ISRCTN16496629 https://doi.org/10.1186/ISRCTN16496629

Impact of menstrual cups on adolescent girls' reproductive health and education

Submission date 17/03/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/03/2026	**Overall study status** Ongoing	
Last Edited 18/03/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims

Adolescent girls are acutely susceptible to sexual and reproductive health (SRH) harms through incomplete biological development, inadequate knowledge of menstruation and puberty, lack of autonomy, social pressures around sex, and harmful gender norms. In many low- and middle-income countries (LMICs), including Kenya, where poverty and gender-based violence are pervasive, girls face sexual abuse, have limited agency to navigate sexual encounters safely, and may resort to transactional sex to obtain daily essentials including menstrual hygiene products. This leaves girls vulnerable to adolescent pregnancy, child marriage, sexually transmitted infections (STIs) and school dropout, with lasting effects across the life course. Trials are needed to test interventions that combine effects that improve girls' menstrual needs, reduce risky sexual behaviours, and modify social norms. We have conducted prior trials evaluating the impact of menstrual (cups, sanitary pads) and structural (cash transfer) interventions on SRH and school outcomes in about 4750 schoolgirls in rural Kenya. We found menstrual cups were acceptable to parents and to younger and older adolescents, and girls reported improved menstrual hygiene and school engagement and reduced stigma. Cups reduced the incidence of STIs and bacterial vaginosis, suggesting they are a multipurpose tool, improving menstrual care and reducing sexual risks. Our data suggested earlier-aged cup use, e.g., soon after the first menstrual period, may offer the highest protection to maintain a healthy vaginal microbiome. However, our prior trials missed robust measurement and evaluation of the effect of menstrual cups on adolescent pregnancy and on education outcomes such as school dropout, absence, and exam scores. Funding has been provided allowing us to improve our study methods to fully evaluate menstrual cups as a multipurpose tool. Our study aims to evaluate if the provision of menstrual cups will impact educational, sexual and reproductive health and social equity outcomes compared with girls maintaining usual practice in junior schools in western Kenya.

Who can participate?

The main trial participants are girls attending as day students in junior schools in Siaya County, western Kenya. Girls can participate if they live in the study area, attend the selected junior schools, have parent consent and themselves assent, and have no disability that would preclude them from being able to join the study activities. Our target population are girls in the first year of junior school (grade 7), who would be followed up until they complete junior school (grade 9), e.g., over approximately 2.5 years.

What does the study involve?
This study includes a menstrual cup group and a control group (where participants are provided the menstrual cup at the end of the study). At the randomisation ceremony head teachers allocate schools to the cup or control group. Informed parent consent through school meetings will first take place before eligible schoolgirls are invited to join and assent. Following participant enrolment, a baseline self-completed survey will be conducted among participants in school, with follow-up surveys conducted every 6 months. A variety of qualitative studies will be conducted among participants agreeing to join activities across the course of the study. Absence will be recorded through software, enabling more accurate recording by teachers. Participants reported to drop out will be visited in their homes to verify this, record pregnancies, and continue biannual surveys to maximise completeness of survey coverage. In a sample of about 10 schools, a sub-study will take place in about 600 girls (300 in the cup group and 300 in the control group). Following parent consent and their assent, participants will be invited to do vaginal swabs, in a private setting, to investigate the vaginal microbiome and to diagnose if they have bacterial vaginosis and/or an STI. Private individual treatment will take place after test rests are obtained. Costings will be conducted throughout to enable the trial data to be used for cost-benefit and cost-effectiveness analysis. In addition to activities among the participants, additional studies will be conducted among a variety of stakeholders to provide contextual information to help understand trial outcomes and to inform policy implications.

What are the possible benefits and risks of participating?
Girls will receive a menstrual cup, puberty and hygiene education, and training on safe and effective use. The control group will receive a small stationary item at enrolment and a menstrual cup (with training) at the end of the study. Participants are thought likely to benefit from improving their self-esteem and autonomy by contributing to the study. Participants in our previous studies reported enhanced esteem through study participation.
The risks for schoolgirls participating in this study include initial embarrassment discussing menstruation with possible shame associated with poor management. This will be mitigated by discussion with the female staff who have worked with adolescent girls for many years. Girls may also feel discomfort when first using the menstrual cup until they are familiar. This will be addressed through training of female experts who will be available to support safe and effective use, with repeat training monthly for 3 months, then quarterly, plus SMS messaging if further support in between training is required. Girls may be triggered by some questions on sexual and reproductive health or behaviours; our female counselling staff will be available, and we have a safeguarding pathway prepared should girls need additional counselling support. Girls in the sub-study investigating STIs and the vaginal microbiome may find the process of swabbing overwhelming; we have trained nurses and female counsellors to assist with every step, and all activities will be conducted in privacy. Treatment of infections is conducted confidentially by our study nurses. Finally, participants are informed from study start and during procedures that they have the right to withdraw at any time with no negative consequences should they so wish.

Where is the study run from?
Kenyan Medical Research Institute (Kenya)

When is the study starting and how long is it expected to run for?
May 2026 to December 2028

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

Who is the main contact?
Prof. Penelope Phillips-Howard, penelope.phillips-howard@lstmed.ac.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Prof Penelope Phillips-Howard

ORCID ID
https://orcid.org/0000-0003-1018-116X

Contact details
Department of Clinical Sciences, Pembroke Place
Liverpool
United Kingdom
L3 5QA
+44 (0)7985431005
penelope.phillips-howard@lstmed.ac.uk

Additional identifiers

Study information

Scientific Title
Impact of menstrual cups on adolescent girls' reproductive health and education

Acronym
IMARA

Study objectives
Primary objective:
To determine the impact of menstrual cups provided to junior school (JS) girls on pregnancy and school dropout

Secondary objectives:
1. To measure the age-specific rates of pregnancy and child marriage in JS girls and identify antecedent risk factors associated with these outcomes
2. To determine the rate, risk factors and reasons for dropout and absenteeism among junior schoolgirls
3. To measure the impact of the menstrual cup on learning via adapted assessments and the Kenya Junior School Education Assessment
4. To determine the impact of menstrual cups on girls' sexual behaviours, including age of sexual début, coerced sex, number and age of partners, condom/contraception use
5. To examine the effect of the menstrual cup on the vaginal microbiome, STIs and BV in a representative sub-study
6. To determine the cost-effectiveness and separately, cost-benefit of the menstrual cup when

given to schoolgirls
7. To determine the uptake and safety profile of menstrual cups

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 13/03/2026, Liverpool School of Tropical Medicine Research and Ethics Committee (Pembroke Place, Liverpool, L3 5QA, United Kingdom; +44 (0)151 702 9396; lstmrec@lstmed.ac.uk), ref: 0136

2. approved 10/03/2026, Scientific and Ethical Review Unit (Mbagathi Way, Nairobi, 54840, Kenya; +254 (0)722205901; seru@kemri.go.ke), ref: 5379

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Reproductive health and education

Interventions
Schools are the unit of randomisation (clusters), and girls the unit of measurement. A census of junior schools in the area will be completed. A computer-generated randomisation list will be produced by the trial statistician at LSTM. Randomization will adjust for school-level characteristics (e.g., school size) to ensure balance across study arms. Schools with head teacher approval will be randomly allocated into two arms using a 1:1 ratio. The actual allocation of schools to study arms will be revealed using community ceremonies with the Head Teachers of the school. Because schools allocated to the ‘usual practice’ will receive menstrual cups at the end, cup allocation may be perceived by communities as an intervention provided ‘immediately’ vs ‘delayed’.

Participants will be randomised (through school allocation) to one of two arms:
1. One menstrual cup (CouldYou?®) with education and training materials for safe, effective cup use.

2. ‘Usual practice’ control (control arm), who will receive a stationary item (notebook) at the beginning of the study and the menstrual cup with training on safe use and care at study end.

Menstrual cups are medical-grade silicone-based receptacles inserted in the vagina to collect menstrual blood and are safe, cost-effective, and environmentally friendly. There are now over 100 brands of menstrual cups worldwide. Branded menstrual cups have been registered and approved in numerous countries including the United States Food and Drug Administration (US FDA class 2 registration). In the US, menstrual cups are classed as a medical device and in Europe as a hygiene product. In 2022, ISO established a new committee to define standards for menstrual products (https://www.iso.org/committee/8933440.html). This includes ISO for menstrual cups: ISO/TC 338 (https:committee.iso.org/home/tc338). Kenya, Uganda, South Africa, Ghana, Namibia, Eswatini, Sudan and Egypt are participating members in Africa, along with most countries in America, the Middle East, Asia, Europe and Australasia. Kenya is represented by the Kenya Bureau of Standards (KREBS)(https://www.iso.org/member/1854.html).

The menstrual cup used in this study (CouldYou?) (https://couldyou.org/period-poverty/) is made from medical-grade silicon and manufactured in a cGMP manufacturing company, which is also ISO 13485 certified; cups are manufactured in ISO 8 clean rooms and are FDA-registered (FDA registration #3018179390). CouldYou? Cups are distributed within Kenya for menstrual cup programmes, although not in the rural area of our study, and have KPPB licence approval (KPPB # PPB/DON/00277/24).

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
Menstrual cup (CouldYou?®)

Primary outcome(s)
1. The combined incidence of adolescent pregnancy and/or school dropout measured using follow-up surveys at 6 monthly intervals and verification house visits over approximately 2.5 years

2. Safety: Incident cases of toxic shock syndrome measured using community surveillance at endline, approximately 2.5 years

3. AKIBA Sub-Study: Prevalence of optimal community state type (CST-I, Lactobacillus crispatus dominated) measured using follow-up surveys at termly intervals over approximately 2.5 years

Key secondary outcome(s))
1. Incidence of adolescent pregnancy measured using follow-up surveys at 6 monthly intervals and verification house visits over approximately 2.5 years

2. Incidence of school dropout measured using follow-up surveys at 6 monthly intervals and verification house visits over approximately 2.5 years

3. Incident mental health disorders measured using follow-up surveys using Patient Health Questionnaire-9 (PHQ-9) and EuroQoL at 6 monthly intervals over approximately 2.5 years

4. AKIBA Sub-Study: Incidence of bacterial vaginosis (BV) and sexually transmitted infections (STIs) (composite of gonorrhea, chlamydia, trichomoniasis) measured using follow-up surveys at annual intervals over approximately 2.5 years

Completion date
31/12/2028

Eligibility

Key inclusion criteria
Schools:
1. Junior day schools in select sub-counties in Siaya County
2. Schools that educate girls or are co-educational
3. Schools receiving approval to participate from the Head Teacher

Main trial participants:
1. Girls attending junior schools (JS)
2. Girls who are day students
3. Girls who live in the study area
4. Girls who have parental consent and assented
5. Girls who have no severe disability precluding them from participating

Others:
Parents: Parents or guardians of girls participating in the trial who consent to participate
Boys: Boys in same schools as participating girls, who receive parental consent and assent
Teachers: Teachers in study schools who consent to participate

Other stakeholders/community members:
Persons in the community of the study schools who work with or who have responsibility for or relationships with adolescent girls, e.g., local ministry officials, chiefs, religious leaders, community males who consent to participate

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 years

Upper age limit
18 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Schools:
1. Boys-only schools
2. Girls' schools that require boarding
3. Special needs schools

Main trial participants:
1. Girls who live outside the study area
2. Girls who attend boarding schools
3. Girls whose parental consent or girl's assent is refused
4. Girls with a severe disability precluding participation
5. Girls cannot take part if they have an allergy to silicone or if they plan to move from the study area within the next year

Others:
Parents: Parents in non-study schools or in study schools but whose daughters are not enrolled in the study
Boys: Boys in non-study schools or whose parents do not provide consent
Teachers: Teachers outside the study schools or who do not consent

Other stakeholders/community members:
Persons with no knowledge, experience or responsibility for adolescent girls or no knowledge of the local community

Date of first enrolment
01/05/2026

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
Kenya

Study participating centre
Kenya Medical Research Institute
Kisian Campus, Busia Road
Kisumu
Kenya
20778

Sponsor information

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type

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

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 0.9	09/02/2026	17/03/2026	No	No