Feasibility, Acceptability, and Preliminary HIV Care and Psychological Health Effects of iTHRIVE 365 for Black Same Gender Loving Men

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Objectives: This uncontrolled pilot study examined the feasibility, acceptability, and preliminary HIV and psychological health effects of iTHRIVE 365, a multicomponent intervention designed by and for Black same gender loving men (SGLM) to promote: health knowledge and motivation, Black SGLM social support, affirming health care, and housing and other economic resources.

Design: & Methods: We conducted a 14-day daily diary study with 32 Black SGLM living with HIV connected to THRIVE SS in Atlanta, GA. Daily surveys assessed intervention engagement, antiretroviral medication (ART) use, depressive symptoms, anxiety symptoms, and emotion regulation difficulties. App paradata (ie, process data detailing app usage) assessed amount of intervention engagement via page access. Participants began receiving access to the intervention on day 7. After the 14-day daily diary period, participants responded to follow-up items on the user-friendliness, usefulness, helpfulness, and whether they would recommend iTHRIVE 365 to others. Chi-square analyses examined associations between intervention engagement and ART use, and dynamic structural equation modelling assessed longitudinal associations

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from intervention engagement to next-day psychological health. This intervention trial is registered on ClinicalTrials. gov (NCT05376397).

Results: On average, participants engaged with iTHRIVE 365 over once every other day and accessed intervention pages 4.65 times per day. Among participants who engaged with the intervention, 78% reported it was helpful to extremely helpful, 83% reported it was moderately to extremely useful, and 88% reported it was user-friendly and they would recommend it to others. On intervention engagement days, participants had higher odds of ART use, $\chi^2(1) = 4.09$, P = 0.04, than intervention nonengagement days. On days after intervention engagement, participants showed non-null decreases in depressive symptoms ($\tau = -0.14$; 95% CI: = [-0.23, -0.05]) and emotion regulation difficulties ($\tau = -0.16$; 95% CI: = [-0.24, -0.02]).

Conclusions: Findings suggest iTHRIVE 365 is feasible, acceptable, and positively affects daily ART use, depressive symptoms, and emotion regulation difficulties.

Key Words: Black men who have sex with men, mHealth, multilevel intervention, ART adherence, mental health, clinical trial

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 $\mathbf{B}_{(SGLM)}^{lack}$ gay, bisexual, other same gender loving men (SGLM) practice positive health behaviors at rates comparable to their peers of other racial and sexual identities, 1-3 yet they experience greater rates of health inequities, including those in HIV4 and chronic psychological difficulties. 5,6 Evidence indicates these health inequities are linked to high levels of social isolation,7 low access to culturallyaffirming and effective health care,8 and barriers to housing, transportation, and other forms of economic empowerment⁹ linked to multilevel oppression. 10-12 Despite this evidence, there is a lack of accessible and culturally-affirming health promotion interventions designed to address these multilevel drivers of health inequities experienced by Black SGLM. 1,2,13 Because of this gap, our Black SGLM-led multisectoral team of researchers, service providers, and software developers/ designers developed iTHRIVE 365, a multicomponent intervention that incorporates mobile health (mHealth) with organizationally-delivered services to increase health

information and motivation, Black SGLM social capital, connection to Black SGLM-affirming health care, and access to economic empowerment.¹⁴ The present pilot study aimed to test the feasibility, acceptability, and preliminary effect estimates for HIV care and psychological outcomes for iTHRIVE 365. Please note that we use the term SGLM throughout this article because this is consistent with the language used in the programming of THRIVE SS, the Black SGLM-led administrator of iTHRIVE 365.

Recommendations for best practice in public health have called for interventions that build on community strengths and confront multilevel health barriers to reduce health inequities experienced by communities such as Black SGLM. 15,16 The Information-Motivation-Behavioral Skills (IMB), 17 social capital, ^{18,19} and socioecological^{20,21} theories posit that individual, community, institutional, and structural resources are central contributors to positive health outcomes. This includes individual-level information, motivation to change, and behavioral skills for improving health, ¹⁷ interpersonal bonds among individuals with shared experiences, ^{18,19} and institutional and structural access to effective healthcare, reliable transportation, and housing.^{20,21} Emerging evidence indicates that interventions that use mHealth technologies may effectively facilitate these individual, interpersonal, and structural pathways to positive HIV and psychological health among Black SGLM. For example, recent studies show mHealth interventions are feasible and acceptable for Black SGLM, particularly among Black SGLM with practical barriers (eg, limited funds to reach a physical clinic)²² and psychological barriers (eg, anticipated stigma)²³ to accessing in-person health care in the U.S. South. In addition, interventions using mHealth may be effective in reducing HIV risk by building social capital²⁴ and connection to critical health care resources.²⁵

Thus, in line with recommendations for best practices in HIV treatment and prevention, we developed the multicomponent iTHRIVE 365 intervention that incorporates mHealth tools to reduce barriers to health at the individual level (eg, health information and motivation), interpersonal/network level (eg, social support networks), institutional/health system level (eg, culturally supportive environments), and structural level (eg, access to housing). The development of the intervention used a community-based participatory research (CBPR)²⁶ method in which a Black SGLM-run organization serving Black SGLM in the Atlanta, GA area, one of the Ending the HIV Epidemic (EHE) priority jurisdictions,²⁷ identified priorities and approaches to reach those priorities with a health promotion intervention. As such, this is an intervention developed by and for Black SGLM living in one of the areas of the U.S. South in which Black SGLM are experiencing some of the most profound HIV-related and psychological health inequities.

To examine the feasibility, acceptability, and daily HIV care psychological health impacts of iTHRIVE 365, we used daily diary assessment of a single arm trial measuring changes in antiretroviral treatment (ART), depressive and anxiety symptoms, and emotion regulation across 14 days among Black SGLM. As in the development of the iTHRIVE 365 intervention, we drew participants from Atlanta-area EHE jurisdictions. Because Black SGLM were central to framing

and development of the intervention, we expected iTHRIVE 365 to be feasible (ie, high participant engagement in the intervention) and acceptable (ie, the intervention is highly rated). Given evidence that interventions using IMB strategies, building social capital, and providing access to culturally competent care and economic resources have been linked to positive HIV-related and psychological outcomes, we expected iTHRIVE 365 use to be positively associated with ART use and negatively associated with depressive symptoms, anxiety symptoms, and emotion regulation difficulties.

METHODS

This sample is from a pilot examination of the feasibility, acceptability, and preliminary impacts of the iTHRIVE 365 intervention. 14 The sample consisted of 32 Black SGLM living with HIV and connected with the community-based organization, THRIVE SS. THRIVE SS is an Atlanta, GA based CBO that focuses on health equity for Black SGLM, most of whom are living with HIV, through cultivating peer support, advocacy, and community building. The study team recruited a nonrandom purposive sample through advertisements on THRIVE SS's social media and email blasts. Eligibility criteria for this analysis were: identifying as sexual minority (eg, gay, bisexual), being age 16 or older, identifying as masculine (including cisgender, transgender, and gender expansive people), living with HIV, and being prescribed ART. Of 40 participants who were screened, 38 fit these criteria.

The 32 who participated were not significantly different than the 6 who did not participate across data collected in the screener (e.g., age, sexual identity).

Participant screening and study administration occurred from September to December 2021. After the screener, participants received an invitation to participate in a HIPPAcompliant WebEx informed consent meeting and baseline assessment with a trained research assistant. After baseline was a 14-day daily diary study with surveys administered on an Internet-based Qualtrics platform. Across all days, participants received 8 PM text-messages with links to their daily surveys. For those who had not completed the survey by 9:30 PM, they received an automatic reminder message. Surveys included measures of psychological and behavioral variables. We used simple randomization to vary the order of administration of all instruments. In line with a pre-post, one-arm trial, participants did not have access to the iTHRIVE 365 intervention for days 1-7 then received access to register and use the invention for days 8–14. The follow-up assessment occurred at the end of the 2-week daily diary period. We collected summary paradata (ie, process data detailing app usage) on intervention page access. Participants received \$30 for baseline and follow-up and \$1.50 per survey for the first 7 daily surveys and \$2.50 for the next 7 surveys, with a \$5 bonus for completing all surveys (total maximum: \$93). The Rutgers University institutional review board approved all study procedures.

iTHRIVE 365 Intervention

iTHRIVE 365 is a multicomponent intervention that uses mHealth features in alignment with 4 community priorities

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identified in our formative CBPR research: 14 (1) Support HIV and psychological health knowledge and motivation; (2) Foster a sense of community and positive social connections among Black SGLM; (3) Connect users to Black SGLM-affirming health care, including HIV treatment and mental health care; (4) Provide resources for housing, transportation, and other economic empowerment. In line with best-practices for administering and testing interventions with mHealth components with trials of intervention principles (TIPs),²⁸ iTHRIVE 365 deploys intervention elements that contain content that may be updated to maintain user engagement, but ultimately serve to accomplish delineated intervention strategies that match the community priorities. iTHRIVE 365 uses these intervention elements: (1) Weekly HIV and psychological health information and motivation content and daily health notifications; (2) Online moderated forums, interpersonal chats, and community calendars; (3) Linkage to biopsychosocial health care via THRIVE SS's network of Black SGLM-affirming providers; and (4) Housing and economic resources through THRIVE SS's direct support and referral network.

The health knowledge and motivation content includes a health maintenance notification system and content covering HIV and psychological health content that are evidence-based and culturally-tailored by the Rutgers School of Public Health and THRIVE SS team for Black SGLM. The health maintenance notification system allows users to input the timing and dosage of medications or health practices (eg, mindfulness meditation) to receive personalized reminders. Similar notification systems, such as automated pill reminders, have been shown to improve ART adherence.²⁹⁻³¹ The HIV health content includes educational and motivational material developed by THRIVE SS that is supported by evidence-based HIV treatment approaches. 32,33 The psychological health content includes psychoeducation and exercises from cognitive behavioral therapy (CBT),³⁴ positive psychology (PPI),35 and dialectic behavioral therapies (DBT)³⁶ aimed at promoting individual education and motivation and facilitating users to identify and replace negative thought and behavioral patterns consistent with a transtheoretical approach.³⁷ In the pilot version of iTHRIVE 365 tested here, the health knowledge and motivation content was housed in the home/landing and pill reminder pages.

The social support content includes a community calendar that provides up-to-date information on THRIVE SS-led and other Black SGLM community events in the Atlanta, GA area and gives users the option to receive reminder notifications about them. It also includes evidence-based features 13,38 such as a moderated forum with discussions on topics generated by THRIVE SS staff or proposed by users and approved by staff. These forums have supported discussions on topics such as confronting stigma, medication side effects, and shared interests in popular culture. In line with guidance from formative focus groups, 14 the forums are meant to support community around more than just HIV (eg, finances, music) and include community guidelines that require users to refrain from personal attacks, hateful language, and other forms of communication that may cause forums to be unsafe for users. Forum moderators are THRIVE SS staff who identify violations of community guidelines. The interpersonal chat is a private chat between 2 users that is only restricted if a user reports a violation of community guidelines. In the pilot version of iTHRIVE 365 tested here, the social support content was housed in the community, calendar, and chat pages.

The access to affirming health care feature allows users to request THRIVE SS institutional support including linkage to psychotherapy, Black SGLM support groups, HIV care, and COVID care. THRIVE SS draws on a network of Black SGLM-affirming Atlanta, GA-area health care providers that has been developed and vetted by THRIVE SS over 10 years through site visits and qualitative evaluations from staff and members that assess aspects of affirming contexts (eg, ease of access, patient comfort, and provider cultural humility). Given the timing of the deployment of this version of iTHRIVE 365 in 2021, we included a CDC COVID screener (https://www.cdc.gov/screening/index.html) in this section.

The housing and economic empowerment resources linkage features allow users to request free transportation, food assistance, culturally-appropriate clothes, and connection to housing support. Transportation costs are covered through paid transit passes and direct cash assistance. Clothes and food assistance are provided on-site at THRIVE SS and through THRIVE SS partner organizations. Housing assistance is managed by THRIVE SS case workers and includes transitional housing at a THRIVE SS-owned transitional home that provides housing for up to 5 months for those seeking a permanent residence and referrals to housing vouchers and other housing support in THRIVE SS's network. In the pilot version of iTHRIVE 365 tested here, the access to affirming health care and economic empowerment features were housed in the linkage page. Additional information on the intervention is available in the intervention development article.¹⁴

MEASURES

iTHRIVE 365 Feasibility and Acceptability

We assessed feasibility through self-reported daily intervention engagement and summary paradata on amount of intervention engagement via the frequency of page access (ie, page 'clicks').³⁹ We assessed acceptability through follow-up self-report items assessing user-friendliness, usefulness, and helpfulness of the intervention (eg, "How [user-friendly/useful] did you find the iTHRIVE 365 app?"; scale: 0 [not at all useful]) to 4 [extremely useful]) and whether they would recommend it to others ("Is this an app that you would recommend to others?"; scale: 0 [No] to 1 [Yes]).

iTHRIVE 365 Engagement

We assessed intervention engagement with a single dichotomous no(0)/yes(1) item ("In the past 24 hours, did you access the THRIVE 365 app?"). We decided on this approach rather than common paradata approaches to intervention duration and frequency, ³⁹ given the pilot web-based app prototype of iTHRIVE 365 tested here allowed participants to remained logged-in, which obfuscated these intervention engagement metrics.

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Antiretroviral Treatment Use

A single dichotomous no(0)/yes(1) item assessed ART use over the past 24 hours: "In the past 24 hours, did you take ART medication?"

Emotion Regulation

A validated four-item version of the Difficulties with Emotion Regulation Scale^{40,41} assessed emotion regulation. Participants rated the extent to which they had been experiencing each item (eg, "In the past 24 hours, I've been experiencing my emotions as overwhelming") in the past day on a scale from 0 (not at all) to 3 (completely). We used an average across all items for each time point.

Anxiety and Depressive Symptoms

The PHQ-4 assessed anxiety and depressive symptoms. 42 Participants rated the extent to which they had been experiencing each item the past day (eg, "In the past 24 hours, I've been feeling nervous, anxious, or on edge") on a scale from 0 (not at all) to 3 (completely). We used an average across all items for each time point.

Data Analytic Plan

To examine the feasibility and acceptability of iTHRIVE 365, we evaluated descriptive data of daily selfreport engagement data and page access paradata (feasibility) and whether they found it useful, user-friendly, and whether they would recommend it to others (acceptability). To examine the impact of iTHRIVE 365 engagement, we ran a χ^2 to test for differences in ART use between days in which participants did and did not engage with iTHRIVE 365. We chose this rather than a day-level approach given there was a high ART use rate, which limited analytic options, given there was small within- and between-level variance. For psychological outcomes, we estimated dynamic structural equation models (DSEM) for the intensive longitudinal data (ILD) produced by the daily surveys.⁴³ DSEM is an analytic approach that combines time-series analysis, multilevel modeling, and structural equation modeling as it can model: within-person lagged associations across many repeated measures, between-person differences in individual-level processes, and multiple latent and outcome variables, respectively.44 Our models followed best practices in two-level DSEM for ILD in Mplus 8.4,43 with analyses as multilevel models that specify within-person variance (ie, change in outcome for a single person from day to day) and betweenperson variance (ie, differences between participants' overall outcomes). The standard DSEM approach within Mplus uses Bayesian Markov Chain Monte Carlo estimation to aid in convergence and flexibility. For readers unfamiliar with Bayesian statistics, there are no P-values associated with effects; however, typical frequentist inference can be approximated by calculating a 95% credible interval for each parameter and testing whether 0 is within the interval. Intervals that do not contain 0 are analogous to "significant" in a traditional frequentist analysis.

We examined associations between iTHRIVE 365 engagement and next day outcomes with a multilevel vector autoregressive models (VAR (1)) in the DSEM framework.⁴³

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All models adjusted the effects of engagement for app availability since app registration occurred starting on day 8 of the study. As an example, the models examining the association between iTHRIVE 365 engagement (T365) and depressive symptoms (Dep) can be written statistically as

Within-Person

$$Dep_{ti} = \alpha_{1i} + \varphi_{1i} Dep_{(t-1)i}^{C} + \beta_{1i} T 365_{(t-1)i} + e_{1ti}$$
 (1)

T $365_{ti} = \nu_1 + \varphi_2 T \ 365_{(t-1)i} + \beta_2 \ Access_{ti}$

Between-Person

$$\alpha_{1i} = \gamma_{00} + u_{0i}$$

$$\beta_{1i} = \gamma_{10} + u_{1i}$$

$$\phi_{1i} = \gamma_{20} + u_{2i}$$

With distributional assumptions,

$$\mathbf{e}_{i} \sim N \quad \left(\mathbf{0}, diag\left[\sigma_{1}^{2}, \sigma_{2}^{2}\right]\right)$$

$$\mathbf{u}_{i} \sim N \quad \left(\mathbf{0}, \begin{bmatrix} \tau_{00} & \\ \tau_{21} & \tau_{11} \\ 0 & 0 & \tau_{22} \end{bmatrix}\right)$$
(2)

In the first expression in the within-person equation, Dep is the depressive symptoms outcome, t indexes time (in days, $t=1,\ldots,14$), i indexes individuals ($i=1,\ldots N$), α_{1i} is a person—specific intercept for depressive symptoms, φ_{1i} is the autoregressive effect capturing the carryover of depressive symptoms from the previous day to the current day, Dep^C is latent-centered depressive symptoms such $Dep^C = Dep_i - \alpha_{1i}$ (latent centering helps alleviate Ludkte's and Nickell's bias in time-series models), ⁴⁴ β_{1i} is a time-varying covariate effect of T365 access the previous day on depressive symptoms during the current day, and e_1 is a normally distributed within-person error with variance σ^2 . The second expression in the within-person equation is a probit model because T365 use is dichotomous such that ν_1 is the threshold for T365 use, φ_2 is the carryover effect of T365 use the previous day onto T365 use during the current day, and β 2 accounts for whether person i had access to the intervention at time t.

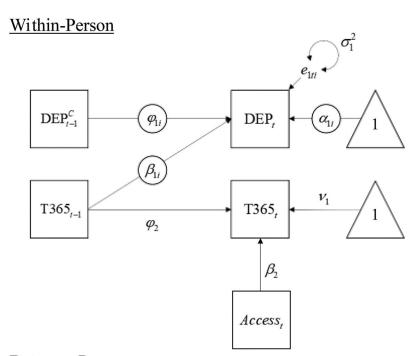
In the between-person model, γ are fixed effects that capture the average effect of the parameter across all persons, and u are normally distributed random effects capturing person-specific deviations from the fixed effects. The variances of the random effects are captured by the diagonal elements of the tau-matrix; one random effect covariance between depressive symptoms intercepts and the

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lagged T365 effect is also estimated as denoted by the au_{10} element in the off-diagonal. Figure 1 features a path diagram for this model.

In line with best practice recommendations for DSEM with small sample sizes, 45 we used range-restricted priors of Uniform[0,1] for the random effect variances τ_{00} , τ_{11} , and τ_{22} to stabilize the sampling in the MCMC optimization. This approach does not encode subjective prior beliefs, but rather just limits the prior's support to a range of values that the outcome can take. Mplus default priors were used for other

parameters that are minimally influenced by sample size including improper $N(0, \infty)$ for regression paths or random effect covariances and improper InvGamma (-1, 0) for within-person error variances. Parameters were estimated via Markov Chain Monte Carlo with a Gibbs sampler using 2 chains thinned by 10 iterations with a minimum of 20,000 iterations. Convergence after 20,000 iterations was evaluated using the potential scale reduction method using a threshold of $R \le 1.10$. We computed credible intervals with the highest posterior density method.



Between-Person

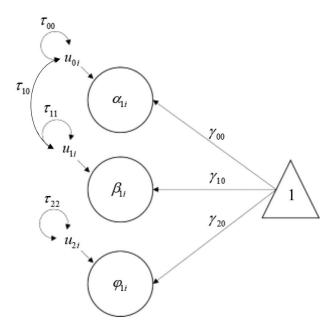


Figure 1. Path Diagram for Dynamic Structural Equation Model. Note: Rectangles represent observed variables, circles represent latent variables, and triangles represent constant.

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TABLE 1. Demographic Characteristics of Participants

	Participants (%)	
	n	%
Race		
Black/African American	30	93.8%
Black, Indigenous, other - Italian	1	3.2%
Other – Jamaican	1	3.2%
Sexual identity		
Gay	25	78.1%
Bisexual	3	9.4%
Queer	2	6.3%
Same gender loving	2	6.3%
Age		
18-24	1	3.1%
25-34	5	15.6%
35-49	10	31.3%
50-64	11	34.3%
Over 65	4	12.5%
Gender		
Man	29	90.6%
Genderqueer/Gender nonconforming	3	9.4%
Income		
Less than \$10,000	2	6.3%
\$10,000 - \$29,999	4	12.5%
\$30,000 - \$49,999	9	28.1%
\$50,000 - \$99,999	11	34.4%
Over \$100,000	1	3.1%
Formal educational attainment		
High school/GED	6	18.8%
Some college	15	46.9%
In college (enrolled)	1	3.1%
Bachelor's degree	6	18.8%
Graduate degree	4	12.5%
Employment		
Unemployed	3	9.4%
Temporary disabled	6	19.7%
Part time	4	12.5%
Full time	19	59.4%
Ethnicity		
Latinx	4	12.5%
Non-Latinx	28	87.5%

RESULTS

Participant demographics are in Table 1. Thirty one of 32 (97%) participants completed the follow-up and participants completed 91% of their daily surveys. Seventy-five percent of participants successfully registered for the intervention and, as such, had access at some point during the 7-day postintervention period. Registered and unregistered participants did not differ across any baseline outcome or demographic variables. The average participant engaged the app on 59% of days, translating to engagement more than once every other day. Paradata showed participants accessed iTHRIVE 365 pages 1042 times. Thus, participants accessed pages on iTHRIVE 365 an average of 4.65 times per day

during the 7-day intervention period (1042 page visits/[32 participants x 7 days]). The most accessed intervention pages were the home/landing (n= 310 times), social support (n = 272 times; community forum page [n = 179], calendar page [n = 60], chat page [n = 33]), and linkage (n = 58 times)pages. The least accessed intervention pages were the health maintenance notification system (n = 7 times) and the COVID screener (n = 1 times). There was not a significant correlation between time and iTHRIVE 365 engagement (r = 0.07, P = 0.27) or page access paradata (r = -0.01, P = 0.92), which indicates engagement did not wane over the intervention period. Among participants who registered for the app, 88% reported it was user-friendly, 83% reported it was moderately to extremely useful, 78% of participants reported it was helpful to extremely helpful, and 88% reported they would recommend it to others.

Regarding the ART outcome, the 14-day average adherence was 94%. On intervention engagement days (96% adherence), participants had higher odds of ART use, χ^2 (1) = 4.09, P = 0.04, than intervention nonengagement days (87% adherence).

For the DSEM models, there were no significant associations between time in the study and any of the outcomes, indicating that we could assume stationarity among our outcomes for these models. Posterior distribution summaries, 95% credible intervals, and within-person standardized effects (where applicable) are presented in Table 2 for the focal parameters in the DSEM models.

For depressive symptoms, the average response was 0.45 and there was notable between-person variability $(\tau_{00} = 0.24, 95\% CI = [0.10, 0.44])$, indicating the average of depressive symptoms was different across people. On average, depressive symptoms showed a non-null decrease of 0.08 points on days after intervention engagement $(\gamma_{10} = -0.08, 95\% \ CI = [-0.18, -0.01])$. On a standardized metric, this was a 0.14 SD decrease (95% CI: = [-0.23, -0.05]). There was between-person variability in the intervention engagement effect ($\tau_{11} = 0.04, 95\%$ CI: = [0.01, 0.09]), and the random effect correlation for the between-person intercepts and the slope of intervention engagement was large and non-null (r = -0.68, 95%CI: = [-0.91, -0.34]). This indicates that participants with higher depressive symptoms overall tended to have larger decreases in depressive symptoms on days after intervention engagement.

For anxiety, the average response was 0.45 and there was notable between-person variability ($\tau_{00}=0.24, 95\%$ CI:=[0.10, 0.42]. On average, anxiety was not different on days after intervention engagement ($\gamma_{10}=-0.03, 95\%$ CI:=[-0.09, 0.03]); however, there was small between-person variability intervention engagement effect ($\tau_{11}=0.01, 95\%$ CI:=[0.01, 0.03]), and the random effect correlation for the between-person intercepts and the slope of intervention engagement was large and non-null (r=-0.81, 95% CI:=[-0.99, -0.47]). This indicates that participants with higher anxiety intercepts tended to have larger decreases in anxiety symptoms on days after intervention engagement.

TABLE 2. Dynamic Structural Equation Results

	·			Std.
Outcome	Parameter	Estimate	95% CI	Effect
Depressive	Intercept, fixed effect	0.45*	0.26, 0.66	
	Intercept, variance	0.24*	0.10, 0.44	
	T365, fixed effect	-0.08*	-0.18, -0.01	-0.14
	T365, variance	0.04*	0.01, 0.09	
	Int, T365 correlation	-0.68*	-0.91, -0.34	
Anxiety symptoms	Intercept, fixed effect	0.45*	0.26, 0.64	
	Intercept, variance	0.24*	0.10, 0.42	-0.05
	T365, fixed effect	-0.03	-0.22,0.20	
	T365, variance	0.01*	0.01,0.03	
	Int, T365 correlation	-0.80*	-1.00, -0.47	
Emotion regulation symptoms	Intercept, fixed effect	0.54*	0.36, 0.70	
	Intercept, variance	0.21*	0.11, 0.36	-0.16
	T365, fixed effect	-0.06*	-0.12, -0.01	
	T365, variance	0.02*	0.01, 0.04	
	Int, T365 correlation	-0.38	-0.74, 0.04	

Note: T365= iTHRIVE 365 intervention.

Estimate = median of the posterior distribution, CI: = credible interval using the highest posterior density method, Std. Effect = Standardization using the average of within-person standardization method, * indicates that 0 is not in the 95% credible interval of the parameter and is analogous to being statistically significant in a frequentist inference.

The average emotion regulation difficulty was 0.54 and there was notable between-person variability ($\tau_{00} = 0.21, 95\%$ CI: = [0.11, 0.36]). On average, emotional regulation difficulties showed a non-null decrease of 0.06 points on days after intervention engagement ($\gamma_{10} = -0.06, 95\%$ CI: = [-0.12, -0.01]). On a standardized metric, this was a 0.16 SD decrease (95% CI: = [-0.24, -0.02]). There was between-person variability intervention engagement effect ($\tau_{11} = 0.02, 95\%$ CI: = [0.01, 0.04]) for emotion regulation difficulties. However, the between-person correlation between intercepts and intervention engagement was not different from zero (r = -0.38, 95% CI: = [-0.74, 0.04]), indicating that people with higher average emotional regulation difficulties did not benefit from the intervention differently.

DISCUSSION

This pilot study indicates that iTHRIVE 365, a multicomponent intervention that seeks to promote HIV and psychological health information and motivation, social support, affirming health care, and economic empowerment among Black SGLM, is feasible, acceptable, and positively impacts daily HIV and psychological health outcomes. Specifically, we

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found that participants engaged with the intervention over 1 of every 2 days and accessed intervention pages an average of 4.65 times per day. Among participants who accessed the intervention, 78% reported it was helpful, 83% reported it was useful and 88% reported it was user-friendly and would recommend it to others. On days participants engaged with iTHRIVE 365, they were more likely to take their ART medication, and on the next day, they reported lower depressive symptoms and emotion regulation difficulties. Results also show participants with higher depressive and anxiety symptoms tended to benefit the most from the intervention. Overall, iTHRIVE 365 seems to be a promising tool to improve HIV and psychological health among Black SGLM.

The results showing short-term feasibility and acceptability of iTHRIVE 365, which incorporates mHealth, is a critical finding given regular interest and engagement from users are critical perquisites for mHealth interventions.²⁸ Regarding efficacy, although few evidence-based interventions have been found to promote HIV and psychological health among Black SGLM, 13 our results indicate that iTHRIVE 365 improves ART use, depressive symptoms, and emotion regulation among Black SGLM on a daily basis. Given most current formulations of ART must be taken daily to be optimally effective, these early findings suggest that iTHRIVE 365 holds promise for helping Black SGLM living with HIV to maintain this vital daily health practice. These results are also important because, although most health interventions for Black SGLM are not tailored to promoting mental health, ¹³ iTHRIVE 365, which includes mental health promotion content, seems to improve daily mental health outcomes among Black SGLM. Taken together, these results suggest that iTHRIVE 365 can be a helpful tool that Black SGLM living with HIV can use to support their overall wellbeing, and may help to reduce community-level viral load and promote psychological health.

Critically, participants in our study were primarily from Ending the HIV Epidemic (EHE) priority jurisdictions, which are some of the geographic regions that experience the greatest levels of HIV and psychological health inequities for Black SGLM.⁴⁶ The mHealth tools within iTHRIVE 365 designed to promote social support and affirming health care may have been particularly impactful given some of the most profound obstacles for Black SGLM in these EHE jurisdictions are social isolation and a lack of health care resources.^{7,22} mHealth resources also provide a low-cost, low-barrier approach to reaching Black SGLM who otherwise may be experiencing practical barriers (eg, limited funds to reach a physical clinic)²² and psychological barriers (eg, anticipated stigma)²³ to in-person health care. Thus, the present results suggest that iTHRIVE 365 may be an impactful tool in ending the HIV epidemic among Black SGLM in EHE jurisdictions.

LIMITATIONS AND FUTURE DIRECTIONS

iTHRIVE 365 is a novel and innovative HIV and psychological mHealth intervention developed by Black SGLM for Black SGLM. These strengths notwithstanding, there are several limitations of note. First, participants had

some difficulty with the intervention registration process, leading to a 75% registration rate among participants. The intervention is currently being revised to streamline this registration process to promote easier access. Future studies will be needed to test whether these adjustments improve registration rates. Second, our DSEM models showed null effects for daily anxiety. However, our results indicate that the participants who may have benefitted from the intervention the most are those who started with the highest levels of depressive and anxiety symptoms. It is possible this result is indicative of regression to mean. Alternatively, it may indicate iTHRIVE 365 intervention may be particularly important for Black SGLM who are experiencing higher levels of psychological distress. Additional daily research with iTHRIVE365 is needed to reconcile these possibilities. In addition, this pilot study only examined these outcomes across a 2-week period. Given these mixed results, additional longitudinal research with larger samples is needed to examine these outcomes across short-term and long-term periods. It will also be essential to examine whether participants maintain engagement with iTHRIVE 365 beyond the two-week period assessed in this pilot research.

Finally, additional research is needed to examine the effects of accessing different intervention components (eg, health information and motivation content vs. social support content) and theoretically-relevant mediators of intervention effects, such as whether iTHRIVE 365 promotes HIV and psychological health through its effects health education and motivation, social support, affirming health care and housing and economic empowerment.

CONCLUSIONS

Community-led solutions for addressing HIV are needed to successfully bring about an end to the HIV epidemic, particularly for communities that experience the greatest burden of HIV in the United States, including Black SGLM. The present study indicates iTHRIVE 365, our multicomponent intervention developed through a community-based participatory process led by Black SGLM, shows promise in helping Black SGLM living with HIV to improve their short-term HIV and psychological health outcomes.

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