

# A scaled up structural intervention program versus current national HIV prevention program

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<b>Registration date</b> 11/06/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/01/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

HIV is a virus that attacks the immune system and weakens the body's ability to fight infections and disease. Early results from a recent three-country study in southern Africa suggest that a package of interventions that address social and economic factors, including gender inequality, gender violence, and poor access to education, can lower HIV infection rates among young women, who bear the brunt of new HIV infections in the region. The Government of Botswana intends to introduce these interventions nationwide. This study will enable the country to do this in a way that measures its impact and allows for adjustments at key steps along the way. The aim is to reduce the number of new HIV infections in Botswana by a combination of behaviour change communication (audio dramas) and structural changes (improved access of young women to poverty eradication programmes).

### Who can participate?

All people aged 15 and above resident in the participating districts in Botswana

### What does the study involve?

At regular intervals the participating districts are randomly allocated to introduce the intervention until all districts have crossed over to receive the intervention. The intervention involves activities that focus on the empowerment of women aged 15-29, arranging existing local health, social and other services in favor of the most vulnerable, especially young women, and using an audio-drama to stimulate community-wide discussion about gender violence and HIV risk. HIV prevalence among women aged 15-29 is measured at the start of the study and on completion of the intervention in year 4.

### What are the possible benefits and risks of participating?

Young women may benefit from being at lower risk of HIV, and fewer infections of young women will mean fewer infections passed on to young men.

### Where is the study run from?

CIET Trust (Botswana)

When is the study starting and how long is it expected to run for?  
August 2013 to July 2018

Who is funding the study?  
Government of Botswana

Who is the main contact?  
Prof. Neil Andersson

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Neil Andersson

**Contact details**  
CIET, Universidad Autónoma de Guerrero  
Acapulco  
Mexico  
CP39640

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
CIET CD2-INSTRUCT

## Study information

**Scientific Title**  
Inter-ministerial National Structural Intervention Trial: a stepped wedge trial of HIV prevention in Botswana

**Acronym**  
INSTRUCT-Botswana

**Study objectives**  
To study whether a scaled up structural intervention program decreases human immunodeficiency virus (HIV) prevalence over 30 months compared to the current national HIV prevention program, using a stepped wedge design.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Not provided at the time of registration

**Study design**

Stepped-wedge cluster randomised controlled trial, district as unit of allocation, intervention and analysis

**Primary study design**

Interventional

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

Community

**Study type(s)**

Prevention

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

HIV prevention

**Interventions**

30 districts randomly assigned to intervention groups, stratified by development status and HIV prevalence.

The structural intervention: Activities focus on empowerment of women aged 15-29 years, concerting existing local health, social and other services in favor of the most vulnerable, especially young women, and developing an enabling environment using an audio-drama to stimulate community-wide discussion about gender violence and HIV risk.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

HIV sero-prevalence among women aged 15-29 years. Outcome measured on completion of the intervention in year 4 and compared with the baseline of the second group of communities

**Secondary outcome measures**

Protective knowledge, attitudes, subjective norms, intention to change, agency, discussion of prevention, behaviours related to gender violence and HIV risk and prevention

**Overall study start date**

01/08/2013

**Completion date**

31/07/2018

## **Eligibility**

**Key inclusion criteria**

For intervention:

All districts will be eligible for randomization to receive the intervention. In each intervention district, all residents aged 15 and above will be eligible. Different intervention activities will address different groups of the population, who will be free to decide whether to take up the offer:

1. Economic empowerment including skills workshop and government structural support offered to women aged 18-24, especially those not in school or employment.
2. Audio-drama discussion groups will be offered to all ages and both sexes
3. Concerting of service provision will include discussions with all local service-providers (all eligible)

For impact surveys: Young women and young men aged 15-29 years in 10 clusters (random selection of enumeration areas from the recent census) in each of five intervention and five non-intervention districts.

**Participant type(s)**

All

**Age group**

Adult

**Lower age limit**

15 Years

**Sex**

Both

**Target number of participants**

300,000 people living in five intervention districts

**Key exclusion criteria**

For intervention: No district will be excluded. Within each intervention district, people not resident in the district will be excluded to minimize contamination (by people in other districts hearing of the interventions and wishing to take advantage of them, thus diluting the measured impact).

For impact surveys: Field workers will not interview or take blood samples from anyone they judge to be unable to give informed consent or to understand the survey questions.

**Date of first enrolment**

01/08/2013

**Date of final enrolment**

31/07/2018

## Locations

**Countries of recruitment**

Botswana

Mexico

**Study participating centre**

CIET, Universidad Autónoma de Guerrero

Acapulco

Mexico

CP39640

## Sponsor information

**Organisation**

The Autonomous University of Guerrero (Universidad Autónoma de Guerrero) (Mexico)

**Sponsor details**

Centro de Investigación de Enfermedades Tropicales (CIET)

Acapulco

Mexico

CP39640

**Sponsor type**

University/education

**ROR**

<https://ror.org/054tbkd46>

## Funder(s)

**Funder type**

Government

**Funder Name**

Government of Botswana (Botswana)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	30/10/2018		Yes	No
<a href="#">Other publications</a>	Analysis of young women's social networks	01/06/2020	20/01/2023	Yes	No
<a href="#">Other publications</a>	Survey of young women	01/06/2018	20/01/2023	Yes	No