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# Randomized Controlled Trial of Healthy Divas: A Gender-Affirming, Peer-Delivered Intervention to Improve HIV Care Engagement Among Transgender Women Living With HIV

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**Background:** Transgender women are disproportionately affected by HIV and are less likely to be optimally engaged in care than other groups because of psychosocial challenges. With community collaboration, we developed Healthy Divas, an individual-level intervention to increase healthcare empowerment and gender affirmation to improve engagement in HIV care. Healthy Divas comprises 6 peer-led individual sessions and one group workshop facilitated by a healthcare provider with expertise in HIV care and transgender health.

**Setting/Methods:** To test the intervention's efficacy, we conducted a randomized controlled clinical trial in San Francisco and Los Angeles among transgender women living with HIV; control was no intervention. Transgender field staff conducted recruitment. Assessments occurred at baseline and 3, 6, 9, and 12 months postrandomization. The primary outcome was engagement in HIV care, defined as the sum of (1) self-reported HIV care provider visit, past 6 months, (2) knowledge of most recent CD4 count, (3) self-reported antiretroviral therapy adherence  $\geq 90\%$ , and (4) self-reported antiretroviral therapy adherence  $\geq 80\%$ .

**Results:** We enrolled 278 participants; almost half (46%) were African American/Black and one-third (33%) were Hispanic/Latina. At 6 months, participants in the intervention arm had over twice the odds of being in a higher HIV care engagement category than those in the control arm (aOR = 2.17; 95% CI: 1.06 to 4.45;  $P = 0.04$ );

there were no significant study arm differences in the outcome at the other time points.

**Conclusions:** This trial demonstrates the short-term efficacy of an urgently needed behavioral intervention to improve engagement in HIV care among transgender women living with HIV; ongoing intervention may be needed to maintain positive impact over time.

**Trial Registration:** Clinicaltrials.gov identifier: NCT03081559.

**Key Words:** transgender women, intervention, HIV, engagement in care, gender affirmation

(*J Acquir Immune Defic Syndr* 2022;90:508–516)

## INTRODUCTION

Transgender (trans) women are disproportionately affected by HIV; estimates of HIV prevalence among trans women in the United States are approximately 14%, more than 45 times greater than any other population.<sup>1</sup> Prevalence is even higher among Black and Latina trans women, approximated at 44% and 26%, respectively, compared with 7% among White trans women.<sup>2</sup> Furthermore, trans women living with HIV exhibit suboptimal advancement through the HIV care continuum.<sup>3</sup> Compared with other groups, trans women living with HIV are less likely to be retained in HIV care<sup>3</sup> and receive antiretroviral therapy (ART)<sup>4</sup>; trans women on ART demonstrate lower levels of adherence<sup>5</sup> and higher viral loads.<sup>6</sup> Furthermore, trans women report less confidence in their ability to integrate treatment regimens into their daily lives.<sup>7</sup> As with other populations, trans women living with HIV who are suboptimally engaged in HIV care are at increased risk for negative health outcomes, such as unsuppressed viral load and increased risk of HIV transmission.<sup>3,8</sup>

HIV care engagement among trans women living with HIV is complicated by a complex array of psychosocial challenges, including intersectional stigma (ie, the confluence of multiple forces of stigma and oppression, such as racism, transphobia, HIV stigma), discrimination, lack of access to gender-affirming healthcare, and distrust of healthcare providers and institutions because of past negative experiences.<sup>9,10</sup> These challenges may result in late or no presentation to HIV care, leading to poor health outcomes.<sup>11</sup>

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Because of intersectional stigma, trans women also disproportionately face structural barriers to HIV care, including poverty and unstable housing, familial alienation, limited formal education, limited social support, mental illness, trauma and victimization, and substance use.<sup>12–21</sup>

Facilitators of engagement in HIV care among trans women include receiving psychosocial support from friends and professionals, supportive relationships with medical providers, and having their psychosocial needs met.<sup>22,23</sup> Healthcare empowerment (ie, a sense of being informed, engaged, collaborative and committed to one's health care)<sup>24</sup> and current hormone use have both been found to be positively associated with HIV care engagement among trans women living with HIV.<sup>3</sup> At the individual level, gender-affirming, peer-led interventions may be one of the most effective strategies for improving care engagement and health outcomes among trans women living with HIV.<sup>22,25,26</sup> Gender-affirming interventions should include social gender affirmation, for example, ensuring the use of correct names and pronouns, honoring diversity in clients' gender identities and expressions, and generally creating safe spaces for trans patients to be themselves.<sup>27,28</sup> Gender-affirming interventions should also seek to build psychological gender affirmation, or the internal sense of valuing oneself, being comfortable with one's own gender identity, and having a sense of satisfaction with one's body and gender expression.<sup>29,30</sup> Medical gender affirmation, such as the provision of hormones and other gender-affirming medical care or navigation to such services, is also critical to integrate into interventions for trans and gender diverse people.<sup>28,29</sup> Recent evidence indicates that among trans women of color living with HIV, the implementation of peer-delivered interventions positively affects HIV care visit attendance, receipt of ART prescriptions, and retention in HIV care.<sup>31–34</sup>

Interventions that seek to improve health outcomes among trans women living with HIV must specifically address their unique barriers and facilitators to engagement in HIV care.<sup>35,36</sup> Although several such interventions have been piloted, few have been tested for efficacy in a randomized controlled trial (RCT).<sup>31,34,37–39</sup> To address this gap, we developed and tested Healthy Divas, an intervention grounded in an integrated model of Health Care Empowerment<sup>24,40,41</sup> and Gender Affirmation.<sup>42</sup> The Model of Health Care Empowerment posits that vulnerable populations will experience improved health outcomes when they are informed, committed, collaborative, and engaged in their healthcare, and when they are able to tolerate uncertainty of future health outcomes.<sup>24</sup> The Model of Gender Affirmation is a trans-specific conceptual framework to examine the role of gender affirmation in risk-taking, self-care, and healthcare-seeking behavior among trans women.<sup>42,43</sup> The Model of Gender Affirmation posits that health outcomes improve when trans and gender diverse people's needs for gender affirmation are met through health-promoting means such as social support and gender-affirming medical care.<sup>42</sup>

Given the immense burden of HIV, disproportionately poor health outcomes, and psychosocial challenges, as well as the promise of trans-specific, community-engaged approaches, there is an urgent need to rigorously test gender-affirming, peer-led interventions designed specifically for trans women

living with HIV. The primary objective of this study was to conduct a RCT to test the efficacy of Healthy Divas to improve HIV care engagement among trans women living with HIV.

## METHODS

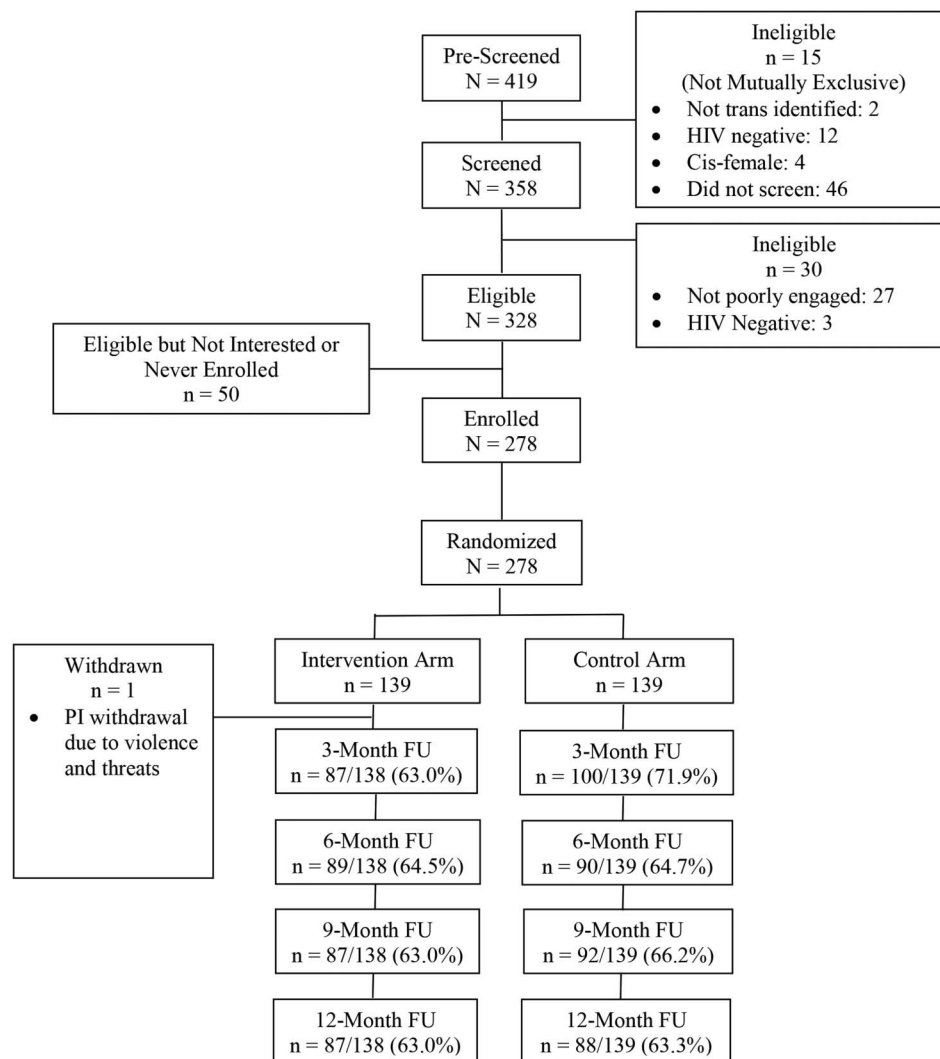
### Study Design and Participants

This study was an interventional, two-arm, randomized controlled superiority clinical trial with stratification and 2 parallel groups with a 1:1 allocation to compare Healthy Divas with a no intervention control condition. The trial was conducted in San Francisco and Los Angeles, California. We took a multipronged recruitment approach: posting flyers in targeted areas (eg, neighborhoods and businesses where trans women are known to frequent); performing outreach to agencies, clinics, community-based organizations (CBOs) that provide trans-specific support services and medical care, shelters, single room occupancy hotels; and accepting direct provider referrals. Teams of trans field staff with community-based research experience conducted recruitment. All study procedures were conducted at trans-friendly field sites in neighborhoods where many trans women live or congregate. In San Francisco, our field site was located in the Tenderloin area, and in Los Angeles, our field site was located on the border between Hollywood and West Hollywood; both study sites were in areas with high HIV prevalence and community viral load burdens.

To be eligible, participants had to be at least 18 years old, assigned male sex at birth but not currently identifying as male, English or Spanish speaking, and living with HIV, confirmed via antibody testing. They also had to report suboptimal engagement in HIV care, as indicated by one or more of the following: (1) not on ART; (2) if on ART, reported less than perfect adherence on a validated adherence rating scale<sup>44</sup>; or (3) reported no HIV primary care appointments in the previous 6 months. All participants provided written informed consent upon enrollment. Participants were reimbursed for their time for study visits (\$40 per visit), check-ins during months when no study visit was scheduled (\$10 per monthly check-in), and for intervention sessions (\$30 per session). The study was approved by institutional review boards at University of California, San Francisco, and Friends Research Institute.

### Study Procedures and Assessments

Potential participants consented to be screened for eligibility. Study staff administered an eligibility survey. HIV status was confirmed via evidence of one of the following: HIV ART medicine prescribed to the participant, verified via pill bottle or current prescription; other medical documentation, such as HIV test results; rapid HIV testing done in study offices; HIV status already verified by another research study for people living with HIV; or contact with the participant's healthcare provider after obtaining a signed release of medical information form. If found eligible and consenting to enroll in the study, participants had their blood drawn for CD4 count and viral load assays, completed the baseline survey using CASIC data collection software,<sup>45</sup> provided extensive locator information (eg, multiple types of information to permit the teams to contact



**FIGURE 1.** CONSORT diagram of study progression and retention.

and/or locate the participant, such as phone numbers, emails, social media account information, CBOs frequented by the participant), and were randomized to either the Healthy Divas intervention group or the no intervention control group. Follow-up assessments, including blood draws and surveys, occurred for 12 months postrandomization at 3-month intervals. Each participant was scheduled for brief monthly check-in visits in the months when there was otherwise no scheduled visit. Monthly check-in visits were highly flexible, occurring either in-person or by phone. At check-in visits, we updated contact information, confirmed date and time of the next study visit, documented 30-day self-reported ART adherence and any changes in medication regimens, and recorded any provider visits that had occurred in the previous month.

### Intervention and Control Condition

Informed by the Model of Health Care Empowerment and the Model of Gender Affirmation described above, we conducted extensive formative research and used a community participatory approach to develop Healthy Divas to optimize HIV care

engagement among adult trans women living with HIV.<sup>9,42,46–48</sup> Healthy Divas uses peer facilitators to support trans women living with HIV in improving their health outcomes by increasing healthcare empowerment with a gender-specific and gender-affirming approach. With peer support, trans women living with HIV build skills to cope with transphobia and HIV stigma, become active and collaborative in their treatment planning, and proactively address challenges to adherence and in their relationships with providers. The intervention is designed to be highly client-centered and thus incorporates multiple types of gender affirmation, including social and psychological gender affirmation, and navigation to medical gender affirmation services, such as hormone therapy. Referrals to other types of gender-affirming services depend on client need (eg, need for legal gender affirmation, such as navigation to legal assistance with name changes or other types of documentation). Healthy Divas also incorporates trans-specific concerns about substance use, provides opportunities for a participant to consider how substance use might be affecting her ability to reach her personal health goals, and supports her ability to access culturally competent treatment if she identifies this as a need. The

**TABLE 1.** Baseline Sample Characteristics by Study Arm

| Characteristic                      | Total<br>N | Control<br>N = 139 n (%) | Intervention<br>N = 139 n (%) |
|-------------------------------------|------------|--------------------------|-------------------------------|
| Gender identity                     | 278        |                          |                               |
| Trans woman/female                  |            | 93 (66.9)                | 95 (68.4)                     |
| Nonbinary/genderqueer               |            | 6 (4.3)                  | 5 (3.6)                       |
| More than one/another gender        |            | 40 (28.9)                | 39 (28.1)                     |
| Age (median, IQR)                   | 278        | 42.5 (33.1–50.5)         | 43.8 (34.8–53.5)              |
| Race/ethnicity (for analysis)       | 278        |                          |                               |
| African American/Black              |            | 63 (45.3)                | 63 (45.3)                     |
| White                               |            | 9 (6.5)                  | 10 (7.2)                      |
| Latina                              |            | 48 (34.5)                | 43 (30.9)                     |
| Another race/ethnicity              |            | 19 (13.7)                | 23 (16.6)                     |
| Undocumented immigration status     | 278        | 13 (9.4)                 | 18 (13.0)                     |
| Education                           | 278        |                          |                               |
| Less than high school               |            | 33 (23.7)                | 45 (32.4)                     |
| Finished high school                |            | 68 (48.9)                | 41 (29.5)                     |
| Technical degree/some college       |            | 34 (24.5)                | 46 (33.1)                     |
| College grad                        |            | 4 (2.9)                  | 7 (5.0)                       |
| Employed (full- or part-time)       | 278        | 22 (15.8)                | 21 (15.1)                     |
| Income in the past 30 d             | 278        |                          |                               |
| \$500                               |            | 59 (42.5)                | 61 (43.9)                     |
| \$1000                              |            | 58 (41.7)                | 51 (36.7)                     |
| \$2000                              |            | 10 (7.2)                 | 21 (15.1)                     |
| \$3000                              |            | 6 (4.3)                  | 3 (2.2)                       |
| \$4000                              |            | 2 (1.4)                  | 1 (0.7)                       |
| >\$4000                             |            | 4 (2.9)                  | 2 (1.4)                       |
| History of homelessness             | 278        | 120 (86.3)               | 112 (80.6)                    |
| Years spent homeless (median, IQR)  | 89         | 2.5 (1.3–4.9)            | 3.0 (1.0–7.5)                 |
| Homeless within past 6 mo           | 278        | 60 (43.2)                | 54 (38.9)                     |
| History of incarceration            | 278        | 105 (75.5)               | 107 (77.0)                    |
| Detectable viral load               | 253        | 87 (68.0)                | 71 (56.8)                     |
| CD4 count (median, IQR)             | 266        | 545 (368–801)            | 523.5 (294–838)               |
| Years living with HIV (median, IQR) | 273        | 11.3 (4.1–20.8)          | 13.1 (4.2–21.3)               |
| History of ART                      | 278        | 105 (75.5)               | 111 (79.9)                    |
| Currently on ART                    | 278        | 91 (65.5)                | 100 (71.9)                    |

development of the Healthy Divas intervention and the implementation of the RCT were informed by a community advisory board composed of trans women living with HIV.

Healthy Divas consists of 6 peer-led individual sessions, held weekly, and one group workshop facilitated by a healthcare provider with expertise in HIV care and trans health. Individual sessions emphasize setting and attaining goals around engagement in health care, including HIV and gender-affirming care, and other priority goals that affect health and/or engagement in health care for the participant. Peer facilitators work collaboratively with participants to develop a personalized health plan and problem-solve around barriers they may encounter when seeking services. All intervention activities were completed for each participant within a 3-month period between November 2016 and November 2019. Peer facilitators were extensively trained and supervised by research staff. Fidelity of intervention delivery

was supported by the use of a detailed facilitator manual specifying session content, procedures, exercises, and activities, and through detailed worksheets completed by the peer facilitator and reviewed by supervisors. The control condition had no intervention; control condition participants had the option to receive the Healthy Divas intervention content after their final (ie, 12-month) assessment visit.

## Randomization

Each study site used stratified randomization by 2 demographic criteria: age and race/ethnicity. At both sites, the age stratification criterion was  $\geq 40$  vs.  $< 40$  years. In San Francisco, the race/ethnicity stratification criterion was Black vs. non-Black race, whereas in Los Angeles, the race/ethnicity stratification criterion was Latina vs. non-Latina ethnicity, because of the racial/ethnic composition of each city. This resulted in a total of 8 distinct strata across the 2 sites:  $< 40$  years old and Black,  $< 40$  years and non-Black,  $\geq 40$  years and Black,  $\geq 40$  years and non-Black,  $< 40$  years old and Latina,  $< 40$  years and non-Latina,  $\geq 40$  years and Latina, and  $\geq 40$  years and non-Latina. The randomization scheme was generated by the study statistician<sup>49</sup> using SAS v.9.4 in randomly permuted block sizes of 2, 4, and 6 and stored for subsequent use in the data collection software package, REDCap, hosted at University of California, San Francisco.<sup>50,51</sup> The resulting randomization allocation table was maintained by the statistician; the research team did not have access to the randomization scheme at any time. Allocation concealment was ensured because the randomization procedure did not release the randomization assignment (to participants or study staff) until the participant had been recruited into the RCT after all baseline measurements had been completed.

## Measures

### Time

Surveys were conducted on 5 occasions: (1) baseline; (2) 3 months; (3) 6 months; (4) 9 months; and (5) 12-months postbaseline. Time was considered discrete in analyses and ranged from 0 to 4.

## Sample Characteristics

Participants reported gender identity, age, race/ethnicity, education, employment status, income, history of homelessness, and history of incarceration reported in the baseline survey.

## Use of Antiretroviral Therapy

We collected self-reported information on current (past 30 days) ART use at baseline by asking “Are you currently (for the past 30 days) taking HIV medications?” (yes vs. no). We also conducted blood draws for viral load at baseline and each follow-up time point and for CD4 count at 6-month intervals. Viral load and CD4 counts were analyzed using commercial laboratories.

## HIV Care Engagement

This was the outcome variable calculated as the sum of 4 pieces of information measuring engagement in HIV care<sup>52</sup>: (1)

**TABLE 2.** Final Model, Fixed Effects on Log Odds Scale

|                           | B           | 95% Confidence Intervals |             | <i>P</i>             |
|---------------------------|-------------|--------------------------|-------------|----------------------|
|                           |             | Lower Limit              | Upper Limit |                      |
| Study arm                 |             |                          |             | $\chi^2 (1) = 1.54$  |
| Control                   | <i>Ref.</i> | —                        | —           | —                    |
| Intervention              | −0.38       | −0.98                    | 0.22        | 0.22                 |
| Time                      |             |                          |             | $\chi^2 (4) = 19.35$ |
| Baseline                  | <i>Ref.</i> | —                        | —           | —                    |
| 3 mo                      | 1.15        | 0.42                     | 1.87        | 0.002                |
| 6 mo                      | 0.93        | 0.18                     | 1.68        | 0.02                 |
| 9 mo                      | 1.41        | 0.63                     | 2.19        | <0.0001              |
| 12 mo                     | 1.39        | 0.61                     | 2.16        | <0.0001              |
| Study arm × time          |             |                          |             | $\chi^2 (4) = 10.64$ |
| 1 1                       | 0.37        | −0.37                    | 1.12        | 0.33                 |
| 1 2                       | 1.15        | 0.38                     | 1.92        | 0.003                |
| 1 3                       | 0.19        | −0.57                    | 0.95        | 0.63                 |
| 1 4                       | 0.79        | 0.01                     | 1.58        | 0.05                 |
| Baseline ART use          |             |                          |             | $\chi^2 (1) = 31.27$ |
| Not on ART                | <i>Ref.</i> | —                        | —           | —                    |
| On ART                    | 1.93        | 1.25                     | 2.60        | <0.0001              |
| Time × BL ART use         |             |                          |             | $\chi^2 (4) = 10.36$ |
| 1 1                       | −0.95       | −1.74                    | −0.15       | 0.02                 |
| 2 1                       | −1.04       | −1.86                    | −0.21       | 0.01                 |
| 3 1                       | −0.78       | −1.62                    | 0.06        | 0.07                 |
| 4 1                       | −1.14       | −1.98                    | −0.30       | 0.01                 |
| Strata                    |             |                          |             | $\chi^2 (7) = 21.09$ |
| SF, Black, ≥40 yrs        | <i>Ref.</i> | —                        | —           | —                    |
| SF, Black, <40 yrs        | 0.94        | −0.12                    | 2.00        | 0.08                 |
| SF, non-Black, ≥40 yrs    | 0.26        | −1.00                    | 1.51        | 0.69                 |
| SF, non-Black, <40 yrs    | 0.37        | −0.81                    | 1.54        | 0.54                 |
| LA, Latina, ≥40 yrs       | −0.59       | −1.76                    | 0.58        | 0.32                 |
| LA, Latina, <40 yrs       | 0.67        | −0.42                    | 1.76        | 0.23                 |
| LA, non-Latina, ≥40 yrs   | −0.40       | −1.43                    | 0.62        | 0.44                 |
| LA, non-Latina, <40 yrs   | −0.45       | −1.49                    | 0.58        | 0.39                 |
| Random intercept variance |             |                          |             |                      |
| Subject                   | 2.57        | 1.89                     | 3.50        | —                    |

N = 994 observations from 278 participants.

self-reported healthcare provider visit for HIV care in the past 6 months (0 = no, 1 = yes); (2) knowledge of most recent CD4

**TABLE 3.** Exponentiated Estimates (Odds Ratios) of Being in a Higher HIV Care Engagement Category by Study Arm (Intervention vs. Control) at Each Time Point

| Time      | Odds Ratio | 95% Confidence Intervals |             | <i>P</i> |
|-----------|------------|--------------------------|-------------|----------|
|           |            | Lower Limit              | Upper Limit |          |
| Baseline  | 0.68       | 0.38                     | 1.25        | 0.22     |
| 3 Months  | 0.99       | 0.50                     | 1.99        | 0.99     |
| 6 Months  | 2.17       | 1.06                     | 4.45        | 0.04*    |
| 9 Months  | 0.83       | 0.40                     | 1.69        | 0.60     |
| 12 Months | 1.51       | 0.72                     | 3.16        | 0.27     |

N = 994 observations from 278 participants.

\**p* ≤ .05.

count (0 = no, 1 = yes); (3) self-reported ART adherence ≥90% (0 = no, 1 = yes); and (4) self-reported ART adherence ≥80% (0 = no, 1 = yes). Self-reported ART adherence was obtained via 2 measures: (1) a visual analog scale of ART adherence,<sup>53</sup> which provides a percent adherence from 0 to 100; and (2) an adherence rating scale<sup>44</sup> that asks “Thinking back over the past 30 days, rate your ability to take all your medications as prescribed,” with 6 possible responses ranging from “very poor” to “excellent.” The 2 adherence measures were combined to calculate at least 80% or at least 90% on both measures. The scores ranged from 0 to 4. If a participant did not report current ART use, their maximum score was 2 because they were not asked the 2 ART adherence questions.

## Analysis

Frequencies for categorical variables and measures of central tendency for continuous variables were calculated to

**TABLE 4.** Exponentiated Estimates (Odds Ratios) of Being in a Higher HIV Care Engagement Category by Being on ART at Baseline (on ART vs. Not on ART) at Each Time Point

| Time      | Odds Ratio | 95% Confidence Intervals |             | P        |
|-----------|------------|--------------------------|-------------|----------|
|           |            | Lower Limit              | Upper Limit |          |
| Baseline  | 6.88       | 3.50                     | 13.52       | <0.0001* |
| 3 Months  | 2.67       | 1.24                     | 5.77        | 0.01*    |
| 6 Months  | 2.44       | 1.12                     | 5.34        | 0.03*    |
| 9 Months  | 3.15       | 1.41                     | 7.05        | 0.01*    |
| 12 Months | 2.20       | 0.99                     | 4.90        | 0.05*    |

N = 994 observations from 278 participants.

\* $p \leq .05$ .

describe the sample. Random intercept mixed-effects ordinal logistic models for the HIV care engagement outcome were conducted in Stata 16.<sup>54</sup> Because of the relatively lower rates of ART uptake in this population, we were also interested in exploring whether there was a differential impact of the intervention based on ART status at baseline. Condition assignment (study arm), survey time point (time), and ART status at baseline were the fixed effect independent variables of interest. An additional fixed effect was randomization stratum, which was included in all models as a control variable to yield unbiased results for the remaining effects.<sup>55</sup> The random intercept term accounted for clustering of repeated measures within participants. Three-way interactions of study arm, time, and ART status at baseline and all 3 constituent two-way interactions were evaluated using backward elimination via Wald tests. Only significant ( $\alpha = 0.05$ ) interactions and their constituent main effects were retained in the final model.

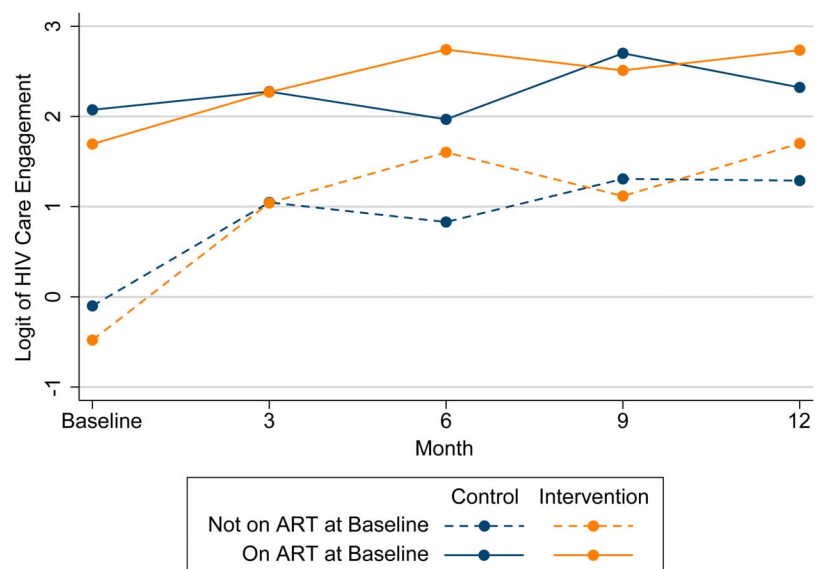
To interpret significant 2-way interactions, simple main effects compared the odds at each time point, of intervention vs. control group assignment and being on ART vs. not being on ART at baseline. To complement numeric simple main effect results, a logit plot of study arm by time for each of the

baseline ART status groups (on ART/not on ART) was produced to display the pattern of the significant two-way interactions. Finally, side-by-side mosaic plots of the cumulative probabilities of the outcome HIV care engagement by time for each study arm provided visual comparisons of probability of inclusion in a particular level of HIV care engagement by study arm assignment. Missing data because of loss to follow-up were assumed to be missing at random; participants with complete and incomplete cases because of loss to follow-up contributed information to the analysis. Missing data because of item nonresponse were minimal (1%) and ignored.

## RESULTS

Between November 2016 and October 2019, 358 individuals were screened, and 278 eligible individuals were enrolled and randomly assigned to the intervention arm ( $n = 139$ ) or no intervention control arm ( $n = 139$ ; Fig. 1); of the 278 individuals, 161 were enrolled at the Los Angeles site and 117 at the San Francisco site. Study participants primarily identified as trans female (51%) or female (11%). Almost half (46%) identified as African American/Black and one-third (33%) reported Latina ethnicity. The sample reported low socioeconomic status; 28% reported having less than a high school degree and only 15% reported working full- or part-time. Financial and housing stability were also low—82% of participants reported income levels less than \$1000 in the past 30 days and 41% reported recent (past 6 months) homelessness. Three-quarters (76%) reported a history of incarceration. Over half (62%) had a lab-verified detectable viral load at baseline, and 69% self-reported current ART use. Table 1 contains baseline characteristics by study arm.

The initial fully specified model contained main effects for study arm, time, baseline ART status, their 3-way interaction and 3 constituent 2-way interactions. In this model, the test of the 3-way interaction effect was

**FIGURE 2.** HIV care engagement by time, study arm, and baseline art status.

nonsignificant [ $\chi^2(4) = 6.56, P = 0.16$ ], and this term was dropped from further consideration. Our second model considered the main effects and all 3 possible 2-way interactions. In this analysis, the 2-way interaction of study arm and baseline ART status was not significant [ $\chi^2(1) = 0.22, P = 0.64$ ] and it was therefore dropped, yielding our final model. The final model contained 2 significant two-way interactions between (1) study arm and time and (2) baseline ART status and time as well as their constituent main effects (Table 2). Because of the presence of the 2 statistically significant interaction terms, simple main effect contrast effects are displayed in Tables 3 and 4 for each interaction separately to facilitate interpretation of the results of the final model.

The interaction of time and study arm was significant [ $\chi^2(4) = 10.64, P = 0.03$ ]. At the 6-month follow-up, those in the intervention arm had twice the odds of being in a higher HIV care engagement category compared with those in the control arm (OR = 2.17, 95% CI: 1.06 to 4.45,  $P = 0.04$ ); there were no significant study arm differences at the other time points. There was also a significant interaction of time and being on ART at baseline [ $\chi^2(4) = 10.36(4), P = 0.03$ ]. There were significant differences at all 5 time points between participants who were on ART at baseline vs. those who were not on ART at baseline such that at each point in time, the odds of being in a higher HIV care engagement category were higher for those who were on ART at baseline; see Table 4 for details.

Figure 2 displays the mean trajectory of each study arm over time separately for those who were on ART at baseline and those who were not on ART at baseline. There is not a significant 3-way interaction of study arm, time, and ART status at BL as reflected by the similar pattern of slopes at each level of baseline ART status. Regardless of baseline ART status, there is an increase in the logit of the outcome at 6 months for those in the intervention arm compared with those in the control arm. The mosaic plot of the cumulative probabilities of being in a particular HIV care engagement category by study arm can be seen in Figure 3. This plot illustrates the larger probabilities of being in the 2 *highest*

HIV care engagement categories for the intervention arm, and, conversely, that the probabilities of being in the 2 *lowest* outcome categories were higher for the control arm at 6 months.

## DISCUSSION

The findings of this RCT provide evidence that the Healthy Divas intervention demonstrated efficacy to improve HIV care engagement among trans women living with HIV at the 6-month follow-up time point; however, there were no immediate (ie, at the 3-month intervention completion time point) or sustained (ie, at the 9- and 12-month time points) significant outcomes. At the 6-month follow-up, participants randomized to the Healthy Divas intervention had more than twice the odds of being in a higher category of HIV care engagement compared with those randomized to the control group. At baseline, we found low rates of current ART use among our participants, along with high rates of laboratory-confirmed detectable viral load. In the context of universal treatment protocols, it is clear that interventions to increase engagement in HIV care, including ART uptake and adherence, are urgently needed for trans women living with HIV. We also tested whether there was a differential impact of the intervention based on one's ART status at baseline and found that the intervention was equally efficacious for both groups, with the same pattern of findings for those who were on ART at baseline as those who were not. It is notable that the intervention was efficacious for both groups of participants, given the relatively modest levels of ART use in our sample.

In this trial, our primary outcome was a behavioral composite of engagement in HIV care, which comprised several HIV care-related variables, is supported by preliminary data, and offers clear direction for promoting greater engagement in HIV.<sup>52</sup> It therefore potentially represents an important contribution in providing an evidence-based approach to improving engagement among this key population at heightened risk of falling out of HIV care. These results establish the efficacy of an intervention that specifically addresses the unique challenges experienced by trans

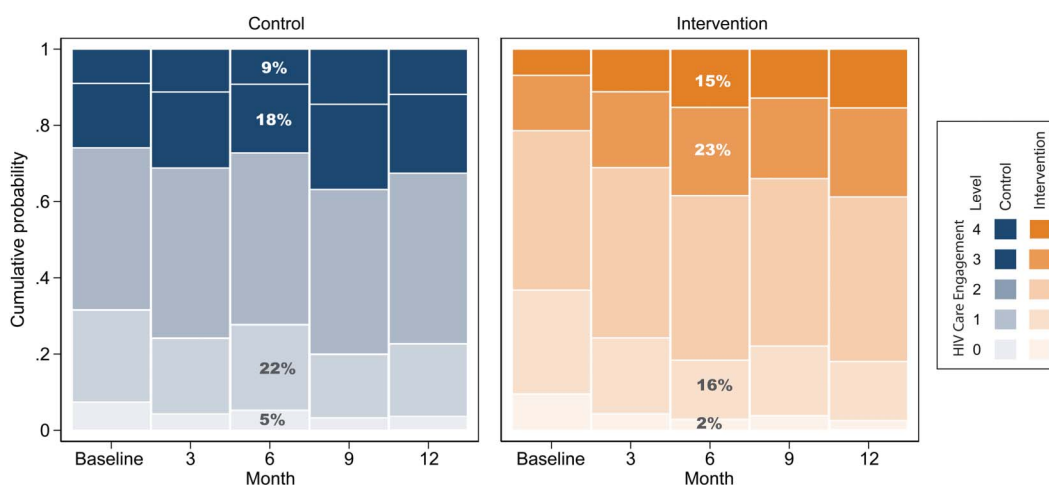


FIGURE 3. Level of HIV care engagement by time and study arm.

women living with HIV, a group whose disproportionate rates of HIV and poor health outcomes warrant focused efforts.<sup>36</sup>

Healthy Divas is currently being replicated in 3 US cities: Birmingham, Alabama; Newark, New Jersey; and Oakland, California.<sup>56</sup> We attribute this early replication to the urgent need for effective gender-affirming and trans-specific, peer-led interventions focused on HIV treatment engagement and outcomes among trans women living with HIV. Furthermore, we are currently conducting an implementation study in partnership with Cal-PEP, a CBO in Oakland, California, to explore barriers and facilitators to the real-world implementation of Healthy Divas. Results from these implementation studies have the potential to transform gender-affirming HIV health care for trans women, a population at dramatically elevated risk for negative personal and public health outcomes.

## Limitations

Despite the strengths of this study, some limitations should be considered when interpreting these findings. The study was conducted among predominantly racial/ethnic minority trans women in 2 urban cities in California, which may limit generalizability to White trans women and those in other geographic regions. Lower-than-expected follow-up rates may have affected our ability to fully assess the impact of the intervention. As an individual-level intervention, Healthy Divas aims to increase healthcare empowerment and gender affirmation and address psychosocial barriers to engagement in HIV care. A limitation of this individual-level intervention approach is that many challenges that contribute to HIV-related disparities among trans women include social, economic, and structural factors, which are beyond the scope of individual-level interventions; however, individual-level interventions are urgently needed to help trans women living with HIV develop skills and coping resources for navigating existing systems. Although many HIV-focused studies support the efficacy of individual-level approaches to behavior change, there is also substantial evidence that intervention effects tend to diminish over time. In our study, we did not find significant differences between the intervention and control groups in HIV care engagement at 9 months and later. In the presence of multiple levels of influence on health behaviors, including structural and interpersonal effects, it may be that individual-level interventions are insufficient to sustain newly adopted behavior changes over long periods. Future research should examine the feasibility and efficacy of ecological approaches to interventions with trans women living with HIV, which could address multiple spheres of influence as intervention targets, including peers, families, and communities.<sup>57</sup> Multilevel interventions are also urgently needed to address the many structural barriers faced by trans women living with HIV.<sup>58</sup>

## CONCLUSIONS

Healthy Divas is an evidence-based, peer-led, culturally relevant intervention to improve engagement in HIV care

among trans women living with HIV. These findings fill a significant public health gap through the evaluation of a theory-driven, piloted, culturally tailored intervention to improve engagement in HIV care among trans women living with HIV. Additional research is needed to inform the adaptation, implementation, and dissemination of Healthy Divas to diverse communities of trans women living with HIV.

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