Project Brief: CHOMA

Title	Youth Friendship Bench SA Optimization of the Friendship Bench mental health intervention for adolescent girls and young women in South African PrEP delivery settings Short title: Youth Friendship Bench SA
Co-primary Objectives	To compare the proportion of young South African women who adhere well to PrEP (based on tenofovir levels detected in a point-of-care [POC] urine assay) between those receiving the Youth Friendship Bench SA plus standard-of-care mental health services versus receipt of standard-of-care mental health services alone, after 3 months. To compare the proportion of young South African women with reduced symptoms of common mental disorders (based on SRQ-20 score) between those receiving the Youth Friendship Bench SA plus standard-of-care mental health services versus receiving standard-of-care services alone, after 3 months
Co-primary outcomes	The PrEP adherence primary outcome is the proportion with PrEP adherence at Month 3, defined as tenofovir (TFV) concentrations ≥1500 ng/mL in urine measured using a urine POC assay. We will also assess the short-term effect of the Youth Friendship Bench SA intervention on PrEP adherence using the urine POC assay at the Week 4 visit. The mental health related primary outcome is the proportion with reduced symptoms of common mental disorders (SRQ-20 scores.
Study Design	This is a randomized hybrid implementation-effectiveness trial which will be conducted in a real-world healthcare setting. Eligible women who accept open label daily oral PrEP (n=126) will be enrolled and randomized 1:1 to either the Youth Friendship Bench SA intervention (plus standard-of-care mental health services as needed) or standard-of-care mental health services alone.
Study population	HIV-uninfected women ages 18-25 in Johannesburg, South Africa, who have symptoms of common mental disorders as evidenced by a score greater than or equal to 7 on the SRQ-20.
Intervention	Participants randomized to the Youth Friendship Bench SA will be offered up to 5 60-minute counseling sessions conducted at enrollment, Week 2, Week 4, Week 8, and Week 12 and 1 optional group counseling session between their Week 8 and 12 visits. All counseling will be conducted by peer lay counselors, and will be supervised weekly by a trained research psychologist. Participants will have the option to complete counseling sessions remotely via phone and to receive SMS reminders about upcoming clinic visits.
Study duration	Approximately 36 months
Other Partners & Collaborators	University of California, San Fransisco
Sponsors/Donors	National Institute of Health (USA) R00 grant
Study status	222 participants were screening and 116 participants enrolled between 31 March 2023 and 05 October 2023. The last participant follow up visit was completed on 23 January 2024. This study is currently in close out phase.
Contact person	Prof Sinead Delany-Moretlwe
Briefing owner and date	Lisa-Marie Mills, 08 April 2024