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Efficacy of an Empowerment-Based, Group-Delivered HIV Prevention Intervention for Young Transgender Women
The Project LifeSkills Randomized Clinical Trial

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Supplemental content

IMPORTANCE The incidence of HIV infection among transgender women in the United States is extremely high, with young transgender women (YTW) at highest risk; condomless sex is the primary risk behavior for transmission. However, there are no published randomized clinical trials to date examining interventions to reduce sexual risk for HIV acquisition and transmission within this group.

OBJECTIVE To determine the efficacy of a culturally specific, empowerment-based, and group-delivered behavioral prevention intervention to reduce sexual risk for HIV acquisition and transmission in sexually active YTW aged 16 to 29 years.

DESIGN, SETTING, AND PARTICIPANTS Randomized clinical efficacy trial of Project LifeSkills, a group-delivered, behavioral HIV prevention intervention, vs standard of care conducted among 190 sexually active YTW between March 26, 2012, and August 15, 2016, at community-based locations in Boston, Massachusetts, and Chicago, Illinois, to reduce sexual risk for HIV acquisition or transmission. Data analysis was by a modified intention-to-treat approach.

INTERVENTIONS Participants were randomized (approximately 2:2:1) to the LifeSkills intervention (n = 116), standard of care only (n = 74), or a diet and nutrition time- and attention-matched control (attention control) arm (n = 43). The attention control arm was dropped during active enrollment per the Data Safety and Monitoring Board's recommendation. The LifeSkills intervention was delivered in six 2-hour sessions spanning a 3-week period.

MAIN OUTCOMES AND MEASURES Primary outcome was change in the number of self-reported condomless anal or vaginal sex acts in the 4 months before the baseline assessment and that reported at the 4-, 8-, and 12-month visits.

RESULTS Of the 190 study participants, the mean (SD) age was 23.4 (3.4) years (range, 16-29 years); 47 (24.7%) were white, 83 (43.7%) were black or African American, 25 (13.2%) were Hispanic or Latina, and 35 (18.4%) were another race/ethnicity. From baseline to 4 months, the LifeSkills group had a 30.8% greater mean (SE) reduction in condomless sex acts (2.26 [0.40] at baseline vs 1.22 [0.22] at 4 months) compared with the standard of care group (2.69 [0.59] at baseline vs 2.10 [0.47] at 4 months) (risk ratio [RR], 0.69; 95% CI, 0.60-0.80; $P < .001$). Similarly, the LifeSkills group had a 39.8% greater mean (SE) reduction in condomless sex acts at the 12-month follow-up visit compared with the standard of care group (0.71 [0.13] vs 1.40 [0.32]; RR, 0.60; 95% CI, 0.50-0.72; $P < .001$).

CONCLUSIONS AND RELEVANCE Among YTW at sexual risk of HIV acquisition or transmission, the LifeSkills intervention resulted in a 39.8% greater mean reduction in condomless sex acts during the 12-month follow-up in comparison to the standard of care group. This trial is the first to date to demonstrate evidence of efficacy for a behavioral intervention to reduce sexual risk in YTW.

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For transgender women in the United States, evidence suggests that the prevalence of HIV is very high, including among young transgender women (YTW) aged 16 through 29 years.[1,2] A meta-analysis of the burden of HIV infection for transgender women worldwide found that HIV prevalence in the United States was 21.7% (95% CI, 18.4%-25.1%); transgender women had 34-fold increased odds of HIV infection compared with all adults of reproductive age.[3] In addition, among more than 500 transgender women tested for HIV infection (with no known previous positive HIV test results) in Miami, Florida, San Francisco, California, and Los Angeles, California, 45% of all new HIV infections were among those aged 20 through 29 years,[4] suggesting a particularly high incidence rate among YTW.

Condomless anal sex represents a primary risk of HIV acquisition and transmission for transgender women, with high rates of sexual risk reported in small studies of YTW.[1,5,6] Transgender women may also acquire or transmit HIV and other sexually transmitted infections through condomless vaginal sex. For those who have undergone gender confirmation surgery (eg, penile inversion or sigmoid colon vaginoplasty), condomless vaginal sex as a receptive partner may confer HIV risk.[7,8] For transgender women who have not had or do not want gender confirmation surgery, HIV risk may also occur through condomless vaginal sex as an insertive partner; research shows heterogeneity of sexual practices for transgender women with cisgender females and/or with another transgender individual.[9] Whereas evidence suggests safety and efficacy of biomedical interventions, including preexposure prophylaxis (PrEP), to prevent HIV infection among men who have sex with men and transgender women in clinical trials,[10] the practice of initiating PrEP has been quite low among transgender women (<10%).[11] Furthermore, adherence to PrEP among transgender women in the Preexposure Prophylaxis Initiative (iPrEx) trial[12] was suboptimal. Evidence also suggests that adherence to PrEP is particularly low among the young.[13] Given the challenges with both initiating and potentially adhering to PrEP, combination HIV prevention approaches, including promotion of condom use, are more effective than PrEP alone in high-risk populations.[14]

Very few intervention studies have focused on the reduction of sexual risk in transgender women. In a recent critical review of behavioral interventions for HIV prevention among transgender women,[15] the results identified only 4 interventions that were formally tested for transgender women and only 1 that was tested for YTW in particular. These 4 of 5 studies documented small to moderate effect size estimates, with evidence of diminishing effects over time (ie, all ≤3 months of follow-up).[15] None of these studies had been included in the Centers for Disease Control and Prevention's (CDC's) compendium of HIV prevention interventions because of low quality (eg, lack of a comparison condition, lack of sufficient follow-up, small analytic sample, or a combination of these factors).[16]

The Project LifeSkills intervention[17,18] addresses the specific challenges to sexual safety among YTW, including structural, developmental, and interpersonal factors. A previous CDC-funded pilot trial[17] provided evidence of both feasibility and initial efficacy to reduce sexual risk (51 participants with 84% retention at 3-month follow-up and >40% reduction in condomless anal sex). Hypothesized mediators of the intervention effect include empowerment processes (eg, collective self-esteem and integration) and HIV-related prevention and health promotion targets (ie, HIV-related information, motivation, and behavioral skills). A detailed description of the rationale, measurement, analysis, and findings regarding mediation of the intervention effects is provided in the eMethods in Supplement 1 (see also eTable 1, eTable 2, and eFigure in Supplement 1). The LifeSkills curriculum includes 6 modular (ie, independent) sessions to communicate basic HIV-related information (eg, transmission modes and related risks), to develop motivation (eg, to protect oneself), and to promote behavioral skills (eg, condom use and sexual partner communication and negotiation) through an empowerment-based approach.

Given both the lack of evidence-based interventions and disparate risk for HIV infection among YTW, rigorous testing of interventions for this population is warranted. The purpose of this study was to test the efficacy of the LifeSkills intervention to reduce sexual risk for HIV acquisition and transmission among YTW aged 16 through 29 years in a randomized clinical trial of sufficient size and length to meet CDC standards of best evidence. A secondary aim was to test hypothesized mediators of the intervention effect given our theoretical model of intervention effects (eMethods, eTables 1 and 2, and eFigure in Supplement 1).

Key Points

Question Does the Project LifeSkills intervention reduce condomless vaginal or anal sex acts among young transgender women?

Findings In this randomized clinical efficacy trial of 190 young transgender women, individuals who received the LifeSkills intervention had a significantly greater reduction in condomless vaginal and anal sex compared with those who received standard preventive care during the 12-month follow-up period.

Meaning The Project LifeSkills intervention reduced sexual risk for HIV infection and transmission in young transgender women, a population with extremely high rates of HIV infection.

Methods

Study Design and Participants

This randomized clinical trial was completed in the cities of Boston, Massachusetts, and Chicago, Illinois, in the United States. Participants were recruited (until 300 participants were enrolled) using various approaches, including outreach to community-based organizations and other venues. Eligibility criteria of participants included those (1) aged 16 through 29 years; (2) assigned male sex at birth who now self-identify as female, transgender women, or on the transfeminine spectrum; (3) who are English-speaking; (4) who had no plan to move from the local area during the 12-month study period; and (5) who had a self-reported sexual risk in the preceding 4

months. HIV serostatus was not a criterion for eligibility. The study was approved by institutional review boards at Ann & Robert H. Lurie Children's Hospital and The Fenway Institute (the full trial protocol is available in Supplement 2). Written informed consent was obtained for each participant with parental consent waived for minors (aged 16-17 years). Participants were incentivized for study visits ($25 for the initial visit and $50 per visit thereafter) and for group participation ($10 per session, with an additional $10 per week for perfect attendance).

Intervention

The LifeSkills intervention was delivered in 2-hour, small-group sessions twice a week for 3 consecutive weeks. Fidelity of intervention delivery was supported using approaches recommended by the Treatment Fidelity Workgroup of the National Institutes of Health Behavior Change Consortium.[19] Fidelity ratings for each session included 18 items reflecting content delivery, process, and professionalism.

Randomization

Individual randomization to study conditions was completed in cohorts. Assembly of cohorts was necessary to have sufficient numbers of participants in the group-delivered arms (ie, ≥3 individuals). The initial randomization scheme called for individual-level assignment in blocks of 5 (2:2:1) to LifeSkills, standard of care (SOC) only (ie, HIV/sexually transmitted infections testing and counseling), or attention control (diet and nutrition time- and attention-matched control condition with no active intervention component). Assembly of large cohorts (≥15 individuals) for randomization to all 3 arms was not feasible; thus, after the sixth cohort, the randomization scheme was revised. The modified randomization scheme reflected a random, cohort-level assignment to 1 of 2 modalities (1:1), with an individual-level assignment nested within each modality: LifeSkills vs SOC (1:1) or LifeSkills vs attention control (2:1). Both the cohort-level and individual-level random assignments were computer-generated in blocks of 2 (1:1) or 3 (2:1). The randomization scheme was concealed from both the participants and the study staff and then revealed at the randomization visits after each complete cohort had been assembled. Because of poor feasibility of accrual to the attention control, randomization to this arm was discontinued in September 2015 per the recommendation of the Data, Safety, and Monitoring Board for this trial.

Study Assessments

Participants completed a baseline study visit that included a standardized quantitative assessment via computer-assisted self-interviewing as well as standard preventive screening for HIV infection (ie, third-generation testing algorithms at each site for those reporting HIV-negative or unknown infection status) and urogenital gonorrhea and chlamydia infections (first-catch urine sample via nucleic acid amplification testing) coupled with pretest and posttest counseling.[20] Additional assessments were conducted at 4-, 8-, and 12-month follow-up visits, with additional HIV/sexually transmitted infection screening at the 4- and 12-month visits.

The primary outcome for this study was change in the number of condomless anal or vaginal sex acts for a specific time period. Items assessing sexual behavior in the preceding 4 months were adapted for YTW from the AIDS Risk Behavior Assessment.[21] Sequential questions asking the participant to estimate the number of recent anal and vaginal sex partners (ie, insertive and receptive anal and vaginal sex partners) and the number of condomless sex acts by type of sex (anal or vaginal) with these partners provided the basis for the primary outcome (a count variable). The secondary outcome was change in the total number of sexual partners reported in the 4 months before the baseline visit compared with subsequent 4-month intervals at 4-, 8-, and 12-month visits.

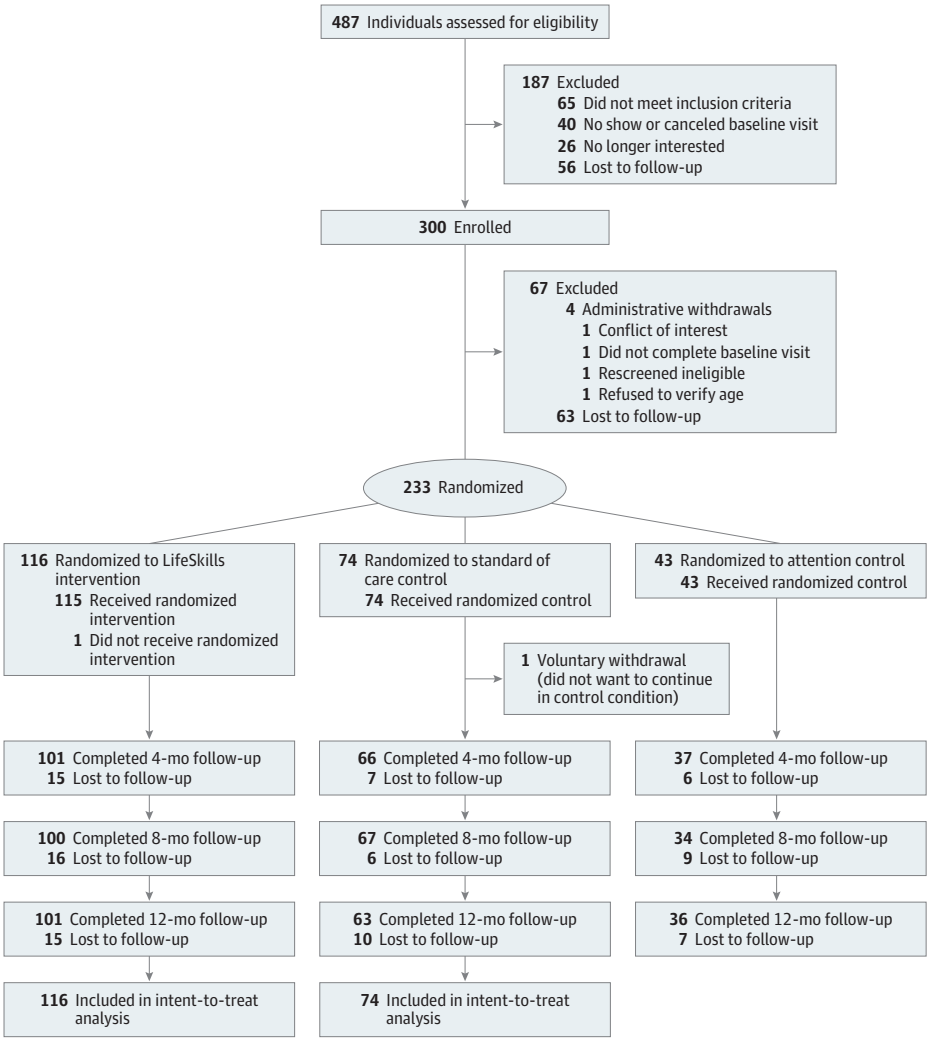
Statistical Analysis

The primary power analysis was based on detecting a 40% (or greater) change in the rate of condomless sex acts (anal or vaginal) between groups during the study; all groups were expected to show improvements from baseline. Based on these data, with a power of 80% and $\alpha = .05$, we estimated a target of 107 completers per group. Given low feasibility for randomization to the attention control arm and low statistical power, that group was dropped from the final analyses. Primary analysis, therefore, followed a modified intent-to-treat approach.

Prior to data analysis, we examined the distribution of the outcome variables, including the number of condomless sex acts and the number of sexual partners. To correct for extreme outliers (eg, ≥300 condomless sex acts in the past 4 months), we winsorized the data at the 99th percentile; that is, any observations (n = 2 for each outcome measure) that were greater than the 99th percentile were recalibrated to the value at the 99th percentile, and any observations less than the first percentile were recalibrated to the value of the first percentile.[22] Final models without winsorization showed similar trends.

To examine the difference in the rate of change for the outcome variables, as is common in analyses of longitudinal designs, we used mixed-effects models with a participant-level random intercept to allow the baseline outcome measure (eg, condomless sex acts) to vary across participants and account for within-participant correlation.[23] Intraclass correlation for condomless sex acts was 0.49, suggesting that, for each individual, the outcome measures were moderately correlated across time points. For the outcome measures, which were count variables, a Poisson distribution and log link were specified, which allows for improved modeling of count variables in which the variance increases with the mean, values are discrete, and values have a lower bound of 0. The models contained terms for intervention group assignment, time, and their interaction; a significant effect for the interaction indicates differences in the change of the outcomes from baseline to follow-up for the intervention groups. For outcomes that did not have a significant effect for the interaction, we removed the interaction term and assessed whether there were overall changes across study follow-up that could not be accounted for by the intervention (ie, a significant effect for time). For each outcome, we estimated and presented means (SEs) for each time point.

Figure 1. CONSORT Diagram



The attention control (diet and nutrition time- and attention-matched control) group was discontinued during active enrollment per the recommendation of the Data Safety and Monitoring Board.

Complete-case analyses were conducted; therefore, no data were imputed. Missing data for the primary outcome at each time point ranged from 12.1% to 13.7%. Analyses were conducted with SAS, version 9.4 (SAS Institute Inc) and Stata, version 15 (StataCorp). Two-sided $P < .05$ denoted statistical significance.

Results

From March 26, 2012, to August 15, 2016, 487 individuals were screened, 300 were enrolled, and 233 were randomly assigned to 3 cohorts: 116 individuals to the LifeSkills intervention, 74 to SOC only, and 43 to attention control and followed up for 12 months (**Figure 1**). The deviation from the original blocked design of a 2:2:1 ratio resulted in an imbalance between conditions. The modified randomization scheme, which called for randomization initially at the cohort level, variation in cohort size, and an uneven number of cohorts, all contributed to the imbalance. However, there were no statistically meaningful imbalances between conditions.

Of the 190 study participants, 47 (24.7%) were white, 83 (43.7%) were black or African American, 25 (13.2%) were Hispanic or Latina, and 35 (18.4%) were of another race/ethnicity. The YTW (aged 16-29 years) had a mean (SD) age of 23.4 (3.4) years. Of the overall sample, 40 participants (21.1%) were determined to be HIV infected at the baseline assessment visit: 35 participants with previously diagnosed HIV and 5 with newly diagnosed HIV (**Table 1**).

The Poisson mean (SE) number of condomless sex acts during the 4 months before the baseline assessment was 2.06 (0.30). Although participants in both groups reduced the number of condomless sex acts at the 12-month follow-up visit, those women in the LifeSkills group had a greater reduction in comparison with the SOC group (**Figure 2** and **Table 2**). From baseline to 4 months, the LifeSkills group had a 30.8% greater reduction in condomless sex acts (2.26 [0.40] at baseline vs 1.22 [0.22] at 4 months) compared with the SOC group (2.69

Table 1. Characteristics of 190 Young Transgender Women in Project LifeSkills, Overall and by Study Condition

Characteristic	Overall (N = 190)	LifeSkills (n = 116)	SOC (n = 74)
Study site, No. (%)			
Boston, Massachusetts	98 (51.6)	60 (51.7)	38 (51.4)
Chicago, Illinois	92 (48.4)	56 (48.3)	36 (48.6)
Sexual identity, No. (%)			
Gay/homosexual	49 (25.8)	31 (26.7)	18 (24.3)
Lesbian	10 (5.3)	6 (5.2)	4 (5.4)
Bisexual	38 (20.0)	25 (21.6)	13 (17.6)
Straight/heterosexual	73 (38.4)	42 (36.2)	31 (41.9)
Other	20 (10.5)	12 (10.3)	8 (10.8)
Primary race/ethnicity, No. (%)			
White	47 (24.7)	30 (25.9)	17 (23.0)
Black/African American	83 (43.7)	53 (45.7)	30 (40.5)
Hispanic/Latina	25 (13.2)	14 (12.1)	11 (14.9)
Other	35 (18.4)	19 (16.4)	16 (21.6)
Born outside US, No. (%)	10 (5.3)	6 (5.2)	4 (5.4)
Highest educational level, No. (%)			
<High school	45 (23.7)	27 (23.3)	18 (24.3)
High school or GED	66 (34.7)	35 (30.2)	31 (41.9)
Some college or vocational school	63 (33.2)	42 (36.2)	21 (28.4)
Undergraduate degree or higher	16 (8.4)	12 (10.3)	4 (5.4)
No health insurance, No. (%)	50 (26.3)	36 (31.0)	14 (18.9)
Ever had HIV test, No. (%)	171 (90.0)	104 (89.7)	67 (90.5)
HIV infected at baseline, No. (%)	40 (21.1)	23 (19.8)	17 (23.0)
STI diagnosis at baseline, No. (%)	4 (2.2)	3 (2.7)	1 (1.4)
Any exchange of sex within last 4 mo, No. (%)	51 (26.8)	33 (28.5)	18 (24.3)
Ever taken feminizing hormones, No. (%)	123 (65.1)	75 (65.2)	48 (64.9)
Ever had gender-confirming medical procedures, No. (%)[a]	36 (19.0)	25 (21.7)	11 (14.9)
Age, mean (SD), y[b]	23.4 (3.4)	23.6 (3.5)	23.0 (3.4)
Type of condomless sex act within past 4 mo, median (IQR), No.[c]			
Total (0-330)	1 (0-5)	1 (0-5)	1 (0-5)
Anal (0-260)	1 (0-4)	1 (0-4)	1 (0-4)
Vaginal (0-200)	0	0	0
Receptive oral (0-120)	1 (0-5)	1 (0-5)	1 (0-5)
Sexual partners within past 4 mo (0-70), median (IQR), No.[c]	2 (1-4)	2 (1-4)	2 (1-4)

Abbreviations: GED, general equivalency diploma; IQR, interquartile range; SOC, standard of care; STI, sexually transmitted infection.

[a] Gender-confirming medical procedures include surgery, laser therapy, etc.

[b] Age range for all participants was 16 to 29 years.

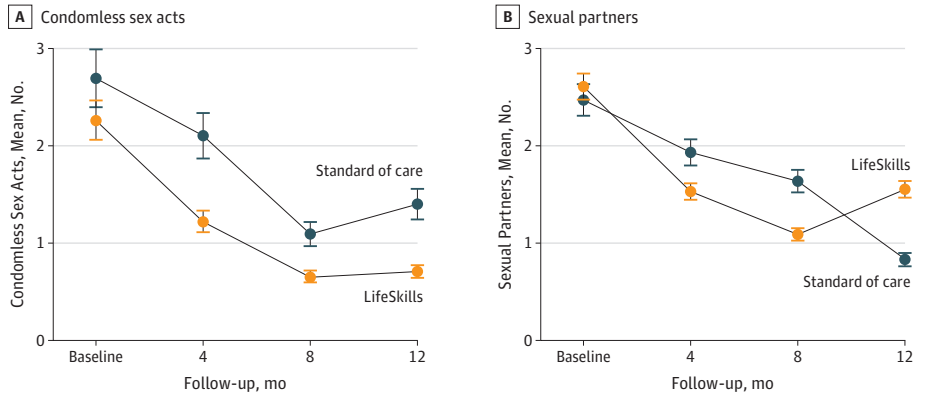
[c] The range of the number of condomless sex acts and the number of sexual partners within the past 4 months is listed in parentheses. To correct for extreme outliers (eg, ≥300 total condomless sex acts in the past 4 months), the data were winsorized at the 99th percentile, and any observations less than the first percentile were recalibrated to the value of the first percentile.[22]

[0.59] at baseline vs 2.10 [0.47] at 4 months) (risk ratio [RR], 0.69; 95% CI, 0.60-0.80; $P < .001$). Similarly, the LifeSkills group had a 39.8% greater reduction at the 12-month follow-up visit compared with the SOC group (0.71 [0.13] vs 1.40 [0.32]; RR, 0.60; 95% CI, 0.50-0.72; $P < .001$).

We performed a sensitivity analysis fitting our Poisson models for condomless anal sex and condomless vaginal sex separately as outcomes. Each was significant alone and showed a pattern similar to that of the combined sex acts variable. Participants in both the LifeSkills group and SOC group reported fewer sexual partners at the 12-month follow-up visit. From baseline to the 4-month follow-up visit, the LifeSkills group had a 25.0% greater mean (SE) reduction in number of partners (2.61 [0.27] at baseline vs 1.53 [0.17] at 4 months) compared with the SOC group (2.47 [0.32] vs 1.93 [0.27]; RR, 0.75; 95% CI, 0.59-0.95; $P = .02$). The LifeSkills group had a 22.8% smaller mean (SE) reduction at the 12-month follow-up visit compared with the SOC group (1.55 [0.17] vs SOC, 0.83 [0.14]; RR, 1.77; 95% CI, 1.32-2.38; $P < .001$) (Figure 2 and Table 2).

Regarding the feasibility of intervention delivery, attendance at intervention sessions was 80.3% (559 of 696 sessions attended) across cities and intervention cohorts. In Chicago, the attendance was 83.9% (282 of 336 sessions attended) and in Boston was 76.9% (277 of 360). The LifeSkills intervention was delivered to approximately 3 to 4 individuals per cohort in each city (mean [SD], 3.5 [1.0] in Chicago and 3.5 [1.3] in Boston). Mean (SD) intervention fidelity was 34.1 (2.1) of 36 fidelity items (94.8%) across sites and cohorts. With respect to participant acceptability, 83 of 86 (96.5%) LifeSkills participants (with complete acceptability data) rated the program as very good or good quality, and 85 of 86 (98.8%) indicated that they would refer a friend to receive the intervention.

Figure 2. Number of Condomless Sex Acts and Sexual Partners for 190 Young Transgender Women by Study Condition and Assessment Time



Means (SEs) were modeled using Poisson mixed-effects analyses.

Table 2. Model-Predicted Outcomes for 190 Young Transgender Women in Project LifeSkills, by Study Condition and Assessment Time Point[a]

Outcome Measure	Mean (SE), No.[b]							
	Baseline		Month 4		Month 8		Month 12	
	LS	SOC	LS	SOC	LS	SOC	LS	SOC
Condomless sex acts	2.26 (0.40)	2.69 (0.59)	1.22 (0.22)	2.10 (0.47)	0.66 (0.12)	1.09 (0.25)	0.71 (0.13)	1.40 (0.32)
Sex partners	2.61 (0.27)	2.47 (0.32)	1.53 (0.17)	1.93 (0.27)	1.09 (0.13)	1.64 (0.23)	1.55 (0.17)	0.83 (0.14)

Abbreviations: LS, LifeSkills; SOC, standard of care.

[a] $P < .001$ for differences in the rate of change for both outcome measures.

[b] Means (SEs) are estimated using Poisson distribution and are calculated through the use of mixed-effects analyses.

Discussion

Our findings provide evidence that Project LifeSkills is both a feasible and efficacious intervention that reduces HIV risk behavior among YTW aged 16 through 29 years. Exposure to the intervention resulted in a 39.8% greater reduction in condomless sex acts in the LifeSkills group compared with the SOC group for the 12-month intervention period, suggesting a robust intervention effect. Previous HIV prevention studies have followed participants for 3 or fewer months[15]; thus, findings suggest sustainability of the intervention effect in this population. Findings with regard to the number of sexual partners were mixed; however, the LifeSkills intervention content did not focus on limiting the number of partners but rather on the use of condoms and protection of self and others; therefore, this finding is not completely unexpected.

Project LifeSkills used a community-participatory approach to develop an HIV prevention intervention curriculum grounded in the social realities of the target population.[17,18] The curriculum is a novel contribution to the existing literature and uses an empowerment framework including specific content on environmental factors facing YTW, such as securing safe housing, accessing medical care, and obtaining employment. The curriculum also directly addressed the lure of commercial sex work, a complex HIV risk for the intervention's target population.[1] LifeSkills is also a peer-led and peer-delivered intervention, which may be a key characteristic for success in this population. We believe that the intervention was effective because of this combination of characteristics, ie, grounded in participant social realities, focused on empowerment and practical needs, and delivered by peers. The high level of participant-rated satisfaction with the intervention reflects the salience of this approach.

Among study participants, 58% reported at least 1 episode of condomless anal sex within 4 months prior to their baseline visit. More than 20% of the sample (21.1%) was HIV infected at baseline, which is an extremely high prevalence of HIV infection for such a young age group but consistent with the pilot study and other published literature from community-based samples of YTW.[1,17] These data provided further evidence that a subset of YTW acquired HIV at a very young age, highlighting the need for intervention development efforts focused on both primary and secondary HIV prevention. Furthermore, given previous evidence of inconsistent condom use in high-risk populations[24] and low uptake of and adherence to PrEP,[12,13] concentrated efforts are needed to promote combination HIV prevention approaches[14] in YTW to include targeted HIV testing and promotion of condom use; efforts to identify, promote, and sustain PrEP use in the highest-risk YTW; and community-based efforts to intervene on drivers of HIV risk, such as those reflected in the LifeSkills intervention.

The CDC High Impact HIV/AIDS Prevention project[25] publishes and continually updates a Compendium of HIV Prevention Interventions with Evidence of Effectiveness.[16] Currently, this Compendium includes 84 HIV risk-reduction, evidence-based behavioral interventions; however, to date,

none of them is available for or targets the transgender community. More interventions for transgender women are needed that meet criteria outlined in the CDC's Compendium for "Best Evidence" risk reduction[16] such as inclusion of an appropriate and concurrent comparison arm, random or minimally biased assignment to study arms, and samples of at least 50 participants per arm, among other criteria. As a group-level intervention with a rigorous randomized clinical design, Project LifeSkills should fully meet these criteria.

Limitations

Limitations should be considered when interpreting these findings. The study was conducted in only 2 geographic locations in the United States, which may limit generalizability to a broader sample of YTW. The intervention contained considerable content that was specific to the process of medical gender transition and may not resonate with young women who either have completed the gender transition process or have no intention of initiating it. In addition, the study was powered on behavioral outcomes, which may be subject to reporting bias, and not on incident HIV infection. Tracking incident HIV infection would be the strongest indicator of a prevention effect but would have required several thousands of YTW to be enrolled. The intervention curriculum was written before the advent of PrEP, a promising biomedical prevention strategy that should be integrated into behavioral interventions targeting transgender women. For example, content regarding both PrEP and treatment as prevention (for HIV-positive individuals) could be integrated throughout the LifeSkills modules in concert with the current intervention content on condom use. We believe this integration will strengthen the potential impact of the intervention, in particular the difficulty of sustaining consistent condom use over time. Because the LifeSkills intervention is modular, individual sessions could be delivered alongside other programming focused on PrEP and treatment as prevention. This strategy would be consistent with combination HIV prevention approaches that are widely recommended[26] to optimize progress to local and national goals.

Conclusions

Using the CDC Compendium criteria[16] as a framework, we believe that Project LifeSkills is the first well-supported, evidence-based, behavioral risk-reduction intervention for HIV prevention among YTW. Additional research is needed to show independent replication of these findings and to guide the implementation and dissemination of Project LifeSkills to other US communities as well as to other parts of the world where HIV prevention among transgender women is a public health priority.

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Concept and design: Garofalo, Kuhns, Mimiaga.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Garofalo, Kuhns, Biello, Mimiaga.
Critical revision of the manuscript for important intellectual content: All authors.
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