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

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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
• 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.
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

- 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
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
• 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)
• 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
Repeated measures logistic regression modeling dichotomous adherence (≥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

- 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 ≥85% of doses
Percent of Participants Reaching At Least 85% Adherence

OR = 1.30 per month (95% CI = 1.12 - 1.51), p < .001, d = .87

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

% of Participants

- Stayed Nonadherent
- Nonadherent to Adherent
- Stayed Adherent
- Adherent to Nonadherent

Intervention
Control

#ADHERENCE2016
Discussion

- *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.

Amico et al 2006; Langebeek & Nieuwkerk, 2015
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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