



LOS ANGELES COUNTY  
**COMMISSION ON HIV**



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*Join us in developing a progressive and inclusive agenda to address the disproportionate impact of HIV/STDs in the Black community*

# BLACK CAUCUS

## Virtual Meeting

**Thursday, March, 2023\***

*\*meeting rescheduled*

**4:00-5:00pm (PST)**

Agenda and meeting materials will be posted on <http://hiv.lacounty.gov/Meetings> \*Other Meetings

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REGISTRATION NOT REQUIRED + SIMULTANEOUS TRANSLATION IN SPANISH AND OTHER LANGUAGES NOW AVAILABLE VIA CLOSED CAPTION FEATURE WHEN JOINING VIA WEBEX. CLICK [HERE](#) FOR MORE INFO.

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### TO JOIN BY COMPUTER:

<https://lacountyboardofsupervisors.webex.com/lacountyboardofsupervisors/j.php?MTID=m732cdfc38c9b29b7e9323bc0c9a00847>

Meeting Password: BLACK

### TO JOIN BY PHONE:

1-213-306-3065 Access Code/Event #: 2593 474 7745

For a brief tutorial on how to use WebEx, please check out this video: <https://www.youtube.com/watch?v=iQSSJYcrglk>

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# LOS ANGELES COUNTY COMMISSION ON HIV



510 S. Vermont Ave., 14th Floor • Los Angeles, CA 90020 • TEL (213) 738-2816  
HIVCOMM@LACHIV.ORG • <https://hiv.lacounty.gov>

## BLACK CAUCUS Virtual Meeting Agenda

Thursday, March 23, 2023 @ 4:00PM-5:00PM

To Join by Computer:

<https://lacountyboardofsupervisors.webex.com/lacountyboardofsupervisors/j.php?MTID=m732cdf38c9b29b7e9323bc0c9a00847>

Join by phone: 1-213-306-3065

Password: BLACK Access code: 2593 474 7745

1. WELCOME, INTRODUCTIONS & MEETING GUIDELINES 4:00PM-4:05PM
2. COH STAFF REPORT/UPDATES 4:05PM-4:07PM
3. CO-CHAIR REPORT/UPDATES 4:07PM-4:10PM
  - Organizational Capacity Needs Assessment | Updates (if applicable)
4. PRESENTATION 4:10PM-4:40PM

Project Rise: Randomized Controlled Trial of Rise,  
A Community-Based Culturally Congruent Counseling Intervention to  
Support Antiretroviral Therapy Adherence Among Black/African American  
Adults Living with HIV | Research Findings Presented by Laura M. Bogart, PhD; Matt G.  
Mutchler, PhD; and Sean J. Lawrence
5. DISCUSSION 4:40PM-4:50PM
  - Prioritize & Planning 2023 Workplan Activities
    - Next steps & future of the Black/AA Community Task Force Recommendations
    - Community listening sessions to address the state of HIV in the Black community
    - Community Engagement and Communications
6. RECAP AND NEXT STEPS 4:50PM-4:55PM
7. PUBLIC COMMENT & ANNOUNCEMENTS 4:55PM-5:00PM
8. ADJOURNMENT 5:00PM



## LOS ANGELES COUNTY COMMISSION ON HIV



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HIVCOMM@LACHIV.ORG • <http://hiv.lacounty.gov>

### CODE OF CONDUCT

We welcome commissioners, guests, and the public into a space where people of all opinions and backgrounds are able to contribute. We create a safe environment that celebrates differences while striving for consensus and is characterized by consistent, professional, and respectful behavior. Our common enemies are HIV and STDs. We strive to be introspective and understand and clarify our assumptions, while appreciating the complex intersectionality of the lives we live. We challenge ourselves to be self-reflective and committed to an ongoing understanding. As a result, the Commission has adopted and is consistently committed to implementing the following guidelines for Commission, committee, and associated meetings.

**All participants and stakeholders should adhere to the following:**

- 1) We strive for consensus and compassion in all our interactions.**
- 2) We respect others' time by starting and ending meetings on time, being punctual, and staying present.**
- 3) We listen, don't repeat what has already been stated, avoid interrupting others, and allow others to be heard.**
- 4) We encourage all to bring forth ideas for discussion, community planning, and consensus.**
- 5) We focus on the issue, not the person raising the issue.**
- 6) We give and accept respectful and constructive feedback.**
- 7) We keep all issues on the table (no "hidden agendas"), avoid monopolizing discussions and minimize side conversations.**
- 8) We have no place in our deliberations for homophobic, racist, sexist, and other discriminatory statements and "-isms" (including misogyny, transphobia, ableism, and ageism).**
- 9) We give ourselves permission to learn from our mistakes.**

Approved (11/12/1998); Revised (2/10/2005; 9/6/2005); **Revised (4/11/19; 3/3/22)**



## **BLACK CAUCUS**

**Thursday, February 23, 2023 | 4:00PM to 5:00PM**

### **VIRTUAL MEETING SUMMARY**

Meeting packet is available at: <https://hiv.lacounty.gov/meetings/>

*\*Contact staff for verification of attendance*

#### **1. Welcome & Introductions**

Co-Chairs Danielle Campbell and Gerald Garth welcomed attendees and led introductions.

#### **2. Co-Chair Report & Updates**

##### 2023 Co-Chair Open Nominations & Elections

Danielle Campbell and Gerald Garth were reelected as the 2023 Black Caucus Co-Chairs

##### 2023 Meeting Frequency & Schedule

Overall sentiments were shared that meeting consistently will sustain member engagement and commitment and focus should be on optimizing our time together by ensuring agendas and discussions are concise, action oriented and are aligned with the Caucus' objectives. A suggestion was made to consider extending meetings by 30 minutes to allow for thoughtful deliberations on agenda items; tbd.

The Caucus will continue to meet on the third Thursday of each month @ 4-5PM virtually. Please note that the March 16 regular meeting will be rescheduled due scheduling conflict with the workforce conference hosted by DHSP, March 16-17. Please hold your calendars for Thursday, March 23 @ 4-5PM – confirmation forthcoming.

##### Organizational Capacity Needs Assessment | UPDATES

Julie Tolentino (DHSP) provided a brief update on the Caucus' organizational capacity needs assessment and shared DHSP is finalizing its contract with Raniyah Copeland, who will be leading the implementation of the assessment and related activities. Raniyah will begin the first phase of implementation by piloting the assessment with Dr. William King. Updates to follow.

#### **3. DISCUSSION**

##### 2/9/23 NBHAAD Panel Presentation | FOLLOW UP & FEEDBACK

Positive feedback was shared regarding the Commission's February 9th NBHAAD panel presentation hosted by the Black Caucus and facilitated by Danielle and Gerald. The panelists included Abraham Johnson, DaShawn Usher and Leisha McKinley-Beach. Feedback included expressions of appreciation and inspiration in seeing Black leaders in the field sharing their experience.

### 2023 Proposed Workplan

The Caucus reviewed its workplan. Regarding workplan item #4, Leon Maultsby offered CDU as a possible site for community listening sessions. Members were requested to recommend additional items to add to the workplan

#### **4. Recap & Next Steps**

- Commission staff to confirm March 23 meeting date considering DHSP's Workforce Conference which is scheduled for March 16-17, 2023.
- Continue momentum in rebuilding the Caucus' movement by focusing on and completing workplan activities.

#### **5. Public Comment & Announcements.**

- What We Think" Project

Shawn Griffith presented on the "What We Think" project; a project formed by the LGBTQIA2+ Subcommittee of the Los Angeles County Department of Mental Health. The project is designed to elicit opinions of Black Gay Male Elders over 50 regarding health, aging, housing, and financial stability among other social determinants of health. The primary focus is to assess mental health needs. A survey will also be available; participants will receive a \$10 gift card. For more information, please contact Shawn at [shawngrifla@gmail.com](mailto:shawngrifla@gmail.com) ; flyer in meeting packet.

- 2023 "PrEP" Campaign Development: Call for Graphic Artists

Julie Tolentino (DHSP) announced a call for artists to participate in an upcoming PrEP Marketing Campaign focused on Black communities in Los Angeles County. Julie expressed thanks and appreciation for the Caucus' vision as the PrEP campaign for the Black community was a part of the Black/African American Community Taskforce (now Black/AA Caucus) recommendations. Flyer in meeting packet.

#### **6. Adjournment**

## Black Caucus Workplan 2023

Adopted 1/19/23  
(Updates in highlights for 3/23/23 meeting)

**PURPOSE OF THIS DOCUMENT:** To identify activities and priorities the Black Caucus will lead and advance throughout 2023.

**CRITERIA:** Select activities that 1) represent the core functions of the COH and Caucus, 2) advance the goals of the 2022-2026 Comprehensive HIV Plan (CHP), 3) identify strategies to address the Black/AA Community Task Force Recommendations, and 4) align with COH staff and member capacities and time commitment.

**CAUCUS RESPONSIBILITIES:** 1) Facilitate dialogue among caucus members, 2) develop caucus voice at the Commission and in the community, 3) provide the caucus perspective on various Commission issues, and 4) cultivate leadership within the caucus membership and consumer community.

#	GOAL/ACTIVITY	ACTION STEPS/TASKS	TIMELINE/ DUE DATE	STATUS/COMMENTS/SUGGESTIONS
1	<b>Organizational Capacity Needs Assessment for Black-led Organizations</b>	Administer a qualitative and quantitative needs assessment to the nine selected, Black-led organizations to help inform and implement a TA program so that Black-led organizations can better compete for County contracts.	Initial target date: February 2023; ongoing	Final draft submitted to DHSP on 1/19/23 for piloting. Status updates will be provided by DHSP and/or Caucus Co-Chairs as appropriate.
2	<del>National Black/AA HIV/AIDS Awareness Day (NBHAAD)</del>	<del>Plan activity(ies) promoting health/wellness, lifting the Black community, and addressing stigma and the disproportionate impact of HIV within the Black community</del>	February 2023	<del>SUGGESTION: Convene a Part 2 of Candid Conversations (or "Black" Table Talk) on how BLACK MEN &amp; WOMEN living with/impacted by HIV can better support one another; refer to the 2022 NBHAAD activity led by Danielle &amp; Gerald at the 2/10/22 Commission meeting.</del>  <del>Also, tie in announcement of needs assessment.</del>
3	<b>Next steps &amp; future of the Black/AA Community Task Force Recommendations</b>	Review recommendations for revisions/updates and determine next steps.	2023	Prior discussions included adding a demographic section for those who are incarcerated, ultimately addressing the industrial prison complex.



#	GOAL/ACTIVITY	ACTION STEPS/TASKS	TIMELINE/ DUE DATE	STATUS/COMMENTS/SUGGESTIONS
4	<b>Community listening sessions to address the state of HIV in the Black community</b>	Hold candid community conversations by Black folx, for Black folx, addressing stigma and its relation to the faith-based community	2023	Recommended by Dr. Wilbur Jordan who agreed to host the sessions @ CDU.
5	<b>Community Engagement and Communications</b>	<p>Efforts around active recruitment, social media engagement, amplifying other Black HIV-centered communications (ex. A Black women's focus during NGWHAAD, Black men's focus during National Gay Men's Awareness Day (NGMHAAD, etc.)</p> <p>Communications to serve recruitment and retention. Ex. What does recruitment look like? Do we want at least one representative from Black-led, Black-serving orgs? What are the members' responsibilities?</p>		<p>COMMENT: A lot of folks don't even know the Caucus exists and many don't know how much great work is happening. We have an opportunity to better amplify the Caucus's work through strategic communications.</p> <p>This would also look at effective delegation and engagement, getting more folks active in the room</p>



# *Rise*, a Community-Based Adherence Intervention for Black Americans Living with HIV

Laura M. Bogart, PhD

Sean J. Lawrence, BA

Matt G. Mutchler, PhD



SOCIAL AND ECONOMIC WELL-BEING





# About Us

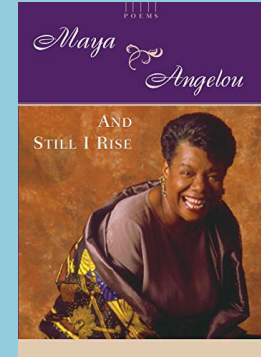
## Who We Are



Rise is based on APLA Health's Treatment Advocacy Program and was developed with community stakeholders



**APLA**Health



Name chosen by  
community  
stakeholders from a  
Maya Angelou

poem

Funded since 2006 by the National Institutes of Health

# How does Rise work?

## INDIVIDUAL LEVEL

- Client-centered counseling in trusted community organization with trained lay peer counselors
- Non-judgmental, empathetic style (Motivational Interviewing) to increase motivation
- Acknowledgment of discrimination and mistrust



3 core sessions  
(first month)  
2-6 booster  
sessions as  
needed (last 5  
months)

## STRUCTURAL LEVEL

- Assess unmet needs
- Referrals to substance use treatment, behavioral health services, food assistance, housing, and other services
- Follow-up on referrals and addresses barriers to receiving services

# How did we evaluate Rise?

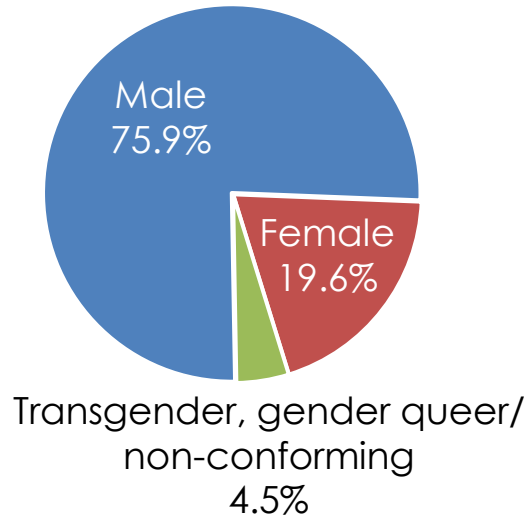
We conducted a randomized controlled trial (RCT) to assess adherence among Black adults living with HIV who were either in or not in Rise



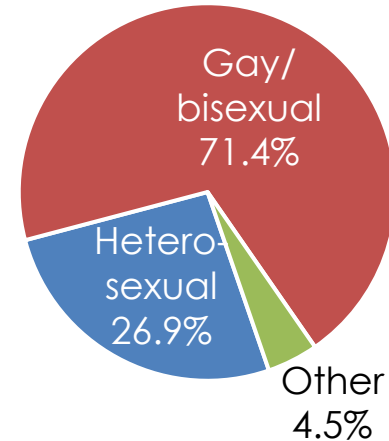
- 245 Black adults with HIV in Los Angeles County, California participated (122 intervention, 123 control)
- Monitored adherence with electronic caps (see picture)
- HIV viral load (blood draws, medical records)
- Baseline & 7- and 13-month follow-up surveys (stigma, mistrust)
- Gift card incentives: \$30 at baseline and 1-month check-in, \$20 for each check-in visit, \$40 at 7-months, \$50 at 13-months, \$10 per intervention session

# Results: Participant Characteristics

## Gender Identity



## Sexual Identity



# Participant Characteristics

Average Age: 49



Unhoused Past Year:  
35%



Employed: 16%

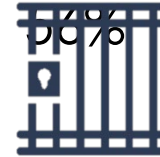


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Annual Income < \$10K:



Ever Incarcerated:





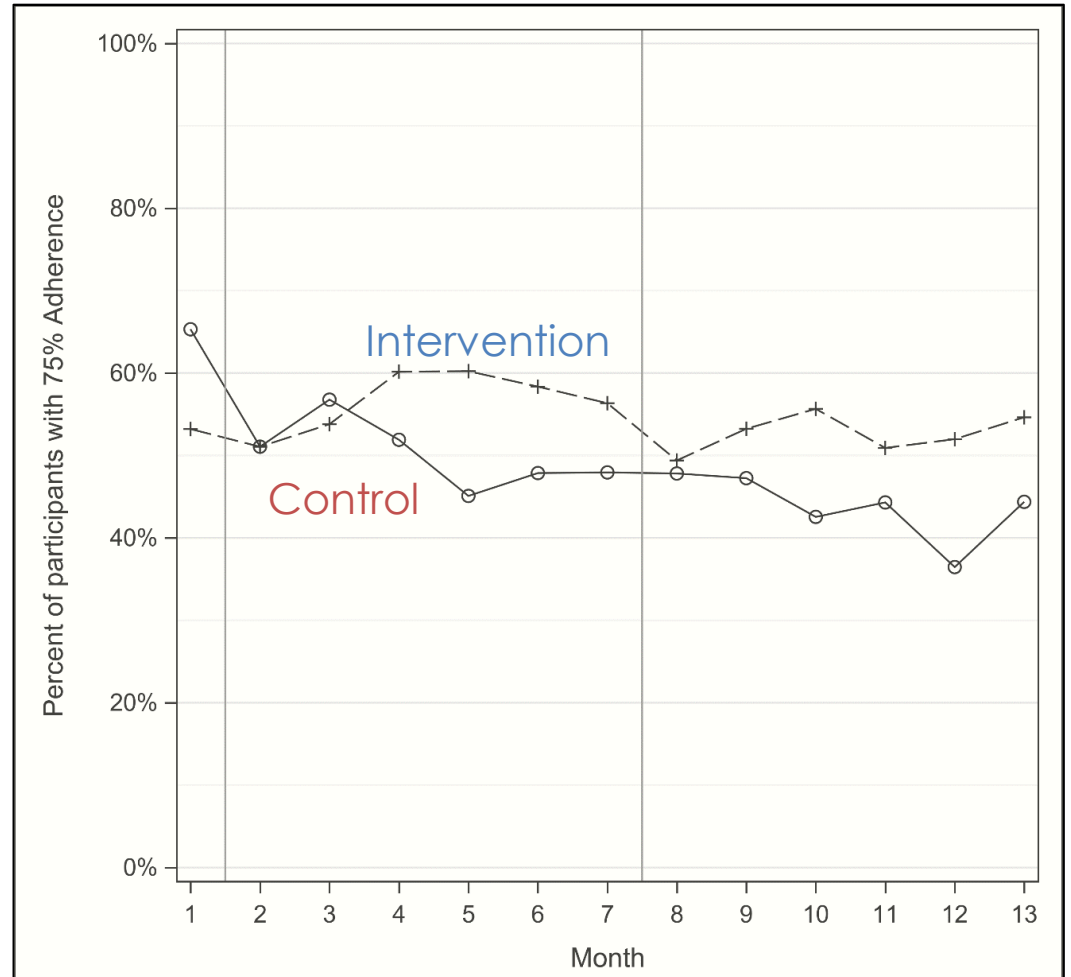
# Questions

***Any questions or comments so far about project Rise?***

# Results

Rise clients had better adherence than clients who were not in Rise

Rise worked better for younger clients



# Rise adherence effects were stronger during the pandemic

## PRE-PANDEMIC



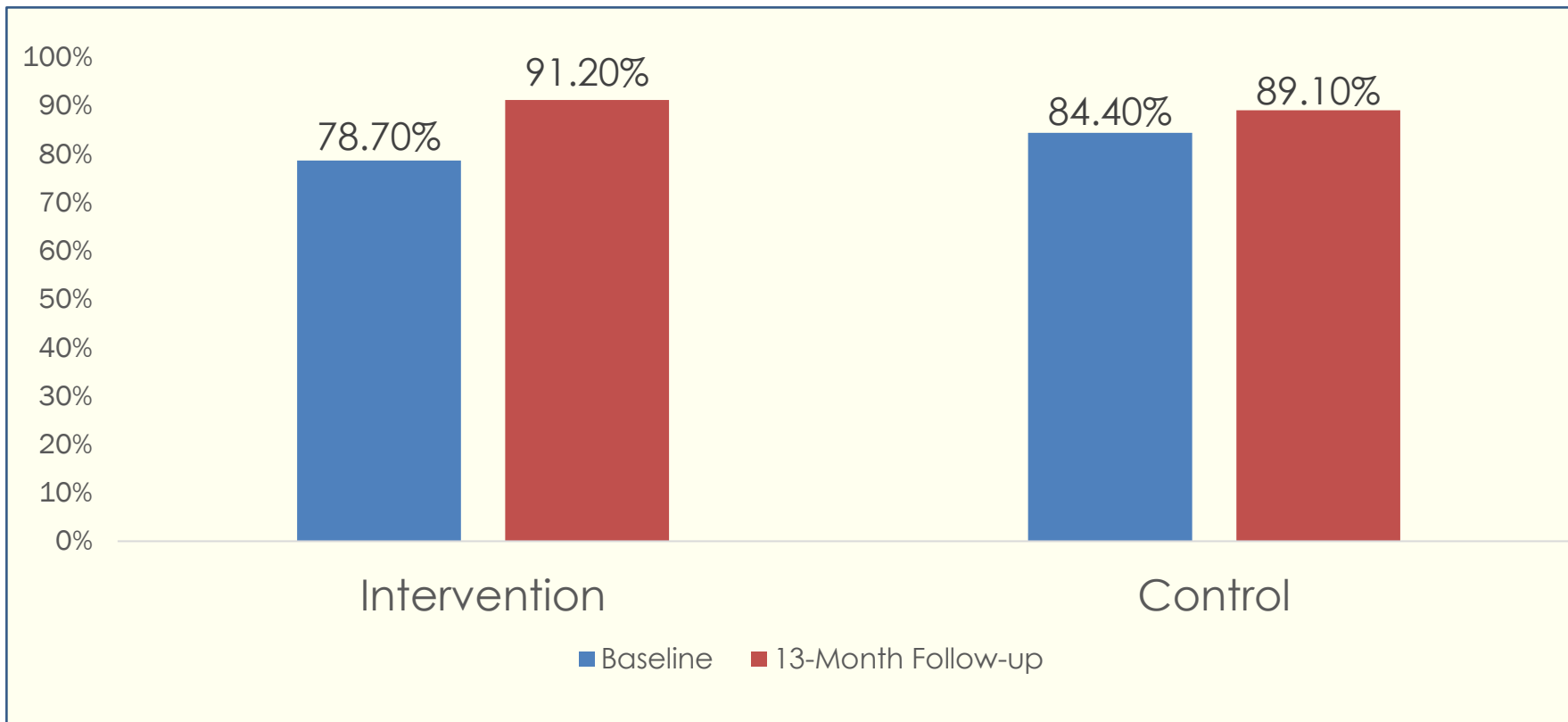
Intervention sessions conducted in person **slightly improved adherence** in comparison to the control condition

## DURING PANDEMIC

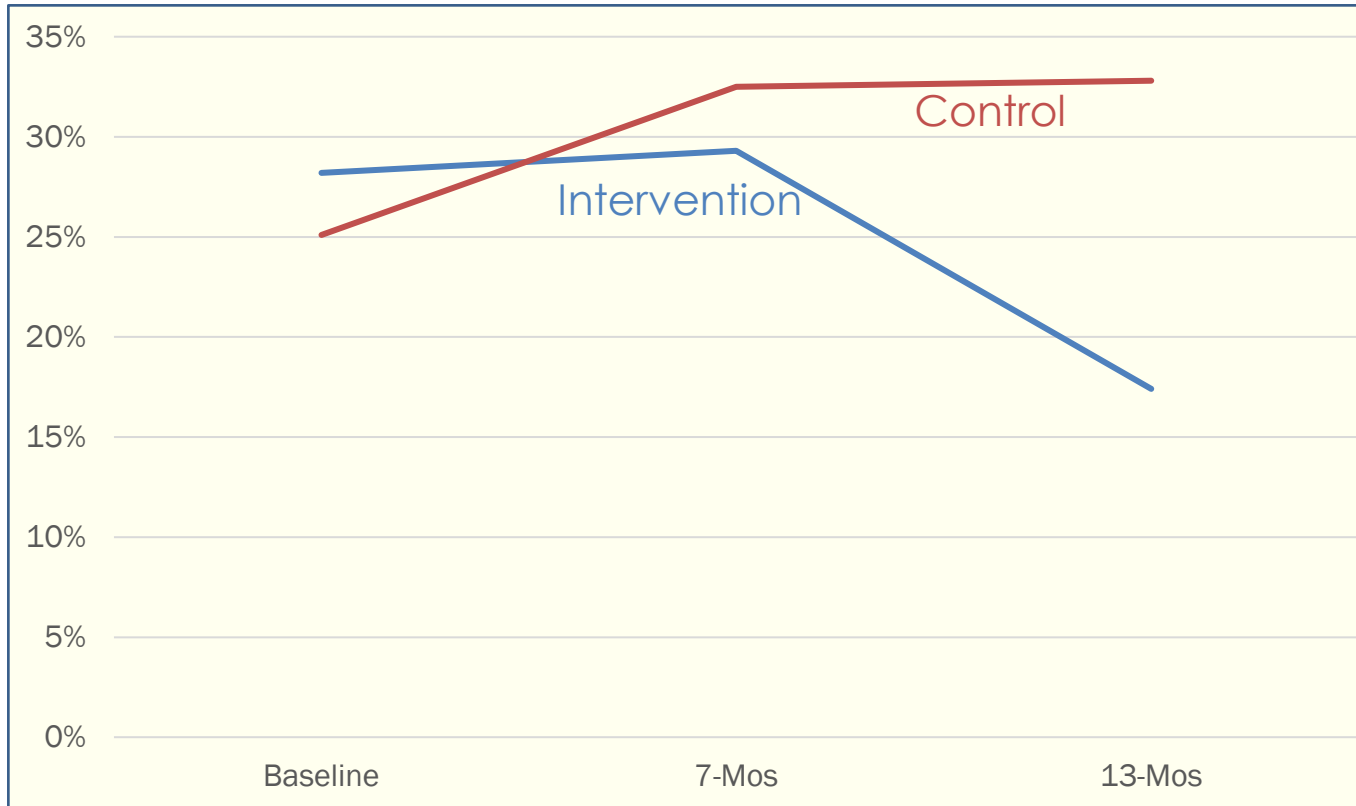


Intervention sessions conducted by telephone **significantly improved adherence**

# Rise clients did not have significantly higher viral suppression



# Rise led to decreased HIV stigma



# In sum: Rise was beneficial for adherence



Rise had strong long-term adherence effects across sexual and gender identities, income and education, and other characteristics



Effects were stronger among younger participants, possibly because they identified with the peer counselor, who was closer in age



- Effects were stronger during the pandemic
- Rise may have helped to protect against negative pandemic effects
  - Phone sessions may have been preferable



## Next Steps: Proposed UCLA-CDU CFAR EHE Supplement

- Stakeholder engagement (community organizations, providers, peer counselors) in Los Angeles County, CA and Jefferson County, Alabama in order to:
  - Re-design Rise to be serostatus-neutral (ART & PrEP adherence/uptake); flexible for phone, virtual, and in-person delivery; and long-acting injectables as well as pills
  - Develop Rise training package (website, manual, videos)

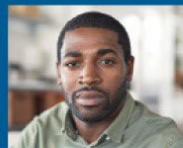
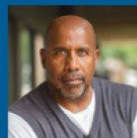
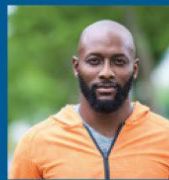
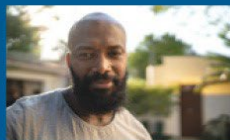
# Limitations

- A lot of clients dropped out of the study during the pandemic
- We could not draw blood during the pandemic
- Most participants were sexual minority men
  - Fewer women and people who are transgender participated

# Let's talk about your health.

Join us for a research project that gives **Black men** a safe space to get support for their **racial and sexual identities**.

- Over eight weeks, participate in group discussions that explore ways to cope with discrimination
- Complete four interviews and three brief check-ins over one year
- Receive up to \$510 in gift cards



## Our Current Research: Still Climbin'

# Questions

***Any questions or comments?***

***For more information, see***

**<https://www.rand.org/well-being/social-and-behavioral-policy/projects/rise-hiv-treatment-adherence.html>**

**<https://aplahealth.org/services/community-based-research/>**

# Acknowledgments

## Funders

- National Institute of Nursing Research (R21 NR010284, R01 NR017334)
- National Institute of Minority Health and Health Disparities (R01 MD006058)

## Collaborators

- Matt Mutchler (APLA Health & California State University Dominguez Hills)
- Glenn Wagner, Sebastian Linnemayr, Bonnie Ghosh-Dastidar, David Klein (RAND)
- Kathy Goggin (Children's Mercy Hospital & University of Missouri, Kansas City)
- Jeff Bailey, Sean Lawrence, Damone Thomas, Keshav Tyagi (APLA Health)
- APLA Health Community-Based Research CAB



## Join us for Project Rise.

This study provides Black/African American individuals living with HIV a **confidential and safe** space to receive advice and support.

- Discuss topics such as taking your medications and how to talk to your doctor
- Complete interviews and blood draws over 13 months
- Receive up to 9 counseling sessions
- Receive up to \$320 in gift cards

To participate, visit [srg.rand.org/rise](http://srg.rand.org/rise) or contact us at [projectrise@apla.org](mailto:projectrise@apla.org) or (213) 201-1324.





# Randomized Controlled Trial of Rise, A Community-Based Culturally Congruent Counseling Intervention to Support Antiretroviral Therapy Adherence Among Black/African American Adults Living with HIV

Laura M. Bogart<sup>1</sup> · Matt G. Mutchler<sup>2,3</sup> · Kathy Goggin<sup>4</sup> · Madhumita Ghosh-Dastidar<sup>1</sup> · David J. Klein<sup>1</sup> · Uzaib Saya<sup>1</sup> · Sebastian Linnemayr<sup>1</sup> · Sean J. Lawrence<sup>2</sup> · Keshav Tyagi<sup>2</sup> · Damone Thomas<sup>2,5</sup> · Mahlet Gizaw<sup>1</sup> · Jeff Bailey<sup>2</sup> · Glenn J. Wagner<sup>1</sup>

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## Abstract

Structural inequities have led to HIV disparities, including relatively low antiretroviral therapy adherence and viral suppression rates among Black Americans living with HIV. We conducted a randomized controlled trial of Rise, a community-based culturally congruent adherence intervention, from January 2018 to December 2021 with 166 (85 intervention, 81 control) Black adults living with HIV in Los Angeles County, California [M (SD)=49.0 (12.2) years-old; 76% male]. The intervention included one-on-one counseling sessions using basic Motivational Interviewing style to problem solve about adherence, as well as referrals to address unmet needs for social determinants of health (e.g., housing services, food assistance). Assessments included electronically monitored adherence; HIV viral load; and baseline, 7-month follow-up, and 13-month follow-up surveys of sociodemographic characteristics, HIV stigma, medical mistrust, and HIV-serostatus disclosure. Repeated-measures intention-to-treat regressions indicated that Rise led to significantly (two-fold) higher adherence likelihood, lower HIV stigmatizing beliefs, and reduced HIV-related medical mistrust. Effects on HIV viral suppression, internalized stigma, and disclosure were non-significant. Moreover, Rise was cost-effective based on established standards: The estimated cost per person to reach optimal adherence was \$335 per 10% increase in adherence. Interventions like Rise, that are culturally tailored to the needs of Black populations, may be optimal for Black Americans living with HIV (ClinicalTrials.gov #NCT03331978).

**Keywords** Adherence · Antiretroviral therapy · Black/African American · HIV · Motivational Interviewing · Randomized controlled trial

## Resumen

Las desigualdades estructurales han dado lugar a disparidades relacionadas con el VIH, incluyendo la relativamente baja adherencia a la terapia antirretroviral (TAR) y las tasas de supresión viral entre los afroamericanos que viven con el VIH. Conducimos una prueba controlada aleatoria de Rise, una intervención de adherencia culturalmente congruente basada en

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<sup>5</sup> HEALING with HOPE Corp., Los Angeles, CA, USA



la comunidad, desde Enero de 2018 hasta Diciembre de 2021 con 166 (85 intervención, 81 controlada) adultos afroamericanos que viven con el VIH en el condado de Los Ángeles, California [M (SD)=49.0 (12,2) años; 76% de hombres]. La intervención incluyó sesiones de asesoramiento individualizadas, usando el estilo básico Motivacional para las entrevistas, para resolver los problemas de adherencia como también referencias para confrontar sus necesidades insatisfechas de los determinantes sociales de la salud (por ejemplo, servicios de vivienda y asistencia de alimentos). Las evaluaciones incluyeron la adherencia monitoreada electrónicamente; la carga viral del VIH; y encuestas de referencia, seguimiento a los 7 meses y seguimiento a los 13 meses sobre características sociodemográficas, el estigma del VIH, la desconfianza médica y divulgación del estado serológico respecto al VIH. Los efectos sobre la supresión viral del VIH, el estigma interiorizado y la revelación de información no fueron significativos. Además, Rise fue rentable según los estándares establecidos: El costo estimado por persona para alcanzar la adherencia óptima fue de 335 dólares por cada 10% de aumento en la adherencia. Las intervenciones como Rise, que se adaptan culturalmente a las necesidades de las poblaciones afroamericana, podrían ser óptimas para los estadounidenses afroamericanos que viven con el VIH.

## Introduction

Compared to other races and ethnicities, Black people living with HIV (PLWH) are less likely to be engaged in HIV care and to receive and adhere to antiretroviral therapy (ART), and consequently are less likely to be virally suppressed [1–3]. These disparities, which have persisted throughout the HIV epidemic, may be a result of structural inequities (e.g., social and economic marginalization, intersectional stigma and discrimination), as well as responses to such inequities (e.g., internalized stigma, medical mistrust) among Black Americans [3–8]. To end the HIV epidemic, there remains an urgent need to identify effective, feasible adherence interventions to address inequities, and responses to such inequities, among Black Americans living with HIV, across all gender and sexual identity subgroups.

Among the 26 interventions compiled by the CDC's HIV Prevention Research Project in the Compendium of HIV Medication Adherence Evidence-based Behavioral Interventions (EBIs), nearly all improved ART adherence, with over half using self-reported adherence measures [9]; and of the CDC's Compendium of Structural EBIs, which address environmental, social, and economic factors that influence individual-level behaviors, 12 addressed social determinants of health (e.g., stigma and discrimination, food assistance), of which three showed significant adherence effects (using pharmacy records or self-reports) [9]. Only one, an intervention in which financial incentives were provided for adherence, was determined to show “best evidence” for self-reported adherence and viral suppression effects [10]. A review of 41 systematic reviews from 1996 to 2017 found mixed but significant effects of behavioral counseling interventions on adherence [11]; few of the studies had large sample sizes (> 100 participants), and the reviewed literature was limited in terms of culturally congruent interventions tailored for populations with higher HIV rates (e.g., men who have sex with men, lower-income populations). Another systematic and meta-analytic review of psychological interventions found short-term small-to-moderate effects

on adherence and small effects on viral suppression [12]. Interventions with both behavioral and structural components may be needed for improving long-term adherence.

In Los Angeles County, where the present study was conducted, the Los Angeles County Department of Public Health recommends “person-centered interventions... that respond directly to the challenges and needs of [Black] populations” [13]. However, many evidence-based HIV adherence or structural-level interventions have taken a one-size-fits-all approach, for delivery across racial and ethnic groups. There is a general lack of culturally congruent adherence interventions that are customized to Black Americans' shared racial and ethnic identities, beliefs, history, and experiences, including addressing adaptive and ineffective responses to historical and experienced inequities (e.g., medical mistrust, internalized stigma) [14]. For example, although many of the studies included in the CDC's Compendium (of adherence or structural/social determinants of health interventions) involved substantial proportions of Black participants, only one was specifically tailored for Black Americans—an adherence intervention for young Black men who have sex with men (Project nGage) that used motivational interviewing (MI) and cognitive behavior therapy strategies to address barriers to care; in an RCT, the intervention showed significant effects on self-reported adherence and care engagement [15].

To address the need for evidence-based, cost-effective, culturally congruent interventions for Black Americans, we conducted an RCT of Rise, an adherence counseling intervention for Black adults living with HIV. Rise, which was named after a poem by Maya Angelou [16], is led by a peer counselor situated in a community-based organization; counselors work with clients to problem solve around adherence barriers and link clients to services to address unmet needs for social determinants of health. Rise was culturally tailored through in-depth formative work, community engagement, and pilot studies in the context of an academic-community partnership; prior articles fully describe intervention content [17–20]. A pilot RCT showed large adherence effects

immediately post-intervention [17], although the follow-up time period was too brief for Rise to be considered for wide dissemination as an EBI in the CDC Compendium. In the present study, we extended the follow-up period to 6-months post-intervention and conducted a cost effectiveness analysis to inform future implementation efforts. Only two RCTs in the CDC's HIV Compendium (for adherence and structural interventions) included a cost effectiveness analysis, and neither were conducted in community-based non-clinic settings, implemented in the U.S. with Black Americans, or led by peer counselors [21, 22].

## Methods

### Setting and Community Engagement

The present study was conducted between January 2018 and December 2021 (with recruitment and enrollment from January 2018 to July 2020, final adherence assessments in June 2021, and final viral load assessments from medical record abstraction in December 2021). The study setting was a large community-based HIV services organization, APLA Health & Wellness, which is attached to a Federally Qualified Health Center (FQHC) in Los Angeles (LA) County, California. As of December 31, 2021, an estimated 59,400 people aged 13 and older were living with HIV in LA County; Black individuals had the highest rates of new diagnoses, and the lowest ART adherence, and viral suppression rates of all races/ethnicities [13]. In 2021 in LA County, 54% of Black PLWH showed viral suppression versus 63% of White PLWH.

The team partnered with a community advisory board (CAB) facilitated by the APLA Health Community-Based Research Department. The CAB included Black/African American clients and program staff from APLA Health and other local organizations that serve Black PLWH. The CAB met 1–2 times per year throughout the study and provided input on study design, recruitment materials and venues, and results interpretation. CAB members also aided in participant recruitment.

### Study Design and Procedures

#### Participant Eligibility and Recruitment

Eligibility criteria included: (1) Black/African American racial/ethnic identity, (2) HIV-positive serostatus, (3) 18 years of age or older, (4) prescribed ART for at least 6 months (so that baseline adherence would likely be stable), (5) self-reported adherence problems (i.e., missed at least one ART dose in the past month) and/or detectable viral load (based on biological assessment in the last 6 months);

(6) willing to use an electronic adherence monitoring device; and (7) able to communicate in written and spoken English. (Note that one participant was prescribed ART but did not fill the prescription; this participant was excluded from the adherence analysis.)

Participants were recruited through multiple active and passive means: outreach (e.g., presentations, fliers) to program staff and clients (at the partner organization and other local organizations); in-reach (internal client referral in the partner organization); community/street outreach (e.g., active recruitment at local events); social media outreach (e.g., on Facebook); transportation assistance for the first study appointment if needed; participant incentives for referrals; and discussion groups about adherence for potential participants [23]. Additionally, we developed a partial online pre-screener for use during outreach events (with a \$1 incentive); participants who screened as eligible on the partial screener were called by the study team to complete the full screener.

#### Visit Schedule

Study assessments occurred at baseline, and 1, 3, 5, 7, 9, 11, and 13-months post-baseline. At baseline and 7- and 13-months follow-up, participants completed a 1.5–2-h assessment using Questionnaire Development Survey audio computer-assisted interview software (Lumina Corps). Additionally, at baseline, participants received a Medication Event Monitoring System (MEMS) bottle cap (AARDEX, Inc.) for continuous adherence monitoring. Blocked one-to-one randomization (to intervention or no-treatment control) occurred at 1-month follow-up, when staff also downloaded adherence data, for a pre-randomization, pre-intervention adherence measure. During check-in appointments at 3, 5, 9, and 11 months, staff updated participants' personal and medical contact information. Adherence data were downloaded at every post-baseline study assessment for the evaluation, as well as during every intervention session for the intervention implementation. Viral load assessments were collected to correspond to the 1, 7, and 13-month study time-points (described in detail below).

During the COVID-19 pandemic, starting March 13, 2020, survey assessments and intervention sessions were conducted via telephone instead of in person. (The last survey assessment occurred on June 18, 2021, and the last intervention session occurred on November 4, 2020.) A total of 125 participants (63 control, 62 intervention) completed at least one assessment during the pandemic, and 27 participants had at least one intervention session during the pandemic. Study staff met participants at the community partner's food bank weekly to deliver gift card incentives and download electronic adherence data.

Note that the intervention counselor led telephone rather than video sessions during the COVID-19 pandemic, which allowed intervention sessions to continue seamlessly from the beginning of stay-at-home orders. Because of data security concerns, the institutional review board of record did not immediately approve video sessions (and the recording of video sessions for supervision purposes), and a proportion of participants did not have access to the necessary technology for video sessions.

### Incentives and Human Subjects Protections

Incentives were provided in the form of gift cards to local businesses: \$30 at baseline (pre-randomization), \$30 for the 1-month randomization visit, \$20 for each check-in visit, \$40 for the 7-month assessment, and \$50 for the 13-month assessment. Participants received \$10 for transportation/time reimbursement for every intervention session attended.

Participants provided written informed consent and signed a HIPAA medical release form for HIV viral load. The RAND Human Subjects Protection Committee approved the study (HSPC#2016-0940).

### Intervention Description

Intervention sessions were conducted by a Black peer counselor who received a two-day training on basic MI style (using open-ended questions and reflective listening, and offering information) [24], structured intervention manual content, study procedures, human subjects protections, needs assessment procedures and referral resources (to address social determinants of health), and HIV-related medical information. The counselor had experience and knowledge about HIV and local Black communities and conducted session role-plays to master content. As has been done in prior effective adherence intervention research [25, 26], the structured manualized aspects of the intervention that directly addressed adherence were delivered in an autonomy supportive MI style that emphasized empathy and client autonomy [27]. The peer counselor was trained to use structured open questions and reflect back what clients said (without confronting or pushing).

One-on-one intervention sessions occurred over a 6-month period and included 5 required sessions: three core intervention sessions over the first month (at weeks 1, 2, and 4) and two booster sessions at months 4 and 6. Participants who evidenced non-adherence during the 4- and 6-month booster sessions were offered up to 2 additional booster sessions during months 4 and 6 (up to 4 total). Core session 1 content included building rapport, introducing the intervention and its goals, providing psychoeducation about ART and adherence, assessing attitudes about treatment and adherence, and conducting a needs assessment for social

determinants of health. The needs assessments created a structured approach for the counselor to attend to clients' holistic needs and communicate empathy, providing referrals and warm hand-offs for any unmet needs (e.g., by contacting the agency's housing services or food assistance program); in subsequent meetings, the counselor followed up on referrals and offered additional support as needed.

At the beginning of every session, electronically monitored adherence data were downloaded and used as a basis for problem-solving discussions around adherence, as well as for determining whether participants needed additional booster sessions. Specifically, the counselor and clients viewed electronically monitored adherence (MEMS cap) data together, and the counselor used structured questions to improve understanding of adherence patterns. In all sessions after session 1 (including booster sessions), in addition to checking in about referrals and unmet needs and downloading adherence data, the counselor supported clients in applying problem-solving steps to adherence barriers. In core session 2, the counselor additionally discussed tailoring adherence to daily routine cues, and in core session 3, the counselor discussed ways to enhance social support for adherence, checked in about the provider-patient relationship, and offered to interact with clients' HIV provider.

Cultural tailoring throughout sessions included integration of discussions on stigma and discrimination (related to HIV and its intersectionalities, including race and sexual minority status, if applicable), medical mistrust, disclosure, and sources of resilience in Black communities (e.g., spirituality, social support), given associations of these constructs with adherence in prior research with Black or majority Black samples [4–6, 14, 28–31].

### Usual Care Control Description

Control participants did not receive the intervention. As all study participants had been prescribed ART, control participants were assumed to be receiving routine ongoing care from a healthcare provider. Due to their income levels, most participants had access to the Ryan White medical case management program, which includes assessment of service needs and medical and social service coordination. Although providers ask about adherence issues in routine care, the assessment and any solutions to address issues may not be systematic or evidence-based.

### Intervention Counselor Supervision and Fidelity

An MPH-level supervisor was trained on the manualized intervention and fidelity monitoring, to mirror the way that the intervention might be supervised in practice, if it were implemented in community-based organizations. The MPH

supervisor completed a fidelity form for each intervention session, by listening to session audio-recordings and checking whether key elements of the intervention were covered and the counseling was consistent with MI style. The MPH-level supervisor provided weekly feedback on content and fidelity. One PhD-level clinical psychologist on the team provided training, booster training, and check-in calls as needed for problem solving. Another PhD-level clinical psychologist and the supervisor double-coded a random sample of ten participants' sessions for fidelity to session content (yes/no/partially/not applicable to session) and MI spirit [32] to ensure that the MPH-level supervisor was accurately coding the sessions [mean content rating Kappa=0.73; mean MI rating Kappa=0.70].

## Assessment

### Potential Covariates and Moderators

Table 1 shows the socio-demographic and health-related characteristics that participants reported using standard measures: age (continuous), Latinx ethnicity, sex at birth, gender identity (coded as cisgender male, cisgender female, and transgender, gender queer, or gender non-conforming), education level (coded as less than high school graduate vs. high school graduate), income (< \$10,000 vs. \$10,000 or greater), employment status (coded as full-time or part-time work vs. not working), housing status in last 12 months [coded as stable (e.g., own or rent) vs. unstable

**Table 1** Baseline characteristics of analytic sample by treatment arm [(% or M (SD))]

	N	Overall (n = 245)	Control (n = 123)	Intervention (n = 122)	p <sup>d</sup>
Socio-demographic and health-related covariates					
Male (at birth)	245	80.4%	81.3%	79.5%	0.75
Gender identity	245				0.88
Cisgender Male		75.9%	77.2%	74.6%	
Cisgender Female		19.6%	18.7%	20.5%	
Transgender or gender queer/non-conforming <sup>a</sup>		4.5%	4.1%	4.9%	
Latinx	245	9.0%	8.9%	9.0%	1.00
Sexual orientation	245				0.99
Straight or heterosexual		26.9%	26.8%	27.1%	
Gay or bisexual		71.4%	71.5%	71.3%	
Not sure, in transition, or something else		1.6%	1.6%	1.6%	
< HS graduate	245	13.1%	13.0%	13.1%	1.00
Employed (PT or FT)	244	15.6%	17.2%	13.9%	0.60
Annual income < \$10 K	241	44.0%	40.5%	47.5%	.30
Married/cohabitating	244	9.4%	12.2%	6.6%	0.19
Ever incarcerated, lifetime	245	50.6%	51.2%	50.0%	0.90
Stable housing <sup>b</sup>	244	52.5%	54.5%	50.4%	0.61
Depressed <sup>c</sup>	242	28.9%	32.5%	25.2%	0.25
Age	245	49.0 (12.1)	48.8 (12.0)	49.1 (12.4)	0.88
Years since HIV diagnosis	237	17.1 (9.6)	17.1 (9.5)	17.1 (9.8)	0.98
Outcomes at baseline					
Viral suppression					
Per venipuncture or medical records (weighted %)	211	81.9%	82.6%	81.1%	0.77
Per self-report	228	72.8%	71.7%	73.9%	0.77
75% adherence (electronically monitored) (weighted %)	230	60.6%	65.0%	56.1%	0.17

<sup>a</sup>1 transgender man, 8 transgender women, and 2 gender queer/nonconforming individuals; dichotomized as cisgender male vs. cisgender female or transgender male or female for analysis purposes only

<sup>b</sup>Stable housing is defined as not reporting having lived in any type of place in the past 12 months other than "own home/apartment."

<sup>c</sup>Depression was assessed with the PHQ-8 as a dichotomous score ( $\geq 10$ )

<sup>d</sup>p-values comparing control vs. intervention with t-test for continuous characteristics, Fisher's exact test for binary characteristics, chi-square test for characteristics with > 2 categories, and weighted logistic regression for adherence and viral suppression per venipuncture or medical record abstraction

(e.g., homeless)], marital/relationship status (coded as married/cohabitating with partner vs. not), sexual orientation (coded as heterosexual vs. gay, lesbian bisexual, something else, or “other”), any lifetime incarceration, and number of years since HIV diagnosis. Depression was assessed with the PHQ-8 and derived as a dichotomous score (of  $\geq 10$ ) [33].

### Psychosocial Outcomes

Psychosocial topics that were addressed in the intervention sessions were assessed: The Medical Mistrust Inventory was used for general medical mistrust ( $\alpha = 0.81$ ) [34] and the HIV Conspiracy Beliefs scale was used for HIV-specific medical mistrust ( $\alpha = 0.90$ ) [4, 35]. Internalized HIV stigma was assessed with the Internalized AIDS-Related Stigma Scale ( $\alpha = 0.88$ ) [36]; and two stigmatizing beliefs about HIV (that PLWH are responsible for their illness and that they deserve to be punished) were assessed, with responses dichotomized as either or both endorsed or neither endorsed [37, 38]. Three items assessed disclosure of HIV-serostatus to some, none, or all friends, family, or partners; items were combined into one dichotomous measure (“no” versus “any” disclosure).

### Adherence

Daily adherence was monitored electronically over the 13-month study period using MEMS caps that record bottle opening dates and times. Participants received the cap about 1-month prior to the first check-in, to capture pre-intervention adherence and allow for time to decrease reactance to the assessment. For participants on more than one antiretroviral medication, the medication with the more complex dosing schedule, or the base medication if all medications had the same schedule, was used [39]. At subsequent assessments, adherence data were downloaded and, to increase the validity of the adherence assessment, participants were asked to answer questions about how often the cap was not used as intended in the past two weeks (e.g., bottle opened without removing a dose or when multiple doses were removed at once); data at each time-point were adjusted using these responses [40]. The main outcome measure was dichotomous (“optimal”) adherence, operationalized as adherence to at least 75% of doses (versus less than 75%), at baseline (months 0 to 1), during the intervention period (months 1–7), and post-intervention (8–9, 9–10, 10–11, 11–12, or 12–13 months), based on research suggesting virologic suppression around this level of adherence [41].

### HIV Viral Load

At baseline, and 7 and 13-months post-baseline, study staff certified in phlebotomy conducted venipuncture to assess HIV viral load at the FQHC connected to the HIV services organization (pre-pandemic; see above). When the study phlebotomist or FQHC space was unavailable, participants were accompanied using a ride-sharing service to a local laboratory testing site. In addition, participants self-reported the date and result of their most recent HIV viral load test at baseline and follow-up assessments. When possible, medical record abstractions of viral load were obtained from 6 months prior to baseline to 12 months after the intervention period. During the COVID-19 pandemic, study venipuncture activities were disallowed at the clinic, necessitating reliance on self-report and medical records abstraction to document viral load for all study time-points after March 13, 2020.

### Statistical Analysis

After calculating descriptive statistics for all variables, we assessed comparability between groups on socio-demographic and health-related characteristics by testing differences between participants in the intervention group and control group, using Fisher’s exact tests for binary characteristics, chi-square tests for categorical characteristics with more than two levels, and t-tests for continuous characteristics (Table 1).

The primary intention-to-treat approach to assess intervention efficacy was a repeated-measures regression model analyzing all follow-up observations with adjusted standard errors for within-participant clustering of repeated measures and nonresponse weighting for missing data, including as predictors the study arm, the baseline value of the outcome, and, if applicable, covariates. Survey outcome observations may have come from either the 7- or 13-month follow-up survey and viral suppression observations may have been measured near either the 7- or 13-month follow-up survey (and each participant could contribute up to two follow-up responses); electronically monitored adherence observations may have been measured at any month post-intervention (and each participant could contribute up to 6 monthly follow-up measurements between months 7 and 13).

For continuous outcomes, Cohen’s *d* effect sizes were estimated by dividing adjusted regression coefficients by the pooled standard deviation of the outcome at baseline; for dichotomous outcomes, Cohen’s *d* effect sizes were estimated by dividing adjusted log-odds by 1.81 [42]. For all regressions, we used as covariates baseline socio-demographic and health-related variables that were associated with the outcome at follow-up, controlling for the baseline



value of the outcome, at  $p < 0.05$ . No covariates were significantly associated with the adherence or viral suppression outcomes.

To account for any potential differences between participants with complete data versus those lost to follow-up as well as to reduce bias, we used nonresponse weights to account for missingness in outcomes at follow-up, following recommended procedures for missing clinical trial data [43]. For survey-based outcomes, individuals were weighted by the inverse of an estimate of the probability of completing either follow-up survey; the probability was estimated from logistic regression using socio-demographic and health-related covariates that were not missing for any participant. For viral load outcomes, for which there was substantial missingness at baseline and follow-up, a nonresponse weight was first calculated for presence of viral load data at baseline using similar methods and the same predictors as described for survey-based outcomes. Another weight was created for presence of viral load data at either follow-up, and the final weight used in analysis of intervention efficacy was calculated as the product of the baseline and follow-up weights. To derive nonresponse weights for electronically monitored adherence, one weight was created for presence of data at the first month post-baseline and another for presence of data at any post-intervention month; weights were then standardized to have a mean of one within month and multiplied by the baseline weight for final analysis weights.

Two sets of follow-up analyses were conducted. A series of regressions were conducted to determine whether any of the socio-demographic and health-related characteristics moderated any intervention effects on the main outcomes (adherence and viral suppression), by assessing the interaction of each socio-demographic and health-related variable with the intervention indicator separately (or, one at a time). In addition, a sensitivity analysis was conducted to assess whether the intervention effect was moderated by intervention delivery mode (in person before the COVID-19 pandemic versus telephone during the COVID-19 pandemic).

### Cost Data Collection and Cost Effectiveness Analysis

We conducted a cost effectiveness analysis based on program costs for the 6-month intervention and effectiveness from baseline to 6 months post-intervention. Costs were related to materials (e.g., MEMS caps, bottles, and software; tablets), administrative costs (e.g., time taken to complete forms), and intervention costs (primarily time taken to deliver intervention sessions). Intervention costs were obtained monthly from the counselor implementing the intervention (and conducting the 60-min sessions described above) and the counselor's direct supervisor, who regularly listened to a subset

of audio-recorded sessions and met with the counselor to discuss the sessions. These activities were costed using an hourly salary rate for each staff member. We also included participant remuneration and the costs for the two-day MI training for the counselor and supervisor, as well as costs to supervise the supervisor for a limited period.

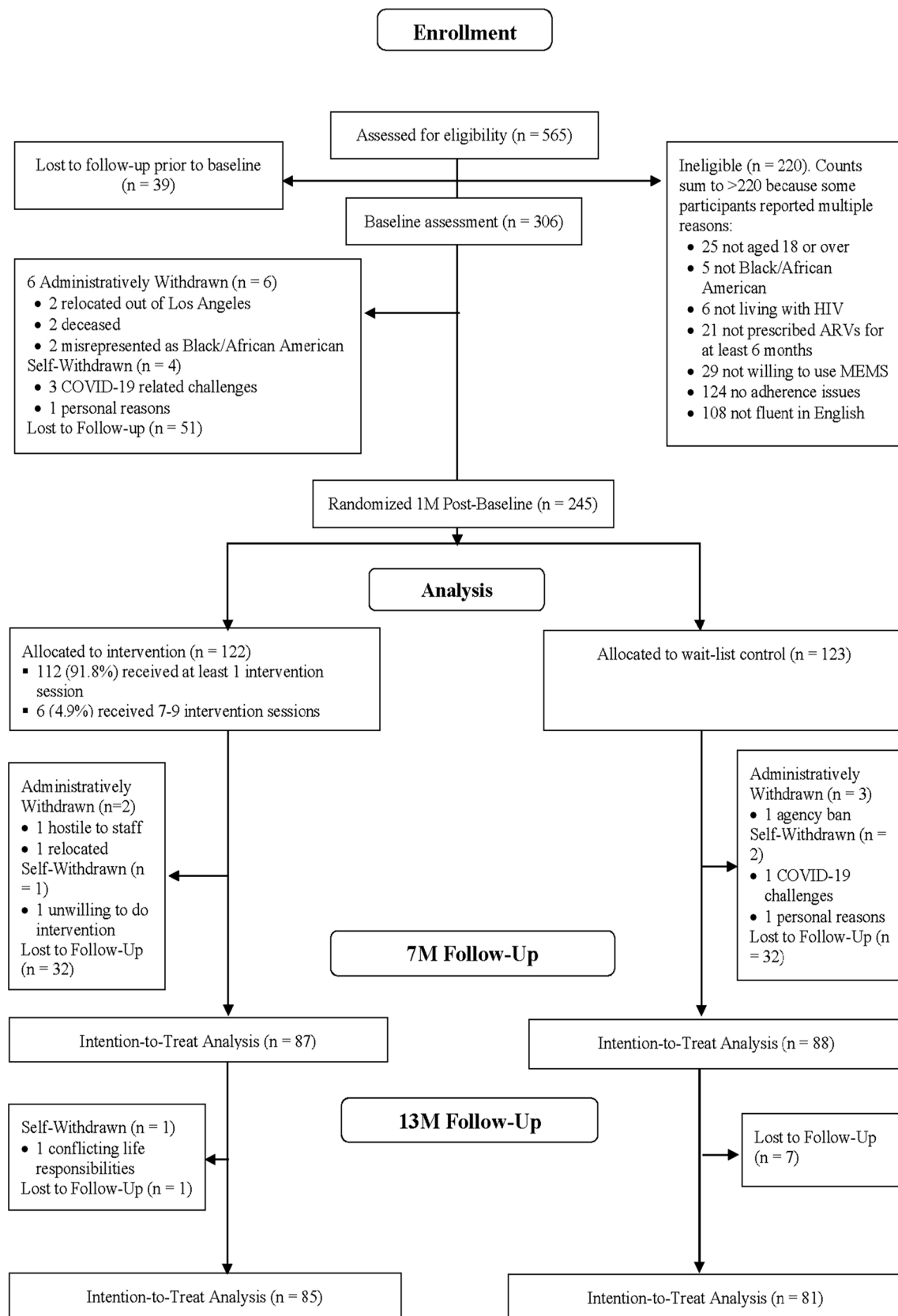
The cost-effectiveness ratio was calculated as the cost per participant divided by the relative effect size in the intervention arm compared to the control. Consistent with prior research, we used the effect size as the group mean at follow-up, obtained using the recycled predictions method, to calculate the cost per person of a 10% increase in adherence from baseline to 6 months post-intervention [44]—as a change in mean adherence by 10% can have a significant effect on HIV viral load [45]. The standard errors are derived by calculating means of predicted values, adjusting for clustering. All costs in USD are reported in 2022 prices.

## Results

### Participant Flow

As shown in Fig. 1, of the 565 individuals screened, 345 were eligible and 220 were not eligible. Of the 345 eligible participants, 306 attended the first study visit in which they completed the baseline survey and received a MEMS cap for electronic adherence monitoring; 61 did not attend the one-month visit and thus were not randomized (51 were lost to follow-up and could not be re-contacted despite multiple attempts, 4 self-withdrew, and 6 were withdrawn by the study team). Thus, 245 were randomized (122 intervention, 123 control). Post-randomization, 2 intervention participants and 1 control participant were administratively withdrawn, 2 intervention participants and 2 control participants self-withdrew, and 33 intervention participants and 39 control participants were lost to follow-up. The final sample sizes for the intention-to-treat analyses were 175 at 7-month follow-up (71%; 87 intervention, 88 control) and 166 (68%; 85 intervention, 81 control) at 13-month follow-up.

Note that the team had originally proposed to recruit 350 participants at baseline, and anticipated an 80% retention rate, for a final analysis sample size of 280 (140/arm). Under these assumptions, using power analysis calculations for generalized linear mixed models with correlated binary outcomes [46], we would have had 80% power to detect a minimum detectable difference of 6.9% ( $d = 0.14$ ) between the intervention and control arms on adherence. The final analysis sample size of 166 was substantially lower than intended but adequate to observe a significant difference between arms.



**Fig. 1** CONSORT diagram of participant flow through the Rise study

## Baseline Participant Characteristics

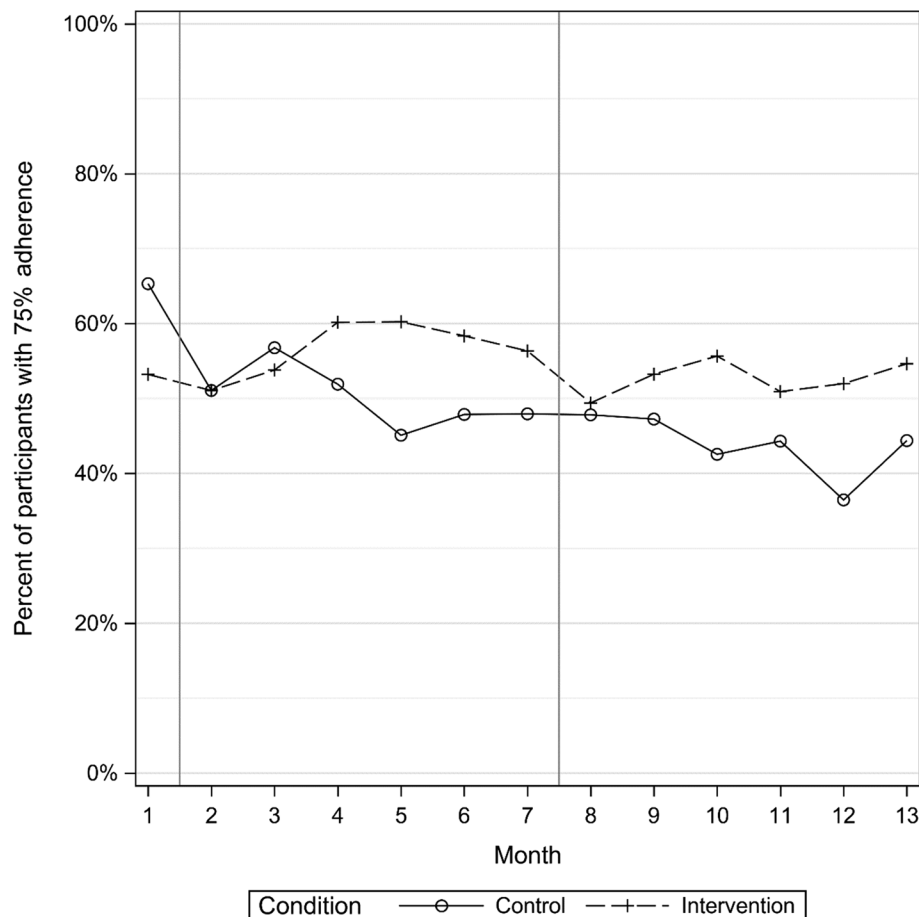
As shown in Table 1, at baseline, participants averaged about 49.1 years-old ( $SD = 12.4$ ) and had been living with HIV for an average of 17 years. Most identified as male (76%) and gay or bisexual (71%); a fifth identified as cis-gender female. Although 87% had at least a high school diploma, only 16% were currently employed (full or part time), and 44% had an annual income below \$10,000. Half currently were in an unstable housing situation (e.g., no permanent residence, living on the street), and half had ever been incarcerated. Twenty-nine percent screened positive for depression. In addition, over 80% were virally suppressed (based on venipuncture by study staff or medical record abstraction) and 61% had taken at least 75% of doses prescribed. Participant characteristics did not significantly differ by study arm at baseline. There were no significant differences in baseline characteristics by mode of intervention sessions [in person (pre-COVID-19) or by telephone (during COVID-19); data not shown and available upon request], suggesting low potential sampling bias during the pandemic.

## Effect of Rise on Electronically Monitored Adherence and Viral Suppression

As shown in Fig. 2, a greater number of participants in the intervention than the control condition showed optimal (at least 75%) adherence at nearly every time-point except baseline. The repeated-measures logistic regression indicated a significant intervention effect on dichotomous adherence,  $OR (95\% CI) = 2.0 (1.1-3.6)$ ,  $p = 0.03$ , Cohen's  $d = 0.4$ .

Moderation analyses indicated that a significant age by intervention condition interaction for adherence; no other socio-demographic characteristics were significant moderators of the intervention effect. Specifically, the effects of Rise on adherence were stronger for younger participants, log odds ( $se$ ) =  $-0.06 (0.03)$ ,  $p = 0.03$ . For participants whose age was 1 SD below the mean, the intervention effect was stronger [ $OR (95\% CI) = 5.4 (1.7-17.0)$ ,  $p = 0.004$ ] than those of mean age [ $OR (95\% CI) = 1.7 (0.9-3.1)$ ,  $p = 0.08$ ] and those whose age was 1 SD above the mean [ $OR (95\% CI) = 1.5 (0.8-2.8)$ ,  $p = 0.18$ ]. The Cohen's  $d$  effect size was 0.3 for a 10-year difference in age, indicating that for every 10-year decrease in age, there was a small-to-medium

**Fig. 2** Percentages of participants with optimal adherence (75% of doses taken, per electronic monitoring) throughout the 13-month study period by treatment condition. The vertical line between 1 and 2 months represents the end of the baseline period, and the vertical line between 7 and 8 months represents the end of the intervention period. Percentages are weighted for presence of adherence data and restricted to the  $N = 164$  included in the model estimating the effect of Rise on adherence





increase in the intervention effect. Note that the age moderation effect is likely not a proxy for years living with HIV, as the age moderation effect persisted even when controlling for years since diagnosis, and years since diagnosis was not a significant moderator of the adherence effect (data not shown)].

The sensitivity analysis indicated that intervention sessions conducted by telephone (during the pandemic) significantly improved adherence, OR (95% CI) = 3.0 (1.2–7.6),  $p=0.02$ , and intervention sessions conducted in person (pre-pandemic) marginally improved adherence, OR (95% CI) = 1.7 (0.9–3.2),  $p=0.098$ , in comparison to the control condition.

Intervention participants showed raw score, but non-significant, improvements in viral suppression from baseline to 13-month follow-up (weighted percentages = 78.7% to 91.2%, respectively) compared to control participants (weighted percentages = 84.4% to 89.1%, respectively). Specifically, the repeated-measures regression predicting viral suppression (using venipuncture and medical records data) did not reveal a significant intervention effect, OR (CI) = 1.8 (0.6–5.2),  $p=0.26$ ,  $d=0.3$ .

### Effect of Rise on Psychosocial Outcomes

As shown in Table 2, the repeated-measures regressions indicated that Rise led to reduced HIV-specific medical mistrust  $b$  (se) =  $-0.2$  (0.1),  $p=0.02$ ,  $d=0.2$ , but not to significantly reduced general medical mistrust,  $b$  (se) =  $0.1$  (0.1),  $p=0.44$ ,  $d=0.1$ . In addition, Rise reduced the likelihood of endorsement of stigmatizing beliefs about HIV, OR (95% CI) =  $0.6$  (0.3–1.0),  $p=0.05$ ,  $d=0.3$ , although this effect

became marginal when controlling for gender (which was significantly associated with stigmatizing beliefs), OR (95% CI) =  $0.6$  (0.3–1.0),  $p=0.07$ ,  $d=0.3$ . Intervention effects on internalized HIV stigma,  $b$  (se) =  $0.0$  (0.1),  $p=0.73$ ,  $d=0.03$ , and HIV-serostatus disclosure, OR (95% CI) =  $0.6$  (0.1–2.7),  $p=0.51$ ,  $d=0.3$ , were non-significant.

### Cost Analysis

We calculated a cost of \$335 per person in the intervention arm both prior to and during the pandemic. Although electronic monitoring with MEMS was not used during the pandemic for intervention sessions, costs for MEMS (the largest component of costs) were included in the analysis during the pandemic, because participants may have assumed that their adherence was being monitored as part of the intervention (as many continued to store their medications in bottles with the MEMS caps provided for the study assessment). Note that, if MEMS costs were not taken into account, the cost of conducting the intervention telephone sessions during the pandemic would reduce to \$227.

For the intervention sessions conducted prior to the pandemic, the cost effectiveness analysis indicated an intervention cost of \$465 per 10% increase in adherence, with a range of \$317–875, based on the 95% confidence interval of the intervention effects. By comparison, during the pandemic, when sessions were conducted via telephone, the cost effectiveness analysis indicated a cost of \$141 per 10% increase in adherence, with a range of \$124–165, entirely driven by the larger effects of telephone sessions on adherence. Note that if MEMS costs during the pandemic were

**Table 2** Effect of Rise on psychosocial outcomes

Psychosocial construct	Baseline M (SD) or %		7-Month follow-up M (SD) or %		13-Month follow-up M (SD) or %		b (SE) or OR (95% Confidence Interval)	Cohen's d	p-value
	Intervention	Control	Intervention	Control	Intervention	Control			
Medical mistrust									
General medical mistrust	2.58 (0.66)	2.56 (0.64)	2.65 (0.68)	2.56 (0.65)	2.68 (0.76)	2.64 (0.60)	0.05 (0.07)	0.09	0.44
HIV-specific medical mistrust	2.74 (1.05)	2.56 (1.03)	2.62 (1.16)	2.65 (1.03)	2.41 (1.05)	2.59 (1.19)	−0.21 (0.09)	0.22	0.02
HIV stigma									
Stigmatizing beliefs <sup>a</sup>	28.2%	25.1%	29.3%	32.5%	17.4%	32.8%	0.57 (0.32–1.00)	0.31	0.05
Internalized stigma	2.65 (1.44)	2.99 (1.37)	2.47 (1.39)	2.61 (1.31)	2.22 (1.32)	2.55 (1.37)	0.04 (0.10)	0.03	0.73
HIV serostatus disclosure	96.0%	95.7%	96.5%	96.7%	96.6%	98.9%	0.60 (0.13–2.74)	0.28	0.51

<sup>a</sup>When participant gender was adjusted (which was significantly associated with stigmatizing beliefs about HIV), OR (CI) =  $0.59$  (0.34–1.04),  $p=0.07$ , Cohen's  $d=0.29$

not considered, the cost per 10% increase for the intervention reduced to \$96.

## Discussion

Our RCT of Rise showed strong long-term effects on ART adherence among Black Americans living with HIV up to 6-months post-intervention. Adherence was assessed with daily electronic monitoring, a more valid, rigorous measure of adherence than self-report, which was used by over half of trials in the CDC's EBI Compendium for HIV medication adherence [9]. Intervention effects were durable, with small-to-medium effect sizes, across a diverse sample comprised of multiple gender and sexual identity subgroups, as well as for those with stable and unstable housing, and at all levels of socio-economic status.

Intervention effects were greater among younger participants and those who received the intervention through telephone sessions during the COVID-19 pandemic. Younger participants may have been more likely to identify with the intervention counselor, a peer who was closer in age. In addition, Rise may have helped to buffer negative pandemic-related impacts (e.g., loss of housing), because Rise helped to address unmet needs related to adherence (e.g., warm handoff to housing services). Accordingly, a prior analysis of a subset of Rise participants found that participants who experienced more COVID-19 related social, economic, and negative health care impacts early in the pandemic showed lower ART adherence [47]. However, the pandemic time-period was confounded with telephone intervention delivery in our study. It is possible that telephone intervention sessions were preferable to the study population, regardless of pandemic conditions, due to transportation challenges—or that the pandemic increased the acceptability of telephone sessions because of concerns about in-person meetings and more social isolation, especially in 2020. Further studies are needed with randomization by intervention delivery mode (telephone vs. in-person), in post-pandemic times, in order to attribute the difference in adherence to intervention delivery mode.

Effects on viral suppression were non-significant, and both the intervention and control conditions increased in viral suppression rates. Because the intervention focused on problem solving around adherence issues, participants were eligible if they had missed any doses in the past month, even if they were virally suppressed. New ART regimens are robust despite non-adherence [41], and some participants who missed more than 20% of their doses in the present study were virally suppressed. Including people who had suppressed viral load likely reduced the statistical power to reveal a viral suppression effect. Moreover, during the pandemic, we could no longer directly assess viral load via

venipuncture and complete medical records data could not be obtained due to clinic understaffing; thus, we could not obtain precise measures of viral load that paralleled the study adherence assessments for every participant.

A primary purpose of Rise is to bolster adaptive and decrease ineffective responses to HIV inequities, including reducing medical mistrust and HIV stigma—and effects were revealed on these psychosocial outcomes in our RCT. Rise led to reduced medical mistrust, in the form of HIV conspiracy beliefs, but not general medical mistrust—likely because the intervention content focused primarily on addressing HIV-relevant medical mistrust. For example, the intervention included strategies for using an MI style to elicit discussions on participants' beliefs about ulterior motives of pharmaceutical companies and unethical medical experimentation for HIV treatment, by acknowledging historical and ongoing discrimination as a reason for mistrust and eliciting participants' beliefs prior to offering accurate information about ART. With the exception of a cognitive behavior therapy ART adherence intervention for Latino sexual minority men [48], almost no interventions have reduced medical mistrust [14]. In addition to use of MI style, factors such as the positioning of Rise in a community, non-healthcare setting, program delivery by a peer counselor from the study population, and development of the intervention in the context of a community-academic partnership, likely contributed to the reduction in medical mistrust found in this RCT. Further research with larger sample sizes is needed to fully explore mechanisms of the adherence effects observed for Rise overall and by subgroups, especially regarding responses to inequities such as coping with intersectional stigma and discrimination among women and sexual and gender minority individuals.

While some studies use outcomes such as preference-weighted quality-of-life measures or a quality-adjusted life year (QALY) to estimate cost-effectiveness [49], other studies, such as the present study, have calculated the cost-effectiveness using a cost per 10% adherence gain or cost per viral load gain [50]. These studies suggest that interventions costing less than \$1000 per patient per year for a 10% increase in adherence are cost-effective [51]. Rise was \$465 per person to implement prior to the pandemic and \$141 per person to implement during the pandemic (and even less without electronic adherence monitoring costs). Thus, we conclude that Rise was cost-effective even using the lower bounds of effectiveness, before or during the pandemic. Even though intervention sessions cost less during the pandemic (owing to no electronic adherence monitoring and sessions being conducted by telephone), we do not show reduced costs in this scenario as the costs for electronic monitoring were already paid for at the beginning of the intervention and thus conservatively accounted for in

the cost analysis. The increased cost-effectiveness is driven entirely by the larger intervention effects observed during the pandemic.

This RCT had several limitations. The COVID-19 pandemic led to revised data collection and intervention procedures and a substantial loss to follow-up and missing data, in addition to severely impacting many PLWH [47]. Thus, our intervention effects must be considered in the context of the pandemic; implementation of Rise in a different historical period could yield different effects. Although we attempted to evaluate the impact of COVID-19, the true effect of the pandemic on the outcomes is unknown. In addition, the advent of potent ART regimens meant that, although participants were selected based on an eligibility criterion of non-adherence, most were virally suppressed at baseline; thus, we had limited statistical power to assess the intervention effects on the likelihood of viral suppression among those who were not suppressed. Furthermore, although women comprised a fifth of the sample, the majority of participants were Black sexual minority men; further research is needed to test the effects of Rise with larger subgroups of people of different gender and sexual identities. Research also is needed to evaluate implementation of Rise in settings with fewer resources, with lower access to services to address unmet needs; in the present study, Rise was tested in a large community-based organization connected to a FQHC that had multiple auxiliary support programs (e.g., housing linkage, food assistance).

## Conclusions

In this RCT, Rise proved to be an effective culturally congruent community-based intervention to address adherence issues. It will be important for future research to adapt Rise for new ART technologies, such as long-acting injectable ART. Dissemination and implementation research is needed to test low-cost, effective models for training community-based peer counselors to deliver Rise, as well as for implementing Rise via telephone and without electronic adherence monitoring. These future efforts would enable Rise to better reach under-served and under-resourced communities and, ultimately, to reduce health inequities.

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**Data Availability** All authors ensure that the data support the published claims and comply with field standards.

## Declarations

**Conflict of interest** The authors have no relevant financial or non-financial interests to disclose; the authors have no conflicts of interest to declare that are relevant to the content of this article; all authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript; and the authors have no financial or proprietary interests in any material discussed in this article.

**Ethical Approval** This study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments. All study procedures were approved by the RAND Human Subjects Protection Committee (HSPC 2016-0940).

**Consent to Participate** Informed consent was obtained from all individual study participants.

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