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

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SHINE:
Strengthening Health with Innovation and Engagement
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

Oppression

Lack of Access

HIV Criminalization

Ableism

Food Insecurity

Healthcare Systems

Isms

Immigration System

Problematic Laws

Unemployment

Neighborhood Deprivation

Transportation

Healthcare Deserts

Unstable Housing

Racism

Heterosexism

Mass Incarceration

Policies

Poverty

Cisgenderism

Strong advocate for equity and inclusion.
Impact of HIV among Black women

CDC 2021 Figures
Intersectional Adversities linked to ART Adherence

Violence/Trauma/Abuse
Racism
HIV Stigma
Gender-Related Stress

ART adherence

(Dale & Reid, 2023)
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 and 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

Enrollment

Screened for eligibility (n = 248)

Excluded (n = 178)
- Not meeting inclusion criteria (n = 105)
- Declined to participate (n = 4)
- Excluded at Baseline following assessment (due to ineligibility and lack of availability; n = 69)

Randomized (n = 70)

STEP-AD Intervention

Allocated to intervention (n = 35)
- Received all 9 sessions of the intervention (n = 33)
- Received 5 sessions, unresponsive to phone calls after.
- Received part of session 1, expressed fear around revisiting past trauma and withdrew

Allocation

Allocated to ETAU (n = 35)
- Received allocated ETAU (n = 35)

ETAU/Control

3-Month Follow-up (T2)

Lost to follow up
(Declined to continue intervention; Unresponsive to phone calls) (n = 2)

6-Month Follow-up (T3)

Lost to follow up (Unresponsive to phone calls) (n = 1)

Lost to follow up (n = 3)

Lost to follow up (n = 3)
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 over time.

- We examine if the STEP-AD intervention was effective by accounting for baseline differences. The model is given as,

\[ H_{it} = \beta_0 + \gamma_0 \text{Treated}_i + \beta_1 \text{DT}_t + \gamma_1 (\text{Treated}_i \times \text{DT}_t) + \epsilon_{it} \quad i=1,..,n \text{ and } t=1,2,\ldots,T. \]
### Socio-demographics

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