ISRCTN53353725 https://doi.org/10.1186/ISRCTN53353725

Home-based voluntary human immunodeficiency virus (HIV) counselling and testing in Zambia

Submission date	Recruitment status	[_] Prospectively registered
19/03/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2020	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
A community randomised trial on acceptability, feasibility, preventive impact and cost effectiveness of home-based voluntary human immunodeficiency virus (HIV) counselling and testing in Zambia

Study objectives
Home-based voluntary human immunodeficiency virus (HIV) counselling and testing is more acceptable and gives higher uptake than clinic-based voluntary counselling and testing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Zambia Research Ethics Committee gave approval on the 26th March 2009 (ref: 007-12-08)
2. Regional Ethical Committee of Western Norway gave approval on the 26th February 2009 (ref: 024.09)

Study design
Community-randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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)

Interventions
A baseline survey will be conducted in 28 villages. 14 villages will be randomised to intervention (home-based voluntary HIV counselling and testing [VCT]) and a follow up survey will be conducted in both intervention and control villages after 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Uptake and acceptability of VCT, measured at baseline and with follow-up surveys.

Secondary outcome measures
Changes in sexual risk behaviour, stigma and life-events, measured at baseline and with follow-up surveys.

Overall study start date
23/03/2009

Completion date
31/12/2009

Eligibility

Key inclusion criteria
Household members (either sex) aged 16 years and above in the 28 selected villages

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1400

Total final enrolment
1694

Key exclusion criteria
1. Aged below 16 years
2. Not ordinary household members
3. People without full mental capacity
4. People under influence of alcohol or illegal drugs

Date of first enrolment
23/03/2009

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Zambia

Study participating centre
University of Zambia
Lusaka
Zambia
PO BOX 50110

Sponsor information

Organisation
Swedish International Development Cooperation Agency (SIDA) (Sweden)

Sponsor details
Valhallavägen 199
Stockholm
Sweden
105 25

Sponsor type
Research organisation

Website
http://www.sida.org

ROR
https://ror.org/01fn7me06

Funder(s)

Funder type
Research organisation

Funder Name
Swedish International Development Cooperation Agency (SIDA) (Sweden)

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	01/06/2013	30/12/2020	Yes	No