

EMPOWER: An evaluation of a combination HIV prevention intervention that includes oral PrEP for adolescent girls and young women in South Africa and Tanzania.

Lead Research Organisation: Wits Reproductive Health Research Institute (Wits RHI)

LRO Partners: Mwanza Intervention Trials Unit (MITU), London School of Hygiene and Tropical Medicine (LSHTM), International Center for Research on Women (ICRW)

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Problem statement:

Gender inequality and gender-based violence (GBV) are significantly associated with an increased risk of HIV acquisition in southern and eastern Africa. It may also influence the uptake and sustained use of biomedical HIV prevention strategies such as oral pre-exposure prophylaxis (PrEP). Limited evidence exists on how to best combine and coordinate HIV, GBV and stigma prevention interventions successfully within health systems.

Purpose:

The overall aim of this demonstration project is to assess whether it is feasible, acceptable and safe to offer oral PrEP as part of a combination HIV prevention package that addresses GBV, stigma and HIV in adolescent girls and young women (AGYW) aged 16-24 years.

Target group: Sexually active women aged 16 to 24 years

Setting: Two PrEP demonstration sites, including one in Johannesburg, South Africa and one in Mwanza, Tanzania.

Scope of Work:

This is a multi-site prospective implementation science study to assess the feasibility, acceptability and safety of offering oral PrEP as part of a combination prevention package that addresses GBV, stigma and HIV in AGYW at substantial risk for HIV infection aged 16-24 years in two demonstration sites (South Africa and Tanzania).

In Part 1, participants who consent for screening will be counselled and tested for HIV and asked about experiences of GBV and stigma. Those that test positive for HIV will be linked to care. Those that report current experiences of violence or stigma, and that are at immediate risk of danger will be linked to care.

In Part II of the study, HIV negative participants will be invited to consent to enrol in a prospective cohort and followed up for a maximum of 15 months. Participants in the cohort will be offered PrEP. Up to 500 PrEP acceptors will be enrolled in the study and followed up quarterly for up to 15 months. Participants who initially decline PrEP at enrolment have the option to accept PrEP during the first 6 months of the study or up until accrual is complete.

Participants who accept oral PrEP will be randomised to a standard adherence intervention OR the standard intervention plus adherence clubs which include a four-session empowerment curriculum.

Primary objectives

To evaluate the feasibility, acceptability and safety of:

1. integrating clinical enquiry and linkage-to-care for GBV and stigma within HIV counselling and testing for AGYW (Part I), and
2. supporting PrEP acceptance, effective use (adherence) and retention in care through adherence clubs that include a four-session empowerment curriculum, compared to counselling and SMS support alone, in HIV negative AGYW (Part II).

Secondary objectives

- To assess correlates of GBV and stigma, and factors associated with linkage-to-care for GBV;
- To assess correlates of PrEP acceptance and time to first acceptance;
- To assess correlates of PrEP adherence and continuation;
- To assess the influence of empowerment interventions on AGYW self-efficacy, empowerment, and relationship dynamics;
- To compare HIV prevention and risk behaviors among PrEP users and non-users;
- To describe patterns of antiretroviral drug resistance among women who acquire HIV infection;
- To evaluate the costs and cost-effectiveness of the combination package and each of its elements;
- To explore the influence of PrEP use on contraceptive use and pregnancy incidence;
- To explore qualitatively, user, provider and community stake-holder satisfaction with intervention components;
- To explore through qualitative and quantitative assessments whether this combination package leads to improvements in quality of care for GBV and HIV.

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www.wrhi.ac.za

www.icrw.org/

www.lshtm.ac.uk/

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