

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

Submission date
25/08/2009

Recruitment status
No longer recruiting

☒ Prospectively registered

☐ Protocol

Registration date
01/09/2009

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
14/08/2013

Condition category
Infections and Infestations

☐ Individual participant data

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