

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

| | | |
|--|--|--|
| Submission date 13/05/2013 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 11/06/2013 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 20/01/2023 | Condition category 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? |
|------------------------------------|---|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 30/10/2018 | | Yes | No |
| Other publications | Analysis of young women's social networks | 01/06/2020 | 20/01/2023 | Yes | No |
| Other publications | Survey of young women | 01/06/2018 | 20/01/2023 | Yes | No |