A Pilot Randomized Control Trial of Motivational Interviewing to Increase PrEP Uptake (MI-PrEP) among Black Women Placed at Risk for HIV in the U.S.

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Context and Isms

Oppression

Isms

Unemployment

Neighborhood Deprivation

HIV Criminalization

Ableism

Healthcare Systems

Food Insecurity

Poverty

Transportation

Heterosexism

Unstable Housing

Racism

Healthcare Deserts

Mass Incarceration

Policies

Cisgenderism

Lack of Access

Immigration System

Problematic Laws

Unemployment
Black Women: Evident HIV & PrEP Disparities

### PrEP (Pre-Exposure Prophylaxis)

**Number of PrEP users, 2022:**
- **Total Number:** 12,990

**Rate of PrEP users per 100,000 population, 2022:**
- **Total:** 215

**Percent of PrEP users, by Sex, 2022:**
- **Male:** 93.0%
- **Female:** 7.0%

**Percent of PrEP users, by Race/Ethnicity, 2022:**
- **Black:** 7.2%
- **Hispanic/Latino:** 12.5%
- **White:** 75.5%

**Percent of PrEP users, by Age, 2022:**
- **Aged 13-14:** 15.3%
- **Aged 15-34:** 40.8%
- **Aged 35-44:** 22.3%
- **Aged 45-54:** 11.0%
- **Aged 55+:** 10.7%

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**CDC 2021 Figures**
Motivational Interviewing

MI has extensive literature demonstrating its efficacy in improving motivation and promoting behavior change and MI can be delivered in brief/low intensive formats.
MI-PrEP Intervention

2-session individual intervention for Black cisgender women placed at risk HIV that combines:

- PrEP information
- motivational interviewing strategies
- light case management

Foundation:

Open Pilot Trial: Conducted among 4 Black women and preliminary findings showed acceptability and feasibility with high satisfaction ratings; increases in PrEP uptake, knowledge, and motivation to use; and decreases in PrEP barriers and medical mistrust.
Methods

- Women were randomized to MI-PrEP or the control condition if they met all eligibility criteria as follows:
  1. Not living with HIV
  2. Identifying as Black and/or African American
  3. Age 18 or older
  4. Cisgender woman
  5. English speaking
  6. Capable of completing and fully understanding the informed consent process and the study procedures and
  7. Meets the Center for Disease Control’s indications for PrEP use at the time of study: (a) any sex with opposite sex partners in the past 6 months and (b) not in a monogamous partnership with a recently tested partner not living with HIV or (c) any injection of drugs not prescribed by a clinician in the past 6 months AND (d) at least one of the following: (i) infrequently uses condoms in sex with one/more partners of unknown HIV status (ii) in a sexual relationship with a partner living with HIV or (iii) any sharing of injection/drug preparation equipment in the past 6 months.

- Forty women were randomized at baseline to MI-PrEP (session 1 with psychoeducation on PrEP and MI, session 2 with MI and light case management) or ETAU (2 sessions consisting of psychoeducation on PrEP).
- Women completed 1 follow-up assessment (1 month after visit 2).
Figure 1. CONSORT Flow Diagram for a Pilot RCT of the MI-PrEP intervention

**Enrollment**
- Screened for eligibility (n = 113)
- Excluded (n = 72)
  - Not meeting inclusion criteria (n = 63)
  - Screened after study capacity (n = 5)
  - Declined participation (n = 4)
- Randomized (n = 41)

**MI-PrEP Intervention**
- Allocated to intervention (n = 21)
  - Received all 2 sessions of the intervention (n = 19)

**Allocation**
- ETAU/Control
  - Allocated to ETAU (n = 20)
  - Received allocated ETAU (n = 20)

**1-Month Follow-up**
- Lost to follow up
  - (Declined to continue intervention; Unresponsive to phone calls) (n = 2)
- Lost to follow up (n = 0)

**Analysis**
- Analyzed
  - For baseline (prior to session 1) analysis (n = 21)
  - For session 2 analysis (n = 19)
  - For 1-month outcomes (n = 19)
- Excluded from analysis
  - For baseline (prior to session 1) (n = 0)
  - For session 2 analysis (n = 2)
  - For 1-month outcomes (n = 2)
- Analyzed
  - For baseline (prior to session 1) analysis (n = 20)
  - For session 2 analysis (n = 20)
  - For 1-month outcomes (n = 20)
- Excluded from analysis
  - For baseline (prior to session 1) (n = 0)
  - For session 2 analysis (n = 0)
  - For 1-month outcomes (n = 0)
Measures

Motivation to Use PrEP (primary outcome). This instrument uses three questions to assess a participant’s readiness and motivation to use PrEP. Participants indicate using a scale of 0-10: 1) the extent to which they are thinking about using PrEP, 2) how important using PrEP is to them, and 3) how confident they are that they will start using PrEP. We assessed each scale separately (range of 0-10), in addition to summed

PrEP Uptake. Survey: At each timepoint, participants reported whether they had spoken to a provider about PrEP, have recently received a prescription for PrEP, and if they have started taking PrEP (0 = No, 1 = Yes). Each question was included separately in analyses to measure change in steps of acquiring and taking PrEP (1). Medical Records Review: At visit 3 women’s medical records were requested to verify whether they were prescribed PrEP.

Knowledge of PrEP. This 12-item scale assesses a participant’s knowledge of PrEP using True/False statements (e.g., “PrEP works best when taken every day”). A point was assigned for each correct response and all points were summed for a total score. A higher score (range of 0-12) indicates greater knowledge of PrEP (1,2).

Barriers to Care Scale (BACS). We used a 7-item version of the Barriers to Care Scale, a self-report measure specific to HIV-related care barriers (4). We edited the statements to ask about barriers specifically related to receiving PrEP-related care. Participants rated the severity of each barrier to PrEP care (e.g., “The lack of transportation to access PrEP.”) on a scale of 1 (Not a problem at all) to 4 (Major problem). A higher score (range of 4-28) indicates that a participant experiences more barriers to accessing PrEP-related healthcare.
Analyses

- Difference-in-difference methodology was conducted utilizing a mixed effect model comparing MI-PrEP to ETAU on changes in outcomes overtime.

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

\[ H_{it} = \beta_0 + \gamma_0 \text{Treated}_i + \beta_1 \text{DT}_t + \gamma_1 (\text{Treated}_i \times \text{DT}_t) + \epsilon_{it} \]

where i = 1,..,n and t = 1,2,…,T.
<table>
<thead>
<tr>
<th>Socio-demographics</th>
<th>MI PrEP (N = 21)</th>
<th>ETAU (N = 20)</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td>$\chi^2 = 3.0, p = 0.22$</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>20 (95.2%)</td>
<td>18 (90%)</td>
<td></td>
</tr>
<tr>
<td><strong>Sexual Orientation</strong></td>
<td></td>
<td></td>
<td>$\chi^2 = 10.0, p = 0.12$</td>
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<tr>
<td>Exclusively heterosexual</td>
<td>13 (61.9%)</td>
<td>17 (85%)</td>
<td></td>
</tr>
<tr>
<td>Bisexual</td>
<td>6 (28.5%)</td>
<td>3 (15%)</td>
<td></td>
</tr>
<tr>
<td><strong>Relationship Status</strong></td>
<td></td>
<td></td>
<td>$\chi^2 = 24.0, p = 0.24$</td>
</tr>
<tr>
<td>Non-cohabiting relationship</td>
<td>5 (23.8%)</td>
<td>7 (35%)</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>7 (33.3%)</td>
<td>8 (40%)</td>
<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td>$\chi^2 = 9.33, p = 0.50$</td>
</tr>
<tr>
<td>Some high school</td>
<td>2 (9.5%)</td>
<td>6 (30%)</td>
<td></td>
</tr>
<tr>
<td>High school graduate or GED</td>
<td>8 (38.0%)</td>
<td>6 (30%)</td>
<td></td>
</tr>
<tr>
<td>Some college</td>
<td>4 (19.1%)</td>
<td>6 (30%)</td>
<td></td>
</tr>
<tr>
<td>Not reported</td>
<td>1 (4.8%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Income</strong></td>
<td></td>
<td></td>
<td>$\chi^2 = 16.0, p = 0.07$</td>
</tr>
<tr>
<td>Less than $5,000</td>
<td>11 (52.4%)</td>
<td>10 (50%)</td>
<td></td>
</tr>
<tr>
<td>$5000-11,999</td>
<td>5 (23.7%)</td>
<td>4 (20%)</td>
<td></td>
</tr>
<tr>
<td>$12,000-15,999</td>
<td>1 (4.8%)</td>
<td>4 (20%)</td>
<td></td>
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<tr>
<td><strong>Housing</strong></td>
<td></td>
<td></td>
<td>$\chi^2 = 23.33, p = 0.03$</td>
</tr>
<tr>
<td>Renting home or apartment</td>
<td>10 (47.6%)</td>
<td>13 (65%)</td>
<td></td>
</tr>
<tr>
<td><strong>Religion</strong></td>
<td></td>
<td></td>
<td>$\chi^2 = 30.6, p = 0.02$</td>
</tr>
<tr>
<td>Christian</td>
<td>5 (23.7%)</td>
<td>5 (25%)</td>
<td></td>
</tr>
<tr>
<td>Baptist</td>
<td>11 (52.4%)</td>
<td>10 (50%)</td>
<td></td>
</tr>
</tbody>
</table>
Findings

Women who completed MI-PrEP (95% retained) compared to ETAU (100% retained) had significantly higher likelihood of speaking to a provider about PrEP (OR=1.40, DiD=0.33, se = 0.17, p < .05).
Findings continued…..

**Intervention Group**

- Within the intervention group women had a significant increase in having a PrEP prescription (visit 2: t(18) = 2.54, p < .05; follow-up: t(18) = 2.88, p < .01), PrEP knowledge (visit 2: t(18) = 2.8, p < .05; follow-up: t(18) = 2.25, p < .05), and motivation/contemplation about using PrEP (visit 2: t(18) = 3.1, p < .01).

- There were also significant decreases in personal financial resources as a barrier to accessing PrEP (visit 2: t(18) = -2.33, p < .05; follow-up: t(16) = -3.38, p < .01) and medical mistrust (visit 2: t(17) = -2.25, p < .05; follow-up: t(14) = -2.75, p < .05).

**Control Group**

- In the control group, we found that there was an increase in obtaining a PrEP prescription (visit 2: t(19) = 2.18, p < .05; follow-up: t(19) = 2.18, p < .05), and increase in talking to a provider about PrEP but only between baseline and follow-up (t(19) = 3.94, p < .001).
Findings continued....
Conclusions and Implications

• Findings indicate preliminary efficacy of a brief MI-PrEP intervention in improving the likelihood of women speaking with a provider about PrEP as well as within group improvements in other outcomes.

• Within group improvements in the control group suggest potential benefits of simply providing knowledge in the context of a research program that is globally affirming.

• A large-scale study is needed to further assess efficacy and examine implementation.
Acknowledgements

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- SHINE Team
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