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Sheroes: Feasibility and acceptability of a community-driven, group-level HIV intervention program for transgender women

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Abstract

Transgender women experience disproportionate risk of HIV acquisition and transmission. We piloted ‘Sheroes’, a peer-led group-level intervention for transgender women of any HIV status emphasizing empowerment and gender affirmation to reduce HIV risk behaviors and increase social support. Participants (N=77) were randomized to Sheroes (n=39) or a time- and attention-matched control (n=38). Sheroes is 5 weekly group sessions; topics include sexuality, communication, gender transition, and coping skills. Control participants attended 5 weekly group movie sessions. At 6-month follow up, HIV-negative and unknown status Sheroes participants reported reductions in condomless intercourse and improved social support compared to control. Among participants living with HIV, both the control and intervention groups reduced their total number of sex partners; this change was sustained at 6-month follow-up for Sheroes participants but not for control participants relative to baseline. Sheroes was deemed highly feasible and acceptable to participants; findings support preliminary efficacy of Sheroes.

Key words: transgender women, HIV, sexual risk, affirmation, intervention

Background

Transgender women, although resourceful and resilient, are a highly vulnerable and marginalized population in the United States (US) as well as globally, experiencing high rates of stigma, discrimination, and violence (1-5). Consequently, given the association of negative health outcomes with stigma and discrimination, transgender women experience severe health disparities across a number of outcomes, including HIV (6-9). Although no national data yet exist in the US, a meta-analysis found that 28% of transgender women tested positive for HIV (7). In California, transgender female clients of publicly-funded counseling and testing sites have higher rates of HIV diagnosis (6%) than all other risk categories, including MSM (4%) and partners of people living with HIV (5%), and African American transgender women have a particularly high rate of HIV diagnosis (29%) (10). Estimates from other urban centers in the US similarly suggest that HIV prevalence rates among transgender women are among the highest of all key populations, especially for transgender women of color, and African American transgender women are most severely impacted (8, 11, 12).

Despite high HIV prevalence, transgender women frequently underestimate their risk of acquiring or transmitting HIV and report low rates of HIV testing (6). They report engaging in multiple types of risk, including unprotected receptive anal sex with multiple partners, sex under the influence of drugs and alcohol, sex work, and sharing needles for injection drugs, hormones, and silicone (as well as other substances) for body modification purposes (13-18). The previously mentioned meta-analysis found that almost half (44%) of transgender women reported condomless receptive anal intercourse, with most reported with sex work clients (39%) and primary partners (37%) (7). Sex under the influence of drugs and/or alcohol is one of the most commonly cited sexual risk factors among transgender women, as it often leads to risky sex (11). Among transgender women, condomless sex is reported to be especially prevalent with primary partners (11, 19), but is also reported with paying and casual partners (20, 21).

Despite high HIV prevalence, public health intervention research has produced few culturally specific, evidence-based HIV prevention interventions for transgender women and none are group-level interventions for adult transgender women. Group-level interventions for cisgender (i.e. non-transgender) women living with HIV have been shown to decrease sexual risk behavior (22), enhance self-esteem, and increase levels of social support within communities that often experience social isolation (23). For women living with HIV, groups

can be a supportive environment within which to practice disclosure of their HIV status (23). Transgender women are likely to benefit in similar ways from a group-level intervention, but interventions specifically designed for transgender women are necessary to address their unique needs and social context.

Conceptualizing transgender women's unique context of HIV risk, especially centering the perspective of transgender women of color, is critical to developing effective prevention and treatment strategies. Based on the Model of Gender Affirmation, we developed 'Sheroes', a community-led group-level HIV intervention for transgender women of any HIV status with an emphasis on the lived experiences of transgender women of color (24). The Sheroes intervention was developed in collaboration with transgender community members, members of a community advisory board, and staff of the Center of Excellence for Transgender Health at the University of California, San Francisco, all of which included a majority of transgender women of color. The name 'Sheroes' (i.e. "She + Hero") was suggested by a community member who participated in our formative work, and the name was then endorsed by the advisory groups.

The Model of Gender Affirmation was developed to contextualize risk behavior among transgender women of color (25). Building upon Diaz's model developed with Latino MSM, which clarifies how internalized oppression leads to sex in high-risk contexts (26), combined with Major & O'Brien's identity threat model of stigma and objectification theory (27), the Model of Gender Affirmation aims to clarify how stigma and oppression lead to HIV-related risk behaviors among transgender women. The Model of Gender Affirmation illustrates how social oppression decreases access to gender affirmation while psychological distress increases the need for gender affirmation, leading to identity threat (Figure 1). Attempts to decrease the threat then happen in high risk contexts, where risk behavior is more likely (13). The Sheroes intervention aims to decrease identity threat by increasing access to gender affirmation. Gender affirmation was integrated into the intervention through role modeling, group discussions, gender-affirming interactive exercises, and the introduction of a 'Shero' in each session to provide empowering examples of transgender women of color in history and current events. In addition to being informed by the Model of Gender Affirmation, Sheroes was shaped by formative qualitative data that guided decisions about how gender affirmation was integrated into the intervention (25).

The primary goal of Sheroes is to decrease risk of HIV acquisition or transmission among transgender women by increasing access to gender affirmation through increasing access to health care, including

transition-related care (such as hormone therapy and surgeries) as well as HIV prevention and treatment, and increasing social support through community building. Social support includes fostering alliances between transgender women through community building and empowering relationships via creation of a "sisterhood" of transgender women who have completed the intervention. Themes from transgender women's experiences are woven throughout the intervention to maximize the cultural relevance, and thus the efficacy, of the intervention (see Table 1). Sheroes consists of 5 group sessions of 6-8 participants conducted weekly. Sessions were conducted by two trained peer co-facilitators who were transgender women of color; sessions consist of group discussions and interactive group activities.

The aim of this study was to conduct a pilot randomized controlled trial (RCT) to examine the feasibility and acceptability of the Sheroes intervention and examine preliminary data on the efficacy of Sheroes to impact the primary outcomes of reducing sexual risk behavior and increasing social support.

Methods

Study design and participants. The pilot randomized controlled trial was conducted in San Francisco, California, from August 2014 to October 2015. Participants were recruited from community-based venues such as transgender-serving community-based organizations, clinics, and social venues, using in-person recruitment strategies and flyering. Participants who previously provided consent to be contacted for research purposes during prior studies were also contacted using their preferred method (email or phone) by either the research assistants or the PI and informed about the study. To be eligible, self-identified transgender women were required to be at least 18 years of age and report condomless sex in the past 3 months. HIV status was not a criterion for eligibility. To be screened for eligibility, participants completed a survey inquiring about demographics, sexual risk behavior, HIV status, mental health, and substance use. The eligibility survey also served as the baseline survey for those who were deemed eligible and enrolled. Participant eligibility was flagged by the computerized survey using a code that appeared when the participant completed the survey. The research assistant then offered eligible and interested transgender women an opportunity to enroll in the pilot RCT; participants were informed that, upon enrollment, they would be randomized to either the Sheroes intervention or a movie night. Informed consent was obtained from all participants. Enrolled participants were stratified by HIV status and randomized by computer to receive either the 5-session Sheroes intervention or a time- and attention-matched control experience. Randomization was stratified by HIV status

and conducted in SAS 9.4 using block randomization with block sizes of two. Peer facilitators received 25 hours of initial training in the Sheroes intervention as well as ongoing supervision which provided opportunities to reinforce concepts and skills from the initial training. The time- and attention-matched control condition consisted of a movie night that was matched to the intervention sessions by number and length of sessions and group size. Participants in the control group watched a standardized set of movies that were deemed by our Community Advisory Board to be of interest but without content that overlapped with the Sheroes intervention. A brief facilitated discussion followed each movie night session, again with careful attention to avoid content that overlapped with the intervention. If randomized, participants were given a schedule of either the intervention or control sessions based on the condition to which they were assigned. Participants received $40 cash reimbursement for their participation in each assessment visit. An additional $40 bonus incentive was offered to participants who completed all 5 sessions. Sheroes participants were invited to complete satisfaction surveys at each session they attended and to participate in a brief post-intervention qualitative interview. The study was approved by the Institutional Review Board at the University of California, San Francisco.

Measures. Participants completed study assessments at baseline and at 3- and 6- months post-randomization. Assessments consisted of computer-assisted self-administered quantitative surveys using RedCAP (28). The primary outcomes for this study were number of partners with whom participants reported engaging in condomless receptive anal sex and self-reported social support, measured using the Social Support Questionnaire (SSQ-6) (29). A sample question from the SSQ-6 is “Whom can you count on to console you when you are very upset?” Each SSQ-6 item is followed by the question “How satisfied are you with this type of support?” Feasibility measures were determined using guidance from the literature on feasibility pilot studies (30, 31). To evaluate feasibility, detailed process records were kept regarding the number and demographic characteristics of individuals who participated in each session and the amount of staff time devoted to recruitment and coordination of each session. Fidelity was monitored using checklists that the peer facilitators would complete at the end of each session to indicate whether all components of the session were implemented. Portions of the audio recordings of the intervention sessions were reviewed at random by the supervisor to ensure fidelity and guide ongoing training for the peer facilitators. To assess acceptability, we administered the Client Satisfaction Questionnaire (CSQ-3) (32) to solicit participant ratings of satisfaction with each session, overall satisfaction with the Sheroes intervention, and the likelihood that they would recommend

the program to others, in addition to an open-ended question that solicited free text feedback. After the final Sheroes session, a research assistant (who was not involved in facilitating the Sheroes sessions) conducted audio-recorded brief (lasting 20 minutes or less) qualitative feedback sessions in which participants described their experiences with Sheroes and provided suggestions for improvements.

Statistical Analysis. Descriptive statistics were calculated using SAS v9.4. Preliminary outcome analyses followed an intent-to-treat approach and were performed using generalized linear mixed models (GLLMs) in Stata v15.1 stratified by HIV serostatus containing fixed effects for group (control, intervention), time (baseline, 3- month follow up, 6-month follow up), and their interaction. Counts of numbers of sex partners outcomes were modeled using a negative binomial distribution and log-link; the mean level of continuous social support was modeled using a normal distribution and identity link. Count outcome models estimated the mean numbers of sex partners as a function of the aforementioned fixed effects plus random intercepts via maximum likelihood whereas the continuous social support mean level was estimated as a function of the fixed effects using restricted maximum likelihood (REML) with an unstructured covariance matrix of the residuals and Kenward-Roger denominator degrees of freedom. Pre-specified simple main effects compared outcomes on time points within each group. All effects were evaluated at alpha = .05. Cases with partial outcome data were included in the analysis with incomplete data assuming to arise from either a missing-completely-at-random (MCAR) or a missing-at-random (MAR) missingness mechanism via the maximum likelihood estimation approach employed in the mixed models analyses.

Results

From August 2014 to October 2015, 137 transgender women were screened for eligibility and 77 were enrolled and randomly assigned to either the Sheroes intervention or a time- and attention-matched control group and were followed for 6 months (Figure 2). Of the 77 enrolled participants, 38 (49%) were Black/African-American, 8 (10%) were Latina, 16 (17%) were White, and 15 (19%) were Multiracial, Native American, or Asian/Pacific Islander (grouped together for reporting purposes due to very low ns). The mean age of participants was 39 (SD = 10.6), and 35 (45.5%) reported HIV-positive serostatus at baseline. Of the participants living with HIV, 28 (82%) were currently using ART. There were no statistically significant differences between intervention and control participants at baseline (Table 2). Comparisons among treatment

arm and demographic characteristics between those lost to follow up (N=27, 35%) and those with one or more follow up interviews (N=50, 65%) yielded no significant differences (lowest observed p-value was 0.28).

Feasibility. Feasibility of the pilot RCT was high; two part-time research assistants (who also served as the peer facilitators of the intervention) enrolled 77 participants over a period of 14 months. Feasibility of implementation of the intervention was also high; of the 39 women who were randomized to the Sheroes intervention, 82% (n=32) attended at least one session and 67% (n=26) participated in all five sessions. Sessions were implemented with high fidelity; only two of the sessions were not implemented as originally designed due to unexpected external interruptions (one fire alarm and one emergency unrelated to the intervention implementation).

Acceptability. At the end of each of the five sessions and at the end of the intervention, women rated their satisfaction with Sheroes on the CSQ-3 as either 'Extremely' or 'Very Satisfied' (no ratings below Very Satisfied); 92% reported that they were 'Extremely Satisfied' with their overall experience with Sheroes. The lowest ratings were for the final session, in which 66% rated 'Extremely Satisfied' (the rest were 'Very Satisfied'); qualitative feedback suggested that a desire for more sessions (and knowing that the group would not meet again) was a reason for several participants' lower rating of the final session. All 24 (100%) participants who completed the Sheroes intervention indicated that they were 'Extremely Likely' to recommend Sheroes to others. In qualitative debriefing sessions, Sheroes participants were asked to describe their experiences with Sheroes and provide suggestions for improvements. For example, when asked about their reactions to Sheroes, participants responded: "I feel very empowered and blessed to have had this experience with my sisters" (37 yo AA); "I learned how to take better care of me in all kinds of ways" (31 yo AA); and "It helped me to feel better about myself and to want to make changes to stay healthy" (42 yo Latina).

Primary outcomes. Among HIV-negative participants in Sheroes, there was no significant group-by-time interaction for the reported number of sex partners with whom participants had condomless intercourse (p=.67) and no significant group-by-time interaction for social support (p=.67). However, planned comparisons within each point indicated statistically significant reductions in the reported number of sex partners with whom participants had condomless intercourse (p=.007) and improved social support (p=.04) whereas number of partners (p=.17) and social support (p=.52) did not change over time in the control group (see Table 3). Among HIV-positive participants, there was no significant group-by-time interaction in the total number of sex partners

(p=.31). Planned comparisons within each group yielded reductions in total number of sex partners over time in both groups (Table 3). Additional follow-up two time-point comparisons of the 6-month time point with the baseline time point indicated that the change was sustained at the 6-month follow-up for the Sheroes group (p=.04), but not for the control group relative to baseline (p=.17; see Table 3 for estimated and means and standard errors for each time point).

Discussion

We have developed and successfully piloted an innovative, group-based, peer-led, community-informed intervention that addresses the unifying lived experiences of HIV-positive, negative, and unknown status adult transgender women. While this pilot RCT was not powered to test the efficacy of the intervention, a fact reflected in the non-significant group-by-time interaction tests, preliminary evidence suggests that Sheroes is a promising intervention for reducing sexual risk behavior while attending to the unique needs of transgender women who are at elevated risk for acquiring or transmitting HIV. A priori within-group comparisons showed that exposure to the intervention resulted in statistically significant reductions in reported condomless sex and improved social support among HIV-negative participants. A priori within-group comparisons among participants living with HIV showed reduced sexual risk behavior regardless of whether they participated in Sheroes or the control group, but those assigned to Sheroes sustained this behavior at the 6-month follow up while those in the control group did not. Both groups reported reduced condomless sex, which may indicate a high need for social support among transgender women. The element of social support may have contributed to a therapeutic effect even among control group participants, though beneficial effects of the control condition were more short-lived than those for Sheroes. Additional research with larger samples over a longer follow-up period is needed to evaluate this innovative strategy for reducing sexual risk among transgender women at risk for acquisition or transmission of HIV. Because Sheroes includes transgender women of any serostatus, it provides a pioneering opportunity to reduce sexual risk behaviors and prevent new HIV infections from both a primary and secondary prevention perspective.

Including transgender women living with HIV and not living with HIV provided opportunities for peer-to-peer education and mentoring around shared challenges and experiences. Peer support and mentoring is essential to decreasing transgender women's sense of isolation, encouraging pride in one's gender identity, and skill sharing for coping with everyday stressors. Issues of race and ethnicity are systematically addressed

in Sheroes with special attention to their intersectionality with gender identity. Thus, integral themes from the lived experience of transgender women who bear a disproportionate burden of HIV are incorporated to maximize the cultural relevance, and thus the efficacy, of the intervention. This pilot RCT of Sheroes provided valuable experience and opportunity for refinement. Feedback from participants included the desire for a "booster" session, providing the opportunity for participants to reunite after graduation from Sheroes and check in with one another about challenges and issues discussed during the intervention.

Limitations. When interpreting these findings, several limitations should be considered. This study was conducted in San Francisco, an urban center in the United States that may result in limited generalizability to other geographic locations. The primary outcome was self-reported, which may be subject to bias. No measurement of negotiated safety was measured in our assessment of sexual behavior, so the risk level of reported condomless sex could not be determined. The Sheroes intervention was developed around the same time as the introduction of PrEP, so limited content related to PrEP knowledge and uptake was integrated into the curriculum. At the time of this study, PrEP use among transgender women was low, but as PrEP use increases and access to PrEP for transgender women improves, it will be important to deliver the most current PrEP information and resources to transgender women who participate in Sheroes. Future larger scale research to test the efficacy of Sheroes should incorporate additional information and outcome measures related to PrEP use among participants, examine outcomes by partner type (e.g. committed, casual, paying) and explore potential differences in outcomes between participants of various racial and ethnic groups. Future efficacy studies may also seek to update and/or adapt some of the content of Sheroes in order to ensure that it reflects current concepts and issues related to transgender health.

Conclusions. This study provides preliminary evidence that Sheroes is a feasible and acceptable group-level intervention for mixed HIV status, adult transgender women. Future research will test the efficacy of Sheroes to reduce sexual risk behavior utilizing a full randomized controlled trial design.

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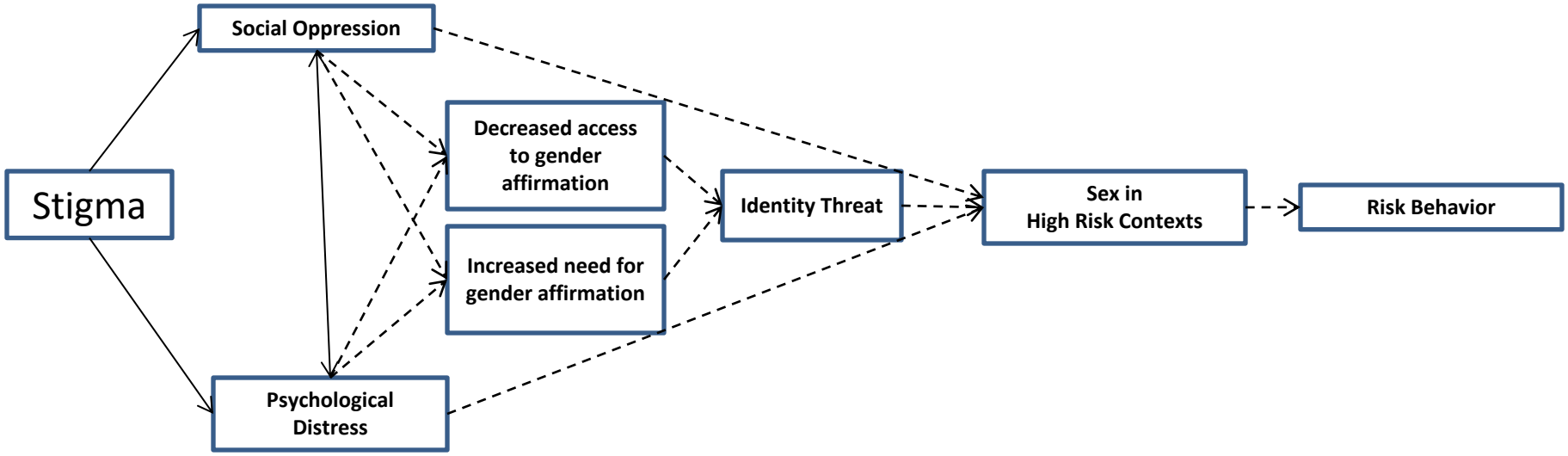
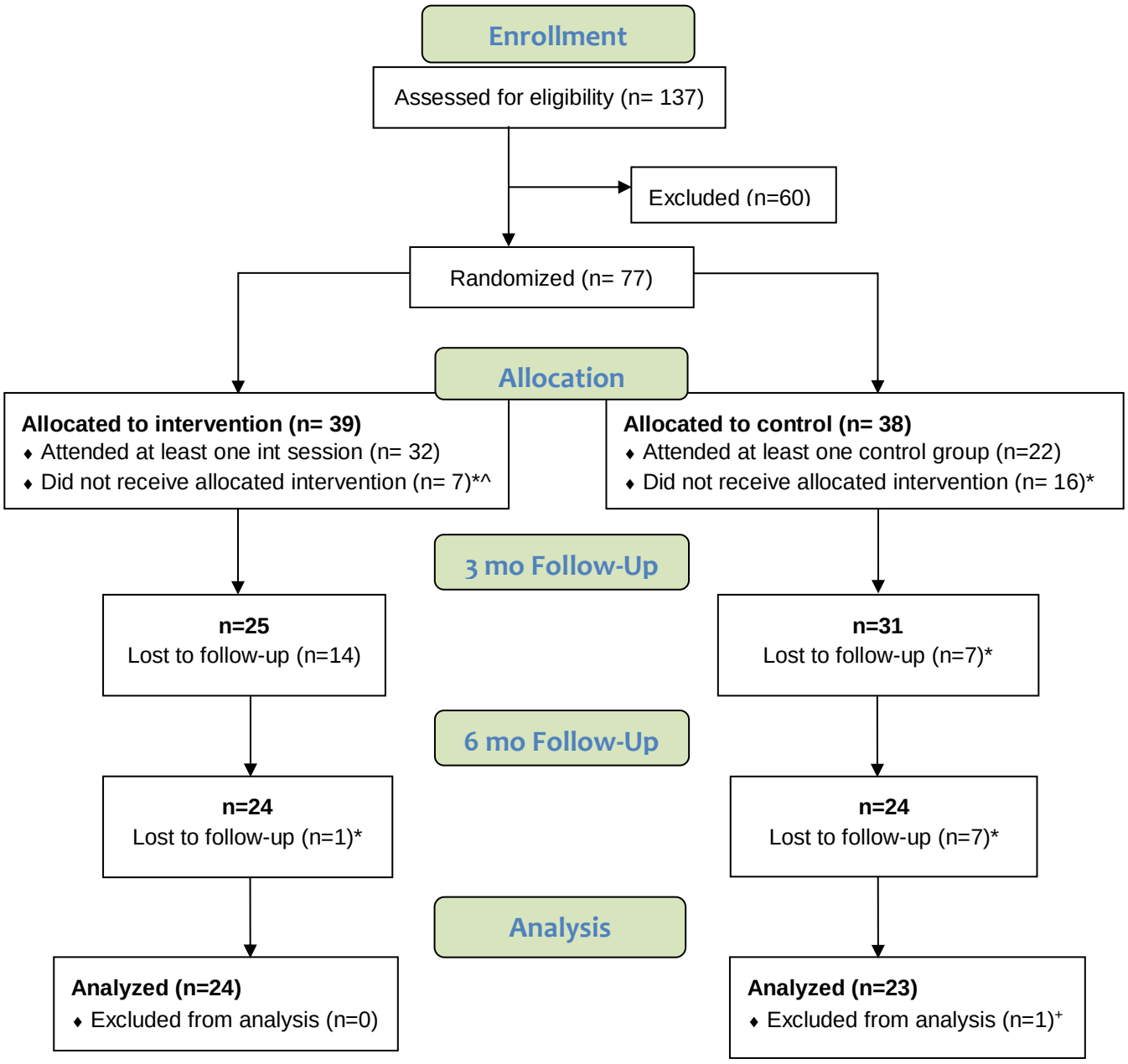


* Pathways with dashed lines are those targeted by the Sheroes intervention.

Figure 1. CONSORT diagram



* no shows / became incarcerated
^ 1 participant was unable to participate in group setting
+ HIV status did not match stratification assignment

Table 1. Sheroes intervention content

Session	Topic	Objectives
1	Gender Pride	Explore and discuss trans identities and historical figures Discuss gender pride and identify positive transgender role models, with a focus on transwomen of color Introduce the concept of self-care, how it relates to one's sense of self-worth, and self-care in thecontext of one's sexual health and HIV status (i.e. safer sex and healthcare seeking behaviors)
2	Looking Good, Feeling Good	Discuss gender affirmation and how it affects self-image, self-care, and power to negotiate safer behaviors Discuss transition-related health care (i.e. hormone use/access, dangers of injection silicone use, safer injection practices) How taking care of your physical health (e.g., nutrition, sleep, HIV) leads to feeling good about oneself
3	Let's Talk About Sex	Provide accurate information on HIV/STI rates and risk factors among transgender women Discuss protection of oneself and one's partners in the context of gender affirmation Discuss the importance of knowing one's status and getting treatment if HIV-positive or STI-positive Offer referrals to transgender-friendly HIV/STI testing and treatment services; discuss barriers to testing and treatment and brainstorm solutions
4	Taking Back the Power	Discuss how transphobia impacts one's sense of personal power and explore ways to reclaim one's power Explore assertiveness skills, practice negotiating safer behaviors and communicating with health care providers Provide an introduction to basic self-defense information and resources to increase skills for coping with transphobic harassment and violence
5	Surviving and Thriving	Discuss how knowing one's status and getting treatment for HIV is vital to self-care Discuss healthy ways of coping with transphobia in relationships and the stress of sex work Consider the effect of substance use on self-care and protection of one's own and partners' sexual health; offer resources and support for addressing substance use and mental health issues Celebrate oneself and trans communities as a vital source of social support; reinforce gender pride

- Each session includes sharing resources to increase participants' access to gender affirming healthcare and services, including linkage to HIV/STI testing and support for engagement in HIV treatment and care

Table 1. Sample baseline characteristics

Characteristic	Total N (%)	Treatment Group N (%)	Control Group N (%)	p-value
Age *(mean/std)*	38.9 (10.6)	40.1 (10.9)	37.8 (10.2)	0.47
Gender identity				0.26
Female	36 (46.8)	21 (53.9)	15 (39.5)	
Transgender female	36 (46.8)	17 (43.6)	19 (50.0)	
Other	5 (6.5)	1 (2.6)	4 (10.5)	
Race/ethnicity				0.60
African American/black	38 (49.4)	18 (46.2)	20 (52.6)	
White	16 (20.8)	7 (18.0)	9 (23.7)	
Latina	8 (10.4)	4 (10.3)	4 (10.5)	
Other	15 (19.5)	10(26.6)	5 (13.2)	
Undocumented immigrant	3 (3.9)	3 (7.7)	0 (0)	0.24
Education				0.68
Less than high school	18 (23.4)	10 (25.6)	8 (21.1)	
HS grad/GED	29 (37.7)	16 (41.0)	13 (34.2)	
Tech/vocational school/some college	21 (27.3)	10 (25.6)	11 (29.0)	
College degree or above	9 (11.7)	3 (7.7)	6 (15.8)	
Recent homelessness				0.39
Never homeless	9 (11.8)	7 (18.0)	2 (5.4)	
Longer than a year ago	28 (36.8)	14 (35.9)	14 (37.8)	
Between 6 and 12 months	10 (13.2)	6 (15.4)	4 (10.8)	
Between 1 and 6 months	6 (7.9)	3 (7.7)	3 (7.7)	
Within the past month	23 (30.7)	9 (23.1)	14 (37.8)	
HIV positive	35 (45.5)	18 (46.2)	17 (44.7)	0.90
History of ART (if (HIV+)	29 (85.3)	16 (88.9)	13 (81.3)	0.53
Current ART use (if (HIV+)	28 (82.4)	15 (83.3)	13 (81.3)	0.87
Newly diagnosed (< 1 year)	1 (2.9)	0 (0)	1 (5.9)	0.49
Years living with HIV *(mean/std)*	13.4 (8.3)	14.3 (8.3)	12.4 (8.5)	0.43

Table 3. Estimated Means (Standard Errors) of Sexual Behavior and Social Support Outcomes

	Condomless Sex Partners[b]		Total Sex Partners[c]		Social Support[d]	
Time	Control	Intervention	Control	Intervention	Control	Intervention
Baseline	3.39 (1.16)	4.60 (1.55)	8.93 (3.59)	6.10 (2.40)	0.28 (0.09)	0.28 (0.08)
3 Months	1.62 (0.76)	1.91 (0.86)	2.92 (1.36)	3.45 (1.57)	0.36 (0.10)	0.35 (0.10)
6 Months	1.57 (0.82)	1.15 (0.56)	5.18 (2.72)	2.73 (1.41)	0.40 (0.14)	0.57 (0.13)
p-value[a]	.169	.007	.001	.049	.522	.044

[a] Test of simple main effect of overall time difference within group (2 degree of freedom test)
[b] *n*=42 HIV-negative participants. Group-by-time interaction *p*=.67.
[c] *n*=34 HIV-positive participants. Group-by-time interaction *p*=.31.
[d] *n*=41 HIV-negative participants. Group-by-time interaction *p*=.67.