

+ **A PILOT RANDOMIZED CONTROL TRIAL OF  
STRIVING TOWARDS EMPOWERMENT AND  
MEDICATION ADHERENCE (STEP-AD) AMONG  
BLACK WOMEN LIVING WITH HIV IN THE U.S.**



**Sannisha K. Dale, PhD, EdM**

**Pronouns: she/her/hers**

**Associate Professor in Psychology & Public Health**

**Director and Founder, SHINE Research Program**

*Co-Authors: Ian A. Wright, Aarti Madhu, Rachelle Reid, Naysha Shahid, Mya Wright, Jasmyn Sanders, Arnetta Phillips, Allan Rodriguez, and Steven A. Safren*



# Disclosures

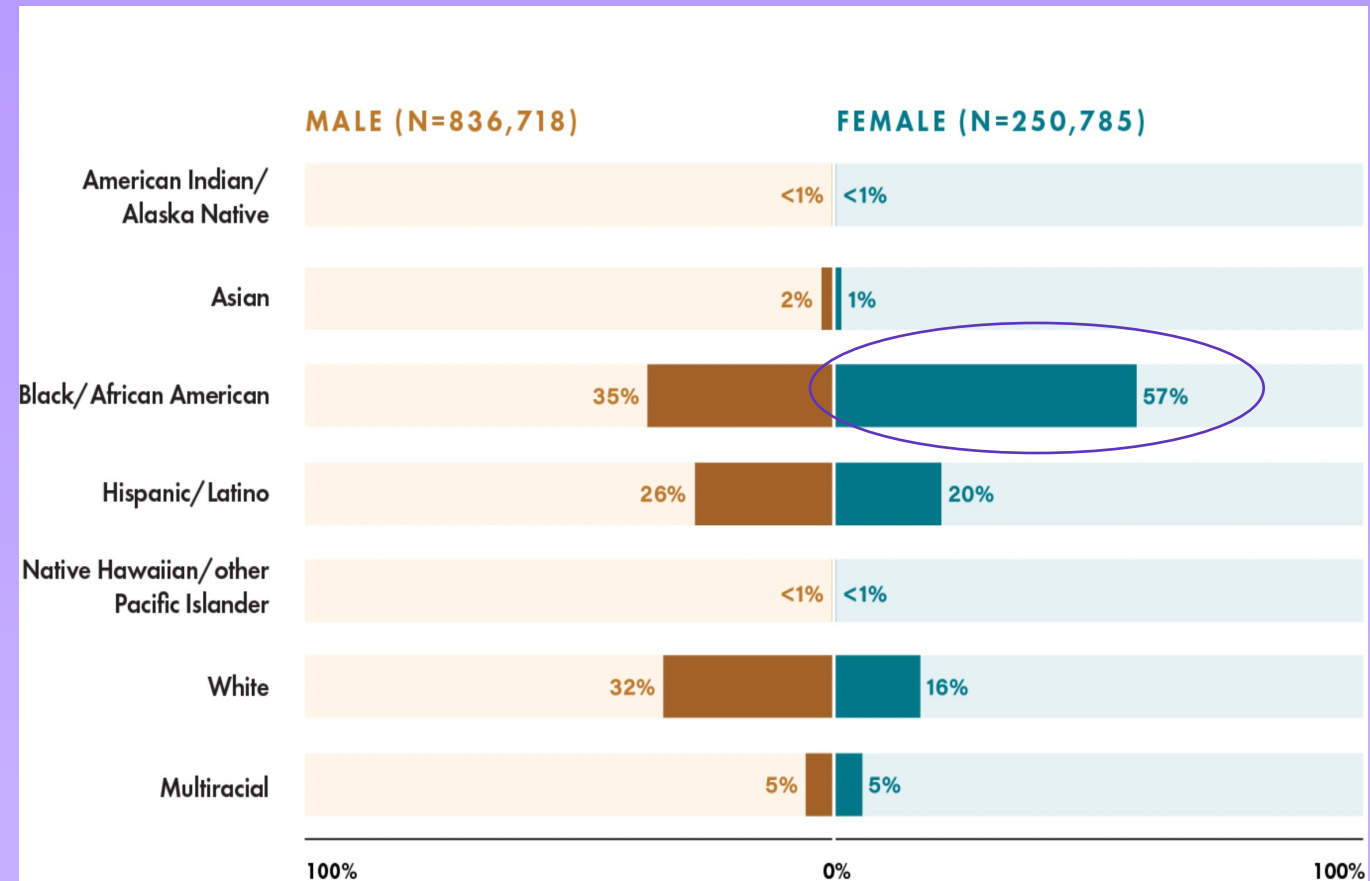
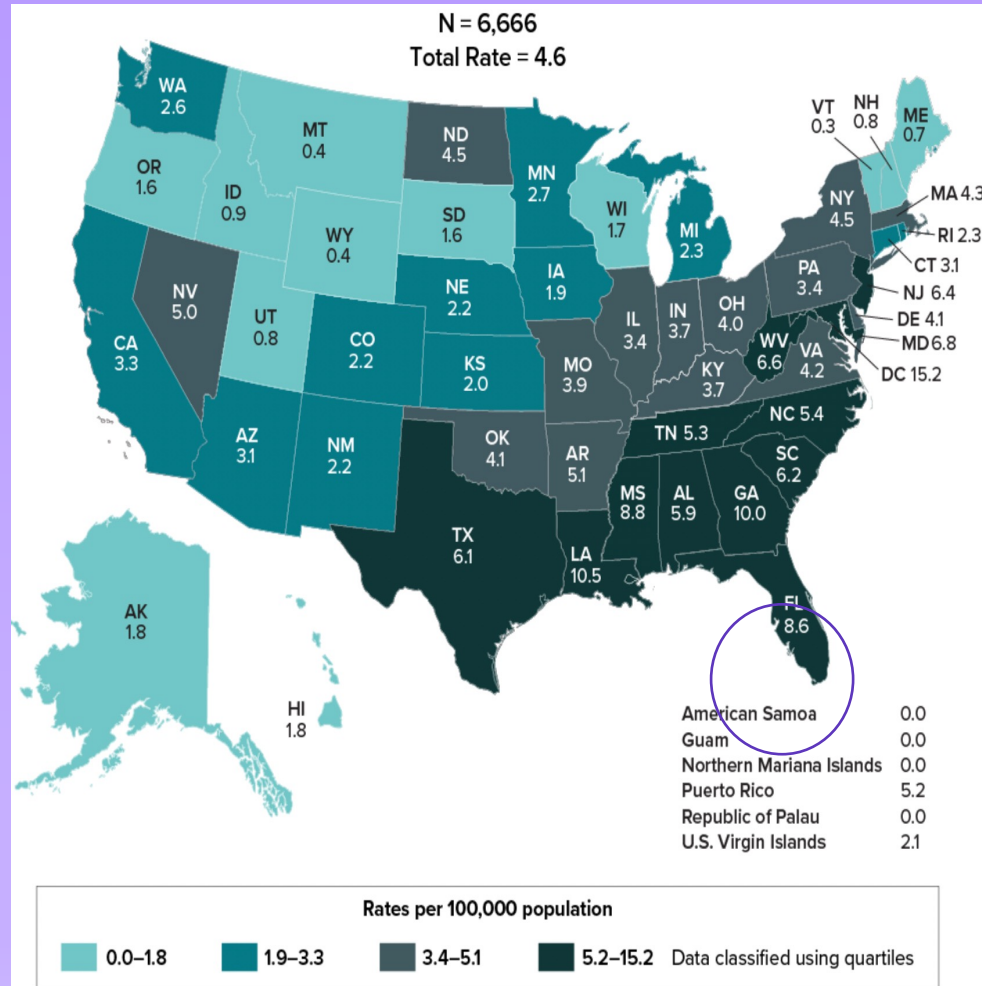
Co-investigator/ Miami Site PI on a Merck & Co. funded project (PI Ojukutu) on " A Qualitative Study to Explore Biomedical HIV Prevention Preferences, Challenges and Facilitators among Diverse At-Risk Women Living in the United States"

Workgroup consultant on engaging people living with HIV for Gilead Sciences, Inc.

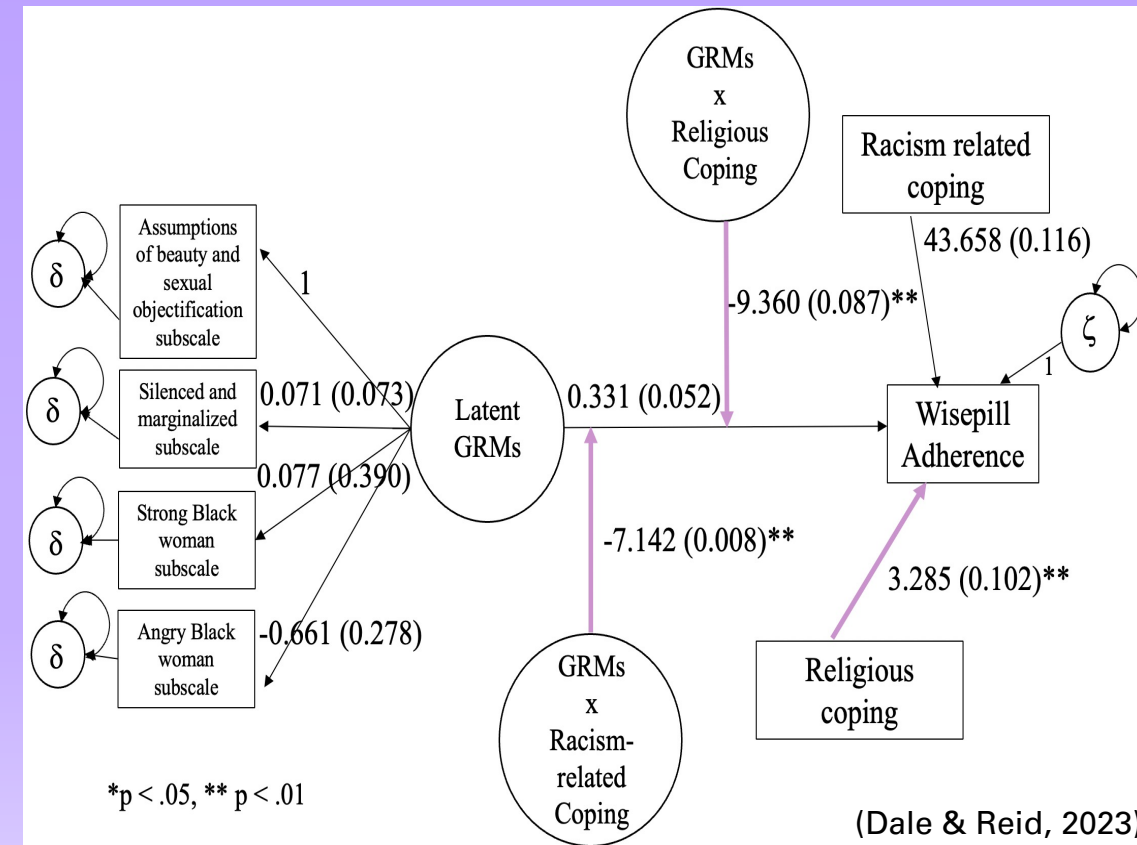
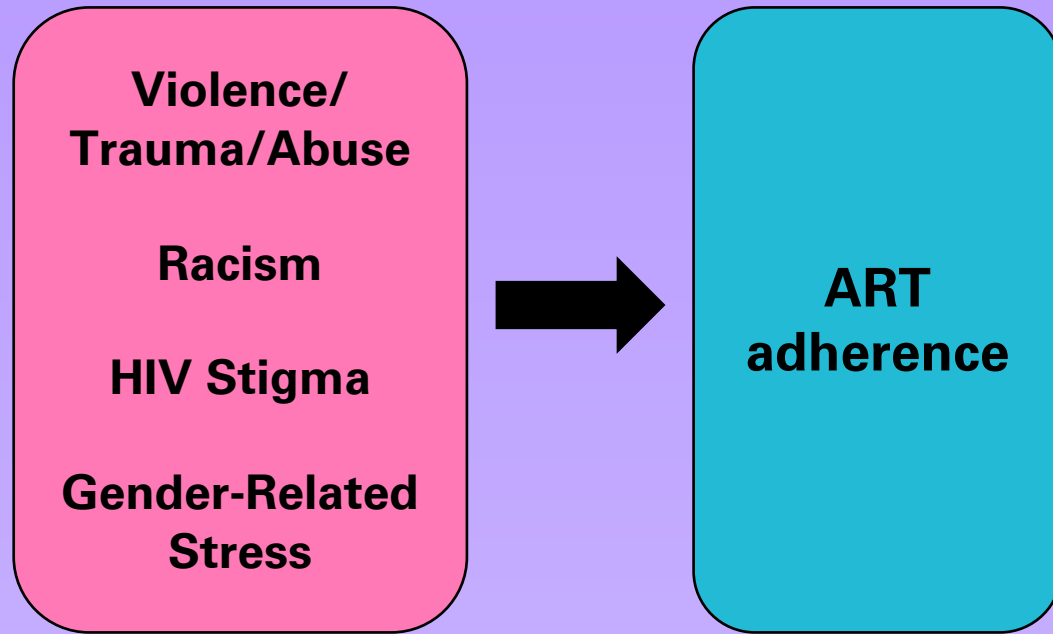
# Context and Isms



# Impact of HIV among Black women



# Intersectional Adversities linked to ART Adherence



# STEP-AD Intervention

10-session individual intervention for BWLWH that combines:

- evidence-based strategies for trauma symptom reduction
- strategies for coping with racial discrimination, HIV-related discrimination and stigma, and gender role stressors faced by women
- exercises to plan and practice self-care consistently
- problem solving techniques for medication adherence (e.g., 1 Life-steps session and ongoing problem solving)



## Foundation:

**Qualitative Work:** Interviews with 30 Black women living with HIV (BWLWH) and 15 community stakeholders were used to inform the development of STEP-AD

**Open Pilot Trial:** Conducted among 5 BWLWH and suggested an increase in adherence and decrease in trauma symptoms.



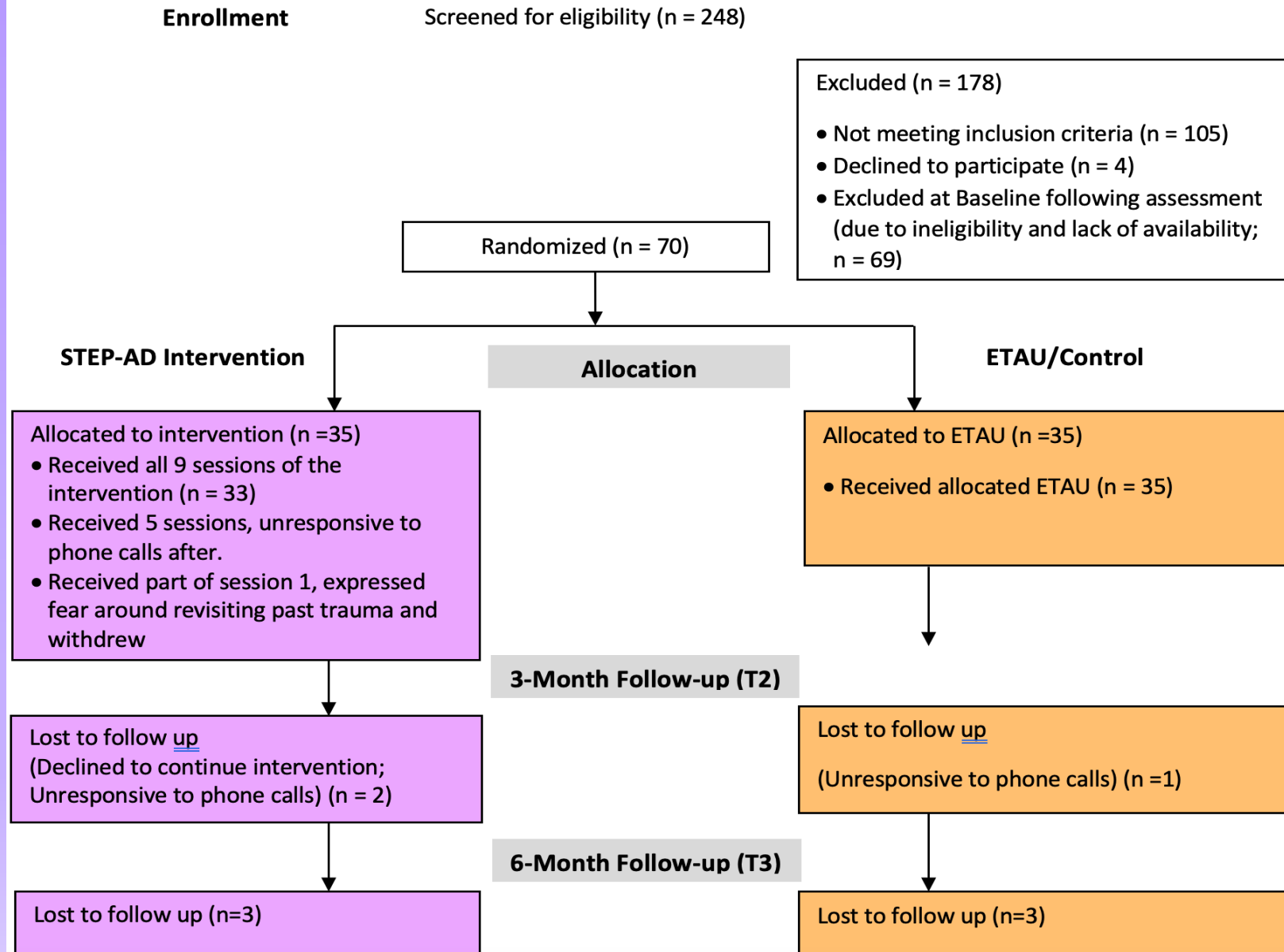


# Methods

- Women were eligible for an in-person baseline assessment if they met the following inclusion criteria
  - (1) Identify as Black and/or African American
  - (2) At least 18 years old
  - (3) English speaking
  - (4) Cis-gender woman
  - (5) History of abuse/trauma
  - (6) Prescribed antiretroviral therapy (ART) for HIV for at least the last two months
  - (7) at risk for negative HIV outcomes as suggested by self-reported detectable viral load within the past year, less than optimal ART adherence (less than “excellent”) , and/or missed HIV-related medical visits within the past year.
- 119 BWLWH were assessed at baseline and 78 met study inclusion criteria and completed one LifeSteps session on adherence prior to randomization to STEP-AD (9 sessions) or ETAU (enhanced treatment as usual with 4 biweekly check-ins).
- Post-intervention, women completed two follow-up assessments (acute at 3 months after)



**Figure 1. CONSORT Flow Diagram for a Pilot RCT of the STEP-AD intervention among Black Women Living with HIV and a history of trauma**





# Measures

- ***ART Adherence (primary outcome)***. The Wisepill medication monitor was used to capture HIV medication adherence. Wisepill monitored a single medication which the participant took the most frequently, or which they had the most difficulty taking. For the two weeks preceding the second baseline visit and the follow-up visits (3 and 6 months) percent ART adherence (days Wisepill was opened ÷ total days) was calculated.
- ***Davidson Trauma Scale*** (DTS; Davidson et al., 1997). The DTS is a 17-item measure of post-traumatic stress disorder symptoms (PTSD) that assesses both frequency and severity for each symptom using a 5-point likert scale (e.g. 0= not at all/ not at all distressing, 4= everyday/ extremely distressing).
- ***Viral Load***. Medical records were reviewed for available information on participant's HIV viral load within the twelve months preceding baseline. Blood draws were also conducted at baseline, acute follow-up (3 months from baseline) and 3-month post-intervention follow-up. CD4 count was also assessed.
- ***Mini-International Neuropsychiatric Interview (M.I.N.I.) for DSM 5*** (Sheehan, 2015; Sheehan et al., 1998). The MINI was administered in a clinical interview by a trained clinician to assess for current diagnoses of PTSD, Major Depressive Episode, Alcohol Use Disorder, and Substance Use Disorder.



# Analyses

- Difference-in-difference methodology was conducted utilizing a mixed effect model comparing STEP-AD to ETAU on changes in outcomes overtime
- We examine if the STEP-AD intervention was effective by accounting for baseline differences. The model is given as,

$$H_{it} = \beta_0 + \gamma_0 \text{Treated}_i + \beta_1 DT_t + \gamma_1 (\text{Treated}_i \times DT_t) + \varepsilon_{it} \quad i=1, \dots, n \text{ and } t=1, 2, \dots, T.$$



# Socio-demographics

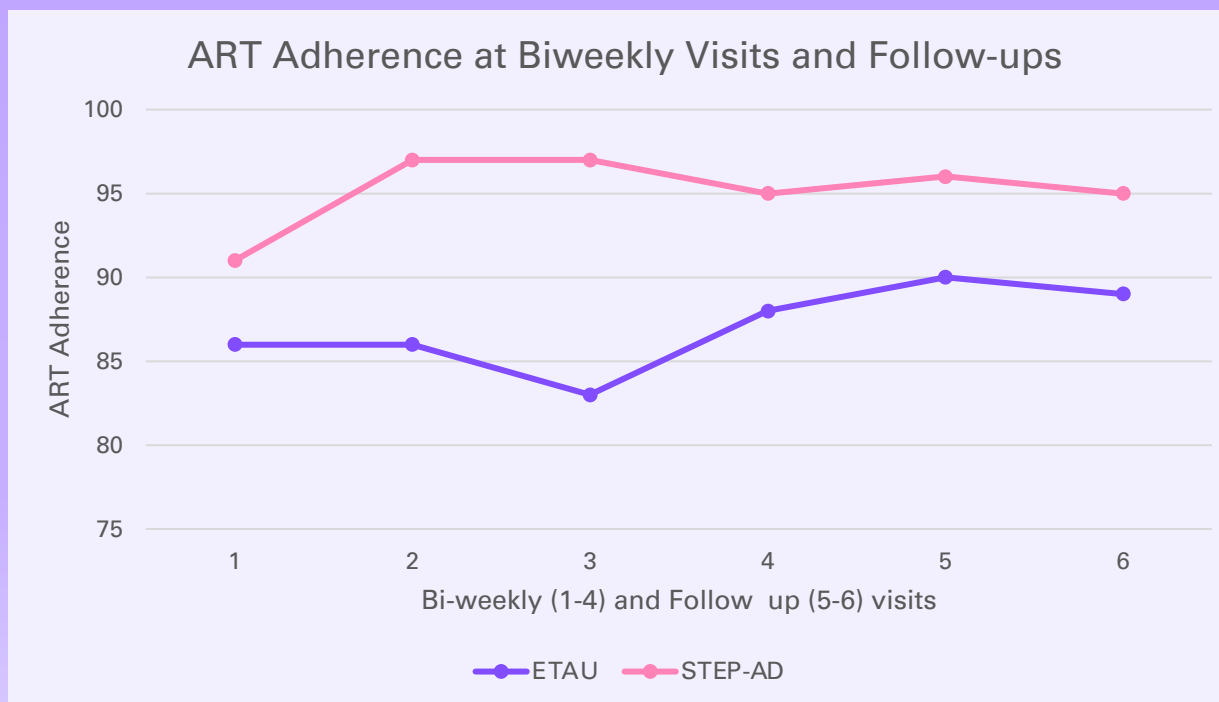
Characteristic		Mean (SD, range) or n (%)	
		STEP-AD	ETAU
<b>Age</b>		47.59 (10.90, 22-59)	49.31 (10.68, 22-65)
<b>Education</b>	Eighth grade or Lower	3 (8.6%)	1 (2.9%)
	Some high school	9 (25.7%)	10 (28.6%)
	High school graduate/GED	14 (40%)	14 (40%)
	Some college	7 (20%)	8 (22.9%)
	College graduate Some graduate school	0 (0%) 1 (2.9%)	2 (5.7%) 0 (0%)
<b>Income</b>	Less than \$5,000	13 (37.1%)	14 (40%)
	\$5,000 - \$11,999	9 (25.7%)	11 (31.4%)
	\$12,000 - \$15,999	3 (8.6%)	7 (6.9%)
	\$16,000 - \$24,999	1 (2.9%)	3 (8.6%)
	\$25,000 - \$34,999	0 (0%)	1 (2.9%)
	\$35,000 - \$49,999	0 (0%)	0 (0%)
	\$50,000 and greater	1 (2.9%)	0 (0%)
<b>Employment Status</b>	Full-time Work	1 (2.9%)	1 (2.9%)
	Part-time Work	1 (2.9%)	4 (11.4%)
	Full or Part-time School	1 (2.9%)	3 (8.6%)
	Neither Working or in School	9 (29.7%)	7 (20%)
	On Disability	19 (54.3%)	21 (60%)
	Other	2 (5.7%)	2 (5.7%)
<b>Housing Arrangement</b>	Renting home or apartment	21 (60%)	23 (65.7%)
	Owned by you or someone else in household	4 (11.4%)	5 (14.3%)
	Publicly subsidized housing	4 (11.4%)	3 (8.6%)
	A friend or relative's home/apartment	2 (5.7%)	2 (5.7%)
	Homeless: sleeping in a shelter	2 (5.7%)	0 (0%)
	Missing	3 (8.6%)	0 (0%)
<b>Place of Birth</b>	U.S. Born	34 (97.1%)	32 (91.4%)
	Non-U.S. Born	1 (2.9%)	3 (8.6%)
<b>Relationship Status</b>	Married	3 (8.6%)	5 (14.3%)
	Cohabiting relationship, unmarried	4 (11.4%)	7 (20%)
	Non-cohabiting relationship	7 (20.0%)	3 (8.6%)
	Single	11 (31.4%)	17 (48.6%)
	Divorced/Separated	5 (14.3%)	3 (8.6%)
	Widow or Loss of Partner	2 (5.7%)	0 (0%)
	Missing	3 (8.6%)	0 (0%)



# Findings

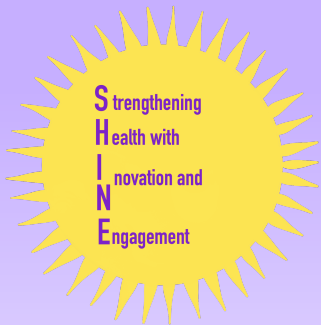
BWLWH who completed STEP-AD (94% retained) compared to E-TAU (100% retained) had significantly

- higher ART adherence (estimate=9.11  $p=.045$ )
- higher CD4 count (estimate=166.96,  $p=.03$ )
- lower likelihood of being clinically diagnosed with PTSD (OR=.07, estimate=- 2.66,  $p=.03$ )



# Conclusions and Implications

- Findings suggest preliminary efficacy of STEP-AD in improving ART adherence, immune function, and mental health by enhancing coping around trauma, racism, HIV-discrimination, and gender-related stressors, core stressors faced by BWLWH
- Next steps may include a large-scale randomized control trial to assess efficacy and implementing the delivery of STEP-AD in settings serving BWLWH







## **Strengthening Health with INnovation and Engagement (SHINE) Research Program**

### **Acknowledgements**

- Research Participants
- SHINE Team
- Community Partners
- Funding Agencies
- NIH/NIMH
- K2MH108439







Dr. Sannisha Dale



sdale@med.miami.edu



(305) 284-1991



SHINE Research Program



shineresearch@miami.edu



<https://shine.psy.miami.edu>



(305) 243-6714



Strengthening  
Health with  
INnovation and  
Engagement