Combining HIV Prevention Options with Mental Health Service Delivery for Adolescent Girls (CHOMA):

Results of a Pilot Hybrid Effectiveness-Implementation Randomized Trial

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Conflict of Interest Disclosure

I have no relevant financial relationships to disclose.
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Background

- Overlapping risk of **HIV acquisition** and **common mental disorders (CMD)** among adolescent girls and young women

- CMD & HIV driven by overlapping **social/structural determinants** of health

- CMD associated with **low PrEP adherence**

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Data from HPTN 082 on persistence of depression symptoms

- Associated with 25% lower PrEP adherence

Velloza et al., JIAS, 2021; Velloza et al., AIDS & Beh, 2020
Background

- Friendship Bench problem-solving, cognitive behavioral intervention
- 4-6 individual therapy sessions + 1 group session
- Delivered by a lay counselor in a safe space

Velloza et al., JIAS, 2024; Chibanda et al., JAMA, 2016; Stockton et al., PLOS ONE, 2020
Our goal was to evaluate preliminary effectiveness, acceptability, feasibility, and appropriateness of our “Youth Friendship Bench SA” intervention to address common mental disorders and PrEP adherence among young South African women.
Study Setting and Population

- Single-site, open-label pilot hybrid effectiveness-implementation trial
- Conducted from April 2023 – Feb 2024
- Already taking PrEP or interested in initiating PrEP
- Elevated CMD symptoms based on Self-Reporting Questionnaire-20 item [SQR-20] score ≥7
- No active, unmanaged psychosis or suicidal ideation or intent
Study Design

Recruit AGYW receiving PrEP from public clinic in Johannesburg

Screen for eligibility, based on South African Adult Primary Care Guidelines and SRQ-20

Enroll & Randomize

Refer out any AGYW with evidence of self-harm intent or psychiatric symptoms to social work team for further assessment and intervention

Youth Friendship Bench SA + SOC:
  Counseling at Enrollment, Week 2 (optional over phone), Week 4, Week 8 (optional over phone), and Week 12

SOC:
  Mental health symptom screen and referrals to social workers as needed at Enrollment, Week 4, and Week 12

Outcomes: PrEP adherence & common mental disorder symptom reduction at Week 12
Statistical Analyses

• Co-primary outcomes, assessed at Week 12:
  • Proportion with PrEP adherence as measured by detected tenofovir (TFV) in urine using a urine point-of-care assay
  • Proportion with reduced symptoms of CMD as measured by SRQ-20 scores <7

• Secondary outcomes:
  • PrEP adherence and CMD symptoms at Week 4
  • Acceptability, feasibility, appropriateness with AIM, FIM, and IAM scales (Likert responses 1-4, items summed and average for each scale)

• Intent-to-treat analyses

• Poisson regression with a log-link and robust standard errors
Screening, Enrollment, & Follow-up

- 222 screened
- 116 enrolled* and randomized

Excluded:
- 44 with low SRQ-20 score
- 40 with unmanaged mental health disorders
- 7 with report of suicidal intent
- 1 aged 26 years or older
- 1 HIV positive
- 14 did not complete procedures or declined enrollment

57 assigned to Youth Friendship Bench SA + SOC
Biological Males
58 assigned to SOC

Week 12 retention:
- Youth Friendship Bench SA + SOC: 37 (65%)
- SOC: 41 (71%)

57 included in ITT analysis
35 included in per-protocol analysis

58 included in ITT analysis
48 included in per-protocol analysis
## Participant Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Intervention N=57</th>
<th>SOC N=58</th>
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<tbody>
<tr>
<td><strong>Age</strong></td>
<td>21 (19 – 22)</td>
<td>21 (20 – 23)</td>
</tr>
<tr>
<td>Some college education</td>
<td>21 (37%)</td>
<td>19 (33%)</td>
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<tr>
<td>SRQ-20 score for depression symptoms</td>
<td>9 (8 – 10)</td>
<td>8 (7 – 10)</td>
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<tr>
<td>GAD-7 score for anxiety symptoms</td>
<td>7 (5 – 11)</td>
<td>6 (4 – 10)</td>
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<tr>
<td>Positive PC-PTSD score for traumatic stress symptoms</td>
<td>28 (49%)</td>
<td>20 (35%)</td>
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<tr>
<td>Gender-based violence</td>
<td>44 (77%)</td>
<td>41 (71%)</td>
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<tr>
<td>Sexual partner in last month</td>
<td>37 (65%)</td>
<td>42 (72%)</td>
</tr>
<tr>
<td>Transactional sex in last month</td>
<td>11 (19%)</td>
<td>11 (19%)</td>
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Effect of the Intervention on PrEP Adherence

PrEP adherence over time:
Urine positive test among 47% at Week 4 versus 43% at Week 12; p=0.25
Effect of the Intervention on Mental Health

Primary Outcome: Week 12 (N=115)
- SRQ-20 Score <7: 100% (N=23/57)
- CMD symptoms declined overall:
  - SRQ-20 <7 among 30% at Week 4 versus 45% at Week 12; p<0.01

Secondary Outcome: Week 4 (N=115)
- SRQ-20 Score <7: 100% (N=20/58)
- 26.3% (N=15/57)
### Intervention Acceptability & Feasibility

**Acceptability of Intervention Measure (AIM)**
Mean Score: 3.5 (Standard Deviation: 0.5)

**Intervention Appropriateness Measure (IAM)**
Mean Score: 3.6 (Standard Deviation: 0.4)

**Feasibility of Intervention Measure (FIM)**
Mean Score: 3.4 (Standard Deviation: 0.5)
Conclusions

- **No intervention effect** on PrEP adherence or CMD symptoms at Week 12
  - **Short-term intervention effect** on PrEP adherence at Week 4
  - **Reductions** in SRQ-20 symptoms in both arms

- **Acceptability**, **feasibility**, and **appropriateness** scores were high
- **Challenging** to retain this population
- Future research is needed to:
  - **Improve** integrated mental health and PrEP services for AGYW over a long-term period
  - **Promote** standard-of-care mental health service delivery in resource-constrained settings

“No one ever asked me how I’m feeling before” Study participant