

Research initiative to support the empowerment of girls

Submission date 02/03/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/03/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/12/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Vulnerability amongst adolescent girls in developing countries is a major problem. Many of these girls have a high risk of unplanned pregnancy and early marriage. In Zambia, around 35% of young rural girls have given birth by the age of 18 years, and the pregnancy rates are particularly high among girls who are out-of-school meaning that almost half never enroll in secondary school. A number of studies have found that giving economic support to girls and/or their families can help them to enroll and stay in school, and a few studies have found that this can postpone having a baby and getting married. Other studies indicate that widespread myths and negative social norms can prevent adolescent girls using modern contraceptives, contributing to high rates of early pregnancy. When teenage girls stay in education, postponing pregnancy and marriage until adulthood, this is linked with healthier and more prosperous lives for the girls – and for their communities. The aim of this study is to find out whether providing economic support to teenage girls and their families in Zambia can reduce the proportion of girls who drop out of school, become pregnant and marry early.

Who can participate?

Female students enrolled in grade 7 in selected rural schools in Zambia.

What does the study involve?

Participating schools are randomly allocated to one of three groups. Those in the first group are given writing materials at the beginning of each school term, such as exercise books and stationery, which they need to complete school and homework. Those in the second group are given the same writing materials as the first group, but also receive economic support. This is in the form of a monthly cash transfer to the girls, an annual grant to their guardians, and having their school fees paid for grade 8 and 9. Those in the third group receive the writing materials and economic support, and in addition there will be meetings for adolescents and adults in the community. For the adolescents there will be fortnightly youth club meetings, as well as six annual community and parent meetings. Participants are able to continue attending the youth club even if they drop out of school. Every six months for 4.5 years, the girls in all groups are followed up and interviewed in order to find out how many have had a baby, are sexually active and are married. Data on their attendance at school in the first two years will also be collected.

What are the possible benefits and risks of participating?

Participants in the second and third groups will benefit from the packages offered in the study, as it could help to keep them in school and prevent unplanned, early pregnancy. There are no notable risks associated with taking part in this study.

Where is the study run from?

The study is run by University of Zambia and takes place in at least 150 rural schools across twelve districts of Zambia.

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

January 2013 to December 2020

Who is funding the study?

1. Norwegian Research Council (Norway)
2. Centre for Intervention Science in Maternal and Child Health (Norway)

Who is the main contact?

1. Dr Patrick Musonda (public)
2. Dr Ingvild Fossgard Sandøy (scientific)

Contact information

Type(s)

Public

Contact name

Dr Patrick Musonda

ORCID ID

<http://orcid.org/0000-0002-1204-6300>

Contact details

University of Zambia
School of Medicine
Nationalist Road, U .T. H.
Lusaka
Zambia
-

Type(s)

Scientific

Contact name

Dr Ingvild Fossgard Sandøy

ORCID ID

<http://orcid.org/0000-0001-5567-4588>

Contact details

University of Bergen
Postbox 7804

Bergen
Norway
5020

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02709967

Secondary identifying numbers
N/A

Study information

Scientific Title

Cluster randomized trial on the effectiveness of a girls' empowerment programme on early childbearing, marriage and school dropout among adolescent girls in rural Zambia

Acronym
RISE

Study objectives

Hypotheses as of 18/07/2016:

1. Economic support will reduce the incidence of childbirth among girls before their 18th birthday
2. A combination of economic support and community dialogue will reduce the incidence of childbirth among girls within 8 months after the end of the intervention and before their 18th birthday

Original hypotheses:

1. Economic support will reduce the proportion of girls who have ever given birth before their 18th birthday
2. Economic support and community dialogue will reduce the proportion of girls who become pregnant during the programme period and who have ever given birth before their 18th birthday

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. University of Zambia Biomedical Research Ethics Committee (UNZA-BREC), 07/09/2015, ref: 021-06-15
2. Regional Ethical Committee of Western Norway (REK-Vest), 09/09/2015, ref: 2015/895

Study design
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 to request an information sheet

Health condition(s) or problem(s) studied

Adolescent childbearing

Interventions

Interventions as of 18/07/2016:

Six randomization ceremonies (each for 2 districts to make sure there are at least 15 schools that are randomized simultaneously) will be held. The randomization will be stratified by district, 1000 allocations of the clusters will be computer-generated by an independent scientist.

Control arm: Participants will receive writing materials at the beginning of each school year. These materials include exercise books, pencils and pens which are needed for school and home work. The materials will be distributed to the school to be shared with the enrolled girls.

Economic intervention arm: Participants receive writing materials and economic support, in the form of a monthly cash transfer to girls, annual grant to guardians, and payment of school fees in grade 8 and 9.

Combined intervention arm: Participants receive writing materials and economic support and community dialogue. The community dialogue will consist of fortnightly youth club meetings, six annual community and parent meetings). The youth club will be for enrolled girls and boys attending the same grade. They will all be allowed to continue in the youth club even if they drop out/quit school. The meetings will include interactive discussions on the benefits of education, early marriage, the risks of early pregnancy, misconceptions around modern contraceptives, and skills training, e.g. negotiation of modern contraceptives use with a sexual partner. The club will be led by a teacher and community health worker or community health assistant.

All participants are followed up biannually via phone, in which participants are interviewed about school enrollment, marriage, childbearing and use of health services.

Original interventions:

For each of 6 areas (each area corresponding to 1-2 districts) approximately 1000 allocations of the clusters that meet balance criteria will be computer-generated by an independent scientist (some randomization areas will include schools in two districts to make sure there are at least 15 schools that are randomized simultaneously).

Control arm: Participants will receive writing materials at the beginning of each school term. These materials include exercise books, pencils and pens which is needed for school and home work. The materials will be distributed to the school to be shared with the enrolled girls.

Economic intervention arm: Participants receive writing materials and economic support, in the form of a monthly cash transfer to girls, annual grant to guardians, and payment of school fees in grade 8 and 9.

Combined intervention arm: Participants receive writing materials and economic support and community dialogue. The community dialogue will consist of fortnightly youth club meetings, four annual community meetings and annual parent meetings). The youth club will be for enrolled girls and boys attending the same grade. They will all be allowed to continue in the youth club even if they drop out/quit school. The meetings will include interactive discussions on education and employment opportunities, early marriage, the risks of early pregnancy, misconceptions around modern contraceptives, and skills training, e.g. negotiation of modern contraceptives use with a sexual partner. The club will be lead by a teacher and community health worker.

All participants are followed up biannually via phone, in which participants are interveiwed about school enrollment, marriage, childbearing and pregnancy.

Intervention Type

Mixed

Primary outcome measure

Primary outcomes as of 18/07/2016:

1. Incidence of births within 8 months of the end of the intervention period is measured using follow-up contact questionnaire at 3.5 years after recruitment
2. Incidence of births before girls' 18th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)
3. Proportion of girls who sit for grade 9 exam is measured using questionnaire at final survey (4.5 years after recruitment) and validated against grade 9 exam results obtained from District educational boards

Original primary outcomes:

1. Proportion of girls who have ever given birth is recorded telephone-based interviews 8 months after the end of the intervention period
2. Proportion of girls who have ever given birth before 18th birthday is recorded telephone-based interviews 8 months after the end of the intervention period

Secondary outcome measures

Current secondary outcome measures as of 17/11/2020:

Pregnancy and childbearing

1. Incidence of pregnancies among girls within 2 years of the end of the interventions is measured using final survey questionnaire at final survey (4.5 years after recruitment)
2. Incidence of births among girls within 2 years of the end of the intervention is measured using final survey questionnaire at final survey (4.5 years after recruitment)
3. Incidence of pregnancies before girls' 16th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)
4. Incidence of births before girls' 16th birthday is measured using final survey questionnaire at

final survey (4.5 years after recruitment)

5. Incidence of pregnancies before girls' 18th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)

6. Socioeconomic inequality in incidence of births before girls' 18th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)

Marriage

1. Incidence of marriage/ cohabitation before girls' 16th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)

2. Incidence of marriage/ cohabitation before girls' 18th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)

3. Socioeconomic inequality in incidence of marriage/ cohabitation before girls' 18th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)

School-related

1. School attendance in grade 8 is measured using follow-up contact questionnaire at 1 and 1.5 years after recruitment

2. School attendance in grade 9 is measured using follow-up contact questionnaire at 2 and 2.5 years after recruitment

3. Proportion of girls enrolled in grade 8 is measured using follow-up contact questionnaire at 1 year after recruitment

4. Average examination scores from grade 9 in English, mathematics and science is measured using grade 9 exam results obtained from District educational boards in December 2018

5. Proportion of girls who enrol in grade 10 is measured using follow-up contact questionnaire at 3 years after recruitment, validated against school registers and final survey questionnaire at 4.5 years

6. Socioeconomic inequality in participation in grade 9 exam among girls is measured using questionnaire at final survey (4.5 years after recruitment) and validated against grade 9 exam results obtained from District educational boards

Other reproductive health outcomes

1. Proportion of adolescent girls currently using modern contraceptives (including use of condom, intrauterine device and hormonal contraception) is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)

2. Proportion of adolescent girls who have been sexually active in last 4 weeks is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)

3. Knowledge of modern contraceptives among adolescent girls is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)

Perceived community norms

1. Perceived community norms regarding education among girls is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)

2. Perceived community norms regarding modern contraceptive use among unmarried adolescents is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)

3. Perceived community norms regarding early marriage among girls is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)

4. Perceived community norms regarding adolescent pregnancy among girls is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)

Other

1. Proportion of girls currently employed or self-employed is measured using final survey questionnaire at final survey (4.5 years after recruitment)

Previous secondary outcomes as of 24/11/2016:

Pregnancy and childbearing

1. Incidence of pregnancies among girls within 2 years of the end of the interventions is measured using final survey questionnaire at final survey (4.5 years after recruitment)
2. Incidence of births among girls within 2 years of the end of the intervention is measured using final survey questionnaire at final survey (4.5 years after recruitment)
3. Incidence of pregnancies before girls' 16th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)
4. Incidence of births before girls' 16th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)
5. Incidence of pregnancies before girls' 18th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)
6. Socioeconomic inequality in proportion of girls who have given birth before 18th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)

Marriage

1. Proportion of girls that are married and/or cohabiting before their 16th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)
2. Proportion of girls married/cohabiting before their 18th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)
3. Socioeconomic inequality in proportion of girls that are married/cohabiting before their 18th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)

School-related

1. School attendance in grade 8 is measured using school attendance records, to be collected retrospectively in December 2018
2. School attendance in grade 9 is measured using school attendance records, to be collected retrospectively in December 2018
3. Proportion of girls enrolled in grade 8 is measured using follow-up contact questionnaire at 1 year after recruitment
4. Average examination scores from grade 9 in English, mathematics and science is measured using grade 9 exam results obtained from District educational boards in December 2018
5. Proportion of girls who enrol in grade 10 is measured using follow-up contact questionnaire at 3 years after recruitment, validated against school registers and final survey questionnaire at 4.5 years
6. Socioeconomic inequality in participation in grade 9 exam among girls is measured using questionnaire at final survey (4.5 years after recruitment) and validated against grade 9 exam results obtained from District educational boards

Other reproductive health outcomes

1. Proportion of adolescent girls currently using modern contraceptives (including use of condom, intrauterine device and hormonal contraception) is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)
2. Proportion of adolescent girls who have been sexually active in last 4 weeks is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)
3. Knowledge of modern contraceptives among adolescent girls is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)

Perceived community norms

1. Perceived community norms regarding education among girls is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)
2. Perceived community norms regarding modern contraceptive use among unmarried adolescents is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)
3. Perceived community norms regarding early marriage among girls is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)
4. Perceived community norms regarding adolescent pregnancy among girls is measured using follow-up contact questionnaire at the end of the intervention period (2.5 years after recruitment)

Other

Proportion of girls currently employed or self-employed is measured using final survey questionnaire at final survey (4.5 years after recruitment)

Secondary outcomes as of 18/07/2016:

Pregnancy and childbearing

1. Incidence of pregnancies among girls within 2 years of the end of the interventions is measured using final survey questionnaire at final survey (4.5 years after recruitment)
2. Incidence of births among girls within 2 years of the end of the intervention is measured using final survey questionnaire at final survey (4.5 years after recruitment)
3. Incidence of pregnancies before girls' 16th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)
4. Incidence of births before girls' 16th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)
5. Incidence of pregnancies before girls' 18th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)
6. Socioeconomic inequality in proportion of girls who have given birth before 18th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)

Marriage

1. Proportion of girls married/cohabiting before their 18th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)
2. Socioeconomic inequality in proportion of girls that are married/cohabiting before their 18th birthday is measured using final survey questionnaire at final survey (4.5 years after recruitment)

School-related

1. School attendance in grade 8 is measured using school attendance records, to be collected retrospectively in December 2018
2. School attendance in grade 9 is measured using school attendance records, to be collected retrospectively in December 2018
3. Proportion of girls enrolled in grade 8 is measured using follow-up contact questionnaire at 1 year after recruitment
4. Average examination scores from grade 9 in English, mathematics and science is measured using grade 9 exam results obtained from District educational boards in December 2018
5. Proportion of girls who enrol in grade 10 is measured using follow-up contact questionnaire at 3 years after recruitment, validated against school registers and final survey questionnaire at 4.5 years

6. Socioeconomic inequality in participation in grade 9 exam among girls is measured using questionnaire at final survey (4.5 years after recruitment) and validated against grade 9 exam results obtained from District educational boards

Other reproductive health outcomes

1. Proportion of adolescent girls currently using modern contraceptives (including use of condom, intrauterine device and hormonal contraception) is measured using final survey questionnaire at final survey (4.5 years after recruitment)
2. Proportion of adolescent girls who have been sexually active in last 4 weeks is measured using final survey questionnaire at final survey (4.5 years after recruitment)
3. Knowledge of modern contraceptives among adolescent girls is measured using final survey questionnaire at final survey (4.5 years after recruitment)

Perceived community norms

1. Perceived community norms regarding education among girls is measured using final survey questionnaire at final survey (4.5 years after recruitment)
2. Perceived community norms regarding modern contraceptive use among unmarried adolescents is measured using final survey questionnaire at final survey (4.5 years after recruitment)
3. Perceived community norms regarding early marriage among girls is measured using final survey questionnaire at final survey (4.5 years after recruitment)
4. Perceived community norms regarding adolescent pregnancy among girls is measured using final survey questionnaire at final survey (4.5 years after recruitment)

Other

Proportion of girls currently employed or self-employed is measured using final survey questionnaire at final survey (4.5 years after recruitment)

Original secondary outcomes:

Pregnancy and childbearing

1. Proportion of girls who have ever given birth after 2 years of programme implementation is measured using follow-up contact questionnaire at 2 years after intervention start (2.5 years after recruitment)
2. Proportion who have ever been pregnant after 2 years of programme implementation is measured using final survey questionnaire at final survey (4 years after recruitment)
3. Proportion who have ever been pregnant before their 16th birthday is measured using final survey questionnaire at final survey (4 years after recruitment)
4. Proportion who have ever given birth before their 16th birthday is measured using final survey questionnaire at final survey (4 years after recruitment)
5. Proportion who have ever been pregnant before their 18th birthday is measured using final survey questionnaire at final survey (4 years after recruitment)
6. Socioeconomic equity in proportion of girls who have ever given birth before 19th birthday is measured using final survey questionnaire at final survey (4 years after recruitment)

Marriage

1. Proportion of girls ever married/cohabiting before their 18th birthday is measured using final survey questionnaire at final survey (4 years after recruitment)
2. Socioeconomic equity in proportion of girls ever married/cohabiting before 18th birthday is measured using final survey questionnaire at final survey (4 years after recruitment)
3. Proportion of unmarried girls with boyfriend is measured using follow-up contact questionnaire at 2 years after intervention start (2.5 years after recruitment)

School-related

1. School attendance in grade 8 and grade 9 is measured using school attendance records, to be collected retrospectively in December 2018
2. Enrollment grade 8 is measured using follow-up contact questionnaire at 1 year after recruitment
3. School drop-out rate before grade 9 completed (will include both regular drop out as well as "push-out", the latter referring to a child not able to obtain a place at the next level of education because of lack of places) is measured using follow-up contact questionnaire at 2.5 years after recruitment and to be validated against school registers of pupils who have sat for grade 9 exams in November 2018.
4. Examination scores grade 9 is measured using grade 9 exam results obtained from District educational boards in December 2018
5. Enrollment grade 10 is measured using follow-up contact questionnaire at 3 years after recruitment
6. Socioeconomic equity in enrollment grade 8 is measured using follow-up contact questionnaire at 1 year after recruitment

Other reproductive health outcomes

1. Current modern contraceptive use (including use of condom, intrauterine device and hormonal contraception) is measured using final survey questionnaire at final survey (4 years after recruitment)
2. Miscarriage and pregnancy termination rate is measured using final survey questionnaire at final survey (4 years after recruitment)
3. Knowledge of modern contraceptives is measured using final survey questionnaire at final survey (4 years after recruitment)

Attitudes and beliefs

1. Control beliefs and behavioural beliefs regarding condoms is measured using final survey questionnaire at final survey (4 years after recruitment)
2. Normative beliefs regarding modern contraceptive use among unmarried adolescents is measured using final survey questionnaire at final survey (4 years after recruitment)
3. Normative beliefs regarding early marriage is measured using final survey questionnaire at final survey (4 years after recruitment)
4. Normative beliefs regarding adolescent pregnancy is measured using final survey questionnaire at final survey (4 years after recruitment)

Overall study start date

01/01/2013

Completion date

31/12/2020

Eligibility

Key inclusion criteria

1. Female
2. Enrolled grade 7 in selected rural schools

Participant type(s)

Other

Age group

Child

Sex

Female

Target number of participants

157 clusters. All eligible girls will be recruited, estimated average 30. Estimated total: 5000 girls

Total final enrolment

4343

Key exclusion criteria

Moved permanently away from area before recruitment.

Date of first enrolment

07/03/2016

Date of final enrolment

14/07/2016

Locations**Countries of recruitment**

Zambia

Study participating centre

University of Zambia

Zambia

P.O.BOX 50110

Sponsor information**Organisation**

University of Zambia

Sponsor details

PO Box 50110

Lusaka

Zambia

-

Sponsor type

University/education

Organisation

University of Bergen

Sponsor details

P.O.Box 7800

Bergen

Norway

5020 Bergen

Sponsor type

University/education

Website

uib.no

Funder(s)**Funder type**

Research organisation

Funder Name

Norges Forskningsråd

Alternative Name(s)

Forskningsrådet, Norwegian Research Council, Research Council of Norway

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Norway

Funder Name

Centre for Intervention Science in Maternal and Child Health (CISMAC)

Results and Publications**Publication and dissemination plan**

1. Planned publication of the study protocol and study results papers in high-ranking journals
2. Planned publication of findings from the formative phases and the pilot study in peer-reviewed journals
3. Dissemination of research findings through reports and presentations at national and international academic and policy related conferences
4. Sharing of preliminary and final research findings with the advisory group (with representatives from the Ministry of Education, Ministry of Health, Ministry of Gender, and the Ministry of Traditional Affairs) and other key stakeholders in Zambia and in meetings with the intervention communities

Intention to publish date

31/03/2021

Individual participant data (IPD) sharing plan

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?
Protocol article	protocol	09/12/2016		Yes	No
Protocol article	cost-benefit and extended cost-effectiveness study protocol	19/12/2017		Yes	No
Results article	Parent-child communication results	16/07/2020	20/07/2020	Yes	No
Results article		09/07/2021	12/07/2021	Yes	No
Results article	Primary outcome results	15/11/2024	27/11/2024	Yes	No
Results article	Lessons from an intervention study on the sustainability of after-school comprehensive sexuality education in Zambia: the perspectives of teachers, health workers and guardians	18/12/2024	19/12/2024	Yes	No