Evaluation of adolescent girls empowerment program (AGEP) in Zambia

Submission date 18/02/2016	Recruitment status No longer recruiting	Prospectively registered		
		[X] Protocol		
Registration date 04/03/2016	Overall study status Completed	[] Statistical analysis plan		
		[X] Results		
Last Edited 23/04/2025	Condition category Urological and Genital Diseases	Individual participant data		

Plain English summary of protocol

Background and study aims

Vulnerability amongst adolescent girls in developing countries is a major problem. These girls often marry early and have a high risk of developing sexually transmitted infections (including HIV) and unintended pregnancies. In Zambia, many girls from poor backgrounds grow up in social isolation and many do not receive appropriate health information and services that ensure a healthy transition from girlhood to womanhood. Many drop out of school, are unable to find employment, lack the ability to make independent decisions, and are not being reached by existing programs for young people. The Adolescent Girls Empowerment Program (AGEP) is a new program which has been designed to find the best way to improve girls' social, health, and economic resources so that they can stay in school longer, avoid early marriage and delay sexual activity to prevent unintended pregnancy, HIV and other STIs. The core component of the program involves weekly mentor-led, group meetings (safe space groups), in which girls are trained on a range of health and financial topics, as well as being given the opportunity to simply talk and build strong relationships with other girls in their community. The program also involves providing the girls with vouchers entitling girls to health services provided by facilities in the community and individual savings accounts in order to help with financial aspects. The aim of this study is to assess the effectiveness of the different elements of the AGEP.

Who can participate?

Girls aged between 10 and 19 who are from disadvantaged backgrounds and live in the study area.

What does the study involve?

Participating communities are randomly allocated to one of four groups. Those in the first group attend weekly mentor-led meetings for two years. These meetings are run by slightly older women from the community and provide training about health, life skills and financial issues, as well as providing a "safe space" to simply talk. Those in the second group attend the mentor-led meetings as well as being given health vouchers which they can use to access health services provided in their community. Those in the third group attend the mentor-led meetings, receive health vouchers and also are given access to girl-friendly individual savings accounts developed in partnership with a Zambian financial institution. Those in the fourth group continue as normal and so not receive any of the AGEP services. At the start of the study and then again after one, two, three and four years, participants are interviewed in order to determine their sexual, marital and financial status.

What are the possible benefits and risks of participating?

Participants who receive the AGEP services may benefit from being able to make new friends, learning important life skills and improving access to health and banking services. All participants also benefit from being tested for HIV and genital herpes, which could help them to change their sexual behaviour if they do have either of these infections. Risks of participating are small and include being asked sensitive questions about their behaviour and the stress involved with being tested for sexually transmitted infections and the potential of testing positive. There is also some very small risk that their HIV and Herpes infection status may become known by others in their communities.

Where is the study run from?

Rural and urban communities within four of the ten provinces of Zambia.

When is the study starting and how long is it expected to run for? November 2011 to September 2018

Who is funding the study? UK Department for International Development (UK)

Who is the main contact? Dr Paul C. Hewett phewett@popcouncil.org

Study website http://www.popcouncil.org/research/adolescent-girls-empowerment-program

Contact information

Type(s) Scientific

Contact name Dr Paul C. Hewett

Contact details

Population Council 4301 Connecticut Avenue Washington, D.C. United States of America 20008 +1 20 2237 9419 phewett@popcouncil.org

Type(s)

Public

Contact name Dr Karen Austrian **Contact details** General Accident House Ralph Bunche Rd Nairobi Kenya 17643 +254 20 2713 480 kaustrian@popcouncil.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers Population Council Protocol 581

Study information

Scientific Title

Cluster Randomized Evaluation of the Impact of the Adolescent Girls Empowerment Program (AGEP) in Zambia on key demographic and sexual reproductive health outcomes

Acronym

AGEP

Study objectives

The Adolescent Girls Empowerment Programme improves key demographic and sexual reproductive health outcomes, including reducing early sexual initiation and early marriage and birth, improving educational attainment, increasing contraceptive use and reducing HIV and HSV-2 acquisition.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Population Council Institutional Review Board, 12/11/2012, ref: 581 2. University of Zambia Biomedical Ethics Board, 12/04/2013, ref: 002-12-12

Study design

Four-arm cluster randomized controlled trial

Primary study design Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

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 reproductive health, HIV and HSV-2

Interventions

Participating communities are randomly allocated to one of four groups, who each receive different components of the AGEP intervention or no intervention (control).

Interventions group 1: Participants receive the safe-spaces mentor-led sessions only. Interventions group 2: Participants receive the safe-spaces mentor-led sessions and health vouchers.

Interventions group 3: Participants receive the safe-spaces mentor-led sessions, health vouchers and a savings account.

Control group: Participants receive no aspects of the AGEP intervention.

The intervention components are given for a period of two years. The intervention is staggered by site, so not all of the ten sites start and end at the same dates. The study conducted a baseline assessment of the research sample prior to study intervention and will follow participants for a total of four years across five total rounds of observation (including baseline). Two years of observation during the intervention roll-out and two years after to explore longerterm impacts.

Core components of the AGEP intervention:

1. Safe spaces: The core of the safe spaces component, implemented in partnership with YWCA Zambia, is a weekly girls' group meeting in which 20 to 30 girls get together with a mentor—a young woman from their community—for short training sessions on a variety of topics as well as a chance to discuss the events of the past week. These ongoing, stable group sessions serve two critical functions: 1) they build a platform in which girls meet and can be reached with a variety of interventions and educational topics, and 2) they build social assets, including friendships, trusting relationships, and self-esteem, that have a positive influence on other dimensions of their lives—their livelihood and health. The safe spaces meetings have become an integral part of what girls expect in their lives and can be sustained in the long term via cultural change. The safe spaces groups are structured in two age cohorts, 10–14 and 15–19, with additional groups for married girls, in order to reach girls with the appropriate programming across the course of adolescence. During their weekly group meetings, girls are trained on a range of health and financial topics, and they have time to simply talk and build strong relationships with other girls in their community.

2. Health voucher: In partnership with the Ministry of Community Development, Mother Child Health (MCDMCH) – now Ministry of Health (MOH) – and InSTEDD, the Council has developed an

e-Health Voucher that AGEP participants can redeem for a package of health services at contracted public and private health providers. The services covered by the voucher include basic wellness exams as well as age-appropriate sexual and reproductive health services. Service providers use text messages to interact with a web-based system that logs and issues authorization for the services in real-time. The Council trains providers at participating clinics in the provision of adolescent-friendly health services and conducts ongoing monitoring and quality-assurance visits at participating clinics. Providers are reimbursed per service provided based on pre-approved rates.

3. Savings account: The Population Council worked in partnership with the National Savings and Credit Bank (NatSave) and Making Cents International to develop the Girls Dream Savings Account that AGEP participants are able to open. The NatSave account has a very low minimum opening balance, and any amount can be deposited or withdrawn with no fee. While girls are able to make deposits on their own, in order to adapt to the Zambian legal minimum age of 18 for opening accounts, girls select a cosignatory—a woman aged 18 or older—to assist with account opening and withdrawals. This financial mentor can be the girl's mother, however the participant has the option to choose another female in her life who she trusts (i.e., older sister, teacher, aunt, neighbor).

Intervention Type

Behavioural

Primary outcome measure

1. Percentage ever had sex is measured using participant survey interviews at baseline, 1 year, 2 years 3 years and 4 years (endline)

2. Percentage ever married is measured using participant survey interviews at baseline, 1 year, 2 years 3 years and 4 years (endline)

3. Percentage ever given birth is measured using participant survey interviews at baseline, 1 year, 2 years 3 years and 4 years (endline)

4. Percentage completed grade 7 & grade 9 is measured using participant survey interviews at baseline, 1 year, 2 years 3 years and 4 years (endline)

5. Percentage ever using modern contraception is measured using participant survey interviews at baseline, 1 year, 2 years 3 years and 4 years (endline)

6. HIV prevalence is measured using household based HIV rapid tests at baseline, 2 years and 4 years (endline)

7. HSV-2 prevalence is measured using household based specimen collection and laboratory testing using Kalon ELISA antibody test at baseline, 2 years and 4 years (endline)

Secondary outcome measures

1. Percentage of girls with positive self-esteem is measured using participant survey interviews at 1 year, 2 years 3 years and 4 years (endline)

2. Percentage of girls reporting physical or sexual violence is measured using participant survey interviews at 1 year, 2 years 3 years and 4 years (endline)

3. Percentage of girls who used a condom at last sex is measured using participant survey interviews at 1 year, 2 years 3 years and 4 years (endline)

4. Average number of friends is measured using participant survey interviews at 1 year, 2 years 3 years and 4 years (endline)

5. Literacy is measured using a sentence-based reading assessment at 1 year, 2 years 3 years and 4 years (endline)

6. Cognition is measured using Raven's progressive matrices assessment at 1 year, 2 years 3 years and 4 years (endline)

7. Numeracy is measured using select questions from the Zambian grade 3, 5 and 7 textbooks at 1 year, 2 years 3 years and 4 years (endline)

8. Average savings per capita per year is measured using participant survey interviews at 1 year, 2 years 3 years and 4 years (endline); for the savings account arm this is also measured from monitoring and evaluation data collected from the banks for the same years

Overall study start date

01/11/2011

Completion date

30/09/2018

Eligibility

Key inclusion criteria

1. Female

- 2. Between the ages of 10-19 at baseline
- 3. Living in selected clusters of the intervention or control arms
- 4. Socio-economically vulnerable
- 5. Never married at baseline

Participant type(s) All

Age group Other

Sex Female

Target number of participants 6,893 targeted participants; 180 clusters; 38 participants per cluster

Total final enrolment 4661

Key exclusion criteria

1. Unwilling or unable to provide informed consent

2. Had guardians who were unwilling or unable to provide informed consent

Date of first enrolment 01/09/2013

Date of final enrolment 31/03/2014

Locations

Countries of recruitment Zambia **Study participating centre Population Council** Plot 3670, No 4. Mwaleshi Road Olympia Park, Lusaka Zambia 10101

Sponsor information

Organisation Population Council

Sponsor details One Dag Hammarskjold Plaza New York United States of America 10017 +1 21 2339 0500 pubinfo@popcouncil.org

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

Planned publication of mid-term evaluation results and final evaluation of results.

Intention to publish date 30/09/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/05/2017		Yes	No
Results article	results	17/03/2020	03/04/2020	Yes	No
<u>Results article</u>		22/07/2020	23/04/2025	Yes	No