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Do behavioral-science-backed board games, health passports, and posters positively change girls' sexual and reproductive health behaviors and attitudes?

Submission date
03/06/2021

Recruitment status
No longer recruiting

Registration date
15/06/2021

Overall study status
Completed

Last Edited
19/12/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Adolescent girls in Burkina Faso face a risk of unintended pregnancy due to a lack of contraceptive use, especially modern methods. The (re)solve project was designed to address contraceptive misperceptions and increase girls' perceptions of their pregnancy risk through a participatory game and a health passport aimed at easing girls' access to health facilities. Additional intervention components included posters in schools and health facilities advertising health-related consultations for girls and name tags identifying providers of youth-friendly health services. The aim of this study is to evaluate (re)solve's impact on girls' intentions to use contraception, among other outcomes.

Who could participate?
Girls aged 14 to 18 years old at participating schools in Ouagadougou and Bobo-Dialasso, and staff aged 18 years and older who implemented the intervention

What did the study involve?
Participating schools are randomly allocated to the intervention group or the control group. All girls in intervention schools are invited to participate in the intervention and the study; a subset of girls are randomly selected to be in the study. The interventions are a package of activities including a facilitated board game, a health passport, and exposure to nametags and posters at schools and health facilities. The control group do not receive any intervention. The study lasts from October 2019 - July 2020. The evaluation includes surveys and interviews with girls in the intervention group at the start and end of the intervention and with implementation staff and experts at the end of the study.

What were the possible benefits and risks of participation?
The intervention may increase girls' intention to use contraception and positively change other contraceptive attitudes. The only risk was that sensitive questions on the survey may make a participant feel uncomfortable, but the participant could withdrawal at any time, or skip a

question. At the end of the study, due to the COVID-19 pandemic, the researchers conducted interviews over the phone. There were additional risks to young girls with this new method - for example, a parent might overhear her conversation during the survey - but extra training and adjustments were made to mitigate these potential issues.

Where was the study run from?
32 schools in Ouagadougou and Bobo-Dialasso (Burkina Faso)

When did the study start and stop?
January 2019 to September 2020

Who funded the study?
The Bill and Melinda Gates Foundation (USA)

Who is the main contact?
Laura Hinson
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
19-0015B

Study information

Scientific Title
(re)solve in Burkina Faso: mixed-methods cluster-randomized trial to see if a school-based behavior change intervention positively changes girls' sexual and reproductive health behaviors and attitudes

Study objectives
Does a behavior-change intervention targeting girls in 4eme and 3eme (equivalent of U.S. 9th and 10th grade) increase girls' intention to use contraception and positively change other contraceptive attitudes, as compared to girls who did not participate in the intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/10/2019, ICRW Institutional Review Board (1120 20th Street NW STE 500, Washington DC 20036, USA; +1 (0)202 797 0007); kreitz@icrw.org), ref: 19-0015B
Approved 23/09/2019, Comite D'Ethique Institutionnel Pour la Recherche en Sciences de la Sante (CEIRSS, BP 7192 Ouagadougou, Burkina Faso; +226 (0)20 98 18 80; Rouamba_noelw@yahoo.fr), ref: A014-2019

Study design
Mixed-methods cluster-randomized control trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Prevention of unintended pregnancy

Interventions
From a list of eligible schools with similar characteristics in Ouagadougou and Bobo-Dialasso, the researchers randomly allocate the intervention to 16 of 32 schools - 8 in one city, 8 in another. The remaining schools are control schools. All girls in intervention schools are invited to participate in the intervention and the study; a subset of girls are randomly selected to be in the study.

The interventions are a package of activities including a facilitated board game, a health passport, and exposure to nametags and posters at schools and health facilities.

The control group do not receive any intervention.

The study lasts from October 2019 - July 2020, with intervention-school girls participating at baseline (before intervention), midline (right after exposure to intervention) and endline (several months after intervention). Control-school girls participated at baseline and endline, quantitative only.

Intervention Type
Behavioural

Primary outcome measure
Percentage of girls with an intention to use contraception in the next 3 months, originally measured using a four-point Likert scale (1=Yes, definitely; 2=Yes, probably; 3=No, probably not; and 4=No, definitely not). The researchers collapsed this to a binary variable (No/Yes) and included the 12 girls at endline who responded that they preferred not to answer in the "No" category. Measured at baseline and endline.

Secondary outcome measures
Measured with quantitative surveys at baseline, midline and endline for the intervention group and baseline and endline for the control group:
1. Percentage of girls who have gone to a health facility for sexual and reproductive health (SRH) services or information ("Have you ever visited a health facility recently for puberty or menstruation information?")
2. Percentage of girls who strongly agree or agree that contraception causes infertility ("Modern contraception can cause infertility")
3. Percentage of girls who strongly agree or agree that contraception is the best option ("If I am having sex and want to avoid pregnancy modern contraception is best option")
4. Percentage of girls who strongly agree or agree that they have the confidence to both get and use contraception ("I feel confident in my ability to get a contraceptive method, if I wanted to avoid pregnancy" and "I feel confident in my ability to use a contraceptive method, if I wanted to avoid pregnancy")
5. Percentage of girls who strongly agree or agree that health care workers do not like to give contraceptive advice to unmarried girls ("Health care workers do not like to give advice to young unmarried girls about family planning")
6. Percentage of girls who strongly agree or agree that unmarried girls should not and do not use contraception and that those around them do not use contraception (a combination of three questions: "Most unmarried girls my age do not use modern contraception to avoid or delay pregnancy," "Most girls think that unmarried girls should not use modern contraception," and "The people most important to me do not think I should use a modern contraception method").

The researchers collapsed those that had a "Yes", "No", "Don't know", and "Prefer not to answer " response into a binary variable with cases responding "Don't know" or "prefer not to answer" classified as "No". They collapsed variables that were originally collected using a four-point Likert scale (1=Strongly agree; 2=Agree; 3=Disagree; and 4=Strongly disagree) into a binary variable (0=Disagree and 1=Agree).

Overall study start date
10/01/2019

Completion date
30/09/2020

Eligibility

Key inclusion criteria
For girls in the quantitative study and qualitative study:
1. At baseline:
1.1. Is in 4eme and 3eme grade at a participating school
1.2. Is between 14 and 18 years old
1.3. Is unmarried
2. At mid or endline: participated in baseline

For the qualitative study with adults:
1. Implemented (re)solve activities or was trained to implement (re)solve activities (facilitator and PYY facility staff) or has some knowledge, expertise or authority on girls sexual and reproductive health and/or has been involved with intervention
2. 18 years of age or older

Participant type(s)
Mixed

Age group
Mixed

Lower age limit
14 Years

Sex
Both

Target number of participants
2400 for the quantitative study across 32 clusters (schools). For the qualitative study, roughly 41 interviews with girls at endline, 35 with implementation staff at endline, and 14 with key informants.

Total final enrolment
2072

Key exclusion criteria
1. Unwilling to participate or consent
2. Parental consent not obtained

Date of first enrolment
01/11/2019

Date of final enrolment
01/08/2020

Locations

Countries of recruitment
Burkina Faso

Study participating centre
32 schools in Ouaguadougou
Ouagadougou
Burkina Faso
-

Study participating centre
16 schools in Bobo-Dioulasso
Bobo-Dioulasso
Burkina Faso
-

Sponsor information

Organisation
International Center for Research on Women

Sponsor details
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Sponsor type
Research organisation

Website
https://www.icrw.org/

ROR
https://ror.org/03v351c14

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
The researchers plan to submit at least one manuscript of the main evaluation for publication in a peer-reviewed journal.

Intention to publish date
01/08/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Laura Hinson (lhinson@icrw.org).
Type of data that will be shared: quantitative (Stata) and qualitative (verbatim transcribed and translated from French Word documents).
When the data will become available and for how long: upon publication (or around October 2021), 5 years.
By what access criteria data will be shared including with whom, for what types of analyses, and by what mechanism: the researchers are open to share the data with individuals who have a research plan.
Whether consent from participants was obtained: Yes
Comments on data anonymisation: All data is de-identified and anonymous
Any ethical or legal restrictions: None
Any other comments: None

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	11/12/2023	19/12/2023	Yes	No