PROJECT YES!

Evidence-Based Structural Intervention Good Evidence – Medication Adherence

INTERVENTION DESCRIPTION

Goal of Intervention

- Improve viral suppression
- Increase antiretroviral (ART) adherence
- Reduce internalized HIV stigma

Intended Population

• Adolescents and young adults (ages 15 - 24 years) with HIV

Brief Description

Project Yes! is a HIV clinic-based peer mentoring program designed to improve adherence to ART, decrease internalized HIV stigma, and improve viral suppression. The program consists of multiple components. Participants attend an orientation meeting with a healthcare provider, an adult caregiver (if invited), and an assigned youth peer mentor. Youth peer mentors are young adults aged 21—26 years with HIV who have successfully transitioned to self-management and are trained and hired as paid HIV clinic staff. During the orientation meeting, the healthcare provider reviews the viral load and shares the goal of maintaining viral suppression or becoming virally suppressed. The youth peer mentor then meets separately with the participant while the health care provider meets with the adult caregiver to discuss intervention-related questions. After the orientation meeting, participants meet with their assigned youth peer mentor monthly for one-on-one meetings for 6 months. They are also invited to attend monthly youth group meetings; the first meeting being required to encourage youth to try a group format. Youth group meetings are facilitated by the youth peer mentor and attended by a healthcare provider when clinical or technical information is needed. Adult caregivers are also invited to attend a total of three caregiver group meetings, held every other month to provide enhanced HIV knowledge and skills to support their youth. Journals are provided to participants to track adherence, engage with educational topics, and reflect on their journeys. Prior to the start of the intervention, participants attending the children's hospital are assessed for physical transition to the adult hospital based on clinical eligibility (e.g., viral load status and opportunistic infections) and psychosocial factors (i.e., not currently experiencing a challenge, such as moving homes or recent death in family). Those who are eligible for transfer are invited to attend a group meeting to tour and familiarize themselves with their new clinic and their assigned youth peer mentor.

Theoretical Basis

• "Five C's" of positive youth development: competence, confidence, connection, character, and caring

• Social Cognitive Theory

Intervention Duration

• One-on-one meetings and youth group meetings delivered monthly for 6 months

Intervention Settings

• Four HIV clinics, including a children's hospital (pediatric clinic), an adult hospital, and 2 primary care facilities (adult clinics)

Deliverer

- Health care provider (as needed)
- Trained youth peer mentors

Delivery Methods

- Discussion
- Observational learning
- Problem-solving
- Role-modeling
- Skills building

Structural Components

- Capacity Building Hired staff/Training
 - $_{\odot}$ Employed and trained youth peer mentors with HIV and placed them in pediatric and adult HIV clinics
- Social Determinants of Health Acceptance and respect
 - Addressed internalized HIV stigma through youth peer mentoring sessions, using trained youth peer mentors with HIV

INTERVENTION PACKAGE INFORMATION

The intervention curriculum is available upon request. Please contact **Julie A. Denison**, Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland 21205.

Email: <u>idenison@jhu.edu</u> for details on intervention materials.

EVALUATION STUDY AND RESULTS

Study Location Information

The original evaluation study was conducted in Ndola, Zambia between December 2017 and February 2019.

Key Intervention Effects

- Improved viral suppression
- Reduced internalized HIV stigma

Recruitment Settings

HIV clinics (i.e., pediatric and adult clinics)

Eligibility Criteria

Patients were eligible if they were between ages 15 to 24 years, aware of their HIV status, had been on ART for six or more months, spoke Bemba or English, and planned to be available to attend study activities over the next 18 months as needed.

Study Sample*

The baseline study sample of 273 adolescents and young adults is characterized by the following:

- 59% female, 41% male
- Mean age of 19 years, min max: 15 24 years
- 88% completed primary school; 11% did not complete primary school, 2% missing
- 63% baseline viral load suppression (<1000 copies/ml)
- 72% self-reported acquiring HIV from parents, 10% through sex, 5% through unspecified way, 12% don't know, 1% missing
- Median years on ART: 7 years

Assignment Method

Participants (N = 276) were randomized to 1 of 2 study arms: Project Yes! Intervention (n = 139) or Standard of Care comparison (n = 137).

Comparison

Comparison arm participants received the standard of care offered at HIV clinics for adolescents and young adults, such as regular clinic visits. They were also given the option of joining the monthly youth group meetings held by the clinic separate from the Project YES! group meetings. After 6 months post-initiation of the intervention, comparison arm participants began the Project YES! intervention, including assessing and transitioning eligible youth from the pediatric clinic to the adult clinic.

Relevant Outcomes Measured

- Self-reported ART medication adherence was measured at baseline and 6 months post-initiation of the intervention, and assessed as having an ART adherence treatment gap of 48 consecutive hours or more in the past 3 months
- Viral suppression was measured at baseline and 6 months post-initiation of the intervention, and was defined as having a viral load of <1,000 copies/mL
- Internalized stigma was measured at baseline and 6 months post-initiation of the intervention, and assessed as reporting internalized HIV stigma if participants agreed to at least 2 of the 3 following questions from the Internalized AIDS Stigma Scale (IA-RSS):
 - $_{\rm O}$ You feel guilty that you are HIV positive
 - You are ashamed that you are HIV positive
 - $_{\odot}$ You sometimes feel worthless because you are HIV positive

Participant Retention

Project Yes! Intervention:

• 91% retained at 6 months post-initiation of intervention

Standard of Care Comparison:

• 84% retained at 6 months post-initiation of intervention

Significant Findings on Relevant Outcomes

- Among participants in the pediatric clinic, Project Yes! intervention participants had a statically significant relative increase in the odds of becoming virally suppressed compared to the Standard of Care participants at 6 months post-initiation (Adjusted for sex and age: OR: 4.66, 95% CI: 1.84 11.78)
- Project Yes! intervention participants had a significant reduction in odds of reporting internalized HIV stigma relative to the Standard of Care participants at 6 months post-initiation (Adjusted for age, sex, and clinic: OR: 0.39, 95% CI: 0.21 - 0.73).

Strengths

None reported

Considerations

Additional significant positive findings on non-relevant outcomes

None reported

Non-significant findings on relevant outcomes

- There were no significant intervention effects on self-reported ART adherence.
- Although there was a significant intervention effect on viral suppression among participants in the pediatric clinic, there were no significant intervention effects on viral suppression for the overall study sample.
 - There were also no significant intervention effects on viral suppression among participants in the adult clinics.

Negative findings

• None reported

Other related findings

- This intervention is also determined to be evidence-based for the Medication Adherence (MA) Chapter.
- In the adult clinics, Project Yes! intervention participants had significantly greater viral suppression at baseline than Standard of Care participants, possibly due to 23 virally suppressed participants from the pediatric clinic who were transitioned to the adult clinic prior to the intervention and were included in the adult clinic population for analysis. This higher level of viral suppression at baseline meant less opportunity for change over time for participants in adult clinics. Additionally, Standard of Care participants in adult clinics had twice the loss to follow-up as the Project Yes! intervention participants in adult clinics, while the loss to follow-up was minimal in both study arms in the pediatric clinic.
- The study authors assessed potential contamination between the two study arms since the study was an individual randomized controlled trial with the intervention and standard of care arms participants receiving HIV care in the same clinics. Across all clinics, less than 5% (n = 12) of participants at the 6-month midline reported they had talked with youth in the other arm about session content (5 intervention group participants and 7 comparison group participants). The topics most frequently discussed across both study arms were ART adherence (n = 9, 3.73%) followed by self-management (n = 7, 2.89%, and viral load tests and how to suppress HIV in the blood (n = 7, 2.89%).

Implementation research-related findings

None reported

Process/study execution findings

- Among the 126 intervention participants with a midline viral load test, 95% (n = 120) attended an
 orientation meeting and the majority (73.8%, n = 93) attended five or six one-on-one meetings with a YPM.
- Almost half (45.2%, n = 57) of the participants attended five or six group meetings.

Adverse events

• There were no known unintended harmful effects of the intervention, according to the authors

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* Percentages may not always add up to 100% due to rounding

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Researcher: Julie A. Denison Department of International Health Social and Behavioral Interventions Program Johns Hopkins Bloomberg School of Public Health Baltimore, Maryland 21205

Email: jdenison@jhu.edu

