

Promoting sexual and reproductive health among high school adolescents in Limpopo province, South Africa (PREPARE): culture-specific norms, attitudes and beliefs

Submission date 26/06/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/07/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/09/2014	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The main aim of this study is to develop new and innovative programmes for the promotion of healthy sexual practices among adolescents in their early adolescence (in school grades corresponding to the age groups 12-14 years) using schools as a medium to deliver these programmes.

Who can participate?

Boys and girls in Grade 8 attending public high schools in Limpopo Province. 2400 adolescents were recruited. The students were from 24 high schools in Limpopo Province. No specific exclusion criteria were used.

What does the study involve?

Half of the schools were randomly allocated to receive the intervention (programmes for the promotion of healthy sexual practices) in 2013, and the other half served as control schools. Participants completed a questionnaire in August 2013 before the intervention. The school-based intervention took place for five weeks and questionnaires were completed again at the completion of the intervention, October 2013.

Intervention- Key Health Promotion Behaviours:

Delay onset of sexual intercourse for those that have not had sex

Carry condoms when planning to have sex.

Consistent correct condom use for those already sexually active.

Teachers were provided with the teachers manual to assist with preparation Learners were also provided with a workbook for self-assessment and group assessment.

What are the possible benefits and risks of participating?

There will be no immediate or direct benefits to participants. We hope that the results will influence policy makers, leading to benefits on a larger scale.

There is little potential risk associated with participation. It is possible that some questions in

the questionnaire may make students feel uncomfortable or emotional. Research staff will be trained to manage these students or refer them for professional help.

Where is the study run from?

The University of Limpopo, South Africa.

When is the study starting and how long is it expected to run for?

The study started in July 2012 and completed in March 2013.

Who is funding the study?

European Commission (EC) Health research program (under the 7th Framework Program).

Who is the main contact?

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Study website

<http://prepare.b.uib.no/prepare-brochure/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

241945

Study information

Scientific Title

Promoting sexual and reproductive health among high school adolescents in Limpopo province, South Africa (PREPARE): culture-specific norms, attitudes and beliefs: a randomised controlled trial

Acronym

PREPARE

Study objectives

Culture-specific beliefs is a key driver to the spread of HIV/AIDS among young people in Limpopo, South Africa.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MRE/HS/21/2011:CR

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet**Health condition(s) or problem(s) studied**

HIV and culture-specific norms, attitudes and beliefs

Interventions

Half of the schools have been randomly allocated to receive the intervention in 2013, and the other half will serve as control schools.

Twelve schools were selected to participate in the teachers training. Fifteen teachers attended the training workshop. The workshop duration was three days. The Proximal programme objectives of this intervention are:

Key Health Promotion Behaviours:

1. Delay onset of sexual intercourse for those who have not had sex
2. Carry condoms when planning to have sex
3. Consistent correct condom use for those already sexually active

Teachers were provided with the teachers manual to assist with preparation. Learners were also provided with a workbook for self-assessment and group assessment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

To measure changes in culture-specific beliefs amongst adolescence.

1. Baseline questionnaire: 01-16 August 2012: Fieldworkers were involved in data collection, and the coordinator supervised the data collection procedures. 24 schools around Mankweng circuit were involved in data collection, 12 intervention, 12 control. The Mankweng main road was used to divide the intervention and the control schools. Grade 8 students, between the age of 12 and 15, were involved in data collection. The learners selected were as follows, intervention 1877 and control 1298.

2. Classroom- based intervention: 20 August - 21 September 2012

3. Follow-up questionnaire: 10-20 October 2012

Data collection took place in 24 schools, 12 intervention and 12 control.

Secondary outcome measures

Reduction in HIV/AIDS prevalence amongst adolescents

Overall study start date

01/07/2012

Completion date

30/03/2013

Eligibility**Key inclusion criteria**

1. Grade 8 high school students between 12 and 19 years
2. Having parental consent for participation
3. Willing to participate in the study

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

2400

Key exclusion criteria

1. Students who are not attending school at the time of recruitment or who are not in Grade 8 at one of the selected high schools

2. Students of whom parents decline to consent to their child's participation
3. Students who are not willing to participate

Date of first enrolment

01/07/2012

Date of final enrolment

30/03/2013

Locations

Countries of recruitment

South Africa

Study participating centre

P/Bag x 1106

Polokwane

South Africa

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Sponsor information

Organisation

University of Limpopo (South Africa)

Sponsor details

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Sponsor type

University/education

Website

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ROR

<https://ror.org/017p87168>

Funder(s)

Funder type

Government

Funder Name

European Commission (EC) Health research program (under the 7th Framework Program) (Grant Agreement number: 241945)

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	18/01/2014		Yes	No