

TERMS OF REFERENCE : SECTION 3

Project title: Uptake and acceptability of a HIV Combination Prevention Intervention package among young people in Zambia and South Africa

Lead Research Organisation: Zambart.

LRO Partners: Desmond Tutu TB Centre Stellenbosch, London School of Hygiene and Tropical Medicine, Imperial College.

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Problem statement:

HIV remains an urgent problem for young people, particularly young women in sub-Saharan Africa who are disproportionately affected. While combination prevention is viewed as the most appropriate approach to HIV prevention, to date there have been no large-scale community-level trials to measure the success of combination HIV prevention among adolescents.

This proposed study of combination prevention in adolescents will be added onto the large HPTN 071/PopART trial in Zambia and South Africa that aims to evaluate a combination prevention strategy, including universal test and treat in a population of 1 million people.

Purpose:

This study will be a community randomised comparison of a combination prevention approach combined with youth targeted interventions, where necessary. It will evaluate the acceptability and uptake of a community-level combination HIV prevention package that includes universal HIV testing and treatment, (UTT) among adolescents aged 15-20 years.

Target group:

Adolescents 15 to 20 years old.

Setting:

Western Cape, South Africa (9 communities) and Zambia (12 communities).

Scope of Work:

This study will be nested in the HPTN071/PopART trial, which is already being conducted in 21 communities in Zambia and Western Cape Province of South Africa. The communities have been randomly arranged into 7 triplets based on geography and HIV prevalence. Within these triplets the 3 communities are randomly assigned to the three study arms.

- Arm A: communities receive a strategy comprising of an offer of universal HIV testing and provision of combination prevention package including condom distribution and male circumcision as well as linkage into care for all HIV positive individuals. This is combined with the offer of universal ART irrespective of CD4 count.
- Arm B: communities receive a strategy comprising of an offer of universal HIV testing and provision of combination prevention package including condom distribution and male circumcision as well as linkage into care for all HIV positive individuals. This is combined with ART provision according to national guidelines for all individuals testing HIV positive.
- Arm C (control arm): communities receive the current standard of care with respect to HIV counselling, HIV prevention strategies and ART provision.

This study will:

- Assess whether the current HIV combination prevention package (PopART intervention) reaches adolescents;
- Implement additional youth-specific activities as determined by the outcomes of the needs assessment and assess the effectiveness of these additional interventions to increase uptake of HIV prevention;
- Measure whether the combination prevention package, including youth-specific interventions, increases:
 - Uptake of HIV testing and retesting
 - Linkage to care
 - Antiretroviral therapy (ART) screening and uptake
 - ART adherence and retention in care
 - Uptake of PMTCT
 - Uptake of voluntary medical male circumcision
 - Safer sexual risk behavior
- Document the effect of the interventions on social networks, stigma, alcohol use, gender based violence, HIV identity, other HIV prevention options and community morale.
- Measure the additional cost of the youth-specific activities and model the overall cost per infection averted; and
- Inform policy and practice for HIV prevention in adolescents.