Adolescent Girls Initiative - Kenya

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|-------------------------------|--|-----------------------------|--|--|
| 18/12/2015 | | [X] Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 24/12/2015 | Completed | [X] Results | | |
| Last Edited 18/01/2024 | Condition category Urological and Genital Diseases | Individual participant data | | |

Plain English summary of protocol

Background and study aims

Many adolescent girls in Kenya face considerable risks and vulnerabilities that affect their education status, health, and general well-being. They are at high risk of early marriage, teenage pregnancy, early sex, unprotected sex, non-consensual sex and sexually transmitted diseases such as HIV. They also have limited income-earning opportunities, are very likely to be illiterate (not able to read and write) and often experience violence and social isolation. The Adolescent Girls Initiative–Kenya (AGI-K) is a study that tests different combinations of initiatives (packages of interventions) in health, violence prevention, wealth creation and education to see which one of these lead to the biggest improvement in their lives. These interventions will be implemented for two years. This study will compare the impact of four different packages of interventions, including a cost-effectiveness component (testing how expensive they are), in order to assess if and how intervening in early adolescence will impact girls' life chances.

Who can participate?

Girls aged between 11-14 and living in one of two marginalized areas of Kenya – either the Kibera slums in Nairobi or the Wajir County in Northeastern Kenya.

What does the study involve?

The goal of AGI-K is to test combinations of packages of intervention that cover violence prevention, education, health and wealth creation. The violence prevention intervention involves establishing a committee in the community which includes religious and community leaders, parents, teachers and young men and women. The group members work together to identify key issues that lead to girls being under-valued and at risk of violence. A contract is then developed which includes an action plan to address these issues. The education intervention is a cash transfer scheme where girls are offered a cash payment as long as they have a 80% school attendance record. They also have their fees paid and are given school kits. The health intervention involves girls meeting in groups once a week. Each group has a female mentor that leads discussions on health, life skills and nutrition. The wealth creation intervention involves teaching about finances, and includes the girls opening bank accounts and a small cash incentive to put in practice what they are being taught. Each girl in Kibera is randomly allocated to receiving one of the following four package combinations:

- 1. Violence prevention
- 2. Violence prevention and education
- 3. Violence prevention, education and health

4. Violence prevention, education, health and wealth creation In Wajir, all the girls within a particular village is randomly allocated to one of the four groups above. Each girl in the study is followed for two years. The effect of the program is assessed using data from surveys.

What are the possible benefits and risks of participating? Participants may benefit from the interventions. There are no risks involved...

Where is the study run from?

The study is led by Population Council, based in the Nairobi office. Research partners include the African Population and Health Research Centre (APHRC) and Itad. The interventions are run by Save the Children in Wajir and Plan International in Kibera.

When is study starting and how long is it expected to run for? January 2014 to December 2019

Who is funding the study?

Department for International Development (UK)

Who is the main contact?

1. Dr Karen Austrian (scientific) kaustrian@popcouncil.org

2. Dr Eunice Muthengi (public) emuthengi@popcouncil.org

Study website

http://www.popcouncil.org/research/adolescent-girls-initiative-action-research-program

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers AEARCTR-0000962

Study information

Scientific Title

Establish the combination of multi-sectoral interventions with the greatest impact on the reproductive health of young adolescent girls in Wajir County and Nairobi Slums.

Acronym

AGI-K

Study objectives

To determine the incremental effect produced by layering multi-sectoral interventions to improve the reproductive health of adolescent girls in marginalized communities.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Population Council Institutional Review Board, 10/09/2014, ref: 661
- 2. AMREF Ethical and Scientific Review Committee, 19/11/2014, ref: P143/2014

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Adolescent reproductive health

Interventions

The goal of the Adolescent Girls Initiative (AGI-K) is to test multi-sectoral packages of interventions in four sectors: violence prevention, education, health and wealth creation. The violence-prevention intervention is a community-level intervention that uses the community dialogues and contracts strategy based on the UNDP/Concern Worldwide model. The education intervention is a conditional cash transfer (CCT) based on 80% attendance over the course of a term. The health intervention will follow the Council's Safe Spaces model in which girls meet in groups once a week under the guidance of a female mentor from the community. The wealth-creation intervention is composed of financial education, which is delivered during Safe Spaces meetings, as well as savings through individual bank accounts (Nairobi) or home banks (Wajir) and a small savings incentives. Using a randomized controlled trial design, researchers will conduct a rigorous impact evaluation of the program. Randomization to intervention packages is at the individual level in Kibera and at the

village level in Wajir. The following packages of interventions will be tested:

- 1. Violence prevention
- 2. Violence prevention and education
- 3. Violence prevention, education and health
- 4. Violence prevention, education, health and wealth creation

The study will follow girls for the two-year intervention period and for two years after completion of the intervention. Using both quantitative and qualitative methods, the program evaluation will examine the impact of the intervention packages while identifying the causal mechanisms driving that impact. Surveys will cover a wide range of topics, including education history, self-esteem, social networks, attitudes and behaviors related to gender, work and savings activity, nutrition status, literacy and numeracy skills, cognitive function, sexual and reproductive health knowledge, marriage history, and sexual behavior.

Intervention Type

Behavioural

Primary outcome measure

- 1. Increased age at first birth
- 2. Increased age at first sex
- 3. Increased age at first marriage

All outcomes to be assessed after 2 years (from the time of the baseline survey) and then again after 4 years using survey data.

Secondary outcome measures

- 1. Violence Prevention: Decreased experience of gender-based violence and improved gender norms related to violence
- 2. Education: Increased mean grade of schooling and increased rate of primary school completion
- 3. Health: Increased knowledge on sexual and reproductive health and improved decision-making skills
- 4. Wealth creation: Increased knowledge on financial education, increased saving and increased participation in income generating activities

All assessed after 2 years and again after 4 years using survey data.

Overall study start date

20/01/2014

Completion date

31/12/2019

Eligibility

Key inclusion criteria

- 1. Girls aged between 11 and 14 years
- 2. Residing within selected study sites
- 3. Not in boarding school at the time of the listing and/or at the time of the baseline survey

Participant type(s)

Other

Age group

Child

Lower age limit

11 Years

Upper age limit

14 Years

Sex

Female

Target number of participants

For the Nairobi sub-study the target is 2,400 girls in intervention site and 600 girls in the external control site. For the Wajir sub-study the target is a total of 2,160 girls with 80 clusters and 27 girls per cluster.

Total final enrolment

4537

Key exclusion criteria

- 1. Girls who were in boarding school at the time of enrollment
- 2. Girls who were no longer residing in the study site at the time of enrollment

Date of first enrolment

24/02/2015

Date of final enrolment

02/06/2015

Locations

Countries of recruitment

Kenya

Study participating centre Population Council, Nairobi Office

Ralph Bunche Rd Nairobi City Kenya P.O. Box 17643-00500

Study participating centre African Population and Health Research Center

Manga Cl Nairobi Kenya P.O. Box 10787-00100

Sponsor information

Organisation

Population Council

Sponsor details

General Accident Insurance HSE 2nd Floor Nairobi Kenya P.O. Box 17643-00500

Sponsor type

Research organisation

Website

http://www.popcouncil.org/

ROR

https://ror.org/03zjj0p70

Funder(s)

Funder type

Government

Funder Name

Department for International Development

Alternative Name(s)

Department for International Development, UK, DFID

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

We plan to publish the study protocol in 2016

Intention to publish date

30/06/2016

Individual participant data (IPD) sharing plan

Not expected to be made available

IPD sharing plan summary

Not expected to be made available

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------|-------------------------------------|--------------|------------|----------------|-----------------|
| <u>Protocol article</u> | protocol | 01/03/2016 | 12/01/2021 | Yes | No |
| Results article | | 24/11/2021 | 26/11/2021 | Yes | No |
| Results article | | 07/02/2022 | 08/02/2022 | Yes | No |
| Results article | longer term (after 4 years) effects | 13/02/2022 | 18/01/2024 | Yes | No |