

Evaluation of the NISITU Program: a study to determine the effect of a gender attitudes and gender based violence program for adolescents in Nairobi, Kenya

Submission date 09/08/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/08/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/08/2018	Condition category Other	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In Kenya, adolescent girls living in urban slums face considerable risks and challenges that affect their safety, health, and general well-being. A 2013 survey, for example, highlighted high levels of exposure to sexual violence and exploitation for girls ages 15 to 19, including sexual harassment, physical, sexual and emotional violence, and unwanted and transactional sex. More than 60% of respondents indicated that wife-beating was acceptable in at least one circumstance and more than a third had experienced some form of gender based violence. Despite growing attention on the importance of engaging men and boys in violence prevention efforts, these programs frequently exclude boys and little is known about their effectiveness. Male engagement programs tend to neither consider girls' and women's needs in the design, nor measure their ability to create positive change for women and girls. Rigorous program design and evaluation is needed to ensure that programs are accountable to women and girls. Since 2008, the Council and partners in Kenya have developed and evaluated an intervention that combines safe spaces, financial and health education, and savings accounts for marginalized girls to build their social, health, and economic assets using a multi-sectoral approach. With support from the NoVo Foundation, this program was brought to more than 8,000 girls in four different urban settings in Kenya. Until recently, these interventions have focused exclusively on girls, engaging community members and parents to gain support for the interventions themselves, but not as program participants. This study seeks—for the first time—to engage boys and men in girl-centered interventions, to determine what works best for girls as well as for boys and men. The study will test what the impact of a health and economic empowerment program, with a strong focus on gender norms transformation, has on both boys and girls. In addition, the study will look at whether the girls are better off when both boys and girls in a community participate in such a program, as opposed to only girls.

Who can participate?

Girls aged 10-19 and boys/young men aged 10-24 living in the participating neighborhoods in Nairobi, Kenya

What does the study involve?

The three neighborhoods are randomly allocated to three groups, two receiving interventions (one with girls only, one with girls and boys/young men) and a control group (receiving no interventions). The intervention includes weekly sessions led by a mentor in the community. The intervention lasts 9 months for boys/young men and 12 months for girls. The participants are put in groups of 20-25 that are segmented by age and sex. The content of the weekly sessions includes sexual and reproductive health topics, financial education, life skills and gender norms /power. In addition the participants are facilitated to open savings accounts for adolescents. Finally, participants ages 18 and above have their savings matched and are given entrepreneurship training. The total period of follow up is one year.

What are the possible benefits and risks of participating?

The benefits to participants include being part of study that will make a contribution toward healthier relationships among adolescents and a reduction in gender-based violence. The potential risks are slight discomfort in answering sensitive questions about experiences with sexual activity and gender-based violence.

Where is the study run from?

Population Council (Kenya)

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

August 2017 to December 2019

Who is funding the study?

NoVo Foundation

Who is the main contact?

Dr Karen Austrian

Study website

<http://www.popcouncil.org/research/nisitu-testing-the-effects-of-implementing-girl-centered-programming>

Contact information

Type(s)

Public

Contact name

Dr Karen Austrian

ORCID ID

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Contact details

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00500

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Evaluation of the NISITU Program: a quasi-experimental study to determine the effect of a gender attitudes and gender based violence program for adolescents in Nairobi, Kenya

Acronym

NISITU

Study objectives

Implementing a gender transformative program with both girls and boys in the same community will lead to better results for girls as compared to only implementing the program with girls. The program will also lead to better outcomes on gender attitudes and experience of sexual and gender based violence for girls overall.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Population Council Institutional Review Board, 16/10/2017, Protocol 829
2. AMREF-Kenya Ethics in Science and Research Committee, 11/01/2018, Protocol 407-2017

Study design

Interventional quasi-experimental study

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Gender attitudes, or to what extent the respondent ascribes to equitable attitudes about roles between males and females, and experience of sexual and gender based violence

Interventions

There are three arms, two receiving interventions (one with girls only, one with girls and boys /young men) and a control (no interventions). The three neighborhoods were randomly assigned to a study arm. The research assistants and implementers are not blinded to the study arm assignment. The study is a single-centre study with all three arms being neighborhoods in the same area of Nairobi, Kenya.

The intervention will include weekly sessions led by a mentor in the community. The intervention will last 9 months for boys/young men and 12 months for girls. The participants will be put in groups of 20-25 that are segmented by age and sex. The content of the weekly sessions will include sexual and reproductive health topics, financial education, life skills and gender norms/power. In addition the participants will be facilitated to open savings accounts for adolescents. Finally, participants ages 18 and above will have their savings matched and given entrepreneurship training. The total period of follow up is one year.

Intervention Type

Behavioural

Primary outcome measure

Gender attitudes, measured using a survey at baseline and endline (15 months)

Secondary outcome measures

1. Experience of sexual and gender based violence, measured using a survey at baseline and endline (15 months)
2. Perpetration of sexual and gender based violence, measured using a survey at baseline and endline (15 months)

Overall study start date

01/08/2017

Completion date

31/12/2019

Eligibility

Key inclusion criteria

1. Girls 10-19 years old residing in study communities
2. Boys/young men 10-24 years old residing in study communities

Participant type(s)

Healthy volunteer

Age group

Mixed

Sex

Both

Target number of participants

5500

Key exclusion criteria

1. Reside outside the study area
2. Outside the specified age range

Date of first enrolment

01/04/2018

Date of final enrolment

15/05/2018

Locations**Countries of recruitment**

Kenya

Study participating centre**Population Council**

Avenue 5, 3rd Floor

Rose Avenue

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Sponsor information**Organisation**

Population Council

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.popcouncil.org>

ROR

<https://ror.org/03zjj0p70>

Funder(s)**Funder type**

Charity

Funder Name

NoVo Foundation

Results and Publications**Publication and dissemination plan**

The plan is to publish the study protocol in 2019 and then the results in 2020 after the endline has been completed. These will be publications in the peer-reviewed literature. In addition the trialists will publish the results in the form of policy briefs so that policy makers and program implementers will have be able to read the results of the study in a digestible manner.

Intention to publish date

01/03/2020

Individual participant data (IPD) sharing plan

The data will be shared in a publicly available repository – the Adolescent Data Hub - <http://www.popcouncil.org/girlcenter/research/hub>. The baseline data will be published in early 2019 and the endline data will be published in the third quarter of 2020. Data will be available upon request from the PI through the portal for the first year after the study is completed and access will be given unless the proposed analysis is already being conducted by study investigators. After that, they will be available without request. Data available will be de-identified and will be stripped of any indicators (names, GPS coordinates, etc) that contain identifying information.

IPD sharing plan summary

Stored in repository