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Home based human immunodeficiency virus (HIV) testing intervention in a rural community in South Africa

Submission date	Recruitment status	[X] Prospectively registered
25/08/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/08/2013	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
Good Start III: An effectiveness study of a home based voluntary counselling and testing (VCT) intervention in a rural community in South Africa

Study objectives
Provision of home based human immunodeficiency virus (HIV) testing in intervention communities will result in increased HIV test acceptance, accelerated access to care and treatment for individuals testing HIV positive and reduced HIV risk behaviour compared to control communities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Council Ethics Committee approval granted on the 25th May 2009 (ref: EC09-003)

Study design
Community randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

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

Interventions
Offer of door to door VCT by trained community counsellors in a rural sub-district in KwaZulu-Natal South Africa. The total duration of the intervention will be 12 to 18 months. There is no cohort follow up. Outcomes will be assessed in a cross-sectional community based post-intervention survey in intervention and control arms 12 to 18 months following the start of the intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Rates of HIV testing will be assessed in the post-intervention community survey in intervention and control arms. Questions to assess this outcome will include history of VCT, number of tests in the past year, and location/s where VCT was obtained. For each community, age and gender specific testing rates will be calculated.

Secondary outcome measures
1. Disclosure of HIV status: the post-intervention survey questions will ask about disclosure of serostatus to spouses, sexual partners and family members. The proportion of respondents reporting each disclosure type will be calculated.
2. Access to HIV care and treatment for individuals who are HIV positive: the post-intervention survey will have questions on access to HIV treatment for individuals testing HIV positive within the previous 12 to 18 months
3. HIV risk behaviour: HIV risk behaviours will be assessed using standardised questionnaire items that have been used previously in international settings. Risks include recent (one-month), intermediate (three-month) and longer-term (one-year), and lifetime measures of sexual behaviour (by partner gender, type of activity, condom use), using partner-by-partner elicitation (up to 5 individuals). We will include measures of relationship type (spouse, friend, casual acquaintance, commercial, etc). Algorithms will be developed to produce easily understood outcome measures (e.g., frequency of unprotected intercourse; proportion of acts using a condom).
4. Uptake of AZT and nevirapine amongst HIV positive pregnant women: women who have delivered a baby within the year prior to the post-intervention survey will be asked if they knew their HIV status and if they received AZT and nevirapine during pregnancy and labour

Overall study start date
14/09/2009

Completion date
15/12/2011

Eligibility

Key inclusion criteria
1. Individuals over 18 years of age, either sex
2. Living in a household in an intervention cluster
3. Providing informed consent. Children under the age of 18 will require parental consent for participation in the study and acceptance of VCT.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
8 intervention clusters with 100 households in each cluster

Key exclusion criteria
1. Inability to understand the intervention and provide informed consent
2. Children under 18 without parental consent

Date of first enrolment
14/09/2009

Date of final enrolment
15/12/2011

Locations

Countries of recruitment
South Africa

Study participating centre
Health Systems Research Unit
Cape Town
South Africa
7505

Sponsor information

Organisation
Centers for Disease Control and Prevention (South Africa)

Sponsor details
c/o Global AIDS Program/South Africa
877 Pretorius St.
Arcadia
Pretoria
South Africa
0083

Sponsor type
Government

Website
http://www.cdc.gov/

ROR
https://ror.org/042twtr12

Funder(s)

Funder type
Government

Funder Name
Centers for Disease Control and Prevention Grants through President's Emergency Fund for AIDS Relief (PEPFAR) (USA) (grant refs: 1U51-PS000729-01; 1U2GPS001137-01; 5U2GPS001137-02)

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?
Results article	results	13/06/2013		Yes	No