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This study aims to improve sexual and reproductive health knowledge and attitudes among young people, age 12-16, living in Uttar Pradesh, India

Submission date
13/01/2022

Recruitment status
No longer recruiting

Registration date
24/01/2022

Overall study status
Completed

Last Edited
07/08/2023

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In India, adolescents face multiple sexual and reproductive health challenges, including but not limited to a lack of knowledge and access to family planning methods, correct knowledge of menstruation and menstrual management supplies, and widespread sexual harassment of girls in public spaces. These factors can have lifelong negative implications for young people. The Kissa Kahani intervention is a multimedia intervention that aims to improve sexual and reproductive health outcomes among young people living in India. The intervention is designed using multimedia tools, animated digital stories, games and graphic novels to raise awareness about menstruation, family planning and sexually transmitted infections, and prevention of sexual harassment. This study aims to find out whether this intervention improves sexual and reproductive health knowledge and attitudes among young people, aged 12-16 years, living in Uttar Pradesh, India

Who can participate?
Healthy boys and girls, aged 12-16 years, living in the Lucknow and Sitapur districts of Uttar Pradesh, India.

What does the study involve?
Participants are randomly allocated into four study groups (three intervention groups and one control group) using a lottery system. The intervention groups receive the intervention on one of the following curriculum topics:
1. Menstruation and its correct management
2. Family planning and sexually transmitted infections (STIs)
3. Prevention of street harassment of girls
Each study curriculum (menstruation, family planning and STIs, and sexual harassment) comprises animated digital stories, graphic novels, and a discussion guide, which aim to raise awareness about the curriculum topic and promote the adoption of correct behaviours. Participants in the first three study groups watch the animated digital stories, read the graphic

novels, and engage in guided discussions.
Participants in the fourth study group (study control group) only read the graphic novels on the curriculum topics (menstruation, family planning and STIs, and street harassment). They did not watch the animated digital stories or engage in discussion groups about the curriculum topics.

What are the possible benefits and risks of participating?
There is the possibility of no direct benefit to adolescents for participating in this study. However, engaging in the Kissa Kahani intervention may teach adolescents about issues of gender equity and sexual and reproductive health, and improve their self-efficacy in addressing these issues in their lives and in their communities. Data collected from this study may be used to further refine the Kissa Kahani curriculum and scale the intervention across communities in India.

Where is the study from?
The Center for Interdiscplinary Inquiry and Innovation in Sexual and Reproductive Health (USA)

When is the study starting and how long is it expected to run for?
March 2021 to May 2022

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

Who is the main contact?
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Contact information

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Additional identifiers

Protocol serial number
IRB 21-0172

Study information

Scientific Title
Kissa Kahani intervention community-based testing

Study objectives
Using a multimedia intervention can help to improve sexual and reproductive health knowledge and attitudes among very young adolescents living in India.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/03/2021, the University of Chicago Institutional Review Board (The University of Chicago Office of Clinical Research, Section of Regulatory Compliance, 5841 S. Maryland Ave., I-625, MC7132, Chicago, IL 60637, USA; +1 (0)773 702 6505; bsdirb@bsd.uchicago.edu), ref: FWA00005565

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Adolescent sexual and reproductive health

Interventions
A randomized controlled trial was conducted of an adolescent sexual and reproductive health intervention, Kissa Kahani, in communities in Sitapur and Lucknow districts in Uttar Pradesh, India. The study was conducted by the Center for Interdisciplinary Inquiry and Innovation in Sexual and Reproductive Health (Ci3), an academic research center based at the University of Chicago in partnership with local organizations in India: the Milaan Foundation and the Institute for Financial Management and Research. The Kissa Kahani intervention was designed based on formative research that was conducted by Ci3 researchers with young people living in Uttar Pradesh for 2 years employing traditional and non-traditional research methods: life course interviews, surveys, key informant interviews, body-mapping exercises, story circles, storytelling

games, and focus group sessions to better understand the experiences of young people in Uttar Pradesh, India. The formative research phase was focused specifically on household dynamics, familial relationships, identity, educational and work experiences, access to and use of technology and health services, and gender norms.

From the findings of the aforementioned formative research, the researchers have developed the Kissa Kahani intervention for girls and boys aged 12 to 14 years addressing the ecology of factors influencing young people's reproductive health and wellbeing. Kissa Kahani is a theory-based, multimedia intervention designed to promote reproductive health and family planning, and emphasize the value of education and financial autonomy for girls in India. The intervention curriculum includes animated digital stories, games, and graphic novels on topics of menstruation, family planning and sexually transmitted infections (STIs), and street harassment.

For testing of the Kissa Kahani intervention in the community, Ci3 and its Indian partners implemented and tested the Kissa Kahani intervention in communities in Sitapur and Lucknow districts in Uttar Pradesh, India. The study population included 1,200 healthy boys and girls, aged 12-16 years. The researchers studied the effects of the intervention on participating subjects' self-reported knowledge, attitudes, and self-efficacy around sexual and reproductive health (including menstrual management, family planning, and STIs), gender equity, and school attendance. The study was conducted with help from local study partners, the Milaan Foundation, and IFMR. The Milaan Foundation was responsible for the delivery of the intervention curriculum. IFMR conducted the study recruitment and data collection and analysis.

Study participants were randomized into four study arms (three intervention arms and one control arm) using a lottery system. The intervention arms received the intervention on one of the following curriculum topics:
1. Menstruation and its correct management
2. Family planning (FP) and STIs
3. Prevention of street harassment of girls

Each study curriculum (menstruation, FP and STIs, and sexual harassment) comprises animated digital stories, graphic novels, and a discussion guide, which aim to raise awareness about the curriculum topic and promote the adoption of correct behaviors. Participants in the first three study arms watched the animated digital stories, read the graphic novels, and engaged in guided discussions.

Participants in the fourth study arm (study control group) only read the graphic novels on the curriculum topics (menstruation, FP and STIs, and street harassment). They did not watch the animated digital stories or engage in discussion groups about the curriculum topics.

Intervention Type
Behavioural

Primary outcome(s)
Self-reported knowledge, attitudes, and self-efficacy around sexual and reproductive health (including menstrual management, family planning, and STIs/HIV), and gender equity, measured using a pre-post questionnaire developed by the research team delivered at baseline and immediately upon completion of the intervention

Key secondary outcome(s)

Value of education for girls and intention to attend/complete schooling, measured using a pre-post questionnaire developed by the research team delivered at baseline and immediately upon completion of the intervention

Completion date
31/05/2022

Eligibility

Key inclusion criteria
Healthy boys and girls, aged 12-16 years, who live in Sitapur and Lucknow districts in Uttar Pradesh, India

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Years

Upper age limit
16 Years

Sex
All

Total final enrolment
1200

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/06/2021

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
India

Study participating centre
The Institute for Financial Managment and Research (Lead KREA)
LEAD at Krea University
C/O Krea University
No: 196, T.T.K. Road, Alwarpet
Chennai
India
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Sponsor information

Organisation
Bill & Melinda Gates Foundation

ROR
https://ror.org/0456r8d26

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. 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

Individual participant data (IPD) sharing plan

All efforts will be made to keep participants' information confidential. All documents will be kept in a locked file cabinet in a locked office in Lucknow and if applicable, the US. All electronic data will be stored encrypted in password-protected files computers in India, and/or on secure University of Chicago servers (for data accessed in the US). All data will be transcribed, verified, translated, deidentified, and analyzed by the Indian study partner, IFMR, after which they will send all records and their analysis to Ci3. This data will NOT be shared with others outside of the project team. All identifiable information will be removed by the IFMR team before sharing the data with Ci3 (including dates and zipcodes/postal addresses).

IPD sharing plan summary

Stored in non-publicly available repository