ISRCTN18195524 https://doi.org/10.1186/ISRCTN18195524

Evaluation of the PEPFAR/USAID Community Responses program in KwaZulu-Natal, South Africa

Submission date
12/01/2017

Recruitment status
No longer recruiting

Registration date
25/01/2017

Overall study status
Completed

Last Edited
24/02/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Gender norms (roles men and women are usually expected to fulfill in society) can be harmful to a woman's health. Unfair and unequal gender expectations can lead to gender based violence (GBV), putting women at risk of being infected with human immunodeficiency virus (HIV). Community response (CR) programs (programs developed to make community level changes) seek to change harmful gender norms and improve health behaviors. Combining HIV testing centers with other health intervention and education programs can help improve access to healthcare as well as reduce HIV infections. Areas with high rates of HIV and GBV in South Africa have implemented CR programs in order to combine education about gender violence with HIV prevention. The aim of this study is to assess a CR program in order to see how well it works at preventing HIV, reducing gender based violence risks and improving the overall health of the community.

Who can participate?
Adults living in the communities where the CR program is taking place who are able to read in English or in the local language.

What does the study involve?
Participants are randomly selected from the areas that receive the CR program. The CR program aims to prevent HIV and sexual and gender-based violence, and includes the Stepping Stones curriculum, community engagement, and awareness-raising around GBV and HIV. Participants fill out four surveys regarding the CR program, one at the beginning of the program and then a further three times at ten month intervals. These surveys assess the knowledge they have gained about HIV, healthcare services, gender norms and sexual based violence in order to see how well the CR program is working.

What are the possible benefits and risks of participating?
There are no direct benefits to participants, but the program can help prevent HIV and GBV. The

main risks of participation are possible breaches of participant confidentiality, as well as exposure to sensitive questions about sex, HIV and other STIs, and GBV during the study interviews. As a result, some of the participants may become uncomfortable or upset.

Where is the study run from?
The study is run from the Population Council (USA) and MatCH Research Unit at the University of the Witwaterstrand (South Africa) and takes place in informal settlements in eThekwini and Ugu in KwaZulu-Natal Province (South Africa)

When is the study starting and how long is it expected to run for?
September 2015 to August 2019

Who is funding the study?
United States Agency for International Development (USA)

Who is the main contact?
Stephanie Psaki

Contact information

Type(s)
Scientific

Contact name
Dr Stephanie Psaki

ORCID ID
https://orcid.org/0000-0002-0332-7653

Contact details
Population Council
One Dag Hammarskjold Plaza
New York
United States of America
10017

Type(s)
Scientific

Contact name
Dr Julie Pulerwitz

Contact details
Population Council
4301 Connecticut Avenue NW, Suite 280
Washington, DC
United States of America
20008

Type(s)
Scientific

Contact name
Dr Paul Hewett

Contact details
Population Council
4301 Connecticut Avenue NW, Suite 280
Washington, DC
United States of America
20008

Type(s)
Scientific

Contact name
Dr Mags Beksinska

Contact details
MatCH Research Unit
University of Witwatersrand
34 Essex Terrace
2nd Bldg, Ground Floor
Westville
Durban
South Africa
3692

Additional identifiers

Protocol serial number
PC741

Study information

Scientific Title
Evaluation of the PEPFAR/USAID Community Responses program among adults in informal settlements in KwaZulu-Natal, South Africa

Study objectives
The primary goal of the proposed Community Responses (CR) program evaluation is to determine the extent to which the United States Agency for International Development (USAID) /South Africa-funded CR program (and particularly the effects of community-based HIV/gender-based violence (GBV) prevention programming, which include a component to create demand for related services) is effective at reducing HIV and sexual and GBV risk, and improving related service utilization.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Population Council Institutional Review Board, 05/10/2016, ref: protocol #741
2. The Human Research Ethics Committee (HREC), University of Witwatersrand, 11/01/2017, ref: R14/49

Study design
Multi-centre longitudinal cohort study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
HIV/AIDS, Sexual and gender-based violence (SGBV)

Interventions
All participants are living in communities where the Community Responses program will take place during follow-up, although the timing of program start-up has been randomly staggered. The program, implemented by CCI in South Africa, includes several overlapping components:
1. Standardized HIV prevention interventions
2. Structural interventions for gender norms for HIV and GBV prevention
3. SGBV prevention activities
4. Community dialogues

Adult men and women living in intervention (Community Responses program) communities where the intervention are randomly selected and surveyed at approximate 10 month intervals (baseline, 10, 20 and 30 months). Information will be collected on the following topics: demographic and household socio-economic status, HIV knowledge and use of services, sexual behaviour, gender norms and sexual relationship power, and experience and perpetration of gender-based violence. This information will be used to determine whether the intervention (Community Responses program) is effective in achieving the key outcomes of interest, and to understand any variations in effects between groups.

Routine program monitoring data collected by the organization implementing the intervention is also collected in order to assess the level of exposure to the program within each community.

Intervention Type
Behavioural

Primary outcome(s)
1. Percentage of participants who have obtained the results of an HIV test within the previous six months is assessed using self-reported data from a questionnaire administered at baseline and three follow-up rounds, with 10 months between each round
2. Percentage of HIV-positive participants who have accessed HIV care and treatment services within the previous six months is assessed using self-report data from a questionnaire administered at baseline and three follow-up rounds, with 10 months between each round
3. Percentage of participants reporting using a condom at last sex is measured using the self reported data from a questionnaire administered at baseline and three follow-up rounds, with 10 months between each round
4. Percentage of participants reporting consistent condom use with a partner of unknown HIV

status in the last six months measured using the self reported data from a questionnaire administered at baseline and three follow up rounds, with 10 months between each round
5. Percentage of participants reporting perpetrating or experiencing physical violence within the previous six months is measured using the self reported data from a questionnaire administered at baseline and three follow up rounds, with 10 months between each round
6. Percentage of participants reporting perpetrating or experiencing sexual violence within the previous six months is measured using the self reported data from a questionnaire administered at baseline and three follow up rounds, with 10 months between each round
7. Percentage of participants who hold positive norms regarding gender based violence is measured using the Gender-Equitable Men (GEM) Scale at baseline and three follow up rounds, with 10 months between each round
8. Percentage of participants who hold equitable norms regarding the roles of women and men is measured using the Gender-Equitable Men (GEM) Scale at baseline and three follow up rounds, with 10 months between each round

Key secondary outcome(s))
No secondary outcome measures

Completion date
14/08/2019

Eligibility

Key inclusion criteria
1. Men aged 18-35
2. Women aged 18-24
3. Living in selected communities
4. Can read English or local language
5. Willing and able to give informed consent
6. Willing to participate in three additional interviews
7. Willing to provide research staff with an identity number, address, phone number, and fingerprint scan while participating in the study
8. Agrees to participate in the study for the duration of up to three years; do not reasonably foresee moving out of the study area within that time

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
24 years

Sex
All

Total final enrolment
1528

Key exclusion criteria
1. Lives outside of study area or expects to move within next 3 years
2. Outside of age range
3. Cannot read in English or local language

Date of first enrolment
23/01/2017

Date of final enrolment
15/03/2017

Locations

Countries of recruitment
South Africa

United States of America

Study participating centre
Population Council
One Dag Hammarskjold Plaza
New York
United States of America
10017

Study participating centre
University of the Witwaterstrand
MatCH Research Unit
34 Essex Terrace
2nd Bldg, Ground Floor
Westville, 3629
Durban, South Africa
Durban
South Africa
3629

Sponsor information

Organisation
Population Council

ROR
https://ror.org/03zjj0p70

Funder(s)

Funder type
Not defined

Funder Name
United States Agency for International Development

Alternative Name(s)
U.S. Agency for International Development, Agency for International Development, USAID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/03/2022	24/02/2023	Yes	No
Dataset		27/01/2021	24/02/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes