GirlsRead! Zambia DREAMS Innovation

Submission date 27/01/2017	Recruitment status No longer recruiting
Registration date 02/02/2017	Overall study status Completed
Last Edited 16/08/2022	Condition category Infections and Infestations

[] Prospectively registered

- [X] Protocol
- [] Statistical analysis plan
- [X] Results
- [] 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 leave school early and have a high risk of developing sexually transmitted infections (including HIV) and unintended pregnancies. In Zambia, many girls from poor backgrounds do not receive appropriate health information and services that ensure a healthy transition from girlhood to womanhood. Evidence suggests that providing this female education, particularly secondary school, may act as a 'social vaccine' to prevent the spread of HIV. The primary aim of this project is to determine whether an e-reader based program in combination with a in a safe space platform with a community engagement component will improve literacy skills among adolescent girls, enhance critical thinking skills, improve results on the Grade 7 Composite Exam, and increase the number of girls progressing to secondary school.

Who can participate?

Females who are currently enrolled in Grade 7 in a selected primary school are eligible to participate.

What does the study involve?

Participating schools are randomly allocated to one of three groups. Those in the first group take part in community engagement activities; safe space groups (in groups of 15-20 who meet weekly to participate in discussions about important issues); and receive e-readers, with content that showcases alternative views of gender roles, such as women in political office, and will address issues, such as violence against women, that mentors can raise with their groups to foster discussion about the impact of discrimination and harassment on girls' and women's schooling and health, including protecting themselves from HIV. Those in the second group part in community engagement activities and safe space groups only. Those in the third group complete no additional activities. At the start of the study and 12 months later participants in all groups complete surveys to assess their literacy skills and whether they decide to go to secondary school.

What are the possible benefits and risks of participating?

Benefits to the girl include access to the books on the e-reader, participation in the safe space groups, which aim to provide girls with connections with peers and mentors, and improved education and reproductive health outcomes. Survey participants who have experienced violence will benefit from the availability of referrals. Generally, there are no more than minimal mental and physical health risks for those participating in the study. There is a small risk that confidentiality may be breached. There is also a small possibility that other members of the community, peers or adults, may attempt to steal the e-readers.

Where is the study run from? The study is run from Population Council Zambia and takes place in the districts of Lusaka, Ndola and Chingola (Zambia)

When is study starting and how long is it expected to run for? January 2017 to September 2018

Who is funding the study? U.S. Department of State (USA)

Who is the main contact? Dr Barbara Mensch bmensch@popcouncil.org

Contact information

Type(s) Scientific

Contact name Dr Barbara Mensch

ORCID ID http://orcid.org/0000-0003-1073-9135

Contact details Population Council

1 Dag Hammarskjold Plaza New York, NY United States of America 10017 +1 212 339 0640 bmensch@popcouncil.org

Type(s)

Scientific

Contact name Ms Nicole Haberland

Contact details

Population Council 1 Dag Hammarskjold Plaza New York, NY United States of America 10017 +1 212 339 0676 nhaberland@popcouncil.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 780

Study information

Scientific Title

GirlsRead! Zambia: A novel approach to bolstering literacy and increasing progression to secondary school

Study objectives

The primary aim of this project is to determine through a randomized evaluation design whether an e-reader intervention embedded in a safe space platform with a community engagement component will bolster literacy skills among adolescent girls, enhance critical thinking skills, improve results on the Grade 7 Composite Exam, and increase progression to secondary school.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Population Council IRB, 01/06/2017, ref: 780 2. ERES Converge IRB Zambia, 11/16/2016, ref: 2016-Oct-014; amendment approved 01/25/2017

Study design

Cluster randomised controlled trial

Primary study design Interventional

Secondary study design Cluster randomised trial

Study setting(s) Other

Study type(s) Prevention

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Interventions

Selected schools will be randomly assigned to arms by generating a random number for each school in Microsoft Excel, then sorting by that random number and assigning arms A, B, or C in sequence.

Arm A: Community engagement activities, safe space groups and e-readers. Arm A sessions will devote approximately 30-45 minutes to the safe space curriculum and 30-45 minutes to discussing content on the e-reader.

Arm B: Community engagement activities and safe space groups. Arm B sessions will devote approximately 30-45 minutes to the safe space curriculum and 30-45 minutes to group review of school material in order to determine if time devoted to reading material considered to be entertaining improves literacy skills and performance on the Grade 7 Composite Exam more than time devoted to academic review

Arm C: No activities

Community engagement activities will involve adults who influence girls' opportunities and attitudes toward education to create a supportive environment for the safe space groups, and foster gender equality, literacy development, and secondary school attendance and completion.

Safe space groups will include 15 to 20 girls and will meet weekly, outside of school hours. Groups will be led by female mentors who will facilitate using participatory, learner-centered pedagogies and cover such topics as the right to education, gender-based violence, financial literacy, sexual/ reproductive health (SRH), HIV, and advocacy.

E-readers designed for sub-Saharan Africa will be layered onto this safe spaces model with each girl being given her own e-reader for the duration of the project. In the groups with e-readers, additional time will be spent reading and discussing books together. To ensure equal exposure in terms of time, the girls in the safe-spaces-only group will have homework or other academic support for the same number of minutes. Mentors will be compensated for their time. Content on e-readers will showcase alternative views of gender roles, such as women in political office, and will address issues, such as violence against women, that mentors can raise with their groups to foster discussion about the impact of discrimination and harassment on girls' and women's schooling and health, including protecting themselves from HIV.

Each safe space session is expected to last approximately 60-90 minutes. Holding the "dosage" of the safe space groups constant will allow us to reject the alternative explanation that simply more time in safe space groups could explain improved outcomes.

At 12 months, all participants will complete an endline survey. Additionally, with authorization from the Zambian Ministry of Education, the Grade 7 Composite Exam (the primary school leaving exam) scores will be collected for all girls interviewed at baseline who sat for the exam.

Intervention Type Behavioural

Primary outcome measure

Literacy skills are measured using an assessment developed in English for 6-16 year olds by the People's Action for Learning (PAL) Network for Anglophone African countries at baseline and 12 months.

Secondary outcome measures

1. Time spent reading is measured using a structured questionnaire by asking participants how much time they usually spend reading, how much time they spent in the last day and how much time in the last 7 days at baseline and 12 months

2. Score on the Grade 7 Composite exam is recorded for all participants interviewed at baseline who are sitting for the exam in October 2017

3. Progression to secondary school is assessed using a structured questionnaire by asking participants whether they are enrolled in secondary school at 12 months

4. Numeracy skills are measured using an assessment developed in English for 6-16 year olds by the People's Action for Learning (PAL) Network for Anglophone African countries at baseline and 12 months

5. Attitudes and knowledge:

5.1. Gender attitudes are measured through administering GEM scale questions to participants as well as additional questions about women's rights at baseline and 12 months

5.2. Reproductive health knowledge is measured through a series of questions to participants on HIV and pregnancy risk as well as knowledge about where services can be obtained at baseline and 12 months

5.3. Self-efficacy is measured through a generalized self-efficacy scale administered to participants as well as additional questions on expressing opinion and confidence asking questions at baseline and 12 months

6. Sexual behaviour is assessed using ACASI at baseline and 12 months

Exploratory Outcomes:

1. Critical consciousness is measured through five questions to participants on women's experiences in Zambia regarding gender equity in employment, abuse from male partners, early marriage, and speaking out about injustice at baseline and 12 months

2. Perpetration of school violence is measured through five questions about participant name calling, teasing, stealing, physical violence etc. directed at other students at baseline and 12 months

Overall study start date

03/01/2017

Completion date 30/09/2018

Eligibility

Key inclusion criteria

1. Female

2. Girls enrolled in Grade 7 (last year of primary school in Zambia)

Participant type(s) Other

Age group

Child

Sex Female

Target number of participants

The study will have a sample size of approximately 1152 participants: 36 schools —12 per arm — and approximately 32 participants per school

Key exclusion criteria

1. Not enrolled in Grade 7 2. Male

Date of first enrolment 31/01/2017

Date of final enrolment 30/03/2017

Locations

Countries of recruitment Zambia

Study participating centre Population Council Zambia Plot 3670 No. 4 Mwaleshi Road Olympia Park Lusaka Zambia 10101

Sponsor information

Organisation JSI Research & Training Institute, Inc. (JSI)

Sponsor details 44 Farnsworth Street Boston, MA United States of America 02210 +1 617 482 9485 dreamsfundsmanager@jsi.com **Sponsor type** Industry

ROR https://ror.org/05pgv5n44

Funder(s)

Funder type Government

Funder Name U.S. Department of State

Alternative Name(s) United States Department of State, Department of State, State Department, U.S. State Department, DOS, USDOS

Funding Body Type Government organisation

Funding Body Subtype National government

Location United States of America

Results and Publications

Publication and dissemination plan

The findings of our study will be disseminated in a variety of venues and will reach diverse audiences. Publications in peer-reviewed journals will be pursued in the areas of demography, development and education.

Intention to publish date

30/04/2017

Individual participant data (IPD) sharing plan

The current 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?
<u>Protocol file</u>	version 3	26/06/2018	16/08/2022	No	No
<u>Results article</u>		01/09/2021	16/08/2022	Yes	No