



A Randomized Controlled Trial of *Rise*, a Culturally Congruent Adherence Intervention for HIV-Positive African Americans

Laura M. Bogart^{1,2}, Matt G. Mutchler³, Bryce McDavitt³, David J. Klein^{1,2},
William E. Cunningham⁴, Kathy Goggin⁵, Sean Lawrence³, Nikki Rachal³,
Kelsey Nogg³, & Glenn J. Wagner¹

¹RAND Corporation; ²Boston Children's Hospital/Harvard Medical School; ³AIDS Project Los Angeles & California State University-Dominguez Hills; ⁴UCLA; ⁵Children's Mercy Hospitals & University of Missouri – Kansas City





Background



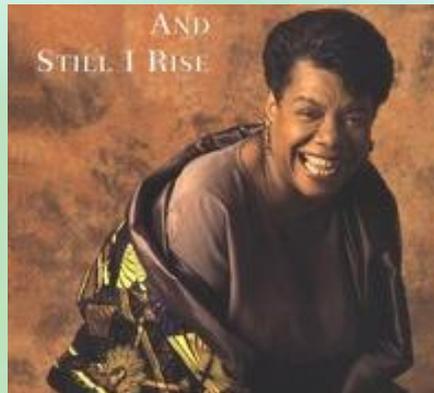
- Relatively few HIV adherence interventions have shown effects on adherence or viral suppression
 - 12 evidence-based interventions, of 67 reviewed (CDC, 2015)
 - 5 had an effect on viral load and 6 on adherence
 - Medium effect sizes
- Few adherence interventions have been culturally tailored specifically for Blacks/African Americans, yet many have large percentages of Black participants
 - Not customized to fit patients' values, beliefs, traditions, etc.



Purpose of the Present Study



- To partner with community stakeholders to develop and conduct a randomized controlled trial (RCT) of a culturally congruent HIV treatment adherence intervention for Black men and women living with HIV
 - Intervention named *Rise* after Maya Angelou poem, *And Still I Rise*





Rise Components



- Client-centered counseling
 - Motivational interviewing style
 - Nonconfrontational, empathetic
 - Increases motivation and self-efficacy for adherence
 - Builds adherence knowledge and skills
 - Addresses adherence barriers, using electronic monitoring adherence data printout
- Assistance with linkage to social services
 - Referrals to services (mental health, substance use treatment, food assistance, transportation)
 - Follow-up on referrals and barriers to receiving services



Rise Structure

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- Core Intervention Sessions over 4 weeks
 - 3 individual one-on-one counseling sessions at weeks 1, 2, and 4
 - 1 group educational session
- Booster Sessions over the next 20 weeks
 - Sessions at weeks 12 and 20
 - Up to 4 additional sessions (weeks 14, 16, 22, & 24) depending on adherence level, as assessed by electronic monitoring



How is *Rise* Culturally Congruent?



- Counselors acknowledge past and current racism that has led to HIV and barriers to adherence
 - Psychosocial barriers, e.g., mistrust, stigma, discrimination, substance use, stress
 - Structural barriers, e.g., poverty
- Placement in a trusted community organization
Some clients may mistrust clinics
- Trained lay peer counselors knowledgeable about (and from) clients' local community
 - Not viewed as part of medical system



Methods: RCT Participants



- 216 participants (108 intervention, 108 control)
 - Analysis sample = 171 (86 intervention, 85 control)
- Eligibility
 - 18 years or older
 - Black/African American
 - On ART
 - Self-reported adherence problems (e.g., missed at least one dose in past month) and/or detectable viral load
 - Willing to use electronic adherence monitoring
 - Not in another adherence intervention



Methods: RCT Measures

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- Electronically monitored adherence using Medication Event Monitoring System (MEMS)
 - Data downloaded from bottle cap at 1.5, 3, 4.5, and 6 months post-baseline
 - Past 2-week adherence calculated at each time-point
 - Adjustment for use of cap (e.g., pocketed doses)





Methods: RCT Measures



- Computer-assisted surveys at baseline, and 3- and 6-months assessed self-reported adherence (percentage of doses taken in last month) and psychosocial variables (e.g., stigma, mistrust)
- Medical records collection of viral load data



Methods: Statistical Analysis



- Repeated measures logistic regression modeling dichotomous adherence ($\geq 85\%$ of doses taken) with intervention, linear time, their interaction, and demographic covariates
 - Post-estimation contrasts examined adherence within intervention and control groups separately
- Post-hoc logistic regressions predicted adherence separately at each follow-up time-point with intervention, baseline self-reported adherence and socio-demographic covariates



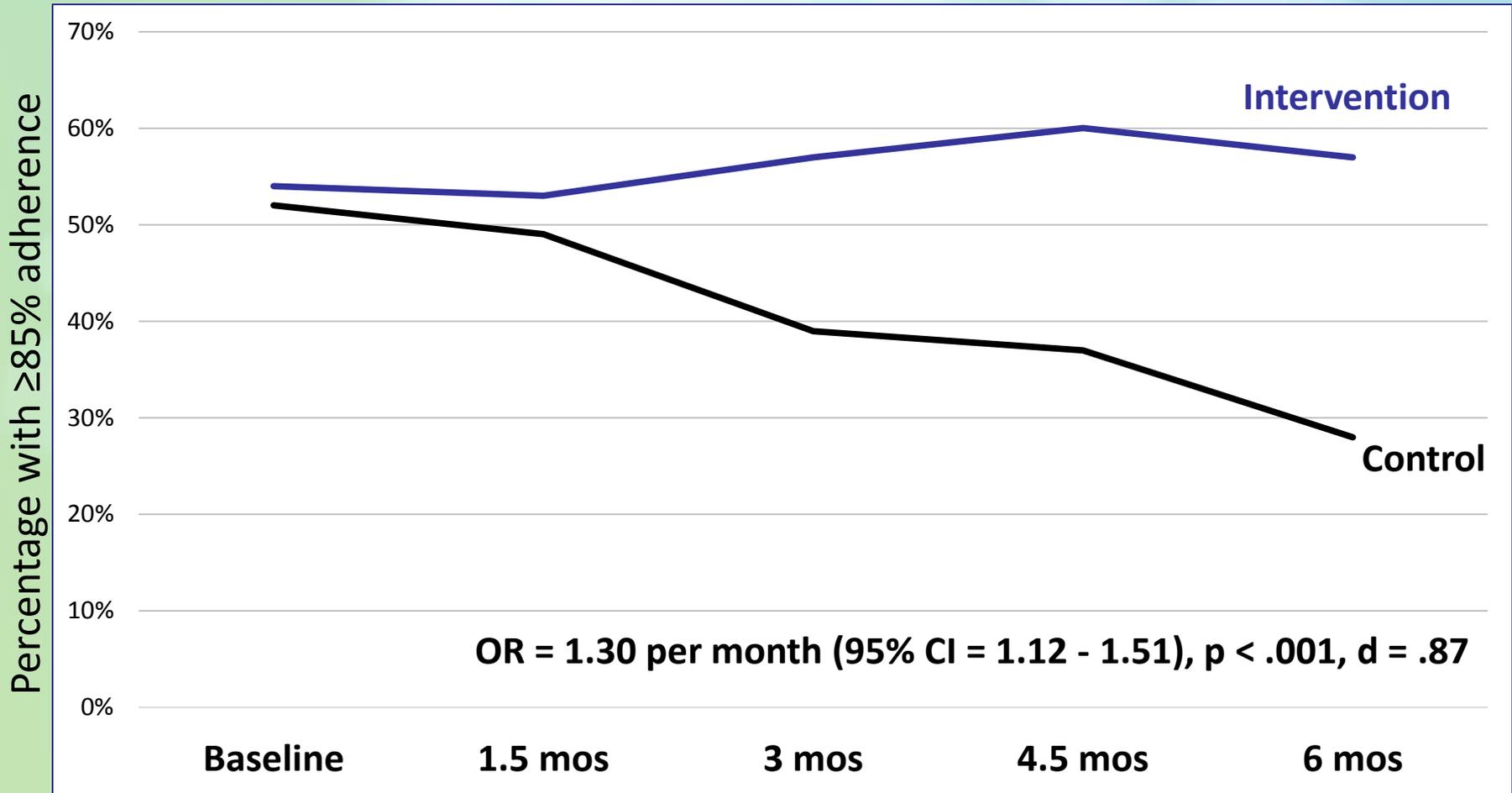
Methods: Participant Characteristics

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- Age M (SD) = 48.6 (10.2) years
- 73% male
- 19% <high school degree
- 65% <\$10,000 annual income
- 94% not working
- 30% not stably housed
- 55% ever incarcerated
- Diagnosed with HIV M (SD) = 15.5 (8.3) years
- Baseline self-reported adherence
 - M (SD) = 79% (22%); 53.1% adherent to $\geq 85\%$ of doses



Percent of Participants Reaching At Least 85% Adherence



Note: Graph shows self-reported adherence at baseline and electronically monitored adherence at all follow-ups

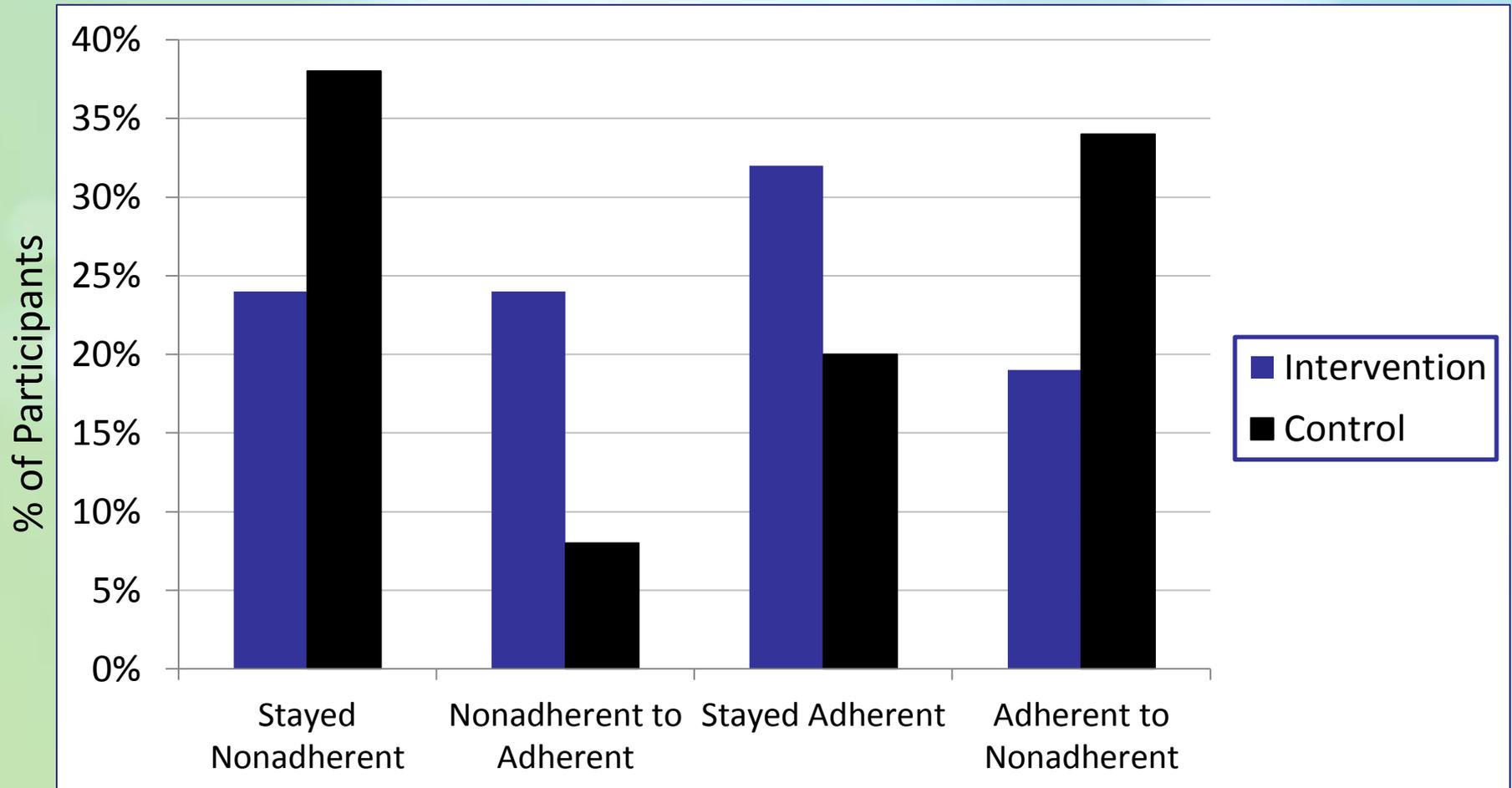


Results: Post-hoc Analyses

- Post-estimation contrasts showed:
 - Adherence in control group significantly decreased per month (OR = 0.80, $p = .005$)
 - Adherence in intervention group remained stable per month (OR = 1.04, $p = 0.60$)
- Separate regressions by time-point showed better adherence in intervention vs. control:
 - 3-months post-baseline (OR = 2.32, $p = .02$)
 - 4.5 months post-baseline (OR = 2.60, $p = .008$)
 - 6-months post-baseline (OR = 4.03, $p = .0004$)



Non-Adherence Patterns from Baseline to 6-Month Follow-Up





Discussion

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- *Rise* resulted in superior adherence in the intervention relative to the control group
- *Rise* showed a large effect ($d = .87$)
 - Mainly due to decreased adherence in control group
- Limitations include lack of viral load assessment and long-term follow-up



Next Steps



- *Rise* RCT with viral load assessment and longer follow-up period
- Examination of factors to guide future implementation and dissemination
 - Cost
 - Barriers to implementation from the client, provider, and organizational perspectives
 - Different implementation models



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Conflict of Interest Disclosure

- None of the authors have any real or apparent conflicts of interest to report