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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/08/2008	**Overall study status** Completed	
Last Edited 02/09/2013	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

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

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/09/2008

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

Age group
Other

Sex
Both

Target number of participants
79 clusters

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)

Sponsor details
PO Box 8500
Ottawa
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Sponsor type
Research organisation

Website
http://www.idrc.ca/index_en.html

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

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	29/08/2013		Yes	No