PopART (HPTN 071)

Evidence-Based Structural Intervention

INTERVENTION DESCRIPTION

Goal of Intervention
- Reduce HIV incidence at a population level

Target Population
- Residents of urban and peri-urban communities in Zambia and Western Cape Province, South Africa

Brief Description

PopART (HPTN 071) is a community-randomized trial of a combination HIV prevention intervention designed to reduce HIV incidence in urban and peri-urban communities in Zambia and Western Cape Province, South Africa. The comparison consisted of two intervention groups (Group A and Group B) to receive the PopART intervention and a standard of care (Group C). The communities randomized to PopART (Groups A and B), utilized specially trained community HIV care providers (CHiPs) to visit households within the community at least once annually during the four-year intervention period. During the home visit, the following services are offered to residents: HIV education and prevention information; HIV counseling and testing; and referrals to the local government clinic for HIV care and provision of antiretroviral treatment (ART) according to the local guidelines (specific to Group B) for participants who tested positive for HIV. Additional services include support for ART retention and adherence, symptom screening for tuberculosis (TB) and sexually transmitted infections (STI), with referrals for diagnosis and treatment, and referrals for male circumcision (for HIV negative males), antenatal care (for HIV positive pregnant women), reproductive health, and family planning services. Condoms are also promoted and provided during home visits. At the local government clinic, in Group A communities, HIV positive individuals are offered universal ART, while in Group B communities, ART was initially offered according to local guidelines, but then universal ART was offered at the study midpoint because of updated WHO guidelines for ART initiation.

Theoretical Basis
- None reported

Intervention Duration
- At least one home visit per year for four years

Intervention Setting
- Residential

Deliverer
- Community HIV care providers (CHiPs)

Delivery Methods

- Counseling
- Referrals
- Supplies (i.e., condoms)
- Testing (i.e., HIV, STI, and TB testing)

Structural Component

- Access
  - Increased access to HIV/STI and TB testing, and condoms
- Physical Structure – Services provided in a non-traditional setting
  - Delivered home-based services, including HIV testing and counseling, linkage to care and ART adherence support, STI and TB symptom screening, condom provision, and referrals for STI and TB diagnosis and treatment, voluntary medical male circumcision (for HIV-negative men), and antenatal care (for HIV-positive pregnant women)

INTERVENTION PACKAGE INFORMATION

An intervention package is available at https://www.nejm.org/doi/suppl/10.1056/NEJMoa1814556/suppl_file/nejmoa1814556_protocol.pdf. Please contact **Richard Hayes,** Keppel Street, London WC1E 7HT, United Kingdom.

Email: richard.hayes@lshtm.ac.uk for details on intervention materials.

EVALUATION STUDY AND RESULTS

Study Location Information

The original evaluation study was conducted in Zambia and Western Cape Province, South Africa between 2013 and 2018.

Key Intervention Effects

- Reduced HIV incidence at a population level

Recruitment Settings

Urban and peri-urban Zambian and South African communities

Eligibility Criteria

Participants were eligible if they resided in one of the 21 urban or peri-urban Zambian and South African study communities. For the evaluation of the intervention, participants were eligible if they were between the ages of 18 and 44 years and lived within households of each community.

Study Sample

Of the total 48,301 participants enrolled, a baseline sample of 38,474 participants was randomly selected. The baseline characteristics of 38,474 participants were as follows:

Group A Intervention†: Combination Prevention with universal ART throughout trial (n = 12,671)

- *72% female, 28% male*

- *40% 18-24 years old, 39% 25-34 years old, 21% 35-44 years old*
- *79% HIV negative, 21% HIV positive*
- *67% HIV-positive participants not currently on ART*
- *44% HIV-positive participants not virally suppressed taken from a random sample of approximately 75 HIV positive participants per community at baseline*

Group B Intervention: Combination Prevention with ART provided according to local guidelines (universal ART from mid-2016) (n = 13,404)
- *71% female, 29% male*
- *39% 18-24 years old, 39% 25-34 years old, 23% 35-44 years old*
- *79% HIV negative, 21% HIV positive*
- *59% HIV-positive participants not currently on ART*
- *43% HIV-positive participants not virally suppressed taken from a random sample of approximately 75 HIV positive participants per community at baseline*

Group C Standard of Care (n = 12,399)
- *70% female, 30% male*
- *40% 18-24 years old, 38% 25-34 years old, 22% 35-44 years old*
- *78% HIV negative, 22% HIV positive*
- *65% HIV-positive participants not currently on ART*
- *46% HIV-positive participants not virally suppressed taken from a random sample of approximately 75 HIV positive participants per community at baseline*

Assignment Method
Communities in Zambia and South Africa (k = 21) were matched in seven sets consisting of three communities. The three communities in each of the seven sets were randomly assigned to 1 of 3 study groups: Group A Intervention (k = 7, n = 12,671), Group B Intervention (k = 7) n = 13,404), or Group C Standard of Care (k = 7), n = 12,399).

Comparison
For the Group C Standard of Care, communities traveled to government clinics and received the usual care, such as HIV testing and ART offered according to local guidelines.

Relevant Outcomes Measured
- The HIV incidence rate was measured in the population cohort as the number of participants who were HIV-negative at enrollment and seroconverted between 12- and 36-months post-initiation of the intervention, divided by the person-years of follow-up.
- Viral suppression was measured as <400 copies of HIV RNA per milliliter at the 24-month follow-up visit of the population cohort.

Participant Retention
Because participant retention is not a criterion for the Structural Interventions chapter, the Prevention Research Synthesis project does not evaluate that information.

Significant Findings on Relevant Outcomes

- HIV incidence was significantly lower among Group B Intervention participants compared to Group C Standard of Care participants (adjusted Rate Ratio = 0.70, 95% CI= 0.55, 0.88, p = 0.006).
    - Among participants aged 25 years or older, HIV incidence was significantly lower among Group B Intervention participants compared to Group C Standard of Care participants (adjusted Rate Ratio = 0.58, 95% CI = 0.43, 0.76, p = 0.001).

Considerations

Additional significant positive findings on non-relevant outcomes

- None reported

Non-significant findings on relevant outcomes

† There were no statistically significant intervention effects for HIV incidence (adjusted rate ratio = .93; 95% CI: 0.74 – 1.18; p = 0.51) or viral suppression for Group A (adjusted rate ratio = 1.16; 95% CI: 0.99 – 1.34; p = 0.07) when compared to the Group C Standard of Care; therefore, the Group A intervention (combination prevention while offering universal ART) did not meet PRS criteria.

- Among participants aged 18 to 24 years, HIV incidence was not significantly lower among Group B intervention participants compared to Group C Standard of Care participants (adjusted rate ratio = 0.92, 95% CI = 0.70, 1.20, p = 0.49). *
- There were no significant intervention effects for viral suppression between the Group B Intervention and Group C Standard of Care.

Negative findings

- None reported

Other related findings

- Since the Group A and B interventions were identical from mid-2016 when local guidelines changed to universal ART, a post-hoc analysis was conducted for Groups A and B combined, compared with Group C Standard of Care. This analysis showed a significant reduction in HIV incidence when Groups A & B were combined (adjusted Rate Ratio = 0.81, 95% CI = 0.66, 0.99, p = 0.04). As noted earlier, there were no significant intervention effects for HIV incidence or viral suppression when Group A was tested alone against the Group C Standard of Care. †
- The estimated percentage of all HIV-positive adults in the community who were receiving ART at the end of the trial was 81% in Group A and 80% in Group B.

Implementation research-related findings

- None reported

Process/study execution-related findings

- None reported

Adverse events

- None reported

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*Information provided by the author

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