

Acquired immune deficiency syndrome (AIDS) prevention through reduced choice disability

Submission date 12/06/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 13/08/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/09/2013	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Acquired immune deficiency syndrome (AIDS) prevention in favour of the choice disabled: a randomised controlled trial to reduce human immunodeficiency virus (HIV) risk in southern Africa

Acronym
NOCHOICE

Study objectives

Why a trial is needed:

Almost all interventions currently addressing acquired immune deficiency syndrome (AIDS) are geared for those who can act on their prevention decisions. Although a recent randomised controlled trial (RCT) showed reduction of sexual violence with an economic intervention, it is not known how this might affect human immunodeficiency virus (HIV) rates. There is little research on complex interventions in AIDS prevention, yet all countries in the region implement multiple intervention prevention programmes.

The issue:

Reduce HIV risk through reducing choice disablement or ameliorating its worst effects on AIDS through sensitisation of local AIDS prevention efforts and economic empowerment. After implementation in Botswana, the eventual objective is a 10-country controlled trial to demonstrate the impact of concerting public services in favour of the choice disabled, primary prevention of sexual violence and economic empowerment.

Please note that as of 24/02/2009 this record has been amended to include a new end date; the initial information at time of registration was as follows:

Initial anticipated end date: 01/09/2012

At this time, the acronym was also changed from 'BART2' to 'NOCHOICE'.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 24/02/2009:

1. Botswana Ministry of Health gave approval on the 26th August 2008 (ref: PPME-13/18/1 Vol IV (4))
2. Namibia Ministry of Health and Social Services gave approval on the 22nd July 2008 (ref: 17/3 /3AP)
3. Swaziland Ministry of Health gave approval on the 26th August 2008 (ref: MH/599B)

Study design

Cluster randomised controlled four-arm factorial trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS)

Interventions

Four interventions, alone and in combination:

1. Optimises local private-public networks to reduce HIV risk in favour of those who cannot implement their prevention choices
2. Sexual violence education through schools, youth groups, granny groups, church groups and local radio, geared to generate endogenous community-specific solutions to reduce sexual violence

3. Focuses on empowerment of the choice disabled through the Organisational Workshop approach
4. Promotion of male circumcision

The interventions will run concurrently for three years, with a follow-up survey in the fourth year.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The 2007 baseline and follow-up survey in year 4 will measure reduced sexual violence and HIV infection in women aged 18 - 29 years. Follow-up of a male (18 - 29 years) cohort established in 2008 will establish the impact of promoting male circumcision (MC), alone and in combination with other activities.

All will be measured in the fourth year.

Key secondary outcome(s)

All will be measured in the fourth year:

1. Protective knowledge
2. Attitudes
3. Subjective norms
4. Intention to change
5. Agency
6. Discussion of prevention
7. Practices related to sexual violence

Likely side effects of the intervention include reduced criminal delinquency and substance abuse.

Completion date

30/08/2012

Eligibility**Key inclusion criteria**

79 nationally representative clusters (100 - 120 households) randomly selected (from population census) enumeration areas.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

Does not comply with inclusion criteria

Date of first enrolment

01/09/2008

Date of final enrolment

30/08/2012

Locations**Countries of recruitment**

Botswana

Canada

Eswatini

Namibia

Study participating centre

1 Stewart Street

Ottawa

Canada

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Sponsor information**Organisation**

International Development Research Centre (IDRC) (Canada)

ROR

<https://ror.org/0445x0472>

Funder(s)**Funder type**

Research organisation

Funder Name

International Development Research Centre (IDRC) (Canada)

Alternative Name(s)

Centre de recherches pour le développement international, IDRC.CRDI, le Centre de recherches pour le développement international (CRDI), el Centro Internacional de Investigaciones para el Desarrollo (IDRC), International Development Research Centre: IDRC, El Centro Internacional de Investigaciones para el Desarrollo, IDRC, CRDI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/08/2013		Yes	No