually confirmed its presence.

Sexual health efficacy was determined by asking participants to rate agreement with statements about discussing sexual history with partners (*e.g.*, ''It is hard to ask a sex partner about other people they have had sex with.'') from the Health Belief Model Self Efficacy for Sexual Discussion scale.[55] A 4-point Likert scale was used, with responses ranging from 0 = ''Disagree'' to 3 = ''Agree.'' Responses were reverse-coded if necessary before summing them to calculate the total score. Cronbach's alpha for our sample was 0.84.

Because most of the outcomes were self-reported, we included an assessment of social desirability in the survey. Questions on the 5-item Marlowe-Crown scale present desirable but unlikely scenarios (*e.g.*, I am always polite even to people who are not courteous to me), with possible responses of 1 = Definitely False–5 = Definitely True. The social desirability score was calculated as the number of extreme responses (*i.e.*, ''Definitely True'' or ''Definitely False'') in the desirable direction[56] and had a Cronbach's alpha of 0.56 in our sample. This total was transformed to a 0–100 scale by multiplying the total by 20 to allow interpretation of the score as a proportion of the total possible, as has been done previously.[57]

Interventions and STI screening

Control condition—Title X standard of care. All study participants received the control condition, a client-centered reproductive health and family-planning counseling session conducted in accordance with the United States Department of Health and Human Services Title X guidelines.[58] With exception of the first three cohorts of enrollees, these sessions were completed by our partner organizations no more than 28 days before the baseline survey; most participants completed them on the same day. Women in the initial cohorts could enroll and schedule their sessions at a later date; however, this practice was discontinued because several participants did not follow through. As part of these counseling sessions, participants discussed family planning options and HIV and STIs. In addition, all study participants were offered condoms and tested for gonorrhea and chlamydia. Urine samples were collected at sites run by the study partners (a federally-qualified health center or a clinical research laboratory) or obtained through the participants' providers. All sites used nucleic acid amplification tests for gonorrhea and chlamydia.

Randomization. After the baseline counseling and interview, participants were randomized 1:1 into the control condition or the FemAALES intervention using a computer-generated random number scheme that used block randomization. Random assignments were prepared in advance and placed in sealed envelopes to be opened by the interviewer. Only those assigned to the FemAALES intervention condition were invited to participate in the FemAALES intervention sessions. The study began with a third intervention arm that had to be discontinued for funding reasons.

Intervention condition—FemAALES. FemAALES was a cisgender-female-focused adaptation of the MAALES intervention, a previously studied effective HIV intervention detailed in Williams et al.[45] The intervention framework was premised upon the TRA/TPB[38,39] Empowerment Theory,[43] and the CTCA Model—an Afrocentric model developed by a prior community-based organization partner[40] that is grounded in SCT.[42] Like its predecessor, FemAALES was developed in partnership with collaborating agencies and was informed by patients, community advisory board members, and qualitative formative research.[5]

The intervention involved nine 2-hour small group sessions over a 4-week period: six core sessions discussed below and three additional ''workshop'' sessions focused on using technology and social media to both find and create quality sources of health information. Participants in these sessions worked together as a group to create sexual health messages using a topic and medium of their own choice. To maintain a sense of group cohesion and safety, participants could not miss session 1 and join the subsequent sessions for that cohort. However, if they missed session 1, they had the opportunity to join one of the subsequently formed cohorts. Participants who opted into the workshops developed a digital health message using a topic and format of their choice guided by our facilitators, who coached them in the use of readily available tools such as cell phones or public computers.

The intervention sessions were facilitated by Black/African American women who were familiar with our population. Facilitators were trained in intervention implementation, digital content creation, HIV, and STIs; prior training or specialized skills were not required. The intervention implementation was remotely monitored by a trained licensed clinical social worker who reviewed at least one randomly selected audiorecording for each cohort, scored the session based on a detailed rubric, and provided periodic feedback to the facilitators to ensure curriculum fidelity.

The primary intervention goals were to (1) decrease the following compared to the standard of care: number of sex partners, frequency of unprotected anal/vaginal sex, and incidence of bacterial STIs, and (2) increase participants' ability to discuss sex and drug use risk with sexual partners along with their self-efficacy for condom use negotiation. The foundation of the six health intervention sessions was the participants' shared experience and history as Black women. Participants identified cultural norms and social influences that encouraged health-promoting behaviors, and also that benefitted their families, communities, and significant others. To facilitate critical thinking, the intervention prompted participants to focus on their past, present, and future while thinking critically about potentially harmful cultural and media influences on Black sexuality, femininity, and masculinity.

Sessions 1 and 2 focused on *the past*: the importance of Black women's identity and histories in sexual decision making, an assessment of participants' health behaviors and family health histories, and interactive HIV education. Sessions 3 and 4 focused on *the present*: identifying current barriers to safer sex, assessing partners' potential risks, developing skills for sexual health negotiation, STI education, and personal health goal setting. Sessions 5 and 6 focused on *the future*: strategies to help participants challenge current negative behaviors, evaluate sexual health decision making and options using critical thinking, set goals, and reaffirm their commitment to the African American community, legacy, cultural pride, one another, and to their own legacies.

Statistical analysis

We used bivariate chi-square tests to assess differences at baseline between the control and FemAALES groups, and between study completers and those lost to follow-up. To investigate changes in outcomes between groups over the follow-up period, we used generalized estimating equations (GEEs) that included an exchangeable working covariance structure to account for correlations between repeated observations in individuals and included all available pairs. For binary outcomes, the GEE used a logit link function. We included age as a covariate in all models because we expect that outcomes may vary as a function of age. Because there were very few cases of gonorrhea, we used data augmentation priors to address the separation resulting from this data sparsity.[59] From the GEEs, we calculated pre-post contrasts examining within-group changes between the baseline and follow-up assessments, using the Bonferroni adjustment for multiple comparisons. We conducted all analyses in SAS version 9.4 and used a $p < 0.05$ to determine statistical significance.

Results

Description of study participants

Figure 1 demonstrates participant flow into the study. A total of 1020 African American women were screened. Among the initially eligible participants (410; 40%), 249 (61%) completed the baseline interview assessment (those who did not were uninterested, did not show for appointments, or were determined to be ineligible based on responses to screening questions within the baseline interview). We included 203 (82%) of those who completed the baseline in this analysis. Most of those excluded from the current analysis ($n = 46$) were randomized to the discontinued arm (27; 59%) or failed to complete the required baseline STI screening (10; 22%). Among the included participants, STI results were missing for 11 at baseline and 8 at the 9-month follow-up because of sample quality issues, missing records, or incorrect tests performed.

Analyzed participants were assigned evenly to the FemAALES ($n = 102$) and to the control ($n = 101$) groups. Seventy-eight percent of the participants completed interviews at each follow-up assessment point (159/203 at 3-month; 158/203 at 9-month follow-up). Participation in the FemAALES sessions was low, with just 46% of those assigned to this group completing any session, leading to a mean overall completion of just 2.0 ± 2.5 ($\pm$ standard deviation [SD]) of the six health sessions. However, among those who attended any group sessions ($n = 47$), session participation was high, with a mean of 4.4 ± 1.8 ($\pm$SD) sessions completed. Participation in the three internet-based sessions was not recorded.

Table 1 presents the sociodemographic characteristics of those randomized to the two conditions. No statistically significant differences in sociodemographics were observed between the intervention and control conditions at baseline. Between those who completed follow-ups and those who did not, the only significant differences were that more of those who completed 3-month follow-ups had post-high school education than those who did not ($p = 0.0462$), a smaller

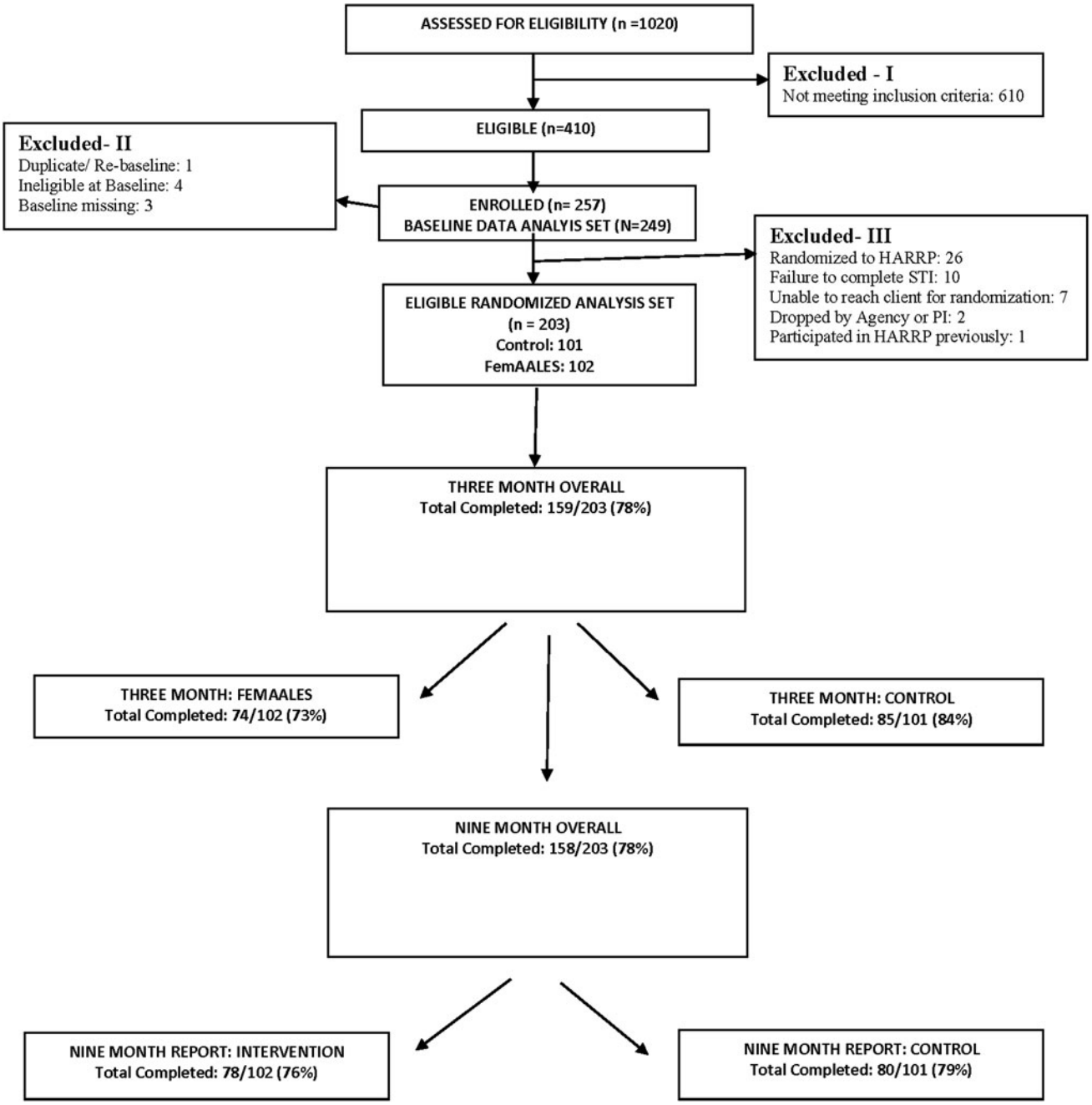

FIG. 1. FemAALES Project—Final Consort Retention Chart. FemAALES, Females of African American Legacy Empowering Self.

number of those who completed the 9-month follow-up had partners who had had extensive incarcerations than those who did not ($p = 0.0277$), and participants who completed the 9-month tended to be older than those who did not ($p = 0.001$). The average age of the participants was 34 (±11 SD). While three-quarters of the participants had finished high school or the equivalent, they were largely low-income and unemployed. Slightly over half had been incarcerated at some point in their lives.

The characteristics of each group's most recent male sex partner at baseline are shown in Table 2. There were no statistically significant differences in partner characteristics. Mean numbers of partner risk factors endorsed were 1.4 (SD = 1.2) and 1.5 (SD = 1.3) for the intervention and control groups, respectively. Nearly 60% of the women had recent male partners who had spent 6 months or more in jail or prison. The most common behavioral risk factor for HIV/STIs reported about women's partners was concurrency, which was reported by 67.3 and 77.1% of the FemAALES intervention and control groups, respectively ($p = 0.1303$ for difference). Approximately 30% reported that their recent partners had used crack cocaine.

Analysis of intervention-related outcomes

The primary outcomes were numbers of sex partners, episodes of condomless vaginal and anal intercourse, incidence

Table 1. Characteristics of Females of African American Legacy Empowering Self Study Participants at Baseline and Follow-up and Tests for Group Differences

	Baseline			*3-month Follow-up*			*9-month Follow-up*		
	Control (n = *101*)	*FemAALES* (n = *102*)		*Completed* (N = *159*)	*Missing* (N = *44*)		*Completed* (N = *158*)	*Missing* (N = *45*)	
Characteristic	% (n)	% (n)	p	% (n)	% (n)	p	% (n)	% (n)	p
Age (mean ± SD)	35 ± 12	33 ± 11	0.2411	35 ± 11	32 ± 11	0.0741	36 ± 11	30 ± 9	0.0010
Education			0.3676			0.0462			0.4158
Less than High School	26.7 (27)	20.6 (21)		23.9 (38)	22.7 (10)		24.1 (38)	22.2 (10)	
GED	8.9 (9)	6.9 (7)		5.7 (9)	15.9 (7)		6.3 (10)	13.3 (6)	
High school diploma	39.6 (40)	52.0 (53)		44.7 (71)	50.0 (22)		45.6 (72)	46.7 (21)	
2- or 4-year degree or certificate or higher	24.8 (25)	20.6 (21)		25.8 (41)	11.4 (5)		24.1 (38)	17.8 (8)	
Employment			0.6014			0.6615			0.2032
Full time	5.9 (6)	6.9 (7)		6.3 (10)	6.8 (3)		5.1 (8)	11.1 (5)	
Part time/ occasional	15.8 (16)	24.5 (25)		18.2 (29)	27.3 (12)		17.7 (28)	28.9 (13)	
Self-employed	7.9 (8)	3.9 (4)		6.9 (11)	2.3 (1)		5.7 (9)	6.7 (3)	
Under the table, off the books work, or a ''hustle''	5.9 (6)	4.9 (5)		5.0 (8)	6.8 (3)		5.1 (8)	6.7 (3)	
Unable to work because of disability	16.8 (17)	16.7 (17)		17.6 (28)	13.6 (6)		19.0 (30)	8.9 (4)	
Unemployed	47.5 (48)	43.1 (44)		45.9 (73)	43.2 (19)		47.5 (75)	37.8 (17)	
Monthly income			0.1525			0.7445			0.6722
<$1000	60.4 (61)	63.7 (65)		61.6 (98)	63.6 (28)		63.3 (100)	57.8 (26)	
$1000–$1,999	25.7 (26)	30.4 (31)		27.7 (44)	29.6 (13)		26.6 (42)	33.3 (15)	
$2000+	13.9 (14)	5.9 (6)		10.7 (17)	6.8 (3)		10.1 (16)	8.9 (4)	
Ever homeless			0.8954			0.9195			0.6768
No	21.8 (22)	22.5 (23)		22.0 (35)	22.7 (10)		21.5 (34)	24.4 (11)	
Yes	78.2 (79)	77.5 (79)		78.0 (124)	77.3 (34)		78.5 (124)	75.6 (34)	
Ever incarcerated			0.7203			0.9570			0.4188
No	44.6 (45)	47.1 (48)		45.9 (73)	45.5 (20)		44.3 (70)	51.1 (23)	
Yes	55.4 (56)	52.9 (54)		54.1 (86)	54.6 (24)		55.7 (88)	48.9 (22)	
Ever married			0.6711			0.8068			0.5386
No	73.3 (74)	70.6 (72)		72.3 (115)	70.5 (31)		70.9 (112)	75.6 (34)	
Yes	26.7 (27)	29.4 (30)		27.7 (44)	29.6 (13)		29.1 (46)	24.4 (11)	
Used internet last 90 days			0.2742			0.4745			0.4277
No	22.8 (23)	16.7 (17)		20.8 (33)	15.9 (7)		20.9 (33)	15.6 (7)	
Yes	77.2 (78)	83.3 (85)		79.3 (126)	84.1 (37)		79.1 (125)	84.4 (38)	

FemAALES, Females of African American Legacy Empowering Self.

of gonorrhea and chlamydia, and sexual health self-efficacy. The latter included condom use self-efficacy, health self-efficacy, discussion partner HIV status, and requesting partner to test for HIV. In both groups, there were increases at follow-up in the percentages of women that requested their partner to get HIV tested, discussed partner's HIV status, and reported condom use (Table 3). There were also small increases in reported sexual health and condom use self-efficacy.

The interaction effect in the GEE compared differences in the primary outcomes of interest between the follow-ups and the baseline for the FemAALES intervention group relative to the control intervention group. The odds of asking their partner to get tested for HIV at 3 months increased twice as much in the FemAALES compared to the control group (Table 4 adjusted odds ratio [AOR] = 2.14; 95% confidence interval [CI], 1.02–4.47; $p = 0.0431$). FemAALES also had a larger increase in sexual health self-efficacy at 3 months compared to the control group (adj$\beta = 1.82$; 95% CI, 0.02–3.62; $p = 0.0471$).

Pre-post contrast tests (Table 5) indicated that while FemAALES participants were more likely to ask their partner to get tested for HIV at the 3-month (AOR = 2.24; 95% CI,

Table 2. Characteristics of Most Recent Male Partner at Baseline

Characteristic	*Control (n = 101) %* (n)	*FemAALES (n = 102) %* (n)	p
Ever had sex with other men			0.1179
No	89.6 (86)	95.6 (87)	
Yes	10.4 (10)	4.4 (4)	
Ever had sex with a transgender woman			0.9893
No	96.8 (90)	96.7 (89)	
Yes	3.2 (3)	3.3 (3)	
Ever spent at least 6 months in jail or prison			1.0000
No	41.2 (40)	41.2 (40)	
Yes	58.8 (57)	58.8 (57)	
Ever injected drugs			0.8878
No	90.8 (89)	91.4 (85)	
Yes	9.2 (9)	8.6 (8)	
Ever used crack			0.7896
No	69.1 (67)	70.8 (68)	
Yes	30.9 (30)	29.2 (28)	
Ever used meth			0.3757
No	81.6 (80)	86.3 (82)	
Yes	18.4 (18)	13.7 (13)	
Had sex with other women concurrently with you			0.1303
No	32.7 (32)	22.9 (22)	
Yes	67.3 (66)	77.1 (74)	
HIV status			0.6503
Negative	97.8 (91)	96.8 (90)	
Positive	2.2 (2)	3.2 (3)	

1.15–4.37; $p = 0.0104$) and 9-month (AOR = 2.35; 95% CI, 1.12–4.94; $p = 0.0164$) follow-ups compared to baseline, control participants were not (AOR = 1.05; 95% CI, 0.54–2.02; $p = 1.000$ and AOR = 1.35; 95% CI, 0.65–2.81; $p = 1.000$, respectively). Sexual health self-efficacy in the FemAALES group was increased at both 3-months ($\beta = 2.61$; 95% CI, 0.97–4.25; $p = 0.0003$) and 9-months ($\beta = 2.65$; 95% CI, 1.08–4.21; $p < 0.0001$); whereas the control group showed a significant increase toward increased self-efficacy only at 9-months ($\beta = 1.74$; 95% CI, 0.01–3.46; $p = 0.0472$).

Contradictory, but non-significant associations were observed for FemAALES assignment and the two STIs (Table 4). Compared with controls, FemAALES participants showed an increased prevalence of gonorrhea at 9 months versus baseline (AOR = 2.25; 95% CI, 0.48–10.48; $p = 0.2999$) and a decreased prevalence of chlamydia at 9 months versus baseline (AOR 0.60; 95% CI, 0.06–5.79; $p = 0.6561$). The gonorrhea estimates were based on just three cases at baseline and one at 9 months, but we report these results because they were part of the study design and primary aims.

In both the intervention and control groups, there were substantial and statistically significant declines in STI/HIV risk factors between the baseline and follow-up periods (Table 5). Both groups had fewer male sex partners at 3-months (FemAALES: $\beta = -0.74$; 95% CI, −1.25 to −0.24; $p = 0.0010$; Control: $\beta = -0.63$; 95% CI, −0.95 to −0.32; $p < 0.0001$) and 9-months (FemAALES: $\beta = -0.69$; 95% CI, −1.19 to −0.18; $p = 0.0026$; Control: $\beta = -0.63$; 95% CI, −1.02 to −0.23; $p = 0.0003$). In addition, partner risk scores were reduced at both follow-ups for both FemAALES (3-month: $\beta = -0.46$; 95% CI, −0.77 to −0.14; $p = 0.0011$; 9-month: $\beta = -0.61$; 95% CI, −1.03 to −0.20; $p = 0.0008$) and control (3-month: $\beta = -0.41$; 95% CI, −0.76 to −0.06; $p = 0.0121$; 9-month: $\beta = -0.48$; 95% CI, −0.87 to −0.08; $p = 0.0097$) study participants. Finally, those assigned to the FemAALES group were more likely to report improved condom self-efficacy at 3-months ($\beta = 3.25$; 95% CI, 0.95–5.54; $p = 0.0016$), as were those in both groups at 9-months

Table 3. Changes in Outcomes Over Time by Group

	Control			*FemAALES*		
	Baseline	*3-months*	*9-months*	*Baseline*	*3-months*	*9-months*
	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)
Requested partner to get HIV tested	57.1 (58)	59.4 (41)	64.6 (42)	38.6 (39)	60.3 (38)	60.3 (38)
Discussed partner HIV status	59.2 (58)	66.7 (46)	66.2 (43)	49.5 (50)	59.7 (37)	60.3 (38)
Used condoms during 80% of vaginal sex	16.7 (16)	36.5 (18)	38.6 (18)	20.4 (20)	39.5 (18)	31.7 (19)
Used condoms during 80% of anal sex	12.5 (3)	40.0 (4)	11.1 (1)	27.6 (8)	35.7 (5)	50.0 (8)
Chlamydia	4.2 (4)	—	2.7 (2)	8.8 (8)	—	4.0 (3)
Gonorrhea	2.1 (2)	—	0.0 (0)	1.1 (1)	—	1.3 (1)
Had condom at interview	18.8 (19)	11.8 (10)	15.2 (12)	20.6 (21)	13.9 (10)	25.6 (20)
	Mean ± SD	*Mean ± SD*	*Mean ± SD*	*Mean ± SD*	*Mean ± SD*	*Mean ± SD*
No. of male partners	1.9 ± 1.2	1.2 ± 1.0	1.2 ± 1.4	2.0 ± 1.5	1.3 ± 1.4	2.3 ± 9.0
Condom use self-efficacy	45.1 ± 10.2	46.7 ± 9.6	48.6 ± 7.6	44.6 ± 9.9	48.2 ± 7.0	48.2 ± 8.2
Sexual health self-efficacy	25.1 ± 6.3	25.7 ± 5.7	26.9 ± 5.4	24.9 ± 6.6	27.6 ± 4.7	27.4 ± 4.9
Partner riskiness score	1.7 ± 1.3	1.3 ± 1.2	1.3 ± 1.2	1.7 ± 1.2	1.2 ± 1.2	1.1 ± 1.3

SD, standard deviation.

Table 4. Comparison of Changes in Outcomes Over Time Between Females of African American Legacy Empowering Self Study and Control Groups—Interaction Terms from Adjusted GEE Models

Dichotomous outcomes	*AOR [95% CI]*	P
Requested partner to get HIV tested		
Intervention x Follow-up (3 months)	2.14 [1.02 to 4.47]	0.0431
Intervention x Follow-up (9 months)	1.74 [0.77 to 3.94]	0.1859
Discussed partner HIV status		
Intervention x Follow-up (3 months)	1.09 [0.54 to 2.20]	0.8183
Intervention x Follow-up (9 months)	1.18 [0.52 to 2.64]	0.6940
Used condoms during 80% of vaginal sex		
Intervention x Follow-up (3 months)	0.89 [0.37 to 2.15]	0.8030
Intervention x Follow-up (9 months)	0.86 [0.33 to 2.24]	0.7626
Used condoms during 80% of anal sex		
Intervention x Follow-up (3 months)	0.16 [0.02 to 1.60]	0.1179
Intervention x Follow-up (9 months)	3.08 [0.28 to 34.16]	0.3588
Chlamydia[a]		
Intervention x Follow-up (9 months)	0.60 [0.06 to 5.79]	0.6561
Gonorrhea[a]		
Intervention x Follow-up (9 months)	2.25 [0.48 to 10.48]	0.2999
Had condom at interview		
Intervention x Follow-up (3 months)	1.09 [0.40 to 2.96]	0.8662
Intervention x Follow-up (9 months)	1.70 [0.68 to 4.27]	0.2551
Continuous outcomes	β *[95% CI]*	P
No. of male partners		
Intervention x Follow-up (3 months)	–0.11 [–0.58 to 0.36]	0.6450
Intervention x Follow-up (9 months)	–0.06 [–0.56 to 0.46]	0.8180
Condom use self-efficacy		
Intervention x Follow-up (3 months)	1.64 [–1.0 to 4.28]	0.2224
Intervention x Follow-up (9 months)	0.21 [–2.66 to 3.08]	0.8861
Sexual health self-efficacy		
Intervention x Follow-up (3 months)	1.82 [0.02 to 3.62]	0.0471
Intervention x Follow-up (9 months)	0.91 [–0.92 to 2.73]	0.3299
Partner riskiness score		
Intervention x Follow-up (3 months)	–0.05 [–0.41 to 0.32]	0.8060
Intervention x Follow-up (9 months)	–0.14 [–0.59 to 0.31]	0.5448

[a]STI test results not collected at 3 months.
AOR, adjusted odds ratio; CI, confidence interval.

Table 5. Changes in Outcomes Between Follow-Up and Baseline for Each Intervention Group —Pre–Post Contrasts

Dichotomous outcomes	*AOR [95% CI]*	p
Requested partner to get HIV tested		
FemAALES 3 months	2.24 [1.15 to 4.37]	0.0104
FemAALES 9 months	2.35 [1.12 to 4.94]	0.0164
Control 3 months	1.05 [0.54 to 2.02]	1.0000
Control 9 months	1.35 [0.65, 2.81]	1.0000
Discussed partner HIV status		
FemAALES 3 months	1.40 [0.72 to 2.76]	0.8302
FemAALES 9 months	1.54 [0.75 to 3.15]	0.5344
Control 3 months	1.29 [0.71 to 2.35]	1.0000
Control 9 months	1.31 [0.62 to 2.75]	1.0000
Used condoms during 80% of vaginal sex		
FemAALES 3 months	1.66 [0.76 to 3.64]	0.4150
FemAALES 9 months	1.76 [0.72 to 4.29]	0.4599
Control 3 months	1.86 [0.84 to 4.13]	0.2059
Control 9 months	2.03 [0.89 to 4.65]	0.1266
Used condoms during 80% of anal sex		
FemAALES 3 months	0.53 [0.05 to 5.94]	1.0000
FemAALES 9 months	2.00 [0.53 to 7.58]	0.7788
Control 3 months	3.35 [0.60 to 18.76]	0.3196
Control 9 months	0.65 [0.04 to 10.24]	1.0000
Chlamydia[a]		
FemAALES 9 months	0.46 [0.09 to 2.41]	0.5834
Control 9 months	0.77 [0.10 to 5.72]	1.0000
Gonorrhea[a]		
FemAALES 9 months	1.11 [0.30 to 4.13]	1.0000
Control 9 months	0.49 [0.15 to 1.64]	0.3754
Had condom at interview		
FemAALES 3 months	0.62 [0.25 to 1.53]	0.7390
FemAALES 9 months	1.31 [0.60 to 2.83]	1.0000
Control 3 months	0.57 [0.23 to 1.39]	0.4559
Control 9 months	0.77 [0.32 to 1.84]	1.0000
Continuous outcomes	β *[95% CI]*	p
No. of male partners		
FemAALES 3 months	–0.74 [–1.25 to –0.24]	0.0010
FemAALES 9 months	–0.69 [–1.19 to –0.18]	0.0026
Control 3 months	–0.63 [–0.95 to –0.32]	<.0001
Control 9 months	–0.63 [–1.02 to –0.23]	0.0003
Condom use self-efficacy		
FemAALES 3 months	3.25 [0.95 to 5.54]	0.0016
FemAALES 9 months	3.66 [0.92 to 6.39]	0.0033
Control 3 months	1.61 [–0.85 to 4.06]	0.4091
Control 9 months	3.45 [1.01 to 5.89]	0.0016
Sexual health self-efficacy		
FemAALES 3 months	2.61 [0.97 to 4.25]	0.0003
FemAALES 9 months	2.65 [1.08 to 4.21]	<.0001
Control 3 months	0.79 [–0.81 to 2.39]	0.8639
Control 9 months	1.74 [0.01 to 3.46]	0.0472
Partner riskiness score		
FemAALES 3 months	–0.46 [–0.77 to –0.14]	0.0011
FemAALES 9 months	–0.61 [–1.03 to –0.20]	0.0008
Control 3 months	–0.41 [–0.76 to –0.06]	0.0121
Control 9 months	–0.48 [–0.87 to –0.08]	0.0097

[a]STI test results not collected at 3 months.

(FemAALES: $\beta = 3.66$; 95% CI, 0.92–6.39; $p = 0.0033$; Control: $\beta = 3.45$; 95% CI, 1.01–5.89; $p = 0.0016$).

Discussion

Our study of the efficacy of a culturally congruent sexual risk-reduction intervention known as FemAALES to address the HIV/STI issues facing many African American women showed improvements in HIV/STI-related risk and protective behaviors in both the control and intervention group between the baseline and the 3 and 9-month follow-up assessments. In several cases, the odds of increased protective behaviors more than doubled, and the odds of risk behaviors were halved, indicating clinically meaningful decreases in potential disease risk. Furthermore, women reported having sex with partners who had fewer HIV/STI risk factors. The changes in most outcomes, however, did not differ statistically between the FemAALES and control groups. While underpowered, the study findings did provide evidence that the FemAALES intervention was more effective than the control condition (client-centered family planning and HIV/STI counseling) in raising Black women's sexual health-related self-efficacy and encouraging them to insist that their male sexual partners test for HIV.

Specific improvements in potential HIV/STD risk factors documented in both groups included increases in condom use self-efficacy and sexual health self-efficacy but not condom use, and substantial declines in numbers and riskiness of male sexual partners. Notable differences in the incidence of bacterial STIs between the intervention and control groups or in changes over time were not found; however, the small numbers of identified cases made it difficult to do so. The Title X standard-of-care control intervention focuses on family planning first and STIs second. Generally, both condoms and STI testing can be, but are not always, part of this counseling session. However, our protocol required that all of our study participants also received condoms, STI information, and STI screening. These factors likely influenced their subsequent decision making related to potential sexual risk behaviors since all participants had increased knowledge about sexual risk and tools for reducing that risk.

The few observed trends in favor of the intervention may be attributed to two aspects of the FemAALES intervention: its holistic approach and its focus on risk factors within Black women's sexual networks. The intervention encouraged participants to place their sexual health in the larger context of community, to attend to their mental health, and to their physical health more broadly, and it addressed behavior change through examination of past experiences, present decision making, and future intent to maintain change. Even though several other STI/HIV risk- reduction programs that have been culturally tailored for Black women in the United States have been effective at reducing personal sexual risk behaviors,[28,60,61] FemAALES differed in its focus on individual-, partner-, and contextual-level risk factors.

The statistically significant and sometimes substantial declines in risk that occurred across time in both groups are worthy of note. We purposely compared FemAALES to a demonstrated effective intervention approach; hence, improvements in the control group may be expected. The content of both intervention conditions included information and resources regarding sexual health, and referrals for emotional/mental health services were made available to all participants during the study course, regardless of study arm. Participants' motives for starting and completing the study may have further enhanced the likelihood of positive change for both groups. Anecdotally, many participants indicated that they had recognized the need to make changes in their lives and relationships and joined the study because of this motivation. Hence, while the intervention may have supported women's desire for self-improvement, some participants may have joined at a point in their lives when they were already contemplating or attempting to make these changes on their own. Finally, study participation itself may have offered ongoing affirmation and positive reinforcement.

The study's findings should be considered in the context of several limitations, including being underpowered, and strengths. Although the results of this study were largely based on self-reported risk behaviors, we were also able to collect data on the incidence of gonorrhea and chlamydia. Participation was limited to one urban center, thus limiting the generalizability to more suburban and rural areas. As we noted that many of the women enrolled in the study may have been particularly motivated to make changes in their lives, it is possible that the intervention may be less effective for others who are less motivated, although we have no evidence that this is the case. Finally, the low intervention attendance highlights several issues with the implementation of this type of research and intervention.

Small group interventions require time to assemble sufficient enrollees to establish a group and find a mutually agreeable meeting time to start sessions. In the interim, individuals can lose motivation or take on additional obligations that fill their time. As part of establishing group safety and sequencing the intervention elements consistent with the theoretical bases of FemAALES, individuals could only join at Session One. This further meant that those who could not attend the first new cohort starting after they enrolled had to wait weeks or months for a new group to form. Multisession interventions that allow participants to enter at any point would limit dropout due to changing schedules and declining motivation, and those involving virtual group sessions would reduce the burden on participants' time by eliminating travel to and from sessions.

Given that our focus included the sexual networks of Black women and empowerment within relationships, the inclusion of romantic partners into programs like FemAALES may help achieve desired reduction in risk.[37] Although this approach is used in the EBAN intervention for HIV serodiscordant couples,[62] inclusion of romantic partners in FemAALES would require substantial shifts in approach, limit participation to women whose partners were willing to take part in such an intervention, and not serve the needs of women in abusive relationships.

Conclusion

While others have shown the importance of culturally tailored interventions for African American and Black women,[34,35] our study suggests that the preventive benefit of this multi-session culturally congruent risk-reduction intervention, compared with a much less intensive single-session intervention, may be limited. Nevertheless, the reported improvements in typically challenging relationship communication related to sexual health and HIV testing among

FemAALES intervention participants have the potential to yield benefits beyond the prevention of HIV/STIs. Skill-building in both discussion of sexual health and encouraging partner testing for HIV are particularly relevant to the current Ending the HIV Epidemic strategy that has shifted its HIV prevention focus from behavioral to biomedical prevention, including HIV testing.[63] Given the multiple stressors and demands experienced by many low-income African American women, it is important that health interventions are both effective and efficient. Although the FemAALES intervention largely did not demonstrate this, the large declines in risk behaviors in both intervention groups signal the importance of recognizing and supporting Black women when they choose to prioritize their own sexual health.

Authors' Contributions

M.O.A.: Writing—Original draft preparation and review and editing.

Q.M.: Supervision, Writing—Review and editing.

T.B.-D.: Project administration, Writing—Review and editing.

K.M.S.: Formal analysis, Writing—Original draft preparation and review and editing.

N.T.H.: Conceptualization, Supervision, Writing—Original draft preparation and review and editing, Funding acquisition.

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