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

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

#### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

#### Type(s)

Scientific

#### Contact name

Dr Neil Andersson

#### Contact details

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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 though 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 inital 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

K1N 6N5

# 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?
<u>Protocol article</u>	protocol	29/08/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025 1	11/11/2025	No	Yes