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Randomised trial of human immunodeficiency virus (HIV)/sexually transmitted infection (STI) prevention in Zimbabwean youths

Submission date	Recruitment status	[_] Prospectively registered
06/04/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/05/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/05/2009	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
RO1 MH 65570

Study information

Scientific Title
The Regai Dzive Shiri Project: a cluster randomised controlled trial to determine the effectiveness of a multi-component community-based human immunodeficiency virus (HIV) prevention intervention for rural youths in Zimbabwe

Acronym
The Regai Dzive Shiri Project

Study objectives
A community-based intervention targeting young people, adults and clinics will be effective in reducing rates of human immunodeficiency virus (HIV), herpes simplex virus type 2 (HSV-2) and pregnancy among young people in rural Zimbabwe.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University College London (UCL) Ethics Committee approved on the 5th November 2002 (ref: 02/0140)
2. Medical Research Council of Zimbabwe approved on the 22nd October 2002 (ref: MRCZ/a/983)
3. London School of Hygiene and Tropical Medicine Ethics Committee approved on the 10th September 2002 (ref: 891)

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
HIV prevention and reproductive health

Interventions
The intervention is theoretically based in social learning theory and the stages of change model. It aims to achieve change in societal norms within communities. The intervention has three

components:
1. The youth programme for in- and out-of-school youths, is delivered by carefully selected and trained Zimbabwean school leavers in the year between leaving school and starting university. These school leavers work as volunteers and go to live and work in the rural communities for 8 - 10 months of the year. They act both as role models for young people and as a bridge between adults and youths within communities. These professional peer educators (PPEs) use well-structured, theoretically based materials which they deliver in a highly participatory way. The programme is delivered to all students and out-of-school youths who wanted to take part and not just those enrolled in the trial cohort.
2. The programme for parents and community stakeholders is a 22 session community-based programme that aims to improve knowledge about reproductive health, to improve communication between parents and their children and to improve community support for adolescent reproductive health. The community component arose from focus group discussions held with parents during the feasibility study. Parents lamented the collapse of traditional communication structures and acknowledged their lack of communication skills. Interestingly young people also said that they struggled to communicate with their parents especially about reproductive health issues and that they saw this as an important barrier to staying safe.
3. The programme for nurses and other staff working in rural health clinics aims to improve accessibility of clinics for out-of-school youth.

These three components are highly integrated. For example, nurses trained to run the clinic intervention also run sessions within the youth and parents programmes and in so doing publicise the accessibility of the clinic. PPEs help run the 'youth corners' at the clinics and help facilitate sessions in the parents programme. Integrating the three components in this way makes them mutually supportive and reinforcing. By living and working so closely with the community it is hypothesised that the PPEs are able to change the norms of that community through challenging the norms that may be detrimental to adolescent reproductive health and reinforcing those that are beneficial.

No specific intervention was introduced in the deferred intervention arm, but standard HIV prevention activities were implemented through the District AIDS Action Committees by local and international governmental and non-governmental organisations across both early and deferred intervention communities. The project provided voluntary HIV counselling and testing through rural health clinics in all 30 communities on one day a month for the duration of the study. Uptake and acceptability was recorded.

The intervention was introduced in 2003 in the early implementation arm and in 2007 in the delayed implementation arm. The intervention ran in the early implementation arm for four years from 2003 - 2007. The final evaluation survey was conducted in 2007 after 4 years of intervention delivery. The final evaluation survey was a representative population based survey of 18 - 22 year olds living in six purposively selected enumeration areas in the 30 study communities - i.e., 180 enumeration areas in all.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

1. HIV prevalence
2. HSV-2 prevalence

Measured in 2007 after 4 years of intervention delivery.

Secondary outcome measures
1. Pregnancy
2. Reported sexual behaviour
3. Knowledge and attitudes related to HIV acquisition and reproductive health

Measured in 2007 after 4 years of intervention delivery.

Overall study start date
31/03/2003

Completion date
31/07/2007

Eligibility

Key inclusion criteria
1. For intervention: young people (aged 12 - 24 years, either sex) living in 15 early intervention implementation trial communities
2. For participation in final evaluation survey: all 18 - 22 year olds living in selected enumeration areas in trial communities

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
Intervention recipients n = 12,000 - 16,000; final evaluation survey n = 6,000

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
31/03/2003

Date of final enrolment
31/07/2007

Locations

Countries of recruitment

England

United Kingdom

Zimbabwe

Study participating centre
Centre for Sexual Health and HIV Research
London
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute of Mental Health (NIMH) (USA) (ref: RO1 MH-65570-01 and RO1 MH-65570-4S)

Alternative Name(s)
Instituto Nacional de la Salud Mental, Mental Health NIMH, NIMH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

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	study design and baseline results	01/10/2008		Yes	No