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Preventing sexual risk behavior and partner violence among adolescents in Cape Town

Submission date
07/01/2013

Recruitment status
No longer recruiting

Registration date
13/02/2013

Overall study status
Completed

Last Edited
05/02/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The PREPARE Project is a study among adolescents in Cape Town (South Africa) which aims to prevent HIV and intimate partner violence (IPV). The project aims to develop, implement and evaluate a comprehensive school-based HIV and IPV prevention programme. The study's findings will help to improve adolescent health and inform the development of school adolescent health policies.

Who can participate?
Boys and girls in Grade 8 attending public high schools in the Western Cape Province. We will recruit between 3000 and 4000 adolescents. The students will be from 42 high schools in the Western Cape Province. No specific exclusion criteria will be used.

What does the study involve?
PREPARE is a school-based HIV and violence prevention programme. Half of the schools have been randomly allocated to receive the intervention in 2013, and the other half will serve as control schools. Participants will complete a questionnaire in February- March 2013 before the intervention. They will complete questionnaires again at the completion of the intervention six months later (August-September 2013, and in February-March 2014.
The intervention consists of 4 components:
1. After-school clubs to prevent sexual risk behavior and partner violence and to promote healthy relationships;
2. A school-based health service;
3. Local police officers involvement in a school safety programme;
4. A photography project to involve students in improving the school safety programme.
The primary outcomes are: 1. Sexual debut; 2. Number of partners; 3. Consistent use of condoms. Secondary outcomes are 1. Live births and terminations of pregnancy among female participants, as counts per school, over a three year time period; 2. Intimate partner violence perpetration and victimization.

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 Cape Town, Department of Psychiatry and Mental Health, Adolescent Health Research Unit (South Africa).

When is the study starting and how long is it expected to run for?
The schools were recruited in 2012 and recruitment of students will start with the new school year, in January 2013. Students will be enrolled in the study for 12-14 months. Live births and terminations of pregnancy as counts per school among female participants will be measured 3 years after the programme is completed, using health service records.

Who is funding the study?
The PREPARE study is funded by the EC Health research program (under the 7th Framework Program). Grant Agreement number 241945.

Who is the main contact?
Professor Catherine Mathews
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Study website
http://prepare.b.uib.no/prepare-brochure/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HREC/Ref: 268/2010

Study information

Scientific Title
Preventing sexual risk behavior and intimate partner violence among adolescents in Cape Town

Acronym
PREPARE project

Study objectives
The intervention will impact on students behavior. We hypothesize that the study will lead to:
1. An increase of the age of participants' sexual debut
2. A decrease of participants' number of partners
3. An increase of consistent use of condoms among participants

Publications are related to phase 1 and 2 of the PREPARE project:

Zuch M, Mason-Jones A J, Mathews C, Henley L. (2012). Changes to the law on consent in South Africa: implications for school-based adolescent sexual and reproductive health research. BMC International Health and Human Rights, 12:3.

Bastien S, Mason-Jones AJ, De Koker P, Mmbaga EJ, Ross DA, Mathews C. (2012). Herpes Simplex Virus Type 2 infection as a biomarker for sexual debut among young people in sub-Saharan Africa. A literature review. International journal of STD and AIDS, Nov;23(11):761-6.

Mason-Jones AJ, Crisp C, Momberg M, Koech J, De Koker P, Mathews C. A systematic review of the role of school-based health care in adolescent sexual, reproductive and mental health. Syst Rev. 2012 Oct 26;1(1):49. [Epub ahead of print]

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Cape Town, Faculty of Health Sciences Research Ethics Committee, 13 October 2011, HREC: Ref: 268/2010

The study has been granted permission from the Western Cape Department of Basic Education, and the Provincial and City Departments of Health for the school-based health service.

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

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
Sexual behaviour; Reproductive health; Intimate partner violence

Interventions
The schools in the intervention arm of the study will receive the intervention, consisting of 4 parts, in 2013. Students in comparison schools will benefit from a delayed intervention programme. One year later, students in these schools will get access to the same materials and teachers, nurses and other staff will receive the same kind of training as was provided for intervention schools.

The intervention comprises four parts and will take place over a period of 5-6 months:
1. A programme of sessions delivered by trained facilitators in after-school clubs on the school premises. The programme aims to prevent intimate partner violence and promote healthy relationships among adolescents. The programme will be conducted over approximately 10-15 afternoons, covering one or two sessions each afternoon, delivered by a trained facilitator. In addition, one session will be delivered by police officers and one by health workers. The sessions are focused on healthy relationships and prevention of HIV and IPV.
2. A school-based preventive health service delivered by a service provider who will provide one drop-in for one and a half hours every week during academic term times in each of the intervention schools. The service will be offered in the afternoons after school has ended, between the hours of 2:30 and 4:00. The service will be primarily available for Grade 8 students in our sample who will be offered an appointment at the service and will be prioritized in service provision. However the service will also be available to all year groups (12 to 20 year olds) who attend the schools.
3. The involvement of local police officers in school safety, to fulfil three responsibilities: crime prevention, education related to violence prevention and the law, and mentoring for those exposed to violence. The police offers will be available at the school at least one afternoon per week to fulfill their educational and mentoring responsibilities. In addition, they will be available for the school at times arranged between them and the school safety committee.
4. A Photovoice project, consisting of 8 sessions, to involve students in improving the safety of their school environment, conducted after school hours on the school premises.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Measures of behavior:
1. Sexual debut

2. Number of partners
3. Consistent use of condoms

Secondary outcome measures
1. Live births and terminations of pregnancy among female participants, as counts per school, over a three year time period
2. Intimate partner violence perpetration and victimization

Overall study start date
16/01/2013

Completion date
30/04/2014

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
Child

Lower age limit
12 Years

Upper age limit
19 Years

Sex
Both

Target number of participants
3,000 to 4,000

Key exclusion criteria
Exclusion criteria at school level
1. Privately run high schools
2. High schools with the peer education programme
3. High schools participating in other similar randomized controlled trials

Exclusion criteria at student level
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 childs participation
3. Students who are not willing to participate

Date of first enrolment
16/01/2013

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
South Africa

Study participating centre
University of Cape Town
Rondebosch
South Africa
7700

Sponsor information

Organisation
European Commission Health Research Programme (Belgium)

Sponsor details
Directorate-General for Research and Innovation
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Sponsor type
Government

Website
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ROR
https://ror.org/00k4n6c32

Funder(s)

Funder type

Government

Funder Name
European Commission Health Research Program (Belgium) - 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?
Results article	results	04/07/2015		Yes	No